STAFF REPORT AND EVALUATION

OF THE

CALIFORNIA RADIATION CONTROL PROGRAM

FOR THE PERIOD

MARCH 15, 1986 TO MARCH 14, 1987

25th Regulatory Program Review

GQ. 9306090098 930503 PDR COMMS NRCC CORRESPONDENCE PDR 300 5 1

AGREEMENT STATE RADIATION CONTROL PROGRAM REVIEW

STAFF REPORT AND EVALUATION CALIFORNIA 1987

STAFF REPORT AND EVALUATION OF THE CALIFORNIA RADIATION CONTROL PROGRAM FOR THE PERIOD MARCH 15, 1986 TO MARCH 14, 1987. The 25th regulatory program review meeting with California representatives was held during the period March 16 to March 27. 1987. in Sacramento. California. The State was represented by Jack McGurk. Chief. Local Environmental Health Services Branch. Joseph O. Ward. Chief. Radiological Health Branch. Gerard Wong. Ph.D., Chief. Radioactive Materials Section, and the Radioactive Materials Section staff. The program review was conducted by Jack Hornor and Beth Riedlinger, NRC Region V. The review meeting in Sacramento was preceded by meetings held during the period February 17 to February 27 in Los Angeles. Orange and San Diego Counties. These meetings, between Mr. Hornor and the management and staff of the regional offices and agencies contracted by the State to inspect agreement materials. were for the purpose of reviewing their programs, conducting field evaluations of inspectors and providing technical assistance. Mr. Hornor also met with Don J. Womeldorf. Chief. Vector Surveillance and Control Branch. who has the responsibility for the proposed low-level radioactive waste site in California. A summary meeting was held on March 27th to discuss the results of the regulatory program review with Alexander Kelter. M.D., Acting Deputy Director. Public Health. Harvey F. Collins. Ph.D., Chief. Environmental Health Division. Mr. McGurk. Mr. Ward and staff. Along with Mr. Hornor, the NRC was represented at this meeting by Carlton Kammerer, Director, State, Local and Indian Tribe Programs and Joel O. Lubenau. Senior Projects Manager. State Agreement Programs.

Included in this review were examinations of selected license and compliance files. the program indicators specified in the NRC "Guidelines for NRC Review of Agreement State Radiation Control Programs." seven field accompaniments of State inspectors, the review of all licenses issued by California since March 1986 and our continuing exchange of information program. Sixteen hours of technical assistance were provided by the NRC staff at the request of the California program management and the San Diego County representatives.

Conclusions:

The State's program for controlling agreement materials continues to be adequate to protect the public health and safety and is now compatible with the regulatory programs of the NRC and the Agreement States.

These conclusions are based on the review of the technical and administrative aspects of the State's regulatory program for controlling agreement material. Further discussion of the findings may be found in the attached confirmatory letter sent to the State Health Officer following the review.

Summary Discussion with State Representatives

During the summary meeting held on March 27. 1987. Dr. Kenneth Kizer. Director. Department of Health Services, was represented by Alexander Kelter. M:D.. Acting Deputy Director, Public Health. Dr. Kelter and the other State representatives were complemented on the significant improvements made in the program and on the findings of adequacy and compatibility. The staff of the Radioactive Materials Section was praised for maintaining a quality inspection program while virtually eliminating a large backlog of overdue inspections. The State was also commended for completing the revision of their regulations to achieve compatibility and for developing a computer system to track the licensing and compliance programs.

Program Changes Related to Previous NRC Comments and Recommendations

I. MANAGEMENT AND ADMINISTRATION

A. Administrative Procedures and Management

Comment

The Radiation Control Program (RCP) should have procedures that assure the staff performs its duties as required with a high degree of uniformity and continuity in regulatory practices. and program management should receive information from the staff pertaining to backlogs, problem cases, inquiries, etc. NRC reviewers found in this and past reviews that insufficient communication between levels of management in the Department. Division and Branch diminishes effectiveness of the RCP. In some cases upper level management is not aware of problems within the Branch, and within the Branch, information necessary for proper program functioning is not always made available to either the staff or supervisors.

