INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF CALIFORNIA AGREEMENT STATE PROGRAM

October 21-25, 1996

FINAL REPORT

U.S. Nuclear Regulatory Commission

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1.0 INTRODUCTION

This report presents the results of the review of the California radiation control program. The review was conducted during the period October 21-25, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Tennessee. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995 and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period January 1993 to October 1996, were discussed with California management on October 25, 1996.

A draft of this report was issued to California for factual comment on March 11, 1997. The State of California responded in a letter dated May 5, 1997 (attached). The State had no factual comments on the proposed final report. The Management Review Board (MRB) met on June 5, 1997, to consider the proposed final report. Based on the existing NRC compatibility policy and the IMPEP evaluation criteria, the review team recommended that California's performance with respect to the indicator, Legislation and Regulations, be found unsatisfactory. The team recommended that compatibility findings for the California program be reevaluated upon final promulgation of California's regulations on Notification of Incidents and the Definition of Land Disposal and Waste Site QA program amendment. The amendments on these two regulations are expected to be adopted by October 1, 1997. Because of the progress to date in the promulgation of these rules and the expected adoption date of October 1, 1997, the MRB determined that a sufficient basis did not exist to support a finding of unsatisfactory for this indicator. The MRB noted that if significant delays in rule adoption occur or if California adopts rules that are not compatible with the NRC equivalent regulations, the MRB could always reconsider the program compatibility finding at a future date. The MRB final recommendation for Legislation and Regulations is satisfactory. The MRB found the California radiation control program was adequate to protect public health and safety and compatible with NRC's program

The radiation control program is located in the State's Department of Health Services (DHS). Within DHS, the California radiation control program is administered by the Radiologic Health Branch (RHB) in the Food, Drugs & Radiation Safety Division. An organization chart is included as Appendix B. The California program regulates approximately 2,100 specific licenses. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) agreement between the NRC and the State of California.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the State on July 5, 1996. California provided its response to the questionnaire on September 16, 1996. A copy of that response is included as Appendix C to this report.

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

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

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on January 29, 1993, and the results were transmitted to Dr. Molly Joel Coye, Director of the California Department of Health Services on April 22, 1993. NRC conducted a followup review of the program in January 1994 to evaluate the status of open issues identified in the 1993 review. A second visit was made in March 1994 to conduct an indepth review of the State's sealed source and device (SS&D) evaluation program. The results of these reviews were transmitted to Ms. S. Kim Belshé, Director of the California Department of Health Services on December 23, 1994.

2.1 Status of Items Identified During the 1994 Followup Program Reviews

The January and March 1994 followup reviews evaluated the status of seventeen recommendations identified as part of the 1993 review. The IMPEP team looked at each item again to determine whether or not the current California program had taken additional actions to close open recommendations. These recommendations are summarized below:

(1) The 1993 review team recommended that the State initiate the process for revising its regulations with sufficient lead time to meet the target implementation date (three years after the NRC effective date) in order to maintain compatibility. Specifically, the following regulations were identified as being overdue for adoption:

- "Decommissioning Rule" 10 CFR Parts 30, 40 and 70 amendments (53 FR 24018) needed by July 27, 1991.

- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) needed by April 7, 1993.

- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) needed by January 10, 1994.

- "Notification of Incidents," 10 CFR Parts 20, 31, 34, 39, 40, and 70 amendments (55 FR 40757) needed by October 15, 1994.

Current Status: California revised a number of its regulations during the review period. On March 3, 1994, the State adopted a revised rule, R-45-93, which is a Part 20 equivalent rule covering "Standards for Protection Against Radiation." This rule adopts NRC's 10 CFR Part 20 by reference and was later incorporated, via license condition, into each of the State's specific licenses. Amendments to add the Safety Requirements for Radiographic Equipment rule were promulgated in July 1994. Amendments to the Decommissioning rule and the Emergency Planning rule were promulgated via Emergency Rulemaking action in October 1995. The amendments on "Notification of Incidents" have not yet been adopted. The review team examined this recommendation as part of the Legislation and Regulations non-common performance indicator (see Section 4.1). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(2) The 1993 review team identified a significant increase in the number of overdue inspections in priorities 1 thru 3 and among initial inspections. Three recommendations were made regarding the Indicator on Status of Inspection Program. These were:

- Every effort should be made to fill three vacant inspector positions.

- The State should re-evaluate the practice of contracting inspections and investigations to county agencies, and if continued, future contracts should hold counties accountable for work not performed.

- The State should develop inspection schedules which strictly adhere to the established inspection priority frequencies. The plan should establish target dates and milestones for assessing progress.

Current Status: The 1994 review team noted that all inspector vacancies were filled and that the county contract agencies were notified that corrective action must be taken if they fall behind in scheduled inspections. The compliance supervisor projects the number of inspections required to meet stated goals and monitors the program's progress monthly. The 1996 review team noted that there were only three inspections overdue, by one week, at the time of the review and these inspections were scheduled to be conducted by the end of October 1996. This recommendation is closed.

(3) The 1993 review team recommended that specific radiopharmacy inspection forms be developed and used uniformly.

Current Status: The 1996 review team confirmed that a revised radiopharmacy supplement to the inspection report form addresses transportation. The review team noted that this supplement is available to the inspection staff and is being utilized during inspections. This recommendation is closed.

(4) The 1993 review team recommended that supervisors should require all inspectors to use inspection forms in the manner prescribed in the procedures. This recommendation relates to inadequate documentation in inspection reports and failure to detect three minor categories of deficiencies during supervisory reviews.

Current Status: The 1996 review team noted that the overall quality of the inspection reports was very good. Only one of the 26 reports reviewed was in need of improved documentation. This recommendation is closed.

(5) The 1994 review team recommended that the State ensure that the proper testing or engineering analysis be performed on SS&D by the manufacturer for the intended use. In addition, the manufacturer should certify that the tests were performed and that the SS&D passed the test. The American National Standards Institute (ANSI) guides should be used as the minimum set of prototype tests for sealed sources and the ANSI guide for devices should be supplemented with appropriate prototype tests for the device's intended uses.

Current Status: The 1996 review team identified six cases, out of the twenty-two SS&D files reviewed, in which comments were made regarding deficiencies in prototype testing. It should also be noted that the review team recommends that the Staff develop a policy on the acceptance of operational history in lieu of prototype tests when considering the useful life of a product. The review team examined this recommendation as part of the Sealed Source and Device Evaluation Program non-common performance indicator (see Section 4.2). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(6) The 1994 review team recommended that the State request and review complete operations manuals and user manuals for device and source installations, service, maintenance, and emergency procedures to determine if any proposed activity would comprise worker safety, device integrity, or put the licensee in non-compliance.

Current Status: The 1996 review team noted that the staff is requesting and reviewing operations and user manuals. The team did however identify a deficiency in a user manual in one of the twenty-two SS&D casework files reviewed. The State staff appears to have adequately addressed this recommendation. This recommendation is closed.

(7) The 1994 review team recommended that the State request detailed drawings and lists of materials from manufacturer/distributors of SS&D for all safety related components. The information is necessary to check if the manufacturer's device/sealed source design will withstand the proposed use. In addition this information is required for an overall understanding of how the safety features operate and to determine if components from one manufacturer's design (i.e., radiography - sealed source and camera combinations) are compatible with each other.

Current Status: A review of selected SS&D evaluation casework files and discussions with the staff indicate an improvement in this area for recently issued evaluations. Several files, however, require a re-examination for completeness. The review team examined this recommendation as part of the Sealed Source and Device Evaluation Program non-common performance indicator (see Section 4.2). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(8) The 1994 review team recommended that the staff re-evaluate the general licensing of the neutron gauge (Model N-002, CA380D101G). It appears that the external radiation levels may exceed the prescribed dose limits for generally licensed devices (>500 mrem/yr). In addition, the gauge did not appear to be adequately prototype tested.

Current Status: The review team again examined this casework file and confirmed the earlier recommendation that this device should be reevaluated. No complete reevaluation was performed. It was further noted that a number of these devices are now in use by several law enforcement agencies. The review team examined this recommendation as part of the Sealed Source and Device Evaluation Program non-common performance indicator (see Section 4.2). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(9) The 1994 review team recommended that the State ensure that the staff receive appropriate training in SS&D reviews. This training should include, but not be limited to, how to read blueprints, training on the use of the registry system, and the necessity of performing independent evaluations of source and device designs. The staff should also review all appropriate ANSI guides.

Current Status: The Senior Health Physicist responsible for industrial licensing and an Associate Health Physicist attended the NRC sponsored sealed source and device workshop in 1995. The review team recommended and the RHB intends to request further training for its staff in this area. The review team examined this recommendation as part of the Sealed Source and Device Evaluation Program non-common performance indicator (see Section 4.2). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

(10) The 1994 review team recommended that all staff performing SS&D reviews should be provided copies of all documents, guides, and information pertaining to SS&D reviews.

Current Status: The five Health physicists responsible for performing sealed source and device evaluations have been provided copies of the sealed source and device workshop manuals and other reference documents. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Status of Materials Inspection Program

The review team focused on five areas in reviewing the status of the State's materials inspection program: (1) capability of the State to maintain and retrieve statistical data on the status of the compliance program, (2) inspection frequency schedule, (3) initial inspections of new licenses, (4) overdue inspections, and (5) timely dispatch of inspection findings to licensees.

The team found that RHB's data system is successfully tracking the compliance actions for the 2,074 specific licenses administered by seven compliance offices which, in addition to the main office in Sacramento, include three regional offices and three counties with staff who perform inspections and investigations under contract with the State. Licensee compliance histories are available instantaneously to the Sacramento office through a network of personal computers which are furnished to all technical staff. The State plans to add the field offices to the network soon; until then, information is provided to the field offices through telephone, fax, and overnight mail. Monthly, quarterly, and annual reports are issued to all supervisors and field offices for verification and work-load adjustment. The data in several ad hoc reports provided to the review team corresponded to the information found during the inspection file reviews.

The team reviewed the State's inspection frequency schedule and confirmed that the State's inspection frequencies for various types of licenses are identical to similar license types listed in the frequency schedule in the NRC Inspection Manual Chapter 2800 (IMC 2800). The State's adherence to the prescribed frequency schedule was verified during the inspection file reviews. The team noted that California schedules inspections of mobile high dose remote (HDR) therapy licensees at one-year intervals, which is the same inspection frequency used by NRC. Because the HDR unit is removed after the treatment is completed, hospitals that use mobile services remain on their normal inspection frequency in accordance with the IMC 2800 schedule.

Initial inspections for licenses with inspection frequencies of five years or less become due six months after the license is issued. Initial inspections of Priority 6 licenses are due 12 months after the license is issued. New licenses are entered into the inspection tracking system at the time that the license is issued. This is done by administrative staff and verified by management when they review the monthly computer reports. Comparison of the computer data with the information gathered during file reviews confirmed that initial inspections are correctly entered and tracked. In their answers to the questionnaire, the State explained the procedure for setting up the first inspection: Three months after the license is issued, the State calls the licensee to determine whether the radioactive material has been acquired. If the licensee does not yet possess the material, the tracking system triggers calls at three-month intervals. After 12 months, the licensee is required to provide written certification to the State that they have not acquired radioactive material. This cycle repeats until the licensee obtains the material and an inspection is scheduled or until the license is terminated. The State justifies this minor deviation from IMC 2800 because of the geographical size of the State and the need to make the most efficient use of staff resources. In NRC jurisdiction, initial inspections are conducted within one year of license issuance whether or not radioactive material is on site.

The review team found no backlog of overdue inspections. During this review period, the State changed the definition of overdue inspections from 150% of scheduled frequency to 125% of scheduled frequency. This is the same criterion used by the NRC. The State effectively used additional staff and changes in work-load assignments to maintain the stricter inspection schedule without incurring backlogs of overdue inspections. This was verified by the review team in examinations of past quarterly and annual reports, current monthly reports, and review of the inspection files. The State is currently conducting reciprocity inspections and meets the criterion in NRC Manual Chapter 1220. The review team's calculations agreed with the State's projections of approximately 700 inspections that must be performed annually in order to maintain the prescribed inspection schedule. During FY 95-96, the State exceeded the goal by performing 718 inspections. In their response to the questionnaire, the State indicated that at any one time, a few inspections would be expected to be overdue by a few days, but not more than two weeks. At the time of the review, the team found three such licenses slightly overdue for inspection, and they were scheduled for inspection by the end of the month. This number is certainly within the 10 percent criteria for overdue inspections as listed in Management Directive 5.6.

The team also evaluated the State's timeliness in issuing inspection findings to the licensee. Review of the computer reports and inspection files showed that, during the review period, the State dispatched over 50% of inspection findings within their goal of 15 days, and that with a few exceptions in complex cases, all were sent within the IMPEP criterion of 30 days.

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

3.2 Technical Staffing and Training

Issues central to the evaluation of this indicator include: (1) the radioactive materials program staffing level, (2) the technical qualifications of the staff, (3) technical staff training, and (4) staff attrition. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed RHB management and staff, and considered any possible backlogs in licensing or compliance actions.

The RHB technical staff includes a Branch Chief and two Supervisory Health Physicists, one for materials licensing and one for enforcement and compliance. The RHB has five position classifications for its technical staff. These are:

- Junior Health Physicist - a trainee position
- Assistant Health Physicist - a first working level position
- Associate Health Physicist - a full journeyperson/lead person position
- Senior Health Physicist - a first supervisory level position
- Supervisory Health Physicist - a second supervisory level position

The Junior Health Physicist classification requires at minimum a bachelor's degree in physical or life sciences. The other positions require the same minimum level of education plus increasing professional work experience at the next lower level.

The licensing section, with a staff of nineteen, is divided into four subsections. Each subsection is supervised by a Senior Health Physicist. Three subsections are directly devoted to materials licensing and one subsection conducts radiological assessment activities in support of license terminations, enforcement and compliance and the Low-Level Waste Site. With respect to the licensing casework, applications are assigned to the staff in turn and based on their level of training and experience. Only Supervisory and Senior Health Physicists have signature authority for licensing documents. The sealed source/device certificates are co-signed by the reviewing staff member and the Senior Health Physicist. There is currently one vacancy in the materials licensing program.

With respect to the enforcement and compliance casework, assignments are made by the Senior Health Physicists based on an inspector's training and experience. Annual inspector accompaniments are conducted by supervisors who closely monitor the performance of

their staff. Routine inspection correspondence is signed by the inspectors, however, Notices of Violation are signed by Senior Health Physicists who have signature authority for non-routine matters.

The RHB encourages all licensing and compliance staff to attend technical courses including: Inspection Procedures Course, Diagnostic and Therapeutic Nuclear Medicine Course, Safety Aspects of Industrial Radiography Course, Teletherapy and Brachytherapy Course, Safety Aspects of Well Logging Course, Health Physics Technology Course and Licensing Practices and Procedures Course. The RHB selects staff to attend these courses based on their work assignment, education, work experience and RHB program needs. Individual staff members may be waived from attending specific courses on a case-by-case basis upon consideration of their past experience and education.

During the review period, seven new employees were hired by the materials licensing and compliance sections. Two of these employees are former NRC inspectors and four others were promoted from the X-ray inspection and certification program. The seventh individual has a Master's degree in Health Physics and professional work experience in radiological consulting. Two of the individuals, both inspectors, have not yet completed all of the requirements to conduct all types of RHB inspections independently. They are, however, being trained, closely supervised and are progressing through the various types of compliance inspections. The new license reviewers are obtaining training appropriate to their duties including on-the-job training with experienced reviewers.

The review team examined the State's response to the questionnaire and reviewed staff training and experience records and found that the staff meets the minimum education and work experience requirements for their duties. The State has established criteria for the qualifications of personnel in each job category. This is addressed through a combination of the position descriptions for each job series and the statement of duties for each employee. Specific courses are not contained in these documents, however, each supervisor selects candidates for specific courses based on each employee's education, past experience and work assignment. With regard to staffing level, attrition is low and the RHB appears to be more successful, than in the past, in recruiting qualified applicants when vacancies occur. At the time of this review, the RHB had only one technical position vacant.

The review team recommends that the State consider keeping a collective staff training record to help formalize technical training as an ongoing requirement for the position and to better allow management to assess the training level of the staff. Waivers granted to individual staff members, from attendance at specific training courses, based on past education and experience should be documented.

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

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the reviewers for thirty-six specific licenses. Licensing actions were reviewed for completeness, consistency, proper radionuclides and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authorities. Comments from casework evaluations performed during the review were discussed with the licensing manager.

License applications were checked to ensure that all essential elements met current regulatory guidance for describing the isotopes and quantities used, qualifications of personnel who used radioactive material, facilities and equipment, and operating and emergency procedures sufficient to establish a basis for licensing actions. Deficiency letters and other correspondence were checked for accuracy, completeness, appropriate regulatory language, and promptness.

Specific licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. Casework files were checked for retention of necessary documents and supporting data. Discussions were held with the license reviewers and supervisors concerning the casework evaluated during the review, and to determine their understanding and implementation of the procedures. The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by most reviewers. The cross-section sampling included twelve of the State's major licenses and included the following types: isotope and instrument product manufacturing, isotope product distribution, industrial radiography, nuclear pharmacy, pool type irradiator, pharmaceutical manufacturer, fixed, mobile, and transportable high dose rate (HDR) afterloaders, gamma knife, academic broad scope, portable gauges, research and development facilities, medical institution, and nuclear medicine private practice. Licensing actions reviewed included four new licenses, nineteen renewals, six amendments, and seven terminations. A list of these licenses with case-specific comments can be found in Appendix D.

The review team also examined the State's procedure for handling license terminations. Licensees are required by regulation to notify the RHB 30 days prior to vacating any facility that may have been contaminated with radioactive material as a result of licensed activities. The Radiologic Assessment Unit is responsible for determining that radioactive material contamination is not present prior to release of a facility for uncontrolled use. Inspection Policy Memorandum (IMP-88-2) revision effective August 15, 1995 details the procedures for: determining the disposition of radioactive material, the need for radiological surveys and confirmatory measurements, review of licensee submittals, the review of reports and records, and the receipt of the final inspection report. The staff utilizes the NRC provided SDMP action plan cleanup criteria, the tables in NRC Regulatory Guide 1.86 on Acceptable Surface Contamination levels and other guidance such as NRC

NUREG/CR-5849 on Conducting Radiological Surveys in Support of License Termination, to address facility/site decommissioning. Information obtained by the inspection staff is communicated to the licensing staff, who are responsible for license terminations, via the License Review Alert Form (RH 2033). The review team has identified the use of RH 2033 as a good practice. All seven license termination case files reviewed adequately addressed the disposition of radioactive materials and the results of radiological surveys or why no surveys were performed.

