DATED: JUNE 18, 1997 SIGNED BY: HUGH L. THOMPSON, JR.

Ms. S. Kimberly Belshé, Director
California Department of Health Services
714/744 P Street
P.O. Box 942732
Sacramento, CA 94234-7320

Dear Ms. Belshé:

On June 5, 1997, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the California Agreement State Program. The MRB found the California program adequate to protect public health and safety and compatible with NRC's program.

Section 5, page 29, of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next review will be scheduled in three years, unless program concerns develop that require an earlier evaluation.

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

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Dr. James Stratton, State Health Officer
Dr. Larry Barrett, Chief
California Food, Drugs and Radiation Safety Division
Dr. David Spath, Chief
Division of Drinking Water & Environmental Management
Mr. Edgar Bailey, Chief,
California Radiologic Health Branch

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bcc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
CPaperiello
Commissioner Diaz
Commissioner McGaffigan

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF CALIFORNIA AGREEMENT STATE PROGRAM

October 21-25, 1996

# FINAL REPORT

U.S. Nuclear Regulatory Commission

## 1.0 INTRODUCTION

This report presents the results of the review of the California radiation control program. The review was conducted during the period 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.

Bob Reyes:
B.S. Radiation Health Physics/Public Health
PhD Education
RSO at Northridge (CSUN) facility for environmental science and radiological health.

Fred Toyama:
B.S. in Physics
U.S. Army Depot (Calibration Center)

Tom Schell:
B.S. X-ray Technology
RSO at San Louis Obispo
HP for State of Arizona/Wyoming
Radiography Licensee

Pete Patel:
B.S. Chemistry
Pharmacy Training
M.M.Sc. - Radiologic Physics
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<br>Technical Staffing and Training<br>Legislation and Regulations<br>Low Level Radioactive Waste Disposal Program |
| Jack Hornor, R-IV | Status of Materials Inspection Program<br>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