Recommendation

We recommend periodic staff meetings at appropriate levels be used to discuss information, policies, ideas and problems. Within the Branch, periodic meetings should be held by the Branch Chief and the supervisory staff and between the supervisors and the licensing and compliance staffs. While the semi-annual meetings held by the Branch with the regional and contract personnel have been beneficial, we believe more frequent meetings of the headquarters staff are indicated.

State Response

Staff meetings, attended by the Branch Chief, supervisors and licensing and compliance personnel, are held on an "as needed" basis but not less than an average of once a month.

Present Status

The communication within the Branch appears to have improved with the increased frequency of staff meetings. The headquarters staff has been meeting once a month with the Branch Chief and supervisors. As of February, the license reviewers and supervisors meet weekly and the compliance staff meets monthly. The semiannual meeting of all headquarters, regional and contract personnel has continued. The communication between the Branch supervision and Department and Division management was improved by temporarily assigning other Division managers to assist the Branch Chief. The permanent effect of this action will be evaluated in later reviews.

B. Management

Comment

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. This type of quality assurance review is not being performed by the Branch.

Recommendation

We recommend program management perform selected reviews of licenses issued by each reviewer, focusing on as many different types of licenses as possible and document them.

State Response

The licensing supervisor has been reviewing all licensing actions issued by every license reviewer on a regular basis for purposes of quality assurance.

In addition to this regular review:

- (1) The licensing supervisor will select the work of one reviewer at a time and perform a thorough and complete review once each week.
- (2) The Chief of the Radiation Management Section will perform the same once a month.

These reviews will be documented.

Present Status

The work of the license reviewers is being periodically reviewed by the Chief of the Radiation Management Section and the staff supervisors.

C. Office Equipment and Support Services

1. Comment

The RCP should have adequate secretarial and clerical support. The size of the support staff has not kept abreast of increased workloads. such as occurred when the materials inspection staff transferred to Sacramento from Berkeley and when the number of technical staff increased. As a result, backlogs of typing and filing are occurring which impede functioning of the program. This matter was also discussed at the last follow-up review.

Recommendation

The support staff should be increased sufficiently to cope with the increased workload.

State Response

The Program Management and Consultation Section is reviewing the RHB support staffing level requirement to determine the need for additional staff. Paid overtime has been authorized for support staff as an interim measure.

Present Status

The backlog of typing and filing had been eliminated by the use of overtime and temporary help from other Branches. A supervisor responsible for organizing the clerical work flow was added at the beginning of February, but otherwise, the staff was not increased. Of the 6.5 clerical positions currently approved, only three (including supervisors) were filled at the time of the review.

2. Comment

Large programs. such as California's. should have automatic data processing and retrieval capabilities. A system using IBM PC's was delivered in August 1984, but the software is not fully functional and the staff has not been adequately trained. The assistance obtained thus far has not been successful in solving this problem. As a result the State is having difficulties in assessing the status of the inspection program, tracking compliance histories of licensees and otherwise obtaining the benefits of a fully operational system.

Recommendation

We recommend assistance be sought from sources with the proper expertise. An alternate measure would be to provide in-depth training to a current member of the RCP staff who would then be responsible for the development and use of the system. as well as training other staff members.

State Response

The Environmental Health Division arranged a panel of experts within the Department to meet with RHB to discuss RHB's data processing needs on June 10, 1986. A list of RHB data processing needs was prepared to help in the assessment of the software/hardware and consultation necessary to make RHB's data processing system fully functional.

Present Status

The ADP capability of the program was significantly improved. Some of the newly added capabilities are:

- a. the ability to track licensing actions from the time they are received until they are completed.
- b. the tracking and projection of due and overdue inspections.
- c. various administrative and accounting functions.
- d. automatic print-out of renewal notices.
- e. the ability to generate ad hoc reports by selecting one or more parameters.
- f. the ability to track open and closed investigations.

All of the programs are now being integrated into a user friendly program which will require the entry of data only once. Upon completion of this project, all staff will be trained according to their level of need.

11. PERSONNEL

A. Staffing Level

Comment

The staffing level should be approximately 1-1.5 person-years per 100 licenses in effect. California is a large state with many complex licenses and sealed source and device evaluations. A staffing level close to the higher figure may be needed to properly administer the program. The current professional staffing level in the Agreement Materials program is 0.83 staff per 100 licenses. Three of the professional staff positions are temporary. There is a current backlog of overdue inspections and a projected schedule of approximately 650 routine inspections per year. Without additional inspection staff, it does not appear that the inspection schedule can be met.