During the review period, one licensee completed a required full decommissioning effort. Interstate Nuclear Services, Inc. (INS) a nuclear laundry at 65 Ray Street in Pleasanton, submitted a decommissioning plan and request for termination of California license number 0739. The decontamination and decommissioning (D&D) was performed by INS with split samples provided to the State for their analysis. The State performed confirmatory surveys during 25 separate site visits over a period of one year. The State staff conducted area-wide surveys and obtained samples from 150 randomly selected locations in and adjacent to the licensee's building. The surveys were conducted in accordance with the RHB's internal procedures and their SDMP-like program, to determine if the licensee met the objectives of their RHB approved D&D plan and to determine if the site meets the requirements for release for unrestricted use. The results of the inspector's confirmatory surveys were documented and communicated to licensing staff who reviewed other pertinent information and determined that the site met the requirements for unrestricted use. The review team confirmed that the RH 2033 Form was on file. In accordance with the State's SDMP-like program, this file has been identified as requiring permanent retention.

It should be noted that the State does not agree with the NRC position that California is responsible for former AEC (pre-Agreement State) sites. This issue is being addressed separately from the IMPEP review.

The review team found that, overall, the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Licenses are issued for a period of seven years. Tie-down conditions reflecting technical changes in the license were almost always stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications. The State's licensing guides and applications were revised to reflect 10 CFR 20 regulations. License policy procedures (licensing manual) were established and, although in some cases not revised since 1988, were complete and followed. Standard license conditions were maintained via database and routinely used for all licensing actions. It was discussed with the staff that the standard condition for leak testing of sealed sources be revised to indicate that sources are to be removed from use and the device decontaminated if found to be leaking. It was noted that the license reviewers were implementing the State's licensing procedures, and that these procedures are consistent with NRC's procedures.

The review team found that the current staff is well trained and experienced in a broad range of licensing activities. License reviewers showed good research skills in using guide and other licensing documents. For all files reviewed it was noted that reviewers

appropriately used the licensing guides and accompanying checklists. Checklists were found to be completed (including initials and dates) by reviewers, then peer reviewed by senior staff and supervisors. Licensing actions were signed by the Supervisory Health Physicist or the Senior Health Physicist of the appropriate section. Pre-license/renewal visits were performed and documented in the files. No potentially significant health and safety issues were identified.

Due to the large volume of licensing actions, operations are divided between medical, industrial, and gauge use sections. Licensing cases are assigned on the basis of background and experience of reviewers. Information provided during the review relative to licensing actions indicated that overall, a very small backlog existed (primarily for amendments). Workloads in each section were adequately maintained including the industrial section which experienced a recent change in the supervisor position.

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

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and the database information for 26 materials inspections conducted during the review period. Because the State completed 1,377 inspections between June 1994 and June 1996, only a very small percentage of the completed inspection reports could be reviewed. Selection of the casework, therefore, focused on including all of the State's materials inspectors and on covering a sampling of a range of license types with emphasis on core licensees. The review included: one hospital with HDR therapy, one mobile HDR, two industrial radiographers, one major manufacturer, one nuclear pharmacy, one Industrial Radiography equipment manufacturer, one waste broker, one broad type A academic, two sealed source manufacturers and distributors, five nuclear medicine hospitals with therapy, one RadioImmunoAssay (RIA) manufacturer and distributor, one RIA kit distribution only, one broad type A laboratory, one biological laboratory, two service, one well-logging, one portable gauge, one fixed gauge, and one RIA storage only. Appendix E provides a list of the inspection cases reviewed in depth with case-specific comments.

The team reviewed the latest version of RHB's Compliance and Enforcement Procedures, dated January 10, 1996, various policy memos issued during the review period, and all current inspection forms. In general, the policies, procedures, and forms were determined to be consistent with the inspection guidance provided in IMC 2800 and IP 87100. The State uses separate supplements to the uniform inspection report form for various classes of license types, such as group medical, industrial radiography including field inspections, radiopharmacy, gauges, remote afterloaders, etc.

According to the State's policy, all inspections are to be unannounced except for initial inspections, inspections of licensees in remote geographical locations, or as necessary to meet with specific licensee management or personnel. Examination of the 26 inspection

reports indicated that, for the most part (18 cases), inspectors are not announcing inspections in advance.

Inspection reports were reviewed to determine if the reports adequately documented the areas inspected as contained in the inspection field notes. The overall quality of the inspection reports was very good, and the areas inspected were satisfactorily documented. Only one of the 26 reports needed improvement in the documentation of the follow-up of previous items of non-compliance and of the exit interview. The files were orderly and contained all documentation including letters and records of telephone conversations. The inspection findings led to appropriate and prompt regulatory action. Enforcement letters were determined to be written in appropriate regulatory language and timely.

It was verified during review of the files and computer records that the inspectors and unit supervisors are following the enforcement procedures. If the inspection results indicate the licensee must take corrective action, a Notice of Violation (NOV) with a cover letter is prepared by the inspector. All enforcement correspondence is reviewed by the unit supervisor, and NOVs require supervisory signature. Items of non-compliance on the NOV are assigned point values according to the seriousness of the infraction. If the point total is 64 or more, the tracking system automatically triggers a follow-up inspection in six months. Follow-up inspections are usually limited to previous items of non-compliance. Review of the computer reports showed that the follow-up inspections are indeed being entered in the data system. During FY 95-96, records show that 11 follow-up inspections were conducted. Licensees who fail to adequately respond with their plan for corrective action within 30 days are contacted by the inspector in an effort to bring the facility into compliance before escalated enforcement action is taken. Escalated enforcement actions are initiated if a violation is serious, if the user does not respond adequately to the NOV, or if the violations remain uncorrected at the time of the follow-up review. Options for escalated enforcement include meetings between the licensee and RHB management, emergency order, and prosecution under the State's criminal code. The records show that eight serious enforcement problems were escalated to management level during FY 95-96.

As another means of escalated enforcement action, California inspectors also have the option to call for an instant end to a serious noncompliant activity encountered in the field by using the User's Declaration Form. This User's Declaration establishes a legally binding agreement between the State of California and the licensee. By using this mechanism, the licensee may voluntarily sign an agreement to take immediate corrective action, including to cease and desist. This is similar to NRC's Confirmatory Action Letter, but it can be executed by the inspector (with management concurrence by telephone) at the time the infraction is found. Records show that 34 User's Declaration Forms were issued in FY 95-96. The review team has identified the use of User's Declaration Forms as a good practice.

The team found that the State's enforcement tracking system is working well. The Chief, Compliance and Enforcement, is able to instantaneously track all compliance actions, including upcoming, due, and overdue inspections, correspondence dates, follow-up

inspections, and the status of open and closed enforcement actions. The field offices have similar systems for tracking enforcement actions within their jurisdiction, and they are kept abreast of the statewide progress by the periodic reports.

Inspectors notify the licensing section of any licensing-related issues through the use of the License Review Alert Form (RH2033). Review of the files indicated the form is being used when necessary to provide the appropriate feedback from inspectors to license reviewers.

The State's radiochemistry laboratory, located in Berkeley, was evaluated during a performance appraisal by the NRC on May 20-24, 1996, in conjunction with the State's Environmental Monitoring Cooperative Agreement. During that review, it was found that the laboratory maintained an excellent inventory of state-of-the-art analytical equipment and instrumentation. It was also noted that the laboratory's performance in the Environmental Protection Agency's cross-check program was excellent. Review team interviews with RHB staff indicated that the turn-around time for samples is satisfactory. Routine samples are analyzed and results are available within one week. For emergencies or incidents, overnight or immediate processing can be authorized.

The team found that the State's inspection agencies have a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments are a good mix of low range GM tubes and pancake probes, micro R meters, high range instruments, instrumentation with calibration standards for alpha detection, a neutron rem meter, and portable multichannel analyzers. Air monitoring equipment is also available.

RHB instruments from both headquarters and the regional offices are calibrated under contract by a private company, Medical Physics Center, located in Sacramento. In addition to performing the calibration, the company tracks the calibration history of all RHB instruments and notifies RHB when each instrument is due for calibration. The State explained that field offices have enough instruments available to be able to return those needing calibration to Sacramento. Los Angeles, Orange, and San Diego Counties are responsible for providing and calibrating their own instruments. Survey instruments in RHB and county field offices were examined during visits by a team member during the review period and found to be in calibration. It was verified through review of the records that instruments are calibrated at least on an annual basis, and staggered so as to always have instruments calibrated within the calendar quarter for use during industrial radiography inspections.

The review team noted that the contract with the company that calibrates RHB instruments had recently expired, and that efforts had not begun to renew the contract.
Each inspector is responsible for maintaining the calibration schedule for their survey instrument. As a backup, however, the contract for calibration services requires that the contractor prompt each inspection region regarding the calibration due date for individual instruments. The review team recommends that the State take action necessary (renew the calibration contract) in order to maintain the instrument calibration schedule.

Supervisory accompaniments of inspectors are performed annually and documented with records kept by the Chief, Enforcement and Compliance. Review of the records showed that the ten health physicists and seven unit supervisors who conduct independent inspections were, with one exception, accompanied by supervisors annually during the review period. One accompaniment was missed in 1995 when the Orange County supervisor retired, but the health physicist involved is an experienced inspector who has had many previous satisfactory accompaniments.

A member of the review team conducted accompaniments of seven California inspectors and supervisors during the review period as follows: On November 9, 1994, a Los Angeles County inspector was accompanied during an inspection of a medical licensee, Groups I-V. On November 10, 1994, an RHB inspector was accompanied during an inspection of a radiographer. On February 28, 1996, an RHB inspector was accompanied during an inspection of a radiographer at temporary job sites. On February 29, 1996, an RHB inspector was accompanied during an inspection of a medical licensee with HDR therapy. On April 2, 1996, the San Diego County supervisor was accompanied during an inspection of a large nuclear medicine licensee. On June 4, 1996, the San Jose RHB supervisor was accompanied during an inspection of a licensee with portable gauges. On June 20, 1996, the Sacramento RHB unit supervisor was accompanied during an inspection of the licensed calibration and training facility at the California Office of Emergency Services. The team found that technical performance of the inspectors was satisfactory and that the inspections were adequate to assess radiological health and safety at the licensed facilities.

In general the inspectors were thorough, understood the regulations, observed good health physics practices and performed the inspections in a professional manner. Exit meetings were held at the appropriate management level, and the inspectors clearly described both the positive findings and items of non-compliance. The portable instruments used during the accompaniments were operational and calibrated. The results of the accompaniments were discussed with the inspectors, their immediate supervisors, and the RHB Chief, Compliance and Enforcement. All California inspectors and supervisors conducting independent inspections have now been accompanied by an IMPEP team member. The team accompaniments are identified in Appendix E.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the IMPEP questionnaire relative to this indicator and reviewed the casework files of incidents, allegations and misadministrations. Events listed in the Nuclear Material Events Database were also reviewed and compared to cases obtained from the questionnaire and the State's own files. Additionally, the review team interviewed the Chief of Enforcement and Compliance and staff assigned to incident response.

The responsibility for initial response and follow-up to incidents and allegations involving radioactive materials is assigned to a member of the technical staff. This assignment comes from the Chief of Enforcement and Compliance or from the Regional Manager. Written internal procedures exist for handling incidents, complaints (allegations) and misadministrations. Initially when an incident, allegation, or misadministration is received, a Form 5010 (Matter Requiring Investigation/Inspection) is filled out by the Health Physicist or Radiation Protection Specialist who first receives the information. Form 5010 contains three copies of event information and is distributed as follows: white copy to the manager, yellow to the investigation file in Sacramento, and the pink copy to the license file. Once the Manager receives the white copy it is assigned to a member of the technical staff for follow-up. The time frame for staff follow-up after receiving notification of an incident or allegation is set by written internal RHB policy at 30 days for normal incidents. Most cases are handled within one or two days of notification. After the incident, allegation, or misadministration is investigated the person conducting the investigation then writes a report which is sent to the Chief of Enforcement and Compliance for review, comment and concurrence. When the event is closed out a Form 8434 (materials investigation closing memo) is filled out and placed in the file. The licensee and/or alleger is notified by letter regarding the results of an investigation.

The review team examined the State's response to thirty-seven events that included various incidents reported since the last review, except for those involving non-Agreement material. The events reviewed involved lost radioactive material, damaged equipment, equipment failures, leaking sources, tripped monitors at a landfill, abandoned material, and overexposures. In addition to the above, twelve allegation files were reviewed. These files involved several technical and administrative issues. The files reviewed were an assortment of the 656 incidents, misadministrations, and allegations on file since the last review. The team reviewed allegations forwarded to the State by the NRC and found that they were appropriately handled. The review team commended the RHB staff for their diligence in providing event data to the NMED tracking system, even though the event data are reported quarterly. A list of the casework files, with comments, is attached as Appendix F.

Based on the cases reviewed, the review team found that the State's response satisfied the performance criteria for this indicator. The level of the response was appropriate to the type of incident and was handled in a reasonable time frame from the initial notification to the close-out of the incident. The State notified the NRC in accordance with NRC guidance though the event data are reported quarterly. Allegations were responded to with the appropriate investigation and follow-up action, and the results were related to the person or the organization that notified the State of the allegation.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery. California has no agreement to regulate uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

The legal authority establishing the RHB and its regulations is derived from the California Health and Safety Code (H&SC). The H&SC contains the Radiation Control Law (Chapter 7.6) which among other things details the State's Agreement with the NRC. The State's Code of Regulations (Title 17) contains specific radiation control requirements including those addressing the Low-Level Radioactive Disposal Site.

During the review period the Governor signed Senate Bill 1360, which became effective on January 1, 1996. This legislation reorganized, renumbered and made non-technical changes to the public health portion of the H&SC. It should be noted that the scope of the State's regulatory authority remains unchanged. A copy of these changes was provided to the team, which reviewed them along with a memorandum to the staff explaining the changes. These changes appear to be non-technical as indicated by the State. The State does not have a sunset provision in its rules.

4.1.2 Status and Compatibility of Regulations

California's final equivalent to the NRC rule "Standards for Protection Against Radiation," Part 20, became effective on March 3, 1994. On July 18, 1994 the following rule became effective: "Safety Requirements for Radiographic Equipment," 10 CFR Part 34. On October 17, 1995 the following rules became effective: "Decommissioning," 10 CFR Parts 30, 40 and 70; "Emergency Planning," 10 CFR Parts 30, 40 and 70; "Decommissioning Recordkeeping: Documentation Additions," 10 CFR Parts 30, 40 and 70. NRC staff has reviewed these amended regulations and found that they are compatible with equivalent NRC regulations.

According to information provided in the questionnaire, since the State does not regulate uranium recovery operations it does not have a rule equivalent to NRC's regulations applicable to uranium recovery contained in 10 CFR Part 40.

- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendments (59 FR 28220) that became effective on July 1, 1994.

The State has a low-level radioactive waste disposal licensee and does have a rule equivalent to NRC's 10 CFR Part 61. However, it has not yet adopted the revision to the low-level radioactive waste regulations equivalent to the following NRC rule:

- "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 amendments (58 FR 33886) that became effective on July 22, 1993. Although the Low-Level Radioactive Waste Site is not yet operational the State indicated that the expected date for adoption of this rule is October 1, 1997.

Current NRC policy on adequacy and compatibility requires that Agreement States adopt certain equivalent regulations no later than three years after they become effective. The State has begun the process of promulgation of the following rules necessary for a compatible program:

- "Timeliness of Decommissioning of Materials Facilities," 10 CFR Parts 30, 40 and 70 amendments (59 FR 36026) that became effective August 15, 1994.

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. California and other Agreement States are expected to have an equivalent rule effective on the same date.

- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective June 30, 1995.

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Part 20 and 35 amendments (60 FR 50248) that became effective October 20, 1995.

The State has placed this regulation on hold pending the outcome of NRC's determination on the compatibility of the Quality Management rule and the revision to 10 CFR Part 35.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provisions for financial assurance that include at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee).

The team reviewed the procedures used in the State's regulation promulgation process and found that the State's formal regulation promulgation schedule takes approximately 10 months. Past experience however indicates that it often takes longer than three years for the State to promulgate its rules. The root causes of this extended promulgation schedule are likely attributed to a combination of complex procedures required for rule promulgation in the State's governmental system, higher priority work and past staff shortages. Emergency regulations can be placed on an expedited promulgation schedule, however, this process reduces the schedule by only 10 days. The public and other interested parties are offered an opportunity to comment on proposed regulations during a 45 day comment period. There is a provision for holding a public hearing on rulemaking, however, there is no requirement that a hearing be held for each rulemaking action. According to program management, the NRC is provided with drafts for comment on proposed regulations early in the promulgation process. The regulations are forwarded to several State administrative, financial and legal offices in accordance with a schedule which contains specific time frames for review and approval. The effective date of a final rule is selected by the Department of Health Services and is at minimum 30 days after approval by the Secretary of State. A copy of the final regulation is then provided to the NRC.

The State's regulations were compatible with those of the NRC at the time of the review, including all regulations necessary for a compatible program that are due by January 1997, except for the following regulations which have not yet been promulgated:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757 and 56 FR 64980) that became effective on October 10, 1991.

- "Quality Management Program and Misadministrations," 10 CFR Part 35 (56 FR 34104) that became effective on January 27, 1993.

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Parts 19, 20, 30, 36, 40, 51, 70 and 170 amendments (58 FR 7715) that became effective on July 1, 1993.

During discussions with the review team, program management explained that the staff is in the process of preparing drafts to amendments on notifications of incidents and the Irradiator rule. The 1994 review team commented that the Notification of Incidents amendments were due for adoption by the State on October 10, 1994. The State reports that compatible regulations in this area are expected to be adopted on October 1, 1997. The Irradiator rule is currently being addressed through license conditions pending adoption of a compatible rule, also in 1997. The case file review of a large pool type irradiator license renewal confirmed the State's use of license conditions to implement Part 36 rule requirements.

Program management reported that the Quality Management Program and Misadministrations Rule (QM rule) is currently on hold pending NRC's resolution of National Academy of Sciences Report issues relating to the regulation of the uses of radiation in medicine. NRC staff is currently deferring compatibility findings, for Agreement States that have not yet adopted a compatible QM rule, pending resolution of the issue of Agreement State compatibility.

The review team recommends that the State make a concerted effort to adopt regulations which are required for compatibility and are overdue for adoption. A special effort should be made to adopt the amendments on Notification of Incidents, the Irradiator rule and the Definition of Land Disposal and Waste Site QA program amendment. Due to the safety benefits attendant to the QM rule, the State is encouraged to adopt a compatible QM rule.

Based on the existing NRC compatibility policy and the IMPEP evaluation criteria, the review team recommended in the proposed final report that California's performance with respect to the indicator, Legislation and Regulations, be found unsatisfactory. The team recommended that compatibility findings for the California program be reevaluated upon final promulgation of California's regulations on Notification of Incidents and the Definition of Land Disposal and Waste Site QA program amendment. Because of the progress to date in the promulgation of these rules and the expected adoption date of October 1, 1997, the MRB determined that a sufficient basis did not exist to support a finding of unsatisfactory for this indicator. The MRB noted that if significant delays in rule adoption occur or if California adopts rules that are not compatible with the NRC equivalent regulations, the MRB could always reconsider the program compatibility finding at a future date. The MRB final recommendation for Legislation and Regulations is satisfactory.

4.2 Sealed Source and Device Evaluation Program

In evaluating the State's SS&D program, the review team evaluated the information provided by the State relative to this indicator in its response to the questionnaire, reviewed the casework, held reviewer interviews, and reviewed registration sheets and background files for 22 certificates of registration sheets issued between January 1993 and October 9, 1996. It is important to note that situations in this program area associated with past management of the program had resulted in many verbal approvals and incomplete reviews of certain areas. The use of verbal approvals resulted in the lack of information for some files and made this a difficult program to assess. It can be best stated that the program had some problems, that these problems have been identified by management and that management is taking corrective action. The new Section Chief has expressed a strong desire to rebuild the State's SS&D program and upper management appears to be very supportive. However, some product safety reviews missed issues that should have been addressed. Although these product(s) are being distributed, the deficiencies noted were not significant relative to health and safety, and no reported failures or equipment problems have been reported to the State.

Further when pertinent written supporting information and drawings could not be located, the review team interviewed State staff and management to address issues and questions that were identified during the IMPEP review. Since the previous supervisor responsible for approving SS&D evaluations is no longer employed by the State, the review team used professional judgment and information obtained from State staff to make a determination on technical adequacy of the SS&D casework files reviewed. Due to a lack of documentation in some specific casework files, the reasons for some of deficiencies noted in Appendix G could not be determined.

The IMPEP review team reviewed the State's SS&D program in two areas, 1) the State's implementation of the steps it took to improve their SS&D Program that resulted from the 1993/1994 Agreement State Review findings and 2) as a non-common indicator for sealed source and device review.

The State took some steps to address the recommendations that resulted in findings from the 1993/1994 Agreement State Review. These recommendations address the following six areas: (1) use of ANSI standards in reviewing products; (2) review of user or operation manuals and QA programs for products; (3) review of drawings and list of materials of construction; (4) reevaluation of a specific neutron gauge used by general licensees; (5) the need for staff training in this program area; and (6) providing copies of necessary information to all the staff members.

California has implemented steps to address recommendations 1, 2, 3, 5, & 6. However, the review team findings indicate that these steps have not been fully implemented. The review team recommends that the State exert greater management oversight over the SS&D evaluation program. The team believes that such oversight is needed to assure full implementation of the recommendations in this area, given that some recommendations from the 1994 followup program review have not been fully addressed. The review team feels that this will allow the State to fully implement past recommendations and to assure

that the staff continues to adhere to the State's own Policy Memoranda in this area. These Memoranda cover the maintenance of SS&D registry information and the procedure for evaluating SS&D's including manufacturing Quality Assurance/Quality Control. Many of the comments noted in the Appendix G could have been eliminated if the procedures were fully implemented. Some State staff expressed concern that they did not have copies of the standards and procedures, however, they did know where to get this information and this was considered to comply with the recommendation to provide copies of information to the staff members.

State staff has not performed a reevaluation of a neutron gauge in recommendation 4, at the time of the IMPEP review due to higher priority work. The Branch Chief verbally committed to performing this task within a few weeks after the IMPEP review. Discussion with staff management indicates that such a reevaluation will be done to determine if the device continues to be in conformance with the general distribution safety criteria. The reevaluation will be done using the additional information provided by users of the product, the vendor, and the specific comments transmitted to the State in letter dated July 12, 1996, from the Office of State Programs. (See recommendation in Section 4.2.1)

Improvements in the nationwide effort to evaluate SS&Ds containing radioactive material led to NRC adoption of 10 CFR 30.32 (g) on "Application for Specific Licenses" and 10 CFR 32.210 entitled, "Registration of Product Information." These regulations were not initially identified as items of compatibility for Agreement States with SS&D evaluation programs. All Agreement States letter SP-95-116 dated July 25, 1995 announced Commission approval of minimum standards for Agreement States desiring to maintain authority to evaluate SS&Ds. In keeping with this guidance, the review team recommends that the State consider adopting regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210. These regulations require manufacturers/distributors to submit certain key product information in support of an SS&D evaluation and permits the State to enforce against those commitments. The review team noted that the State requires manufacturers and distributors of sealed sources and devices to establish and implement manufacturing Quality Assurance and Quality Control programs through their internal Policy Memoranda. More specific guidance in this area is contained in Regulatory Guide 6.9 dated February 1995 entitled, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources Containing Byproduct Material" which is referenced in the internal Policy Memoranda.

4.2.1 Technical Quality of the Product Evaluation Program

The review team reviewed the files and performed staff interviews for the 22 new or revised SS&D registry sheets issued since the 1993/1994 review. This included the State's review and approval of a radiography device for compliance with 10 CFR Part 34.20 for equipment requirements, sources and devices used in well logging applications and sources and devices used by specific and general licensees. The SS&D registry sheets issued by the State and evaluated by the review team are listed in Appendix G. Based on the review of selected SS&D casework files the review team recommends that the State: (1) determine and document in evaluation certificates whether sources approved for use in well logging applications meet the requirement for insoluble as practicable; (2) review and

possibly modify the Section 1.8 of ADAC Laboratories' users manual which appears to condone direct hand contact with the sealed source, i.e., "Hold the Line source with two hands while positioning the source;" (3) obtain SS&D training for those staff members that have not yet had or have limited SS&D training either by using training offered by NRC or another Agreement State program; (4) develop a policy position on including information on the useful life of a product and using operational history data to augment prototype testing when evaluating SS&D; neither is routinely used by the staff during reviews but both are useful information in determining whether a product is acceptable for licensing; (5) determine the actual use conditions for those gauge sources that do not meet the ANSI standard classification for vibration and evaluate the need to modify SS&D sheets if the condition of use is typical for industrial gamma gauging devices as indicated in ANSI N-542; and (6) re-evaluate the Nova R&D Inc., model Cindi neutron device with special attention to the potential exposure received by the general licensed user. If it is determined that the exposure rate exceeds that which is allowed for persons covered under the general license, the device should be reclassified for distribution to persons covered under a specific license and the SS&D evaluation certificate should be amended to reflect any required changes.

State staff are using ANSI standards, Regulatory Guide 10.10 and 10.11 and NRC's Standard Review Plan to perform the evaluations. They rely heavily on the Standard Review Plan and the checklist it contains. This approach should allow the State to identify the majority of the health and safety issues associated with the product under review. Overall, the IMPEP review team identified some concerns with not addressing health and safety issues and some files were deficient in technical quality. The review team also identified several files in which the second signature or audit was not always performed as a technical quality audit. Rather, only wording was reviewed. The review team recommends that the State fully implement a program of peer review of SS&D evaluations as a technical quality assurance measure.

The review team found that the State had developed and implemented procedures to improve the SS&D program. The new Section Chief self-identified some weakness in implementing these procedures and appears committed to rebuilding the program to a model for other regulatory programs to emulate.

It should be noted that several of the findings listed in Appendix G reflect ineffective past management. For example, management did not direct staff to obtain necessary bend test information in one case. In other cases certain information was overlooked as a result of program direction. These are some of the areas that the new Section Chief is addressing.

The State staff expressed concern regarding the use of the term useful life and using operational history data to augment product testing programs. The State believes that such information is a product endorsement, therefore this data is not used during a product review. It should be noted that operational history data from identical or similar devices or sources are a valuable tool in assessing the integrity of the source or device when used with the vendor's estimate of the useful life of the product. The State should review its position with regards to these two terms and take action as it deems necessary if a change in this State position is indeed warranted.

4.2.2 Technical Staffing and Training

The State reported that the current staff all have at least a bachelors degree in physical or biological sciences and several have advanced degrees in nuclear/radiological science. All health physicists have completed the NRC recommended core training courses for materials licensing personnel. Senior Health Physicists have completed more advanced training. During the review period two staff members attended the SS&D evaluation workshop. Formal course work and on-the-job training allows the Health Physicists to operate independently in this area.

All members of the Industrial and Sealed Source and Device Section have signature authority for product review only. Only the Senior Health Physicist or management can perform the final technical review and provide the second signature of the registration certificate. The IMPEP review team found all section members have signature authority but may not have had adequate training to review some products. Below is a listing of the Section members with training and their work experience. The loss of the Industrial Licensing Section Chief presented a challenge to the program. The State is aggressively rebuilding the program as a result of this loss. The State staff discussed with the IMPEP review team a request for State reviewers to work with the Sealed Source Safety Section at NRC Headquarters, which the Sealed Source Safety Section has extended. Both the State and NRC management are considering this request.

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License Reviewer in Georgia
SS&D Workshop

Dave Wesley:
Senior Health Physicist, Section Chief
B.S. and M.S. in Nuclear Engineering
SS&D Workshop

The new Section Chief has identified some training weaknesses and is working to correct them. The Section Chief is developing a team approach to conducting product reviews that will result in two technical reviews and a senior staff or management approval of registration certificates. This action should also provide for some cross training of those persons that need some additional training in this area. The Section Chief is using the States Policy Memorandum system to provide direction to the staff in this program area.

4.2.3 Evaluation of defects and incidents regarding SS&Ds

The review team looked at the State's evaluation of defects and incidents regarding SS&Ds for Industrial Nuclear Inc., (INC) a radiography equipment and source vendor, Measurex Corporation a gauge vendor, Nova R&D Inc., a device vendor and Nucleonic Data Systems (NDS) a gauge vendor that no longer holds a State license. The INC issues involved a change in a radiography source assembly length, evaluation of user instructions that were causing equipment problems, and a change to the lock mechanism of a radiography camera. The Measurex issue involved its use of nominal source activity for labeling of products and shipping papers which is a violation of NRC and Department of Transportation regulations. It should be further noted that inaccurate labeling may affect the level of response to incidents or accidents. This issue involved labeling all products with a maximum nominal activity and then loading the devices with source activities much less than or equal to the nominal activity. The Nova R&D Inc., issue involved the State informing general license users of the device that they must comply with an annual exposure of 100 millirem instead of the 500 millirem the regulations require. The NDS issue involved loading the device with activities greater than that which the State believed they approved. The NDS issue will likely involve a reassessment of the general license safety criteria.

The State had just received the NDS issue and was planning to address the issues. The Measurex case was closed by negotiating a tighter tolerance for defining nominal activity. The IMPEP review team found an incident in which the State took appropriate actions to evaluate root cause of radiography equipment failure, determined and implemented corrective action regarding a source assembly length change and user manual corrections, but never took the final action by amending the registration certificate to provide this information to the other users of the Sealed Source and Device Registry system. The review team recommends that the State amend the appropriate INC SS&D certificates.

The State has decided that they will continue to use the dose criteria defined in 10 CFR 32.51 and not 100 millirem as they had informed at least one general licensed user. This decision was to allow for nationwide consistency for products used under the general license provisions. The review team recommends that the State develop a checklist or internal procedures to follow when approving products for distribution to persons covered under a general license.

Based on criteria for this non-common indicator, the review team recommends a finding of satisfactory with recommendations for improvement. This finding was chosen because the criteria for unsatisfactory appear to deal with frequently failing to address health and safety issues. Because frequently is defined as occurring often or at close intervals this did not appear to be the case based on the cases reviewed and on interviews with the State staff.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of low-level radioactive waste as a separate category. Those States with existing agreements prior to 1981 were determined to have continued low-level radioactive waste disposal authority without the need of an amendment. California, an Agreement State since 1962, has low-level radioactive waste disposal authority, and has issued a license to U.S. Ecology to construct and operate a low-level radioactive waste disposal facility at Ward Valley near Needles, California. California is the host State for the Southwestern LLRW Compact which includes Arizona, North Dakota and South Dakota.

In the process of evaluating this performance indicator, the team reviewed the State's responses to the questionnaire, the qualifications and position descriptions of the staff, discussed statutes and regulations applicable to the site and interviewed the staff assigned to the LLRW program. The land for the Ward Valley Site has not yet been transferred from Federal to State control, therefore, site construction activities have not begun. The team conducted a "forward look" at the State's planned activities during the construction and operational phases of the Ward Valley Project.

4.3.1 Introduction

The State's LLRW program resides within DHS, Division of Drinking Water and Environmental Management. Due to a hold placed on the transfer of the land, the main focus of the LLRW program staff is providing support in responding to challenges to the transfer of the land and the issuance of the license. Some effort is being devoted to developing a disposal rate formula and drafting accompanying regulations.

During the project's site construction phase, the LLRW program will utilize contractor technical support in performing regulatory program activities related to construction and startup of the LLRW disposal facility. To assure licensee compliance with previous commitments, made in their license application, specific tasks under the contract will include:

- reviewing construction drawings and specifications.
- reviewing operating procedures.
- reviewing environmental monitoring plans.
- reviewing administrative records for commitments made by the developer during the licensing process.

- providing on-site inspection services during construction.
- reviewing developer's subsurface geological maps; and
- reviewing site closure plans

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

There were no inspection activities conducted during the review period, therefore, the review team did not evaluate this area.

4.3.3 Technical Staffing and Training

The LLRW Program is in the Division of Drinking Water and Environmental Management of the State Department of Health Services. The LLRW Program is currently staffed by three individuals: the program manager; a research program specialist (Economist); and an office technician. The program manager is a Registered Professional Engineer with a Bachelors of Science degree in Civil Engineering and many years of experience in managing water quality and environmental programs. He is directly involved in administering the license, managing the LLRW contractors, developing regulations, developing specific internal licensing and inspection procedures, and reviewing the licensee's environmental sampling data. Upon transfer of the land, there are plans to hire six additional technical staff. These positions are currently authorized, funded and can be filled on short notice after transfer of the land to the State. General position descriptions and specific work assignments have been developed. These documents were examined by the review team and appear to be appropriate to the regulation of a LLRW site. An organizational chart for the LLRW program is attached to this report as Appendix B.

The program's staffing plan calls for hiring a Senior Engineer, a Senior Health Physicist and four Associate Health Physicists. These positions all require at minimum a Bachelors degree in the physical or life sciences. The Associate Health Physicist positions are journeyperson positions requiring a minimum of three years of professional health physics experience or two years with a Master's degree or equivalent graduate work in radiological science. The Senior Health Physicist position requires two years of experience at the Associate Health Physicist level. The additional staff, including a chemist, will be hired during facility construction. These personnel will be ready to assume their duties before the facility begins accepting waste.

The LLRW program plans to have one employee working full-time at the facility site while construction is ongoing to facilitate the decision-making process.

During the operational phase of the facility, the LLRW program plans to conduct the following inspection related activities:

- On-site inspections at the disposal facility. The LLRW program will have two full-time inspectors on-site at the disposal facility. A health physicist will ensure the operator's compliance with waste acceptance and handling activities, radiation safety programs, radiation detection equipment maintenance and calibration, and environmental monitoring. The health

physicist will also conduct an independent environmental monitoring program to verify the results of the operator's program. An engineer will be used to inspect the construction of the trenches and the trench covers, and will ensure the operator's compliance with operating procedures for heavy equipment used at the facility. The personnel in these two positions will be cross-trained to provide flexibility during employee absences.

- Point-of-origin inspections. The LLRW program plans to conduct point-of-origin inspections of individual LLRW generators' premises in California to ensure compliance with waste form and packaging requirements. Memoranda of Agreement will be executed with other States in the Southwestern LLRW Compact to provide these inspections in a compatible manner for the LLRW generators within those States.

Technical support has been obtained through a contract with ERM Program Management Company of McLean, Virginia for hydrology, geology and engineering. Health physics support is obtained under a subcontract with Rogers and Associates Engineering Corporation of Salt Lake City, Utah. Both firms are recognized environmental consultants and appear qualified for the responsibilities assigned to them.

The LLRW program manager plans to send new health physicists to Industry, NRC and CRCPD sponsored training courses and workshops on LLRW management (performance assessment), disposal, transportation, and inspections. This training will occur during the approximately 18-month construction phase of the project. On-site inspectors will be sent to existing LLRW disposal facilities to observe operations and learn from experienced personnel at operating facilities. On-site inspectors will also work extensively with the LLRW program's construction assistance contractor to gain familiarity with facility construction and operation prior to commencement of disposal operations. Point-of-origin inspectors will be assigned to accompany inspectors from a State with an operating LLRW disposal site to gain familiarity with their inspection program procedures.

The review team recommends that the LLRW program consider keeping official records of each staff member's technical training and participation in workshops, conferences, etc., in the individual's training files. The State should also maintain a collective staff training record to help formalize such training as an ongoing requirement for the position and to better allow management to assess the training level of the staff. Waivers granted to individual staff members, from attendance at specific training courses, based on past education and experience should be documented.

4.3.4 Technical Quality of Licensing Action

The LLRW program issued the Ward Valley facility construction and operating license on September 16, 1993. No license amendments were issued doing the review period, therefore, this area was not evaluated.

4.3.5 Technical Quality of Inspections

There were no inspections conducted by the LLRW program during the review period therefore, this area was not addressed.

4.3.6 Response to Incidents and Allegations

There were no reported allegations in the LLRW area during the reporting period. The State reported that allegations referred to the LLRW program will be handled in the same manner as those reported to the RHB.