Recommendation

We recommend the temporary staff positions be made permanent. existing vacancies be filled, and the staff be increased to a level adequate to meet the inspection frequency schedule.

State Response

The Office of Personnel Services has authorized RHB to fill the three limited term health physicist positions on a permanent basis. New certified hiring lists for Associate and Assistance Health Physicists are expected in the next few days. There are four health physicist vacancies in licensing. Filling these vacancies will bring the professional staff level to 0.91 per 100 licenses. Additional staff positions will be proposed for FY 87/88 to bring the professional staff level to about 1.2 staff per 100 licenses.

Present Status

At the time of the review, all RHB staff positions were filled but one vacancy existed in the Department of Industrial Relations. As of March 1. 1987, the actual professional staffing ratio per 100 licenses was 0.96 with 0.98 authorized. As of July 1, 1987, the authorized level will be 1.14, and the State is currently recruiting for these additional positions.

III. LICENSING

A. Licensing Procedures

1. Comment

License applicants should be furnished copies of applicable guides and regulations. New licensees are not being furnished copies of the regulations nor are they advised how to obtain copies.

Recommendation

We recommend that copies of the applicable regulations and licensing guides be furnished to license applicants and that the revised version of Title 17 be distributed to all licensees as soon as it is printed.

State Response

A requisition has been submitted to the Office of State Printing for updated California Radiation Control Regulations. They are expected to be available mid August 1986. An internal procedure has been established to assure that regulations are available to California licensees in the future.

New license applicants will be furnished copies of all applicable guides, application forms, checklists and an order form for the California Radiation Control Regulations. "Materials Memo No. 95", indicating forms to include with various applications, has been issued to all licensing staff.

All licensees will be issued a notice that updated regulations are available and will be given a regulations order form. Outstanding orders for regulations will be filled by the Office Services Section upon receipt of the regulations from the printer.

Present Status

Advisory letters describing the changes and availability of the new regulations were sent to all licensees on January 9, 1987; however

changes have occurred since that time and new advisories need to be sent. New applicants are furnished with forms to order the regulations.

2. Comment

Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process. In some cases, existing standard conditions are not used by licensee reviewers (e.g., teletherapy licenses). In other cases, largely because the California regulations are not compatible with those of the NRC, the list of conditions provided to the license reviewers is not adequate to cover the situations where they are needed. As a result, several reviewers compose their own conditions, which leads to inconsistencies.

Recommendation

The list of standard license conditions used by the State should be re-evaluated and modified to meet the needs of the program. Staff input should be sought in this effort. The standard license conditions should then be used by all reviewers.

State Response

The standard conditions have been evaluated and modified. Uniform standard license conditions have been consistently used in the past with only an occasional need for special license conditions. This need will continue to exist. Any new proposed standard condition will be reviewed by the staff prior to inclusion with the next revision.

Present Status

The standard license conditions were revised and issued to all reviewers in January 1987.

3. Comment

The RCP should have internal licensing guides, checklists and policy memoranda consistent with NRC practices. The State made policy changes in the memorandum issued after the previous review that significantly improved the overall quality of licenses issued since that time. During this review, the RCP staff voiced the need for clarification in policies dealing with use and retention of checklists, the need for prelicensing visits, documents to be referenced in the tie-down condition and documentation of telephone conversations with applicants.

Recommendation

We recommend program management clarify the licensing procedures in the following areas:

a. Checklists should be reviewed to determine that they contain the essential elements for each type of license issued by the State. Model licenses should be used as guides. Disposition of the completed checklists should be specified.

State Response

Checklists have been developed for applicants with standard licensing requirements. They have been used on a trial basis since May 1985 and have proven to contain the essential elements necessary for a good radiation safety program for each type of license. A list of available guides and checklists has been included with a memo to the entire staff regarding their disposition (Materials Memo No. 96). Samples of various types of licenses are also available to the staff as guides. "Materials Memo No. 97" regarding their use has been distributed.

Present Status

Improved checklists that contain standard licensing requirements have been implemented and samples of various types of licenses are available to the staff for use as guides. It is now the policy to retain the reviewer checklists in the file for two years.

b. Criteria should be established to determine the need for prelicensing visits.