Based on the IMPEP evaluation criteria for the above performance areas, the review team recommends that California's performance with respect to this indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the common and two non-common performance indicators to be satisfactory and the non-common indicator, Sealed Source and Device Evaluation Program to be satisfactory with recommendations for improvements. Accordingly, after consideration of the satisfactory finding for the non-common indicator "Legislation and Regulations," the team recommended, and the MRB concurred, in finding the California program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for action by the State.

1. The review team recommends that the State consider keeping a collective staff training record to help formalize technical training as an ongoing requirement for the position and to better allow management to assess the training level of the staff. Waivers granted to individual staff members, from attendance at specific training courses, based on past education and experience should be documented. (Section 3.2)

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

3. The review team recommends that the State make a concerted effort to adopt regulations which are required for compatibility and are overdue for adoption. A special effort should be made to adopt the amendments on Notification of Incidents, the Irradiator rule and the Definition of Land Disposal and Waste Site QA program amendment. Due to the safety benefits attendant to the QM rule, the State is encouraged to adopt a compatible QM rule. (Section 4.1)

4. The review team recommends that the State exert greater management oversight over the SS&D evaluation program. The team believes that such oversight is needed to assure full implementation of the recommendations in this area, given that some recommendations from the 1994 followup program review have not been fully addressed. (Section 4.2)

5. The review team recommends that the State consider adopting regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210. (Section 4.2)

6. The review team recommends that the State determine and document in evaluation certificates whether sealed sources approved for use in well logging applications meet the requirement for insoluble as practicable. (Section 4.2)

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

8. The review team recommends that the State obtain SS&D training for those staff members that have not yet had or have limited SS&D training either by using training offered by NRC or another Agreement State program. (Section 4.2)

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

10. The review team recommends that the State determine the actual use conditions for those gauging sources that do not meet the ANSI standard classification for vibration and evaluate the need to modify SS&D sheets if the condition of use is typical for industrial gamma gauging devices as indicated in ANSI N-542. (Section 4.2)

11. The review team recommends that the State re-evaluate the Nova R&D Inc., model Cindi neutron device with special attention to the potential exposure received by the general licensed user. If it is determined that the exposure rate exceeds that which is allowed for persons covered under the general license, the device should be reclassified for distribution to persons covered under a specific license and the SS&D evaluation certificate should be amended to reflect any required changes. (Section 4.2)

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

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

14. The review team recommends that the State develop a checklist or internal procedures to follow when approving products for distribution to persons covered under a general license. (Section 4.2)

15. The review team recommends that the LLRW program consider keeping official records of each staff member's technical training and participation in workshops, conferences, etc., in the individual's training files. (Section 4.3)

Good Practice. Along with the recommendations for California, the review team identified the following good practices in California:

1. The use of the License Review Alert Form (RH 2033) used by the inspection staff to communicate information to the licensing staff. (Section 3.3)

2. The use of the User's Declaration Form to establish a legally binding agreement between California and a licensee that can be executed by an inspector in the field to put an instant end to a serious noncompliant activity. (Section 3.4)

LIST OF APPENDICES AND ATTACHMENTS

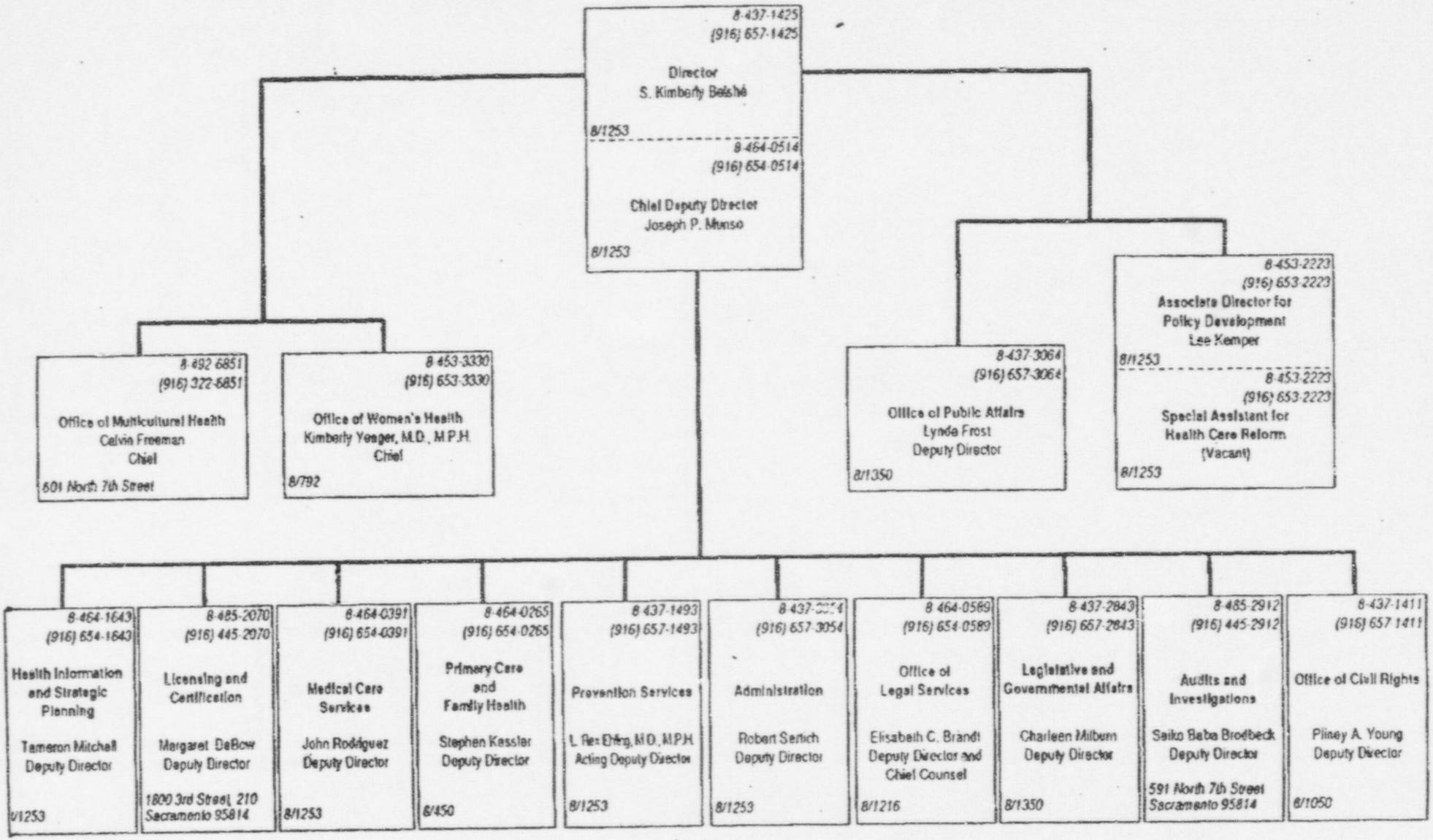
APPENDIX A - IMPEP REVIEW TEAM MEMBERS

Lloyd Bolling, OSP	Team Leader Technical Staffing and Training Legislation and Regulations Low Level Radioactive Waste Disposal Program
Jack Hornor, R-IV	Status of Materials Inspection Program Technical Quality of Materials Inspections
Steven Baggett, NMSS	Sealed Source and Device Evaluation Program
Craig Gordon, R-I	Technical Quality of Materials Licensing Actions
Allen Grewe, Tennessee	Response to Incidents and Allegations

APPENDIX B

ORGANIZATIONAL CHARTS

CALIFORNIA
DEPARTMENT OF HEALTH SERVICES

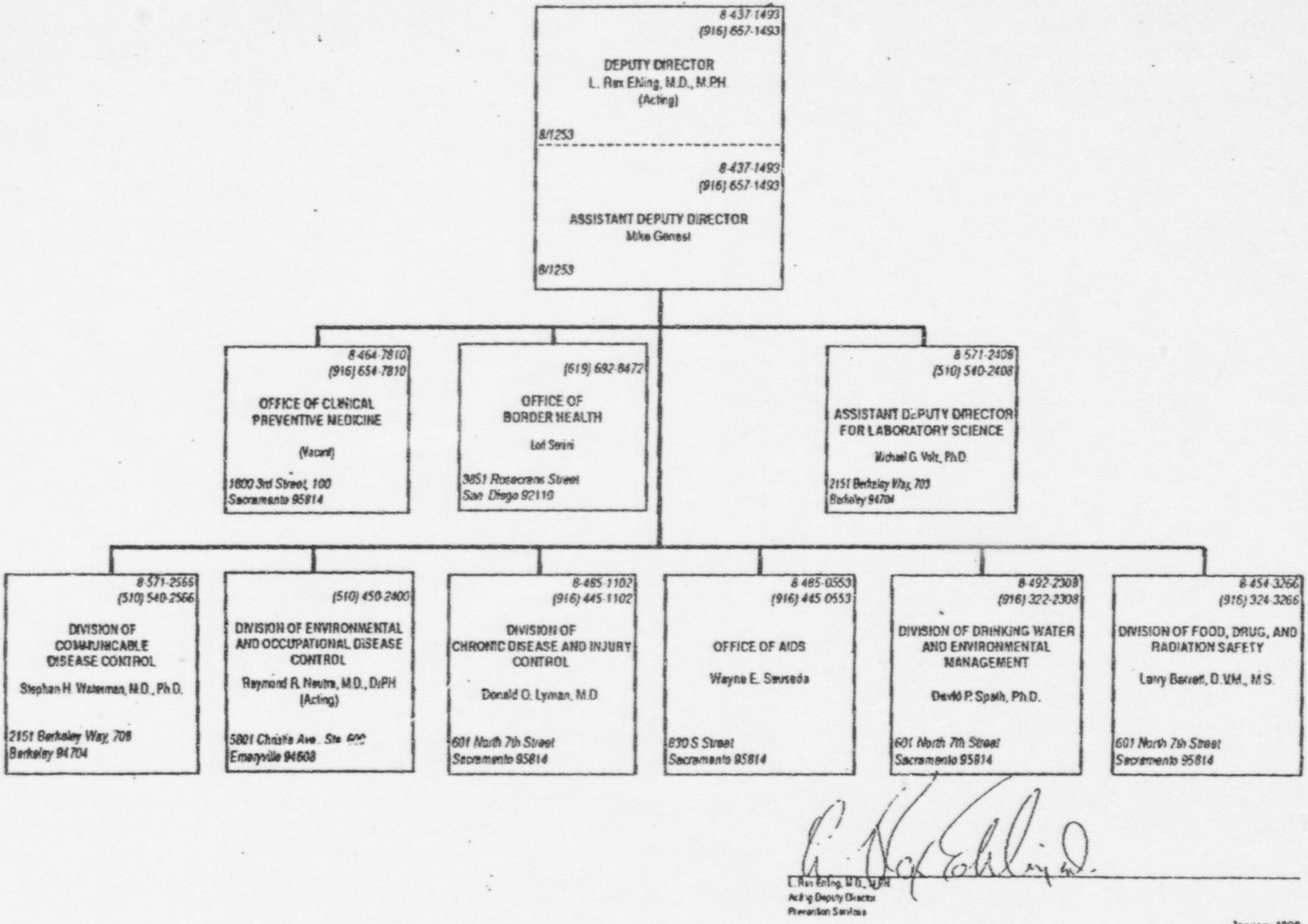


S. Kimberly Belshé

S. Kimberly Belshé, Director
Department of Health Services

January 1998

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
PREVENTION SERVICES



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10960RG.cdr

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APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE- RESPONSE

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE- RESPONSE

Name of State: California
Reporting Period: January 29, 1993 to October 21, 1996

A. COMMON PERFORMANCE INDICATORS

I. Status of Materials Inspection Program

1. Please prepare a table identifying the licensees with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800 (issued 4/17/95). The list should include initial inspections that are overdue.

   There are no inspections overdue by more than 25% of the scheduled frequency according to NRC Inspection Manual Chapter 2800 issued on 4/17/95. California has more than 2100 licensees to inspect; therefore, at any given time there may be one or two licensees overdue for inspection. However, there are no inspections that will be overdue for more than two weeks.

   All new licensees are due for inspection within six months after the license is issued. The licensee is first contacted to verify that they have received the radioactive material authorized under the license. If the licensee has not received material the inspection is NOT conducted, but a notation is placed in the data base that identifies the contact date and the fact that there is no material on hand. A follow up contact will be made, generally within six months. This process is carried out until the new licensee actually receives the radioactive material; at that time the initial inspection is scheduled.

2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.

   We print out workload reports each month that include metrics to graphically display the amount of work completed by each inspection agency. We also print out an inspections overdue report that shows any licensee that will become overdue within the next three, six, or nine months. This enables our staff to plan their work ahead.

According to our standard workload projection of 5.8 inspection actions per month per inspector, all seven inspection agencies have adequate staff to complete their allotted inspection workload. There are no staffing shortages within the radioactive materials license inspection program. Last fiscal year, July 1 1995 through June 30 1996, the program completed 718 materials licensee inspections. This is 34 more than the 684 inspections necessary to maintain our expected workload.

3. Please identify individual licensees or groups of licensees the State/Region is inspecting less frequently than called for in NRC Inspection Manual Chapter 2800 (issued 4/17/95) and state the reason for the change.

There has been a slight modification to Chapter 2800 inspection frequencies for licensees that are authorized to use High Dose Rate (HDR) afterloaders that are supplied by the mobile service Source2site, license #6152. Licensees that utilize mobile services do not have a HDR permanently installed at their facility; therefore, they are not inspected once each year as are the licensees that have fixed HDRs installed. The mobile service delivers the HDR whenever it is needed and when the treatment is completed the unit is removed. The inspection frequency is every three years, the frequency of most other medical licensees (see Attachment I).

4. How many licensees filed reciprocity notices in the reporting period?

There were 53 requests for reciprocity granted in 1995; of these, 13 were inspected during their operations in California. So far in 1996, 36 requests for reciprocity have been granted and there have been five inspections.

a. Of these, how many were industrial radiography, well-logging or other users with inspection frequencies of three years or less?

In 1995, three licensees were well logging operations and two were radiography. So far in 1996, two well logging authorizations and two radiography licensees have been granted reciprocity. All reciprocity inspection reports are filed in a separate location and are available for review.

b. For those identified in 4a, how many reciprocity inspections were conducted?

Thirteen in 1995 and five so far in 1996.

5. Other than reciprocity licensees, how many field inspections of radiographers were performed?

There are 57 licensees authorized to do radiography by the program. The majority of these are authorized field sites or temporary job locations; however, some do not work at field sites even though they are authorized. Last year 53 radiography licensees were inspected and of these 21 had field site audits. A special field site inspection form has been adopted to simplify the field site inspection process (Attachment II).

6. For NRC Regions, did you establish numerical goals for the number of inspections to be performed during this review period? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

II. Technical Staffing and Training

7. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

NAME POSITION AREA OF EFFORT

See Attachment III.

8. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

NEW STAFF:
Robert Greger: Nuclear Engineering, 20 Twenty Years with NRC, hired by Orange County in February 1996.

Philip Scott: Environmental Sciences degree, 2.5 years experience at RHB as an x-ray machine inspector. Promoted to materials inspector in January 1996. Philip has attended some NRC courses but is still considered a trainee.

Dao Pho: Physical Sciences degree. Promoted from x-ray machine inspector to materials inspector in January 1996. He has also attended some NRC courses but is still considered a trainee.

Barbara Hamrick: Former NRC inspector in Region III. Hired by Los Angeles County on 3/29/94.

Steve Doerfler: B.S. degree in Biological Sciences. Former X-ray machine inspector with Los Angeles County, promoted to materials inspector on 3/29/94. He has completed a number of NRC courses since his appointment.

Tara Goode: B.S. in Radiological Science. Former Radiation Protection Specialist in the Certification Unit of the Radiologic Health Branch. Promoted to Assistant Health Physicist in the Materials Licensing/Medical & Academic Unit 9/5/94.

Sudana Chi Kwok: M.S. in Radiological Health Physics and a B.S. in Microbiology. Former consultant for Medi-Physics, Inc. Hired by RHB on July 2, 1996.

9. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1245 and 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

Phillip Scott & Dao Pho have not met all requirements to conduct all types of inspections independent of supervision. However, they both have been trained to perform certain types of inspections, such as soil/moisture gauges, without immediate supervision. Each of them will progress to the next highest level of inspections as NRC courses become available and after specialized training by experienced staff. Their immediate supervisor will document their programs and indicate when they are ready to move to the next level.

Not all license reviewers have completed all required courses (see Attachment IV).

10. Please identify the technical staff who left the RCP/Regional DNMS program during this period.

See Attachment III.

III. Technical Quality of Licensing Actions

11. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, terminated or renewed in this period.

- **Source 2 Site, #6152: A transportable HDR**
- **UC San Diego, #1339: Academic/medical broadscope license issued using the new format and policy of visiting the licensee.**
- **Little Company of Mary, #1258: Redrafting a medical license from an uncooperative licensee. Use of unique license condition to accomplish compliance.**
- **Mobile Technology, Inc., #5919: Mobile HDR**
- **SCANS-Shade, #3087: Termination of license due to noncompliance.**
- **San Diego Gamma Knife, #6072: Unique facility for gamma knife only. Customized conditions.**
- **USC, #0382: Broadscope academic license issued with a visitation.**

12. Please identify any new or amended licenses added or removed from the list of licensees requiring emergency plans?

The list of licensees requiring emergency plans remains the same as the last period. Presently, we are reviewing the license of Isotope Products Lab. (IPL) to determine if this licensee is required to have an emergency plan.

13. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

License #	Variation
0789	Sr-89 compassionate use
6215	P-32 compassionate
1949	Ir-192 short time special use
0064	I-131 special circumstances, exempt from NCRP 37
2530	Sr-89 compassionate use
1624	Sr-89 compassionate use

14. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

- o **Redrafted Medical Application: The application was modified to allow for current technologies and to improve the ease with which the applicant could complete the form. Additional information is also requested with Financial Assurance and by identification by the Tax Identification number.**
- o **Redrafted Statement of Training and Experience: The new form provided for the SSN and a more effortless keying of the facilities of used or experienced.**
- o **Development of a formal document for the transfer of facilities to a new owner: This is a two-part document requiring the signature of the transferor and the transferee.**
- o **Redrafted Guide for Applicants for Radioactive Materials License: Corrects statements and addresses the financial surety and decommissioning funding plans.**
- o **Medical license conditions: Special license conditions were developed for the HDR and Gamma Knife.**

15. For NRC Regions, identify by licensee name, license number and type, any renewal applications that have been pending for one year or more.

IV. Technical Quality of Inspections

16. What, if any, changes were made to your written inspection procedures during the reporting period?

- o **Inspection forms were modified to accommodate changes to the regulations by the adoption of 10 CFR 20 requirements. Inspection staff have undergone extensive training for part 20 requirements.**
- o **Escalated enforcement procedures were revised to cover new procedures (1/10/96).**
- o **Emergency Response procedures were revised (1/10/96).**
- o **Clearance Inspection & Survey procedures were revised (8/15/95).**
- o **Inspector's instrument calibration frequency policy (6/28/96).**
- o **Standard citation paragraphs for 10 CFR 20 & 71 have been issued (9/15/96).**

17. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

Supervisor	Inspector	License Cat.	Date
Donald Bunn	Frank Bold	Gamma Knife	3/23/95
"	Steve Doerfler	Medical	6/14/94
Kim Wong	Kathleen Henner	"	11/2/95
"	Paul Baldenweg	Aero Space	12/7/95
William Lew	Fil Fong	Industrial	11/29/95
"	J. Richard Curtis	"	11/9/95
"	Mark Gotleib	Radiographer	10/18/95
"	Reza Omour	Pharmacy	2/27/96
Bob Funderburg	Ken Furey	Medical	9/11/96
Cass Kaufman	Steve Doerfler	Medical	11/30/95
"	Barbara Hamrick	Manufacturer	12/15/95

18. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.

Copies of each inspector accompaniment are available for review. Procedures are described by the report form. Each Inspection agency manager is responsible for conducting audits of their staff once each year.

19. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?

Complete equipment inventories for all inspection agencies are available for review. The equipment calibration policy is attached (Attachment V).

V. Responses to Incidents and Allegations

20. Please provide a list of the most significant incidents (i.e., medical misadministration, overexposure, lost and abandoned sources, incidents requiring 24 our or less notification, etc.) that occurred in the Region/State during the review period. For Agreement States, information included in previous submittals to NRC need not be repeated. The list should be in the following format:

LICENSEE NAME LICENSE# DATE OF INCIDENT TYPE OF INCIDENT

The following is a breakdown of incidents investigated since the last review period.

Year	1994	1995	1-10/96	
Number of Incidents		**186**	**158**	**84**
Allegations (Complaints)	**59**	**60**	**25**	
Misadministrations	**47**	**42**	**22**	

21. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified?

A complete printout of all incidents is available for review. All investigations have been reported to the NRC through the Events Database program. Significant incidents have been reported by the Abnormal Occurrence format and the NRC Region IV office were notified for those events requiring a P.N.

a. For States, was timely notification made to the Office of State Programs? For Regions, was an appropriate and timely P.N. generated?

See above.

22. For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

See above.

23. In the period covered by this review, were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case.

One individual was not granted a license because of prior compliance problems and making false statements. Three Nuclear Medicine Technologists had their license suspended or revoked for careless acts during the administration of nuclear medicine materials.

24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

a. For Agreement States, please identify any allegations referred to your program by the NRC that have not been closed.

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VI. General

25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

See correspondence between NRC and DHS, dated December 23, 1994, March 8, 1995, and November 8, 1995, for NRC

26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties which occurred during this review period.

The strengths of the California program are in the expertise and experience of individual staff members and the number of staff which allows shifting of work and responsibilities to respond to personnel changes, work emphasis, etc.

Lengthy and complicated budgeting and regulation adoption processes are inherent weaknesses in the California governmental system.

B. NON-COMMON PERFORMANCE INDICATORS

I. Regulations and Legal Authority

27. Please list all currently effective legislation that affects the radiation control program (R.C.P.).

Laws and regulations relating to radiation control are contained in the California Health and Safety Code, Penal Code, and Code of Regulations. Senate Bill 1360 became effective January 1, 1996. This legislation reorganized, renumbered, and made non-technical changes to the public health portion of the Health and Safety Code. Copies of relevant codes are attached (Attachments VI and VII).

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

No

29. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State, explain why they were not adopted, and discuss any actions being taken to adopt them.

The NRC Chronology is appended and reflects the current status of California Radiation Control Regulations. Notification of Incidents, R53-96, has been submitted for adoption. The estimated gestation period of 9.7 months puts delivery in June 1997. Quality Management Program and Misadministrations is on hold pending NRC resolution NAS report issues relating to regulation of medical practice.

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

A copy of California's Regulation Promulgation Schedule is appended (Attachment VIII). Review of this schedule discloses a period of 291 days from submission to effective date.

II. Sealed Source and Device Program

31. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

SS&D Registry Number	Manufacturer, Distributor or Custom User	Type of Device or Source

See Attachment IX.

32. What guides, standards and procedures are used to evaluate registry applications?

The following guides, standards and procedures are used to evaluate registry applications:

1. **Standard Review Plan For Applications For Sealed Source And Device Evaluations and Registrations**

2. **Reg. Guide 10.10, "Guide For The Preparation Of Applications For Radiation Safety Evaluation And Registration Of Devices Containing Byproduct Material"**

3. **Reg. Guide 10.11, "Guide For The Preparation Of Applications For Radiation Safety Evaluation And Registration Of Sealed Sources Containing Byproduct Material"**

4. **Reg. Guide 6.9, "Establishing Quality Assurance Programs For The Manufacture And Distribution Of Sealed Sources And Devices Containing Byproduct Material"**

5. **NSI-N542, "Sealed Radioactive Sources Classification"**

6. **NSI-N538, "Classification of Industrial Ionizing Radiation Gauging Devices"**

7. **NSI-N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography"**

8. **Other ANSI Guides when appropriate.**

9. **RML policy memo 88-7, "Maintenance of Sealed Source and Device Registry Information"**

10. **RML policy memo 89-1, "Sealed Source and Device Registry Sheet Review Procedures"**

33. Please include information on the following questions in Section A. as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Responses to Incidents and Allegations - A.V.20-23

Please refer to responses to the earlier questions.

III. Low-Level Waste Program

34. Please include information on the following questions in Section A, as they apply to the Low-level Waste Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6

There have been no inspection activities during the reporting period. Siting activities were completed by 1990, and construction is being held up by the U.S. Department of the Interior's inability to decide whether to transfer the land for the LLRW disposal facility to the State in a timely fashion.

Technical Staffing and Training - A.II.7-10

Carl Lischeske, the program manager, holds a B.S. degree in civil engineering. Other program staff include an economist (Research Programs Specialist - Economics) and a secretary (Office Technician). Technical support is provided under contract by ERM Consultants, which offers expertise in hydrology, geology, engineering, and health physics (the last primarily through a subcontract with Rogers and Associates.) There are no technical staff currently assigned to the program due to its delayed status.

Technical Quality of Licensing Actions - A.III.11, A.III.13-14

The license for the California LLRW disposal facility was issued in 1993 and has not been amended since that time.

Technical Quality of Inspections - A.IV.16-19

No inspections were performed during the reporting period. The licensee has yet to begin operations and does not yet possess radioactive waste.

Responses to Incidents and Allegations - A.V.20-23

No incidents involving mismanagement of radioactive materials were reported or alleged during the reporting period. DHS responded to a number of persons who expressed concerns regarding the proposed LLRW disposal facility at Ward Valley.

IV. Uranium Mill Program

35. Please include information on the following questions in Section A, as they apply to the Uranium Mill Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6
Technical Staffing and Training - A.II.7-10
Technical Quality of Licensing Actions - A.III.11, A.III.13-14
Technical Quality of Inspections - A.IV.16-19
Responses to Incidents and Allegations - A.V.20-23

TABLE FOR QUESTION 29.

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Any amendment due prior to 1991. Identify each regulation (refer to the Chronology of Amendments)				
Decommissioning; Parts 30, 40, 70	7/27/91	10/17/95	**R-46-93E**: "Decontamination & Decommissioning (also definitions)"	
Emergency Planning; Parts 30, 40, 70	4/7/93	10/17/95	**R-46-93E**: "Emergency Plan"	
Standards for Protection Against Radiation; Part 20	1/1/94	03/03/94	**R-45-93**: "Standards for Protection Against Radiation"	
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	7/18/94	**R-1-94**: "Safety Requirements for Radiographic Equipment"	
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	--------	**R-53-94**: DRAFT regulations 5/15/95.	10/01/97
Quality Management Program and Misadministrations; Part 35	1/27/95	--------	On hold pending NRC resolution of NAS report issues re regulation of medical use.	--------
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96	01/01/93	Now in 10 CFR 20, incorporated by reference in California Code of Regulations, title 17,section 30253.	
Definition of Land Disposal and Waste Site QA Program; Part 61	7/22/96	--------	"Definition of Land Disposal and Waste Site QA Program" NRC staff has determined that CA is compatible	--------
Decommissioning Recordkeeping: Documentation Additions; Parts 30, 40, 70	10/25/96	10/17/95	**R-46-93E**: "Financial Surety for Decommissioning "	
Self-Guarantee as an Additional Financial Mechanism; Parts 30, 40, 70	1/28/97	--------		01/28/97
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97	--------	No Agreement- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards"	--------
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97	--------		8/15/97

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98	--------		01/01/98
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98	--------		03/13/98
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98	--------		03/01/98
Performance Requirements for Radiography Equipment	6/30/98	--------		06/30/98
Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98	--------		08/14/98
Clarification of Decommissioning Funding Requirements	11/24/98	--------		11/24/98
10 CFR Part 71: Compatibility with the International Atomic Energy Agency	4/1/99	--------		04/01/99
Medical Administration of Radiation and Radioactive Materials.	10/20/98			
Termination or Transfer of Licensed Activities: Recordkeeping Requirements.	5/16/99			

APPENDIX D
LICENSE FILE REVIEW

File No.: 1
Licensee: ICN Pharmaceuticals, Inc.
Location: 2727 Campus Drive, Irvine
License Type: Pharmaceutical Manufacturer
Date Issued: 10/08/96

License No.: 1828-30
Amendment No.: 67
Type of Action: Renewal
License Reviewer: P. P.

Comments:
a) Possession limits exceed requirements for emergency plan; licensee evaluation does not show consideration for engineered safety features to reduce potential releases.
b) Licensee changed RSO prior to approval.

File No.: 2
Licensee: Southern California Edison
Location: San Clemente
License Type: Decontamination Service
Date Issued: 08/15/96

License No.: 2132-30
Amendment No.: 13
Type of Action: Renewal
License Reviewer: D. W.

Comment:
a) Action on licensee request to reduce possession limits not found in file.

File No.: 3
Licensee: University of Southern California
Location: Los Angeles
License Type: Academic, R&D
Date Issued: 08/13/96

License No.: 0382-19
Amendment No.: 41
Type of Action: Renewal
License Reviewer: G. P.

Comments:
a) Improper authorization of materials for use in Antarctica.
b) Authorized use on ships offshore not re-evaluated after licensee indicated use was discontinued.

File No.: 4
Licensee: Mobile Technology, Inc.
Location: Los Angeles
License Type: Mobile HDR
Date Issued: 09/19/96

License No.: 5919-19
Amendment No.: 14
Type of Action: Renewal
License Reviewer: G. P.

Comment:
a) Several letters in file requesting administrative changes not reflected in tie-down condition.

File No.: 5
Licensee: Isotope Products Laboratories
Location: Burbank
License Type: Manufacturer
Date Issued: 08/7/96

License No.: 1509-19
Amendment No.: 103
Type of Action: Renewal
License Reviewer: P. P.

Comment:
a) Licensee appears to exceed limits requiring an Emergency Plan.

File No.: 6
Licensee: Isotope Products Laboratories
Location: Burbank
License Type: Manufacturer
Date Amendment Issued: 08/22/96

License No.:1509-19
Amendment No.: 105
Type of Action: Amendment
License Reviewer: P. P.

Comments:
a) No tie-down of July 27, 1994 for Am-241 exemption.
b) August 21, 1996 licensee response letter not in file.

File No.: 7
Licensee: Isotope Products Laboratories
Location: Burbank
License Type: Manufacturer
Date Amendment Issued: 09/6/96

License No.: 1509-19
Amendment No.: 106
Type of Action: Amendments
License Reviewer: P. P.

Comments:
a) No licensee response to Curium issue.
b) September 5, 1996 licensee response letter not in file.

File No.: 8
Licensee: Nucletron Corp.
Location: Encinitas
License Type: HDR Manufacturer
Date Issued: 10/03/96

License No.: 6214-37
Type of Action: New
License Reviewer: D. W.

Comments:
a) Leak test condition does not require licensee to remove and decontaminate devices if sources found leaking.
b) Credentials of new RSO not in file.

File No.: 9
Licensee: Beckman Instruments, Inc.
Location: Fullerton
License Type: Instrument Manufacturer
Date Issued: 11/22/95

License No.: 0441-30
Amendment No.: 64
Type of Action: Renewal
License Reviewer: P. P.

Comments:
a) April 18, 1995 deficiency letter not in file.
b) Tie down referred to wrong licensee response date.

File No.: 10
Licensee: TRW Space and Electronics Group
Location: Redondo Beach
License Type: Research and Development
Date Issued: 09/05/96
License No.: 0816-19
Amendment No.: 61
Type of Action: Renewal
License Reviewer: F. T.

Comments:
a) Leak test condition does not require licensee to remove and decontaminate devices if sources found leaking.
b) Possession limit for SNM not specified.

File No.: 11
Licensee: Space Systems/Loral
Location: Palo Alto
License Type: Research and Development
Date Issued: 07/30/96
License No.: 0550-43
Amendment No.: 56
Type of Action: Renewal
License Review: F T.

Comment:
a) Leak test condition does not require licensee to remove and decontaminate devices if sources found leaking.

File No.: 12
Licensee: Tower Imaging-Roxsan
Location: Beverly Hills
License Type: Nuclear Medicine
Date Issued: 08/07/96
License No.: 2675-19
Amendment No.: 32
Type of Action: Renewal
License Reviewer: G. P.

File No.: 13
Licensee: Los Angeles County Medical Center
Location: Los Angeles
License Type: Hospital
Date Issued: 02/06/96
License No.: 0134-70
Amendment No.: 96
Type of Action: Renewal
License Reviewer: T. G.

File No.: 14
Licensee: Source 2 Site
Location: Emeryville
License Type: Transportable HDR
Date Issued: 10/06/96
License No.: 6152-60
Amendment No.: 3
Type of Action: New
License Reviewer: G. P.

Comment:
a) Operation of mobile HDR is not restricted to use in California.

File No.: 15
Licensee: San Diego Gamma Knife Center
Location: La Jolla
License Type: Gamma Knife
Date Amendment Issued: 09/10/96
License No.: 6072-37
Amendment No.: 4
Type of Action: Renewal/Amendment
License Reviewer: G. P.

Comment:
a) Emergency telephone notification by licensee for overexposure does not specify 24-hour time limit.

File No.: 16
Licensee: Radiation Oncology Center
Location: Walnut Creek
License Type: Portable HDR
Date Issued: 03/19/96
License No.: 3587-07
Amendment No.: 14
Type of Action: Renewal
License Reviewer: G. P.

File No.: 17
Licensee: Univ of Calif Santa Barbara
Location: Santa Barbara
License Type: Academic
Date Issued: 07/29/96
License No.: 1336-42
Amendment No.: 64
Type of Action: Renewal
License Reviewer: G. P.

Comment:
a) License not specific on types of Iodine isotopes authorized.

File No.: 18
Licensee: Pomona College
Location: Claremont
License Type: Academic
Date Issued: 07/01/91
License No.: 0332-70
Amendment No.: 33
Type of Action: Renewal
License Reviewer: G. P.

Comment:
a) RSO provided information about leaving facility and no replacement named.

File No.: 19
Licensee: Los Alamitos Medical Center
Location: Los Alamitos
License Type: Hospital
Date Issued: 08/19/96
License No.: 1807
Amendment No.: 49
Type of Action: Renewal
License Reviewer: G. P.

Comment:
a) Request for deletion of brachytherapy approved but no indication in file if sources transferred.

File No.: 20
Licensee: United Airlines Maintenance Operations
Location: San Francisco
License Type: Radiography
Date Issued: 09/26/94
License No.: 0579-90
Amendment No.: 45
Type of Action: Renewal
License Reviewer: D. W.

Comment:
a) File does not contain operating and emergency procedures licensee requested to change per letter of February 15, 1993.

File No.: 21
Licensee: Spreckels Development Co.
Location: Manteca
License Type: Gauge
Date Amendment Issued: 07/19/96
License No.:3226-39
Amendment No.: 14
Type of Action: Termination
License Reviewer: V. B.

File No.: 22
Licensee: Applied Land Services, Inc.
Location: Pleasanton
License Type: Portable Gauge
Date Amendment Issued: 08/01/96
License No.: 5749-60
Amendment No.: 3
Type of Action: Termination
License Reviewer: V. B.

Comments:
a) File indicates material never received; verified by inspector.

File No.: 23
Licensee: Professional Service Industries
Location: Lombard, IL
License Type: Portable Gauges
Date Amendment Issued: 08/15/96
License No.: 5652-50
Amendment No.: 10
Type of Action: Termination
License Reviewer: D. T.

Comment:
a) Can not determine if licensee's Pittsburgh facility was authorized to accept gauges.

File No.: 24
Licensee: Sweetwater Authority
Location: Chula Vista
License Type: Gas Chromatograph
Date Amendment Issued: 10/07/96
License No.: 3623-37
Amendment No.: 9
Type of Action: Termination
License Reviewer: Z. G.

File No.: 25
Licensee: Campbell Security Equipment Co.
Location: Concord
License Type: Distribution of gauges to GLs
Date Amendment Issued: 09/19/95
License No.: 6156-07GL
Type of Action: New
License Reviewer: B. K.

Comment:

a) License conditions require labeling, furnishing copy of regulations and instructions to general licensees and quarterly reports and transfer in lieu of equivalent regulation of 32.51

File No.: 26
Licensee: Nova R&D, Inc. License No.: 5902
Location: Riverside
License Type: Distribution to General Licensees Type of Action: New
Date Amendment Issued: 05/13/93 License Reviewer: B. K.