State Response

Y ...

This item was clarified during a staff meeting on June 5, 1986. Minutes of this meeting have been distributed to the staff via Memo dated July 10, 1986.

Present Status

The prelicensing inspection criteria were established and discussed in the meeting: however, minutes of the staff meeting are very brief and the licensing procedures have not been updated to include the criteria.

c. Guidance should be developed on the proper documents to reference in the standard license tie-down condition.

State Response

This item was clarified in the staff meeting and memo discussed above.

Present Status

The documents to be included in tie-down conditions have been determined, and the information distributed to the reviewers.

d. Telephone discussions with applicants and licensees should be documented and maintained in the case file.

State Response

Documentation of telephone conversations has been clarified via Materials Memo No. 85. A standard form for reviewers' use was included with this memo.

Present Status

Telephone conversations pertaining to licensing actions are now being documented and retained in the files.

4. Comment

License reviewers assign the license inspection priority. Several licenses were found to have the priority incorrectly assigned.

Recommendation

We recommend supervisory review of all priority assignments.

State Response

This is part of supervisory review. A more detailed priority assignment schedule has been provided to the staff (Materials Memo No. 76C); A complete edit of priority assignments would require incorporation of the updated priority scheme into the data processing system.

Present Status

A new comprehensive table to be used in assigning priorities was issued to the staff. No incorrect priorities were found, during the license file review.

5. Comment

A number of license cases were noted to be under timely renewal for extended periods of time. As an example, a major manufacturer and distributor has been under timely renewal for ten years. The application is no longer current and the existing license does not reflect current regulatory practices.

Recommendation

We recommend that California review all licenses in timely renewal status and develop a program to complete action on the renewal applications. We suggest a target date of one year for completion of pending renewals. In cases where existing licenses and backup applications and correspondence no longer reflect current operations, the licensees should be requested to resubmit complete applications with up-to-date information.

State Response

With the existing staff, RHB is able to review and draft new licenses and amendments within two months. The backlog of renewals total 265, 80 of which are over one year old. We are in the process of hiring additional health physics staff in an effort to reduce this backlog to within one year.

Present Status

According to the licensing supervisor, all renewals over one year old are in the renewal process, and tracking has been computerized to ensure the renewal process is on target. The staff is now able to process new licenses in approximately thirty days, amendments in sixty days and renewals within a year.

IV. COMPLIANCE

A. Status of Inspection Program

Comment

During the review. a defect was revealed in the method used to produce the due/overdue listing used to assign inspections and to assess the status of the inspection program. The due date for an inspection was based on the length of time elapsed since the last inspection, with no means to pick up newly issued licenses. Thus, if an initial inspection was not performed, the license would not be in the tracking system. When the Branch staff prepared a listing of "licenses never inspected," they identified about 200 licenses overdue for their initial inspection (based on the initial inspection schedule in effect at the time the license was issued). 76 due for a routine inspection, and 17 overdue for their routine inspection. None of these cases appeared on the due/overdue list because the initial inspections were not performed.

Recommendation

We recommend that the inspection tracking system be modified to account for all licenses. After this is accomplished, we recommend a manual check of each license file against the computer file. Following this action the initial inspections should be completed in a reasonable time and in any case not later than the date the routine inspection would be due (not overdue) under the current priority schedule.

State Response

The data processing system for due/overdue inspections has been modified to account for all licenses. As a back-up tracking method, since June 1, 1986, inspection agencies are required to furnish weekly inspection progress reports to RHB-Sacramento. RHB has escalated compliance inspection efforts by redirecting two health physicists from the Environmental Unit to conduct full-time compliance inspections. The target for elimination of all overdue inspections is mid March 1987.

Present Status

The computer system is now able to accurately track the status of the inspection program. A manual cross check of all license files against the computer files was performed and it was verified that all licenses are now accounted for. The backlog of inspections overdue by NRC criteria has been eliminated and the State is now concentrating on inspecting licensees that have never been inspected.

B. Responses to Incidents and Alleged Incidents

1. Comment

The NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations. Criteria for reporting significant incidents were outlined in an All Agreement State Letter dated November 23, 1984. Cases in which the reporting requirements were exceeded but which were not reported were found in the files, and the reviewer was advised the State has no written procedures for reviewing the incident file against the reporting criteria.

Recommendation

We recommend written procedures be developed to ensure proper reporting of significant incidents.

State Response

Staff members have been reminded of the criteria for reporting incidents. We shall emphasize these criteria again at the next general staff meeting in fall this year.

Present Status

From review of the incident files, it appears the State is now using the criteria for reporting incidents as stated in the All Agreement State Letter of July 22, 1986; however written procedures have not been developed.

2. Comment

Information on incidents involving licensees is not crossreferenced to license or compliance files and thus license reviewers and inspectors may be unaware of any incidents which may have occurred at a particular facility where an application is under review or an inspection is being planned.

Recommendation

We recommend the State provide a cross-referencing system between the incident file and license and compliance files so that license reviewers and inspectors can readily identify reported incidents which may have occurred at a particular facility.

State Response

The cross-reference system between the incident file and license and compliance files is already in place. A copy of RH 5010 (Initiation of Investigation) is put in the license file to alert reviewers of significant incidents.

Present Status

The incident file is now online and a cross-reference system between the incident file and the license and compliance files is now in place. A copy of the form, Initiation of Investigation, is placed in the other files to alert the reviewer or inspector.

C. Inspection Reports

Comment

Reports should uniformly and adequately document the results of inspections, substantiate all items of noncompliance and health and safety matters and indicate the substance of discussions with licensee management. Eleven of the fifteen reports reviewed contained errors or omissions, such as not completing all sections of the uniform inspection form, short forms (2514) that were not properly signed and dated, items of noncompliance downgraded to recommendations, no indication of interviews with ancillary workers, and no indication of exit interviews with management.

Recommendation

We recommend more thorough supervisory review to assure that inspectors adhere to program policy.

State Response

A memo regarding more thorough supervisory review was issued to all inspectors and inspection agencies in March 1986 (during the week of the NRC audit).

Present Status

The review of the inspection reports showed improvement; however some items, such as documentation of interviews with workers and observation of the licensee's handling of radioactive material are not on the current report forms and were still frequently omitted. Only one standard inspection form is currently being used for all types of licensees and it is not always adequate to describe the scope of the inspection. This issue is addressed in the current correspondence.

.

D. Independent Measurements

Comment

RCP instrumentation should be adequate for surveying licensee operations, and instrument calibration services or facilities should be readily available and appropriate for instrumentation used. There are air flow velometers that have not been calibrated according to Department standard practice and therefore have not been used for licensee inspections.

Recommendation

We recommend that velometer calibration, in accord with Department standard practice, be obtained and that velometers be used for conducting independent measurements as necessary during inspections.

State Response

Velometers are calibrated once a year. Inspectors will use them for conducting independent measurements as necessary.

Present Status

All air flow velometers have now been calibrated and are being used in the field.

EVALUATION OF AGREEMENT STATE RADIATION CONTROL PROGRAM STATE REVIEW; GUIDELINES, QUESTIONS AND ASSESSMENTS

CALIFORNIA MARCH 1987

I. LEGISLATION AND REGULATIONS

A. Legal Authority (Category I)

NRC Guidelines: Clear statutory authority should exist. designating a state radiation control agency and providing for promulgation of regulations. licensing, inspection and enforcement. States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA. Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Questions:

 Please list all currently effective legislation that affects the radiation control program.

Legislation affecting the California Radiation Control Program is incorporated in the Health and Safety Code. Sections 25800 through 25876. This legislation is comprehensive and addresses regulation of use of sources of radiation, environmental monitoring, transportation, waste disposal and nuclear emergency response.

2. What changes have been made to the statutory authority of the State to license, inspect, and otherwise regulate agreement materials since the last review?

The Budget Act for 1986/87 requires that all public health fees including radioactive materials license fees be set at full cost recovery and provides for a one time adjustment in radioactive material license fees to meet this requirement.

 If your State regulates uranium or thorium recovery operations and associated wastes pursuant to an amended agreement and UMTRCA, explain any changes to the statutory authority for these functions.

California does not currently have an amended agreement for regulating uranium and thorium recovery operations and associated waste.