Comments:

a) License condition for labeling, reporting, and providing information to general licensees in lieu of regulation equivalent to 32.51.
b) Section 32.51 - for quarterly reports of transfer the State should advise licensee about this reporting requirement change in that only NRC headquarters reports are required.

File No.: 27
Licensee: Charles Blakely Co. License No.: 5490-43
Location: San Jose Amendment No.: 2
License Type: Redistribution of exit signs to GLs Type of Action: Amendment
Date Amendment Issued: 12/06/95 License Reviewer: B. K.

Comment:

a) No regulation equivalent 32.51.

File No.: 28
Licensee: Measurex Corporation License No.: 1856-43GL
Location: Cupertino Amendment No.: 52
License Type: Distribution Type of Action: Amendment
Date Amendment Issued: 04/12/95 License Reviewer: B. K.

Comments:

a) License condition to require, labelling, reporting of transfer, furnishing information to the general licensee in lieu of 32.51.
b) State has authorized the use of maximum activity with no date of assay requirements for the label.

File No.: 29
Licensee: Medi-Physics, Inc. License No.: 5143-70
Location: Culver City Amendment No.: 15
License Type: Radiopharmacy Type of Action: Renewal
Date Issued: 12/08/95 License Reviewer: G. P.

File No.: 30
Licensee: Advanced Micro Devices, Inc. — License No.: 3771-43
Location: One AMD Place, Sunnyvale — Amendment No.: 67
License Type: Semiconductor Testing — Type of Action: Renewal
Date Amendment Issued: 08/21/96 — License Reviewer: F. T. & P. P.

Comment:
a) Needs more specific reference to ALARA.

File No.: 31
Licensee: Astoria Metal Corporation — License No.: 5049-19
Location: 1815 W. 205 St., Torrance — Amendment No.: 27
License Type: Industrial Radiography — Type of Action: Renewal
Date Amendment Issued: 08/13/96 — License Reviewer: F. T.

File No.: 32
Licensee: Penta Biotech, Inc. — License No.: 6141-41
Location: 353 F. Vintage Park Drive, Foster City — Amendment No.: 1
License Type: Bio-Chemistry Laboratory — Type of Action: Termination
Date Amendment Issued: 09/23/96 — License Reviewer: F. T.

File No.: 33
Licensee: Mallinckrodt Medical, Inc. — License No.: 4943-43
Location: 1328 White Oaks Ave., Campbell — Amendment No.: 14
License Type: Nuclear Pharmacy — Type of Action: Renewal
Date Amendment Issued: 08/13/96 — License Reviewer: G. P.

Files No.: 34
Licensee: French Camp Vineyards — License No.: 5946-40
Location: P.O. Box 84, Shandon — Amendment No.: 2
License Type: Moisture Gauge — Type of Action: Termination
Date Amendment Issued: 07/30/96 — License Reviewer: V. B.

File No.: 35
Licensee: Mills College — License No.: 4730-01
Location: 5000 Mac Arthur Blvd., Oakland — Amendment No.: 10
License Type: Academic — Type of Action: Termination
Date Amendment Issued: 10/08/96 — License Reviewer: S. K.

File No.: 36
Licensee: Sterigenics International — License No.: 3390-30
Location: 1401 Morgan Circle, Tustin — Amendment Nos.: 31 & 32
License Type: Pool Type Irradiator — Type of Action: Renewal & Amendment
Dates Renewal & Amendment Issued: 02/19/96 & 03/29/96 — Reviewer: D. W.

APPENDIX E
INSPECTION FILE REVIEWS

File No.: 1
Licensee: Mission Community Hospital
Location: Panorama City
License Type: medical; group I-V
Inspection Date: 11/9/94

License No.: 1282-70
Inspection Type: routine, announced
Priority: 3
Inspector: S. D.

Comments:
a) Inspector accompanied by review team member
b) Inspection announced to accommodate accompaniment

File No.: 2
Licensee: MMP Quality Inspection
Location: Signal Hill
License Type: industrial radiographer
Inspection Date: 11/10/94

License No.: 4832-70
Inspection Type: routine, unannounced
Priority: 1
Inspector: K. H.

Comment:
a) Inspector accompanied by review team member

File No.: 3
Licensee: T.C. Inspection
Location: Richmond
License Type: industrial radiography, temporary job sites
Inspection Date: 02/28/96

License No.: 5299-07
Inspection Type: routine, announced
Priority: 1
Inspector: F. F.

Comments:
a) Inspector accompanied by review team member
b) 24 hour advance notice to licensee who had been difficult to locate

File No.: 4
Licensee: Brookside Hospital
Location: San Pablo
License Type: medical - HDR therapy
Inspection Date: 02/29/96

License No.: 0209-7
Inspection Type: routine, announced
Priority: 1
Inspector: R. O.

Comments:
a) Inspector accompanied by review team member
b) Inspection announced to accommodate accompaniment and ensure HDR use

File No.: 5
Licensee: Scripp's Hospital
Location: El Cajon
License Type: nuclear medicine
Inspection Date: 04/2/96

License No.: 2311-80
Inspection Type: routine, announced
Priority: 3
Inspector: F. B.

Comments:
a) Inspector accompanied by review team member
b) 24 hour advance notice to licensee to accommodate accompaniment

File No.: 6
Licensee: John Lowney & Associates
Location: Mountain View
License Type: portable gauge
Inspection Date: 06/4/96
License No.: 2356-43
Inspection Type: routine, unannounced
Priority: 5
Inspector: R. O.

Comments:
a) Inspector accompanied by review team member
b) Both field and office inspections conducted

File No.: 7
Licensee: California Office of Emergency Services
Location: Sacramento
License Type: calibration and training
Inspection Date: 06/20/96
License No.: 0146-34
Inspection Type: routine, announced
Priority: 3
Inspector: R. F.

Comments:
a) Inspector accompanied by review team member
b) Inspection announced to accommodate accompaniment

File No.: 8
Licensee: Saddleback Valley Radiology Associates
Location: Laguna Hills
License Type: nuclear medicine & therapy
Inspection Date: 10/25/95
License No.: 3704-30
Inspection Type: routine, unannounced
Priority: 3
Inspector: S. K.

File No.: 9
Licensee: Fisher Scientific
Location: Tustin
License Type: RIA kits - storage only
Inspection Date: 11/28/95
License No.: 4950-30
Inspection Type: announced, routine
Priority: 6
Inspector: S. K.

Comment:
a) inspection announced to ensure licensee staff on premises

File No.: 10
Licensee: Cardio-Vascular Imaging Center
Location: Anaheim
License Type: nuclear medicine
Inspection Date: 02/8/96
License No.: 5739-30
Inspection Type: routine, unannounced
Priority: 3
Inspector: S. K.

File No.: 11
Licensee: San Joaquin General Hospital
Location: Stockton
License Type: medical - diagnostic & therapy
Inspection Date: 02/2/96
License No.: 1294-39
Inspection Type: routine, unannounced
Priority: 3
Inspector: K. F.

Comments:
a) Report did not document follow-up or closure of previous items of non-compliance.
b) Report did not document attendees at exit meeting.

File No.: 12
Licensee: NDC Systems
Location: Irwindale
License Type: manufacturing and distribution
Inspection Date: 11/30/95
License No.: 1451-70
Inspection Type: routine, announced
Priority: 3
Inspector: K. H.

Comment:
a) Inspection announced because of length of driving time to licensee's facility

File No.: 13
Licensee: Little Company of Mary Hospital
Location: Torrance
License Type: nuclear medicine and therapy
Inspection Date: 05/23-24/96
License No.: 1258-70
Inspection Type: routine, unannounced
Priority: 3
Inspector: S. D.

File No.: 14
Licensee: Isotope Product Laboratories (IPL)
Location: Burbank
License Type: manufacturing and distribution
Inspection Date: 08/1-2/94
License No.: 1509-70
Inspection Type: routine, unannounced
Priority: 1
Inspectors: B. H., S. D. & K. H.

File No.: 15
Licensee: Southern California Edison (SONGS)
Location: San Clemente
License Type: service
Inspection Dates: 01/17/95 through 01/2/96
License No.: 2132-30
Inspection Type: phone and mail
Priority: 3
Inspector: K. H.

Comments:
a) Inspector determines by quarterly phone calls that licensee possesses no RAM under this license.
b) Licensee certifies annually that no RAM is possessed; last certification dated 1/2/96.

File No.: 16
Licensee: Mallinckrodt, Inc
Location: Campbell
License Type: nuclear pharmacy
Inspection Date: 03/13/96
License No.: 4943-43
Inspection Type: routine, announced
Priority: 1
Inspector: R. O.

Comment:
a) Inspector felt announcing inspection was justified by length of driving time to licensee's facility.

File No.: 17
Licensee: Berlex Biosciences, Inc.
Location: Richmond
License Type: bio lab
Inspection Date: 12/14/94
License No.: 4498-07
Inspection Type: routine, announced
Priority: 3
Inspector: F. F.

Comment:
a) No apparent reason for announcing inspection.

File No.: 18
Licensee: Allied Ecology Services, Inc.
Location: Fremont
License Type: waste broker
Inspection Date: 07/30/96
License No.: 2873-01
Inspection Type: routine, announced
Priority: 2
Inspector: M. G.

Comment:
a) Inspection announced to ensure licensee staff at site

File No.: 19
Licensee: University of California, Santa Barbara
Location: Santa Barbara
License Type: broad Type A academic
Inspection Date: 12/27-30/94
License No.: 1336-42
Inspection Type: routine, announced
Priority: 2
Inspector: P. B.

Comment:
a) Inspection announced to ensure accessibility of licensee faculty and staff.

File No.: 20
Licensee: Children's Hospital
Location: San Diego
License Type: nuclear medicine and therapy
Inspection Date: 07/5-7/95
License No.: 5518
Inspection Type: routine, unannounced
Priority: 3
Inspector: F. B.

File No.: 21
Licensee: Koch Engineering Corp., Tru-Tec Division
Location: Buena Park
License Type: well-logging
Inspection Date: 03/2/95
License No.: 5474-30
Inspection Type: routine, announced
Priority: 3
Inspector: K. H.

Comment:
a) Inspection announced because of difficulty in locating licensee.

File No.: 22
Licensee: Amgen Incorporated
Location: Thousand Oaks
License Type: bio lab, broad type A
Inspection Date: 09/19-20/95
License No.: 3768-56
Inspection Type: routine, announced
Priority: 3
Inspector: K. H.

Comment:
a) Inspection announced to ensure accessibility of staff and management during 2-day inspection.

File No.: 23
Licensee: Nova R&D, Inc.
Location: Riverside
License Type: distribution
Inspection Date: 10/18/95
License No.: 5902-33
Inspection Type: routine, announced
Priority: 3
Inspector: K. H.

Comment:
a) Inspection announced because of length of driving time to licensee

File No.: 24
Licensee: Source 2 Site
Location: Emeryville
License Type: portable HDR
Inspection Date: 01/16/95
License No.: 6152-60
Inspection Type: initial, announced
Priority: 1
Inspector: R. O.

Comment:
a) Inspection announced for initial inspection of mobile unit.

File No.: 25
Licensee: Industrial Nuclear Co.
Location: San Leandro
License Type: manufacturing and distribution (IR cameras)
Inspection Date: 11/30/95 and 12/7/95
License No.: 2229-60
Inspection Type: routine, announced
Priority: 2
Inspector: F. F.

Comment:
a) Inspection announced to ensure owner available due to controversy regarding procedures.

File No.: 26
Licensee: 3M Company
Location: Petaluma
License Type: fixed gauge
Inspection Date: 01/10/96
License No.: 5282-49
Inspection Type: routine, announced
Priority: 6
Inspector: K. F.

Comment:
a) Inspection announced because of remote location.

APPENDIX F
INCIDENT FILE REVIEWS

File Number: 01
Licensee: NDC Systems
Site of Event: Monrovia, CA
Date of Event: 02/05/96
Investigation Date: 02/09/96
Incident Log Number: 020596
License Number: 1451
Type of Event: Leaking Source
Investigation Type: site visit
Summary of Incident: Licensee removed four 10 millicurie Americium-241 from storage container for leak testing prior to shipping for disposal. During the leak testing procedure it was noted that one or more of the sources were leaking, leading to site and personnel contamination. Incident closed out on 9/24/96.

Comment:
a) Sources at site awaiting disposal at the time of review.

File Number: 2
Licensee: Downey Community Hospital
Site of Event: Downey, CA
Date of Event: 05/25/95
Investigation Date: 05/25/95
Incident Log Number: 052595
License Number: 1418-70
Type of Event: Contamination Event
Investigation Type: site
Summary of Incident: A patient vomited in the parking lot at Los Cerritos Center Mall after receiving a treatment of Iodine-123. Area was decontaminated to release levels.

File Number: 3
Licensee: Aoki Diabetes Research Institute
Site of Event: Irvine, CA
Date of Event: 08/23/96
Investigation Date: 08/24/96
Incident Number: 082396
License Number: 5422-34
Type of Event: Contamination Event
Investigation Type: Phone
Summary of Incident: Contractor broke a sewer line and water in the line went into the trench. Sewer line from Aoki, workers went to request that the facility halt the use of water until the line was fixed and saw employee disposing of RAM down sink (2 microcuries of Iodine-125). Construction supervisor said he needed release telling him it was safe to finish project. Personnel and trench surveyed by a staff member from UC-Irvine Medical Center. No contamination found on personnel or in the trench. Incident closed out 9/12/96.

File Number: 4
Licensee: El Centro Regional Medical Center
Site of Event: El Centro, CA
Date of Event: 01/20/96
Investigation Date: 02/01/96
Incident Log Number: 012096
License Number:
Type of Event: Contamination Event
Investigation Type: Next Inspection
Summary of Incident: RSO of Medi-Physics sent letter dated 1/24/96 to report a cardboard box that was picked up at the hospital revealed 17,514 dpm gross removable on the box and 279 dpm in the vehicle. Letter was also received from the Medical Center stating they received a call from Medi-Physics concerning the above and on 1/18/96 had a spill of 99mTc MDP and sent the box back the next day without a survey. Incident closed out 3/96.

File Number: 5
Licensee: UC Irvine Medical Center
Site of Event: Irvine, CA
Date of Event: 01/24/96
Investigation Date: 03/06/96
Incident Log Number: 030696
License Number: 0278-30
Type of Event: Lost Material
Type of Investigation: Phone
Summary of Incident: A patient was implanted with 50 Iodine-125 seeds on 1/17/96 (right eye against skull). CT scan on 1/24/96 verified all seeds in proper location. During follow-up on 2/29/96 skull x-ray showed only 5 seeds. Examination of patient, home, car, etc. failed to locate seeds. Incident closed out.

File Number: 6
Licensee: Geocon Environmental Consultants
Site of Incident: Jammel, CA
Date of Event: 03/31/96
Investigation Date: 04/04/96
Incident Log Number: 040496
License Number: 3924-80
Type of Event: Lost Material
Type of Investigation: Phone
Summary of Incident: Density gauge missing from job site. Trailer was broken into and gauge stolen.

Comment:
a) Event not listed on Nuclear Material Data Base.

File Number: 7
Licensee: Paul Young Agriculture Service
Site of Incident: Wasco, CA
Date of Event: 05/07/96
Investigation Date: 05/07/96
Incident Log Number: 050796
License Number: 3205-15
Type of Event: Lost Material
Type of Investigation: Phone
Summary of Incident: Campbell Pacific Nuclear Hydroprobe 503 stolen off rear of pick-up truck.

File Number: 8
Licensee: Schlumberger
Site of Incident: Bakersfield, CA
Date of Event: 6/27/96
Investigation Date: 6/27/96
Incident Log Number: 06/27/96
License Number: 144-15
Type of Event: Abandoned Material
Type of Investigation: Phone
Summary of Incident. Well logging source stuck down a hole. Could not retrieve so abandoned down the hole (Cs-137 1.7 curies/ Am-241:Be 16 curies).

File Number: 9
Licensee: Orange County Sheriff-Coroner Department
Site of Incident: Orange County, CA
Date of Event: 6/17/96
Investigation Date: 07/31/96
Incident Log Number: 07/01/96
License Number: R00067
Type of Event: Loss of Control
Type of Investigation: phone
Summary of Incident: P-32 waste was inadvertently disposed of as biohazardous waste. Material had accumulated over a four month period. Containers apparently transferred to the biohazardous waste holding area and picked up by off site service. Incident closed out 8/8/96.

File Number: 10
Licensee: Mad River Community Hospital
Site of Incident: Arcata, CA
Date of Event: 09/22/95
Investigation Date: 09/22/95
Incident Log Number: 092895
Licensee Number: 2482-12
Type of Event: Abandoned Material
Type of Investigation: site
Summary of Incident: A small plastic container with individual compartments and what appeared to be various forms of yellow cake measuring 0.4-0.5 mR/hr at the surface was found on the lawn near the physical therapy department. The container was labeled "CRM - Macalaster Scientific Corp. 30145 - Radioactive Material Kit." Material put into storage in RHB Sacramento storage room.

File Number: 11
Licensee: UCLA
Site of Incident: TCI Colton, CA
Date of Event: 03/16/95
Investigation Date: 03/16/95
Incident Log Number: 031695
License Number: 1335-70
Type of Event: Transportation
Type of Investigation: Phone
Summary of Incident: Waste sent to Thermal Combustion Innovators from UCLA exceeded allowable limits (5 mR/hr surface). Citation issued to licensee. Incident closed out 6/26/96.

File Number: 12
Licensee: Korean Airlines
Site of Incident: Los Angeles, CA
Date of Event: unknown
Investigation Date: 05/03/95
Incident Log Number: 050395
License Number: N/A
Type of Event: lost material
Type of Investigation: phone
Summary of Incident: Thomas Gray and Associates called to notify that they were contacted by Korean Airlines to dispose of a container marked "Radioactive Material" as it turned out the container was a Gamma Industries C-10 source changer that had been mistakenly stored at the airlines freight area (for at least a year). Device shipped to a licensed recipient.

File Number: 13
Licensee: Isotope Products Laboratory
Site of Incident: Burbank, CA
Date of Event: 07/16/96
Investigation Date: 07/16/96
Incident Log Number: 071696
License Number: 1509-70
Type of Event: Contamination event
Type of Investigation: site
Summary of Incident: A 25 millicurie capsule of Am-241 "blew apart" during welding process, resulting in personnel and site contamination.