4. Are copies of the current enabling act and other statutes (e.g., Administrative Procedures Act, Sunshine Act., etc.) which govern the conduct of the agreement materials program on file in the Radiation Control Program (RCP) office and with the NRC? If revisions have occurred since the last review, the changes should be included.

Copies of the statutes are on file with the RCP and have been given to the NRC.

5. If the State's regulatory authorities are divided between agencies, what procedures and memoranda are in effect to provide clear understanding of the divisions of responsibilities and requirements for coordination?

The Department of Health Services contracts with one other State agency, the Division of Occupational Safety and Health (DOSH) a division of the Department of Industrial Relations (DIR), to evaluate license applications and to conduct X-ray and radioactive material compliance inspections. The regulatory responsibilities are conducted under the DHS policy and supervision. An Interagency Agreement exists between the two agencies which sets forth the services to be performed and all terms and conditions of the agreement. Also, Los Angeles, San Diego and Orange Counties are currently conducting compliance inspection activities within their respective jurisdictions under contract and at the direction of the Department. San Bernardino County also conducts radiation machine inspections under a compliance inspection contract.

- 6. Does the State have the authority to:
 - a. apply civil penalties? If so, cite legislation.

California has limited authority to impose civil penalties. This authority is contained Section 25866 of the Health and Safety Code and establishes civil penalties for intentional or grossly negligent violations of the radiation control law and regulations or failure or refusal to comply with an order of the Department.

b. collect fees? If so, cite legislation.

California currently assesses annual fees for radioactive material licenses. These fees are specified in Article 8 of the Radiation Control Regulations. Cost of living adjustments are made on an annual basis pursuant to Section 113 of the California Health and Safety Code.

c. require surety or long term care funds? If so, cite logislation.

Authority exists only for low-level waste sites. See answer (f) below.

- d. require performance bonds or sureties for decompissioning licensed facilities? If so, cite legislation.
 - No.
- require performance bonds or sureties for cleanup of licensed facilities after a contamination accident? If so, cite legislation.
 - No.
- f. require long term care funds for uranium mill or low-level waste facilities? If so, cite legislation.

Yes, the Health and Safety Code Sections 25805, 25810, 25812 and 25813, require surety and long term care funds for low-level waste sites. Regulations to implement the legislation were completed in 1984 and are contained in Radiation Control Regulations, Section 30487 through 30491 inclusive.

g. enter into low-level waste compacts? If so, cite legislation.

California presently has authority in Health and Safety Code Section 25813.5 to enter into a low-level waste compact.

 h. establish, license and/or operate a low-level waste site? If so, cite legislation.

> Authority related to establishment licensing and operation of a low-level waste site is contained in the Health and Safety Code, Sections 25805 and 25811.5 through 25814.

 If any responses to the above question are negative, explain any plans the State may have regarding those issues.

California has no plans regarding these issues.

I.A Reviewer Assessment:

Although it was not discussed in the State's response, regulatory responsibilities for agreement materials are divided between two Branches of the Environmental Health Division, the Radiological Health Branch (RHB) and the Vector Surveillance and Control Branch (VSCB) which has the responsibility of the low-level waste program. In addition, responsibilities for decommissioning and clean-up after a license is terminated are divided between the RHB and the VSCB although no policy or MOU has been established to define the responsibility for each branch. Currently they use different standards for acceptable release levels for unrestricted use, and there is no mechanism for coordinating clean-up efforts. This is contrary to the guidelines and is addressed in the current correspondence.

B. Status of Regulations (Category I)

NRC Guidelines: The State should have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards and effluent limits), and those required by UMTRCA, as implemented by Part 40. The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.

Questions:

 When did the State last amend its regulations in order to maintain compatibility and when did the revisions become effective?

The California Radiation Control Regulations were last amended and became effective March 5, 1987.

 Referring to the enclosed NRC chronology of amendments note the effective date of the NRC changes last adopted by the State.

California Radiation Control Regulations have now been fully revised for compatibility. The NRC regulation requiring removal or defacing of labels on empty RAM containers was filed March 5, 1987, as immediately effective.

3.a. Were there any compatibility items that were not adopted by the State?

No.

b. If so, please identify and explain why they were not adopted.

N/A

I.B. Reviewer Assessment:

As the above answers indicate, the State has now revised all regulations to become fully compatible.

C. Updating of Regulations (Category II)

NRC Guidelines: The RCP should establish procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC. For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable but no later than 3 years. Opportunity should be provided for the public to comment on proposed regulation changes. (Required by UMTRCA for uranium mill regulation.) Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

. .

Questions:

1. Does your State have a schedule or program for revising and adopting changes to regulations within three years of adoption by the NRC?

Yes, this is done on an as needed basis.

 Has your State adopted all regulations deemed a matter of compatibility by NkC within three years? (Refer to NRC chronology.)

Yes, all have been adopted.

3. What are your State's procedures for adopting new regulations? Briefly describe each step in the procedure. The regulations promulgation schedule is as follows:

Activity	Time Frame
Submission of Regulation Proposal to the Office of Regulations	As needed
Review by Office of Regulations	14 days
Review by Office of Legal Services and Budget/ Section/Department of Finance	30 days
Prepare and Distribute Public Notice	30 days
Public Notice Period	45 days
Public Hearing	1 day
Post-Hearing Review and Revision	30 days
Make Revisions Available to Public	15 days
Adoption by Director and Filing with Office of Administrative Law (OAL)	5 days
Office of Administrative Law Review and Filing with Secretary of State	30 days
Post-Filing Waiting Period (Upon a satisfactory showing to DAL, regulations may be filed as immediately effective.)	30 days

4. How is the public involved in the process?

Through hearings and review by the office of Administrative Law.

 a. Does the NRC have the opportunity to comment on draft changes to State regulations?

Yes, copies of the proposed regulations are sent to the NRC before they are sent to the OAL.

b. If so, does your State respond to the comments?

Yes.

I.C. Reviewer Assessment:

As previously noted California has now updated their regulations to be compatible with the NRC. As explained above, the revision process in the State takes approximately eight months after the new regulations are proposed by the RCP. California's problem in the past has related to the fact that the RCP did not initiate the process in a timely manner, and although they are now compatible, they have not established procedures to review the future changes in NRC regulations and to make appropriate amendments to the State regulations.

II. GRGANIZATION

A. Location of the Radiation Control Program Within the State / Organization (Category II)

NRC Guidelines: The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.

1. Attach a dated organization chart(s) showing the RCP and its location within the department and State organization.

The California State organization charts are attached as Appendix A.

 Is the RCP on a comparable level within the State organization with other health and safety programs so as to compete effectively for funds and staff?

Yes.

3. Does the RCP program director have access to appropriate levels of State management?

Yes.

II.A Reviewer Assessment:

The location of the RCP, although several management levels down in the State hierarchy, appears to be receiving adequate resources and is in a satisfactory position to meet the guidelines. Department and division management have given increased attention to the program throughout the last two review periods.

B. Internal Organization of the RCP (Category 11)

NRC Guidelines: The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy. Where regional offices are utilized, the lines of communication and administrative control between the regions and the central office (Program Director) should be clearly drawn to provide uniformity in inspection policy, procedures and supervision.

Questions:

 Attach dated copies of your internal RCP organization charts.

The charts are attached as Appendix B.

 How is the RCP organized so as to provide specific lines of supervision from program management for executing program policy?

The Radiologic Health Branch has been recently reorganized into three specific areas of responsibility: (1) <u>Radiation Machine</u> <u>Control Section</u>. composed of x-ray machine inspection and onsite inspection of certification programs: (2) <u>Radioactive</u> <u>Materials Control Section</u>. incorporating radioactive materials compliance and licensing: and (3) <u>Certification</u>, <u>Registration</u>, <u>and Program Support Section</u>, including x-ray machine registration and certification of x-ray machine operators. Refer to the organization chart for specific lines of responsibility.

- 3. If regional offices are used:
 - a. To whom do regional personnel report administratively?

RHB regional compliance offices (No. & So.) report to the compliance supervisor at RCP headquarters.

b. To whom do regional personnel report technically?

All contracting agencies and regional RHB offices report to RCP headquarters technically.

- If the RCP contracts with other agencies to administer the program:
 - a. Identify the contracting agencies and indicate their responsibilities.