Comment:
a) Incident open next report due 10/31/96, investigation in progress.

File Number: 14
Licensee: Isotope Products Laboratory
Site of Incident: Burbank, CA
Date of Event: 8/96
Incident Log Number: 09/03;/96
License Number: 1509-70
Type of Event: contamination
Type of Investigation: phone

Investigation Date: 09/04/96
Summary of Incident: Air filter had 34 nanocuries of Am-241. Filter had been in place 8/23-30/96 and was counted on 9/3/96. Source of Am was uncertain, but likely to have been result of decontamination of the welding chamber door. Associated with case file number 13, both cases are under active investigation.

File Number: 15
Licensee: Tru-tec Division
Site of Incident: Mobile Oil Refinery Torrance, CA
Date of Event: 06/01/95
Investigation Date: 06/01/95
Incident Log Number: 060595
License Number: 5470-30
Type of Event: Contamination
Type of Investigation: phone
Summary of Incident: Tracer injected into a Hydrogen gas stream, it immediately vaporized and a good dose fraction adhered to the first 2 or 3 feet of the pipe. Dose rate at 35' 2 mR/hr and at 3' 250 mR/hr. Barricade put into place and allowed to decay.

File Number: 16
Licensee: UC-Davis
Site of Incident: UC-Davis
Date of Event: end of 1995
Investigation Date: unknown
Incident Log Number: 020494
License Number: 1334
Type of Event: overexposure
Type of Investigation: Next inspection
Summary of Incident: Finger badge exceeded allowable limits (376R) for researcher utilizing Y-90 in amounts up to 100 millicuries. Hospital modified procedures to prevent reoccurrence. Researcher left the United States. Incident closed.

File Number: 17
Licensee: J.L. Shepherd and Associates
Site of Incident:
Date of Event: 04/22/94
Investigation Date: 04/22/94
Incident Log Number: 050294
License Number: 1777-70
Type of Event: leaking source
Type of Investigation: next inspection
Summary of Incident: Upon disassembly of a dry irradiator for source recycling, a leak test showed 0.5 microcuries. Contamination was also found on the cave manipulator, fingers, and bench top. Surfaces decontaminated and source sent back to GE Vallecitos for reencapsulation.

File Number: 18
Licensee: Dames and Moore
Site of Incident: Long Beach, CA
Date of Event: 10/22/94
Investigation Date: 10/27/94
Incident Log Number: 102494
License Number: 4393-70
Type of Event: loss Material
Type of Investigation: phone
Summary of Incident: Troxler Model 3430 density gauge stolen out of the back of a pick-up truck.

File Number: 19
Licensee: Gemological Institute of America
Site of Incident:
Date of Event: 10/13/94
Investigation Date: 10/14/94
Incident Log Number: 101394
License Number: 5383-70
Type of Event: other
Type of Investigation: site

Summary of Incident: A eight carat diamond was reading 780 mR/hr at the surface according to GIA GM meter survey. The diamond was mailed from NY to CA by Brink's Security and packaged as a limited quantity. RHB showed 8 mR/hr on the surface of the diamond (with correction factor of 169- 1350 mRad/hr).

File Number: 20
Licensee: BFI (VA Medical Center)
Site of Incident: San Diego, CA
Date of Event: 03/23/93
Investigation Date: 03/23/93
Incident Log Number: 032393
License Number: N/A
Type of Event: loss of control
Type of Investigation: phone
Summary of Incident: BFI notified by phone that they received a barrel from VA Medical Center reading 1000 microR/hr above background. Referred to NRC Region V.

File Number: 21
Licensee: Veterinary Tumor Institute
Site of Incident: Pacifica, CA
Date of Event: unknown
Investigation Date: 10/1/93
Incident Log Number: 091593
License Number: 4647-44
Type of Event: Loss of Control
Type of Investigation: Phone
Summary of Incident: A waste container (55 gallon fibredrum) used as a sharps container contained radioactive material. Disposed of by Thomas Gray and Associates. License implemented procedures to prevent reoccurrence. Incident closed.

File Number: 22
Licensee: BKK Landfill
Site of Incident: West Covina, CA
Date of Event: 02/22/96
Investigation Date: 02/22/96
Incident Log Number: 022295
License Number: N/A
Type of Event: Loss of control
Type of Investigation: Site
Summary of Incident: A truck from Rapidway Trash Company set the radiation alarm off. A hot diaper (adult size) was isolated and held for decay. Source traced back to a convalescent home.

File Number: 23
Licensee: Cal Poly Pomona
Site of Incident: Pomona, CA
Date of Event: 04/14/95
Investigation Date: 04/14/95
Incident Log Number: 042495
License Number: 0496-70
Type of Event: Stolen Material
Type of Investigation: Phone
Summary of Incident: Two exit signs were reported stolen and two others were found to be leaking. Cal Poly cleaned up site and leaking signs sent back to Isolite Corporation.

File Number: 24
Licensee: Cal State University, Northridge
Site of Incident: Northridge, CA
Date of Event: 01/17/94
Investigation Date: 02/22/96
Incident Log Number: 03/28/96
License Number: 0319-70
Type of Event: Damage to Equipment
Type of Investigation: phone

Summary of Incident: During the 1/17/94 earthquake six Tritium exit signs fell down and broke. The signs were in the "South Library" which had major structural damage and was closed and has been unoccupied since. This was discovered on 2/22/96. Some residual contamination was found and is going to be cleaned up by ITC.

File Number: 25
Licensee: Construction Material Testing
Site of Incident: Martinez, CA
Date of Event: 03/8/95
Investigation Date: 03/10/96
Incident Log Number: 030995
License Number: 2952
Type of Event: Lost Material
Type of Investigation: site
Summary of Incident: An Anonymous call was received that a gauge belonging to CMT was lost then recovered at/near the Shell refinery. Investigation revealed that the user left the gauge on the ground and was at the refinery gate when he remembered the gauge. Meanwhile the gauge was turned into security. The gauge was recovered by user after several hours but was not reported to RHB. Notice of noncompliance issued.

File Number: 26
Licensee: EMC
Site of Incident: EMC
Date of Event: unknown
Investigation Date: 11/17/95
Incident Log Number: 111795
License Number: 3546-50
Type of Event: Lost/Stolen Material
Type of Investigation: Phone
Summary of Incident: Two 30 gallon drums of LSA waste were either misplaced, lost, or stolen from a warehouse at the Turlock facility. Incident closed out 1/23/96.

File Number: 27
Licensee: FedEx
Site of Incident:
Date of Event: 06/2/96
Investigation Date: 06/2/96
Incident Log Number: 060296
License Number: N/A
Type of Event: Transportation
Type of Investigation: site
Summary of Incident: A truck was involved in an accident and was carrying a Scitec MAP4 lead tester. Fire destroyed the truck and the device could not be found in the debris.

File Number: 28
Licensee: Beckman Instruments
Site of Incident: University of Virginia
Date of Event: unknown
Investigation Date: 07/18/96
Incident Log Number: 072396
License Number: 1313-30
Type of Event: Leaking Source
Type of Investigation: Letter
Summary of Incident: A Beckman LS6000 with a 30 microcurie Cs-137 source was found to be leaking. Leak test showed 0.73 microcuries on the source model 598860 manufactures in 1989. The source is exempted from leak testing, but the instrument was registering unusually high background readings and the source was found to be leaking by the field service personnel. Leak possible due to flaw in small number of source holders manufactured prior to 1993. Beckman initiated several controls to solve the problem and will continue to motor the problem.

Comment:
a) Incident reopened on 10/22/96 along with incidents described in incident case files 30 and 37 for a possible generic design flaw. Active investigation, case open.

File Number: 29
Licensee: Beckman Instruments
Site of Incident: Fullerton, CA
Date of Event: 03/27/96
Investigation Date: 05/13/96
Incident Log Number: 042596
License Number: 0441-30
Type of Event: Lost Material
Type of Investigation: Letter
Summary of Incident: A vial containing 1 mCi of P-32 (aqueous ATP) was found to be missing from the lab of a researcher. Search of the lab and trash did not turn up the material. Incident closed out 5/96.

File Number: 30
Licensee: Beckman Instruments
Site of Incident: University of Minnesota
Date of Event: unknown
Date of Investigation: 02/13/96
Incident Log Number: 021396
License Number: 1313-06
Type of Event: Leaking Source
Type of Investigation: Letter
Summary of Incident: A Beckman LS6000 was indicating a high background and the field service man found the source to be leaking (0.019 microcuries). The source contained 30 microcurie Cs-137 model number 598860 manufactured 1986.

File Number: 31
Licensee: 3 M Company
Site of Incident: Camarillo, CA
Date of Event: 04/26/96
Date of Investigation: 05/14/96
Incident Log Number: 051496
License Number: 4796-56
Type of Event: Leaking Source
Type of Investigation: Letter
Summary of Incident: An Amersham static eliminator model DM1002H10 series 7952KA containing 60 mCi of Po-210 was found to be leaking (0.0062 microcuries). Sent back to Amersham. Incident closed out 6/96.

File Number: 32
Licensee: Amgen Incorporated
Site of Incident: Amgen
Date of Event: 05/23/96
Date of Investigation: 06/12/96
Incident Log Number: 052396
License Number: 3768-56
Type of Event: Lost Material
Type of Investigation: Phone
Summary of Incident: Two vial of I-125 (101 microcuries) inadvertently was disposed of in the routine waste system.

File Number: 33
Licensee: Anheuser Busch
Site of Incident: Van Nuys, CA
Date of Event: 06/20/96
Date of Investigation: 07/3/96
Incident Log Number: 070396
License Number: GL
Type of Event: Lost/Stolen Material
Type of Investigation: Phone
Summary of Incident: Two 15 Ci (each) tritium exit signs were lost or stolen during a construction project.

File Number: 34
Licensee: Baker Hughes Oilfield Operations
Site of Incident: Solano, CA
Date of Event: 03/26/96
Date of Investigation: 03/26/96
Incident Log Number: 032696
License Number: NRC 17-27437-01
Type of Event: Other
Type of Investigation: Phone
Summary of Incident: A well logging tool got stuck down the hole, but was recovered by "fishing." There was minimal damage to the tool and none to the sources.

File Number: 35
Licensee: Industrial Nuclear Company
Site of Incident: San Diego, CA
Date of Event: 05/8/96
Date of Investigation: 05/8/96
Incident Log Number: 052096
License Number: 2229-60
Type of Event: Lost Material
Type of Investigation: Phone
Summary of Incident: ICN reported that a package containing a 53 curie Ir-192 source in a IR-100 camera that was shipped to a licensee in San Diego had not been received and could not be found by FedEx. On 5/21/96 FedEx found the package in Los Angeles, the airbill had become separated from the package.

File Number: 36
Licensee: Industrial Nuclear Company
Site of Incident: Monrovia, CA
Date of Event: 08/16/94
Date of Investigation: 08/16/96
Incident Log Number: 081694
License Number: 2229-60
Type of Event: Damage to Equipment
Type of Investigation: Phone
Summary of Incident: INC received a camera with the teleflex broken at the pigtail. The source was in the locked/shielded position and the break occurred behind the lockball/stopball. It was determined that the break was due to corrosion.

File Number: 37
Licensee: Industrial Nuclear Company
Site of Incident: Monrovia, CA
Date of Event: 06/14/96
Date of Investigation: 07/12/95
Incident Log Number: 072595
License Number: 2229-60
Type of Event: Equipment Failure
Type of Investigation: phone
Summary of Incident: A drive cable adapter failed in the field and would not retrieve the source. Review of failed source and test on similar adapters showed no manufacturing defect, appeared to have been taken apart by licensee.

File Number: 38
Licensee: Beckman Instruments
Site of Incident: Wayne State University & Argonne National Lab.
Dates of Event: 02/5/96 & 03/19/96
Date of Investigation: 04/3/96
Incident Log Number: 041296
License Number: 1313-30
Type of Event: Leaking Source
Type of Investigation: Letter
Summary of Incident: At both locations 30 microcurie Cs-137 source were found to be leaking after reported high background readings on Beckman LS6000 instruments. Both sources were model 598860 sources.

APPENDIX G
SEALED SOURCE AND DEVICE EVALUATION REVIEWS

File Number: 1
Registry No.: CA 406-S-165-S — SS&D Type: Model 3409
Manufacturer: Isotope Products Laboratories, Inc. — Date Issued: 9/20/94

Comments:
a) Request to increase the activity from 30 millicuries to 80 millicuries had not been addressed. verbal authorization may have been given.
b) Should consider the applicability for a bend test requirement on long sources (up to 10.5").
c) Unclear if testing of prototype sources with thin walls was performed after it was engraved. Such a c[illegible]ion would be testing a product as it was designed to be used.
d) External radiation l[illegible]ls are incorrect. Although applicant was required to resubmit dose leak from the source, the final documents that address the reviewers concern in this area could not be found.
e) Safety Analysis Summary refers an ANSI N.42-1077 non-existent standard. The corrected sheet should read N542-1977.
f) No peer review was conducted.
g) Source void volumes not assessed to determine if bubble test is an appropriate method for determining leak testing.

File Number: 2
Registry No.: CA 661-D-103-S — SS&D Type: Model Vari-source HDR
Manufacturer: Varian Associates, Inc. — Date Issued: 4/28/95, amended 9/12/95

Comments:
a) Reviewer applied lessons learned from Omnitron incident to this review.
b) Amendment changed length of source cable - should have considered need to determine if computer controllers needed modification.
c) No peer review was conducted on this amendment.
d) State of Louisiana issued source certificate approving up to 500 cycles and a working life of 120 days. California review continues to reflect 250 cycles, while not a safety issue, it is not clear which number should be used during the assessment of device performance.
e) Some drawings were missing from the file on the unit and on the materials of construction. A lot of detailed information on the tungsten shield was available but not much on devices or other safety features of the device.

File Number: 3
Registry No.: CA 406-S-178-S — SS&D Type: Model A-3411
Manufacturer: Isotope Products Laboratories, Inc. — Gamma Gauge
Date Issued: 11/14/95, amended 2/3/96

Comments:
a) No peer review was conducted.
b) Source can be up to 33 inches long the need for a bend test requirement should have been considered during this review.

c) Weld type is stated as "Electron Beam." Reviewer considered only tungsten inert gas yet also approved use of electron beam without consideration of the different weld parameters i.e., Electron Beam Weld can produce a depth to width ratio of 30 to 1. This makes the weld subject to center cracking if not done properly. Therefore, setup of welding equipment is critical as are details of machining tolerances. The quality control or assurance program should be revised to specifically deal with the requirements of electron beam welding.

d) The conditions of use section not that the sources are permanently mounted in a gauging device. Review of supporting data shows that this is not the case. Reviewer relied on the additional protection afforded the source by the gauging device as part of the approval process.

e) Although approved for use in the broad category of gauging devices, the ANSI classification does not meet the minimum vibration classification as listed in ANSI 542-1977.

f) No void space in sources, use of bubble test to show no leaking is not acceptable. Vendor also wipes all sources -- this is an acceptable method of leak testing. A false sense of security may be developed by use of a bubble test that cannot identify a hole in the source capsules or welded area. It is not clear for what purpose the vendor uses the bubble test.

File Number: 4
Registry No.: C[illegible]0-S-125-S
Manufacturer: North American Scientific, Inc.

SS&D Type: Model IND 1500 Beta Source
Date Issued: 6/5/95

Comments:

a) Source also approved for low energy photons.

b) No peer review was conducted.

c) Maximum activity does not include the plus 20% vendor loading allowance. Reviewer should factor this into maximum activity to simplify the licensing/inspection process.

d) The use of dissimilar metals such as al[illegible]minum/stainless steel interface could lead to a potential corrosion site was not addressed.

File Number: 5
Registry No.: CA 305-D-105-S
Manufacturer: Gamma Metrics, Inc.

SS&D Type: Model SL Services
Date Issued: 5/16/95

Comments:

a) Reviewer relied on test data for CA-305-D-104-S and large robust size of the complete unit in making a determination that the product is acceptable for licensing purposes. Applicants should be encouraged to make a demonstration that the product meets the safety criteria. In using this approach a lot of uncertainties exist because of limited knowledge of the use of the proposed device, which could lead to a review missing important safety consideration.

b) Not clear on how source fits into the device or how it is secured from inadvertent removal.

c) Dose rates when the service door is opened should also be obtained to determine potential exposure to worker who have access to sensor panel for maintenance or repair of electronic components. Such information is also useful to both licensing reviewers and inspectors.
d) Drawings did not have materials of construction, so comparison between the device in CA 305-D-104-S and this one could not be complete.

File Number: 6
Registry No.: CA 471-D-104-B
SS&D Type: Model 301
Manufacturer: NDC Systems, Inc.
Date Issued: 5/15/94 amended 4/28/95

Comments:
a) No peer review was conducted.
b) Drawings have no dimension or materials of construction denoted. Further it is unknown how source is held in place or if use of tamper resistant fasteners were used. Use of tamper resistant fasteners is usually a requirement for devices used by general licensees.
c) No dose scenarios were submitted or analyzed regarding general licensees ability to perform leak test and shutter test. Such an analysis is necessary to determine if the proposed activity meets general license safety criteria.
d) Applicant submitted statements about doses being [more or less] than provided by the applicant. Reviewer should have asked the applicant to explain this since higher doses have an impact on compliance with the general license safety criteria.
e) No QA Manual provided. No other users manuals available with instructions to user on how to conduct leak tests were found. Such instructions are required for general licensees to conduct such activities. Reviewer believed files were in another location but could not produce them during this review. However, the reviewer did believe that the manuals existed and were reviewed.
f) Also, no dose scenarios demonstrating compliance to general license safety criteria was submitted for the product. Reviewer indicated no guidance was provided to review these activities. State has no specific regulation for vendors of these product equivalent to NRC 10 CFR 32.51. The use of checklist may be helpful in these case also a peer review may have helped.

File Number: 7
Registry No.: CA 384-S-116-S
SS&D Type: Model 88
Manufacturer: Industrial Nuclear Company, Inc.
Date Issued: 7/12/95

Comments:
a) No peer review was conducted.
b) Amended in its entirety to reflect changes that had been verbally approved by phone. These type of changes are hard to review given no phone logs appear to have been kept.

File Number: 8
Registry No.: CA 510-S-121-S
SS&D Type: Model MED 360-MD 3620
Manufacturer: North American Scientific, Inc.
Date Issued: 2/20/95

Comments:

a) Could not locate the QC document procedures referenced in this document.
b) Source can be 33 inch in length. A requirement for a bend test should have been considered.
c) No minimal wall thickness of source capsule was specified. Therefore, could not determine if type of welding used by applicant was acceptable. Also it is unclear how the reviewer determined if the prototype source used in the testing was representative of the sources to be produced.

File Number: 9
Registry No.: CA 598-D-113-S
SS&D Type: Model 484-, 484A, 484B, 484C
Manufacturer: JL Shepherd and Associates
Amended in entirety: 11/9/94

Comments:

a) No peer review was conducted. Reviewers name was signed by the same person that performed the second review.
b) Did not use ANSI standard for Category I Irradiators for this review. This standard has specific recommendations for dose rate and interlock performance.
c) Change in Model #'s without reference to old number will cause confusion to license reviewer and inspectors when working with older license documents.
d) Drawing (A-0484-4) notes source rods have aluminum source caps. Dissimilar metals may cause galvanic corrosion cells, also in fire analysis aluminum will melt. Both of these issues should have been challenged as part of the review.
e) No use of lessons learned from the Mark I style irradiator lock that failed if not maintained properly.
f) Testing presented by the applicant not representative of the use conditions. Reviewer relied on operational use, and the lack of reported problems with device since 1983 to make the determination. Application lacks data on function of the safety interlocks.

File Number: 10
Registry No.: CA 406-S-102-S
SS&D Type: Model N-252
Manufacturer: Isotope Products Laboratories, Inc.
Date Issued: 2/1/96

Comments:

a) Source approved for well logging only if pressure tested to 25,000 PSI before release.
b) No peer review was conducted.
c) ANSI Class 43333 denoted on Dwg A3004 yet testing section denotes 77C66535
d) Description indicates both capsules are some length (i.e. 1.[illegible]nches). However, Dwg #A3004 shows 1.48 inches. This is misleading information and could result in the source being forced into a piece of well logging equipment by the user. Such an activity could damage the source.

e) Not clear if well logging regulations regarding specific labeling requirements or determination of insolubility of the various chemical compounds used were applied.

File Number: 11
Registry No.: CA 501-D-102-G
Manufacturer: Measurex Corporation
SS&D Type: Model 4201
Date Issued: 6/23/93

Comments:

a) Increased activity to 3.75 curies of Kr-85 a factor of about 3 increase. No reevaluation to determine compliance with the general license safety criteria was made. Nor did the reviewer believe it was needed. Increases in both beta dose and bremsstrahlung radiations should have been reviewed.
b) No tie-down to a 4/19/93 letter in the references section. This letter is the basis for the amendment action.
c) Appears that the registration sheet and the review approved design of source holder and not the gauging device. Reviewer believes that this is addressed by commitments in the vendors license. Although this information could not be located in the files. Reviewer believes, based on interactions with the licensee, that the source holder is never sold as a gauging device it is always place into a source housing of device.

File Number: 12
Registry No.: CA 510-S-113-S
Manufacturer: North American Scientific, Inc.
SS&D Type: Model MED 3400
Date Issued: 12/18/95

Comments:

a) Source rod materials of construction should have been identified to determine what chemicals affect the materials of construction of the source rod and what is the temperature range that the source rod can withstand. Such information can be used to set limitation on conditions of use of the source.
b) QA/QC program only addressed radiochemical purity and activity based on gamma spectroscopy. Since, beta emitters are approved for use in the source this approach should have been found unacceptable.
c) No peer review was conducted.

File Number: 13
Registry No.: CA 406-S-182-S
Manufacturer: Isotope Products Laboratories, Inc.
SS&D Type: Model A3410
Date Issued: 10/16/96

Comments:

a) Sources can be 33" long bend test requirement should have been considered.
b) Reviewer approved the use of both TIG welding and electron beam weld. Because the advantages and disadvantages are unique to each type of welding. The reviewer should have evaluated both of these welding methods to determine if both were acceptable.

c) ANSI designation given for the source does not meet the vibration requirement for gauging sources as recommended in the ANSI standard. No rationale could be located to support such a deviation from the standard
d) No supporting documentation to support this source review could be located. However, the peer review checklist indicated that all documentation was present and adequate.

File Number: 14
Registry No.: CA 471-D-103-B
Manufacturer: NDC Systems, Inc.
SS&D Type:
Date Issued: 10/22/93

Comments:
Amended by 4/28/95
a) General licensees are authorized to perform shutter check but no review was conducted to determine if the general licensees' exposure from this activity combined with the routine use exposure would still be within the safety criteria.
b) Source is epoxied into a tungsten collimator. Specification of the epoxy, and affect of radiation should have been obtained and analyzed to determine if it will withstand the useful life of the device.
c) No QA Manual was provided or reviewed for this action
d) No peer review of the amendment was conducted.

File Number: 15
Registry No.: CA 533-D-104-G
Manufacturer: Peco Controls Corporation
SS&D Type: Model Gamma 104-P
Date Issued: 1/20/95

Comments:
a) Amended to allow general licensees to conduct certain maintenance activities. However, no dose scenarios were submitted or reviewed to determine compliance with the general license safety criteria.
b) Dwg should have tolerances identified to allow the reviewer to check for binding problems also to determine if spaces around sources will allow sufficient hot glue to be placed around the source.
c) Need specification of temperature and radiation resistance for the hot weld glue used to hold source in place.
d) Exposure rate on direct contact in the beam shows an increase of about 20%. However, the source activity was increased about 200%. Reviewer, should question this data for accuracy of measurement or calculation performed by the applicant.
e) Performance specifications for lexan used as the protective cover should have been obtained. Some lexan degrades as function or time and exposure to environmental conditions such as exposed to UV radiation. Review should determine if loss of lexan cover will maintain integrity for the life of the device.

File Number: 16
Registry No.: CA 598-D-106-S
Manufacturer: JL Shepherd & Associates
SS&D Type: Model 28 (78) Services
Date Issued: 9/15/93, amended 5/18/94

Comments:

a) This revision of a 1980 sheet was to change principal use from Category II to a Category I irradiator.

b) Review should have evaluated design in accordance with ANSI-N433.1, 1977 for Category I irradiators. This standard has performance specification for dose rate and interlocks used in this type of equipment. Also reviewing regulatory Guide 10.9 may have provided some information to be used in the review.

c) Should have reevaluated the lock assembly to determine if generic failure as with Mark I units can occur and what corrective action is needed either by the vendor or the user of the equipment. Reviewer indicated staff was not aware of any lock failures with the Mark I units and therefore did not look into it. This may apply to all JL Shepherd certificated issued.

File Number: 17
Registry No.: CA 384-D-109-S
Manufacturer: Industrial Nuclear Company, Inc.
SS&D Type: Model IR-100
Date Issued: 9/27/93

Comments:

a) Amended in its entirety to reflect that the device and associated equipment meets 10 CFR Part 34 equipment requirements. However, no supporting documentation could be found to confirm that a demonstration by the applicant had been submitted for review.

b) Device Dwgs with dimensions on criteria safety component could not be located.

c) Sources models 32 & 33 had a design change apparently verbally approve in early 1993. The change was in source length from 7.15" to 7" but no change to sheets have occurred. Other regulatory agencies use the information on source assemblies to determine if another suppliers source can be used in the specified device. Inconsistencies in information could result in a vendor supplying a source that meets the registration sheet but will not properly fit or function in a radiography camera.

d) No peer review was conducted.

e) In April 1996 the State evaluated complaints about wording in the user manual for the IR-100 device regarding cranking out the sources and testing the new lock assembly. The vendor was to modify the manual and send out a notice to known users advising them of the change in wording. Nothing could be located to determine if this action was completed by INC. The closure or this action may have been verbally discussed with the vendor.

File Number: 18
Registry No.: CA 510-S-114-S
Manufacturer: North American Scientific, Inc.
SS&D Type: Model MED 3550
Date Issued: 4/27/95

Comments:

a) Low activity calibration source manufactured with epoxy resin.

b) Increased the activity of NARM use in the source. Reviewer should have also corrected the radiation levels affected by the increase in activity.

c) Missing a 9/27/95 letter from the reference section of the registration certificate.

File Number: 19
Registry No.: CA 471-D-102-B
SS&D Type: Model 101, 102, 103, 104, 108, 200, 210, 220
Manufacturer: NDC Systems, Inc.
Date Issued: 4/28/95

Comments:

a) Amended to allow general licensees to remove and reinstall the devices following new labels and instructions. Reviewers did not assess if worker doses still meet the general license safety criteria.

b) Use of epoxy to hold the source in place should have resulted in question regarding the ability of the epoxy to hold up to the radioactive dose and the operational temperature ranges of the devices.

c) Dwg 621710 was missing material of construction, dimension, specific to the automatic shutter systems. This information is necessary for the reviewer to evaluated the adequacy of the test conditions and results submitted to support this amendment request.

d) Automatic shutters that are pneumatic are prone to failures associated with air quality. Particularly in typical equipment users air supply systems. Since the general licensee is relying on the shutter to return the source to fully shield position, specific air purity specifications should have been part of the instruction to the general license.

e) While a shutter cycle shutter test of 10,000 was conducted, it is not clear what this represents in the life of devices and if the environmental ranges the device is used in are addressed by the test.

f) Materials of construction of the label were not assessed to determine if they would likely remain legible for some period when in use.

g) The reviewer should have asked for an additional test to simulate dropping devices, given that the general licensee will remove and reinstall the device and is more likely to drop it and damage it than before when used as a fixed gauge only.

h) No peer review was conducted. Although the reviewer referred to 10 CFR 32.51 when performing this review. The reviewer was unclear on how far he could apply this regulation to a State license. A checklist in this area would have helped resolve the reviewers concern.

File Number: 20
Registry No.: CA 406-S-122-S
SS&D Type: Model HEG-xxx (formerly 225)
Manufacturer: Isotope Product Laboratories, Inc.
Date Issued: 5/31/95

Comments:

a) Sources approved for use in calibration, gauging and well logging applications.

b) Requirements for the use of insoluble forms of radioactive materials and specific labeling requirement for well logging application does not seem to have been addressed. For example no data could be found on solubility of chloride or nitrate in ceramic, or oxides in gold or aluminum.

c) No peer review was conducted.

File Number: 21
Registry No.: CA 598-S-119-S
Manufacturer: JL Shepherd & Associates

SS&D Type: Model 6810
Date Issued: 3/25/95

Comments:

a) No peer review was conducted.
b) Amendment added an alternate source supplier for this generic case of source design.
c) Aluminum is used as a spacer in the capsules. Dissimilar metals could result in formation of a galvanic corrosion cell under the correct conditions. Possible corrosion mode should be evaluated.

File Number: 22
Registry No.: CA 102-D-101-S
Manufacturer: ADAC Laboratories, Inc.

SS&D Type: Model Vantage
Date Issued: 5/8/95, amended 10/12/95

Comments:

a) Not clear if aluminum and steel interface was evaluated for possibility of formation of a galvanic cell that could cause corrosion.
b) Label location and materials of construction of the label were not identified.
c) Actual conditions of use of the device and possible multiple source removal and installations should have been considered as part of the review. Damage from user dropping source, bending it and having to force the source in place or breaking it by bending is to extreme angles is likely given the frequent need for source removal and replacement. This testing or analysis would have augmented the tests submitted for the source housing.
d) Section 1.8 of the user's manual informs user on how to install the source. The manual would appear to require the user to install the source using both hands to hold the source steady. The review should have assessed the hand and whole body doses associated with following the vendors procedure on handling the sources.
e) No peer review was conducted.
f) Dwgs, provide weak information about critical safety components. The dwgs do not provide enough detail on how the source is held in place, material of construction and tolerances between moving components to allow a reviewer to assess the adequacy of the test results.

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY

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May 5, 1997

Mr. Richard L. Bangart, Director
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Bangart:

Thank you for your letter of March 11, 1997, and the Draft Report on the Integrated Materials Performance Evaluation Program (IMPEP) review of California's Agreement State program which was conducted October 21-25, 1996. I have been informed by the staff involved in the review that it was conducted in a very professional manner and that the IMPEP review process itself is a great improvement over the process previously used by the U. S. Nuclear Regulatory Commission (NRC). Especially important was the perspective and balance brought to the review team and its conclusions by the inclusion on the review team of a representative from another Agreement State.

The draft report has been reviewed and found to be accurate in its factual findings.

The draft report identifies two areas of concern, the timely adoption of regulations and the quality of sealed source and device (SS&D) evaluations. The Department of Health Services is trying to make improvements in both of these areas, and I believe that the draft report bears out the fact that improvements have been made in both areas since the time of the last review.

Over the long term, the solution is getting more people to work in these activities. Toward that goal, the Radiologic Health Branch (RHB) has conducted a baseline study of its mandates, responsibilities, and activities and the resources, both people and funding, necessary to meet these. As a result of that baseline study, RHB developed and presented a Budget Change Proposal (BCP) which if approved would significantly increase both the staff and funding of RHB. This BCP was supported by this Department, the Health and Welfare Agency, the Department of Finance, and is included in the Governor's Budget for the next fiscal year beginning July 1, 1997. Presently the BCP is awaiting budget committee hearings in both the Assembly and the Senate. We are optimistic that the BCP will be successful. If approved, there would be an additional $3,123,000 and 38.5 full time equivalents added to the present budget and staff of RHB.

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ATTACHMENT 1

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Additional staff would include two health physicists for regulation development and adoption work and an attorney for efforts related to regulation development and adoption and other activities of RHB requiring legal advice and assistance such as enforcement efforts. Included in the BCP are three additional health physicists and support staff for the unit that performs SS&D evaluations. Also included in the BCP is a request for $180,000 to pay for technical training of the staff of RHB to replace training previously provided by NRC. We still feel that NRC is remiss in not providing training to the staffs of Agreement States, especially in view of the amount of money paid to NRC by licensees in Agreement States and the overall savings in federal costs that the Agreement States provide. I sincerely hope and request that the Commissioners of NRC will reconsider this decision.

With regard to the present status of regulations that were found to be overdue for adoption, the following information is provided:

1. "Definition of Land Disposal and Waste Site QA Program" -- There has been no change in the status of this regulation since the time of the review, and it is still scheduled for adoption by October 1, 1997.

2. "Notification of Incidents" -- This regulation involves a notification requirement that was inadvertently deleted by NRC when it adopted a complete revision of 10 CFR Part 20, and therefore had to be subsequently readopted by NRC. RHB, in adopting 10 CFR Part 20 by reference, also deleted this previously required notification. Proposed regulations to add this provision into the California regulations were submitted to the Office of Regulations (OR) on February 5, 1997, and are currently set for public hearing on June 9, 1997. From the time a proposed regulation is presented to OR, it is a minimum of 274 days before the regulation can become effective unless it is submitted as an emergency regulation, which this one was not. From a practical standpoint, California licensees are already complying with the notification requirements of this regulation because they were used to the old regulation which was rescinded. For example, earlier this year ICN had a fire at its facility that did not meet any of the notification or reporting requirements in the current California regulations; nonetheless RHB was notified immediately of the fire and the resultant damage.

3. "Quality Management Program and Misadministrations" -- California regulations presently contain a more stringent misadministration reporting requirement than do those of NRC. We do not intend to lessen those requirements to be identical to those of the NRC. No action is planned on the quality management program portion of the NRC regulation until the Commissioners of the NRC reach final resolution on the recommendations of the National Academy of Sciences, Institute of Medicine study regarding NRC's role in the regulation of the medical use of radioactive materials and other sources of radiation.

4. "Licenses and Radiation Safety Requirements for Irradiators" -- RHB is currently preparing the regulation package to submit to begin the regulation adoption process. It is anticipated that this package will be submitted to OR by the end of June 1997. Historically, RHB has licensed five large irradiator facilities of the type covered by this regulation; in addition, several other machine irradiation facilities with similar hazards and radiation dose rates are regulated by RHB. The first license for a large irradiator using radioactive materials was issued by RHB on February 20, 1969. In the almost 30 years since, RHB has licensed four additional facilities and overseen the decontamination and decommissioning of two of these facilities. The three currently licensed facilities meet all the licensing requirements in 10 CFR Part 36 and are subject to all safety equipment and procedures of those regulations. During the review these substantive determinations were made by the review team. The absence of California regulations identical to those of NRC does not constitute a health and safety issue at any of the three large irradiators in California. All requirements of 10 CFR Part 36 have been met in the license application review process, license conditions, and other California regulations.

The other program area found to need improvement was the SS&D evaluation effort. RHB has already begun to address all the issues and recommendations noted in the Draft Report. Two staff members, David Wesley, Senior Health Physicist, and Thomas A. Schell, Associate Health Physicist, attended the "Workshop on Sealed Source and Device Evaluations" that was held at NRC Headquarters in Rockville, Maryland, on April 7-11, 1997. As other workshops and training courses become available, other RHB staff will attend to receive training in the new processes and procedures used in SS&D evaluation and documentation. It is anticipated that all issues raised by the Draft Report will be fully resolved by the time of the Management Review Board (MRB) meeting at which final determinations are made with regard to the adequacy and compatibility of the California Agreement State program.

In conclusion, we feel that the Agreement State program in California is not only adequate but is doing an excellent job of protecting the health and safety of radiation workers and other members of the public from the potentially deleterious effects of radiation from radioactive materials. It is our conclusion that the program is in all substantive matters compatible with the requirements, policies, and procedures of the NRC. We believe that MRB will also find the Agreement State program in California adequate to protect the public health and safety and compatible with the regulatory requirements and programs of the NRC.

We look forward to meeting with MRB and our continued mutual effort to maintain and improve the radiologic health of the nation. If we can provide you with additional information or answer any questions, please contact me or Larry Barrett, D.V.M., M.S., Chief, Division of Food, Drug, and Radiation Safety, at (916) 324-3266.

Sincerely,

S. Kimberly Belshé

S. Kimberly Belshé
Director

cc: Dr. Shirley Ann Jackson, Chairman
Mr. Nils Diaz, Commissioner
Ms. Greta Dicus, Commissioner
Mr. Edward McGaffigan, Commissioner
Mr. Kenneth Rogers, Commissioner
U.S. Nuclear Regulatory Commission
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