The Department of Industrial Relations contracts for all industrial compliance inspections with the exception of those located within contract counties. The Counties of Los Angeles. Orange and San Diego contract for compliance inspections within their respective jurisdictions. San Bernardino County contracts for radiation machine compliance inspections only.

b. To whom do contract personnel report administratively?

Contract compliance inspectors report to supervisors within their respective agencies.

c. To whom do contract personnel report technically?

All contracting agencies report through the local supervisor to RCP headquarters technically.

II.B Reviewer Assessment:

The internal organization of the RCP appears adequate to meet the guidelines. This is based on the reviewer's observation of the program as well as the organization charts.

C. Legal Assistance (Category II)

NRC Guidelines: Legal staff should be assigned to assist the RCP, or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program. statutes, and regulations.

Questions:

 Are legal staff members assigned to assist the RCP or do procedures exist to obtain legal assistance expeditiously?

Legal assistance is obtained from staff attorneys in the Office of Legal Services. The Attorney General's Office provides representation for trials and hearings under the Administrative Procedures Act. Assistance from District Attorneys may be sought by the Department to prosecute civil or criminal charges for violations of laws and regulations.

 Is the legal staff knowledgeable regarding the RCP, statutes, regulations and needs?

Some specialization by attorneys in radiation protection matters occurs in practice. This specialization results in familiarity over time with the legal basis and requirements of the Radiation Control Program.

 If legal assistance was utilized since last review, provide a summary of the circumstances.

Legal assistance was used for draft orders, regulations. hearings and prosecution. The following is a summary of the circumstances:

- 1. Radiation Control Regulations.
 - Legal assistance was provided in reviewing the proposed updated regulations.
- 2. California Bionuclear Corporation.
 - The Los Angeles City Attorney assisted our Los Angeles County Contractor to presecute this company for numerous violations.

- 3. International Nutronics, Inc. (INI)
 - The U.S. attorney requested California to revoke INI's two licenses in California after INI was convicted of many serious charges in New Jersey. The Department's Legal Office reviewed the request and decided to assist the RHB to proceed with revocations of those licenses.
- 4. Boothe-Twining
 - The Department's Legal Office is working with staff to refer Boothe-Twining to the Attorney General's Office for revocation of their permit following a finding of serious violation of the Probationary Agreement.
- 5. Alarm Concepts
 - The Los Angeles City Attorney filed action and licensee pleaded <u>Nolo contendre</u>. was fined \$10,000, 6 months' probation, and 100 hours community services work.
- 6. University of Southern California
 - Los Angeles City Attorney filed 179-count criminal action.
- 7. University of California at San Francisco
 - Being evaluated for possible legal action.
- II.C Reviewer Assessment:

As indicated in the State's responses, legal assistance is being provided and used by the program pursuant to the NRC guidelines.

D. Technical Advisory Committees (Category II)

NRC Guidelines: Technical Committees, Federal Agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems. A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans. Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Questions:

 Discuss practices followed for obtaining technical assistance when needed (e.g., consultants, technical and medical advisory committees, licensees, the NRC and other State and Federal

Agencies).

In addition to the technical assistance received from federal agencies such as the NRC, DOE, and the Bureau of Radiologica' Health, the Department uses two technical and medical advisory committees, the Medical Advis ry Committee on Human Use of Radioactive Material and the Low-Level Radioactive Waste Advisory Committee. Special consultants are also used as necessary.

2. What steps are taken to avoid conflicts of interest?

Committee members are subject to the Department of Health Services' Conflict of Interest Cone and must provide a curriculum vitae to the State before their appointment. The Personnel Department requires forms be submitted to them describing the professional background of proposed consultants. These background statements, along with the personal knowledge of the program management, are intended to eliminate conflicts of interest.

 Are any committees involved in setting policies? If so, explain.

The committees do not set policy per se, but they provide input and review of legislation and regulations and they establish standards of competence for nuclear technologists.

 Attach a list showing the membership, specialties and affiliations of the Medical and/or Technical Advisory Committees.

The lists of committee members have been provided to the reviewer.

 Indicate whether the advisory committees are established by statute, by appointment of the Governor, by appointment of the State Board of Health, by appointment of the Agency, or by other means.

The committees are established by statute and mem ers are appointed by the Director.

6. What is the formal meeting frequency of each committee, and are minutes of committee meetings prepared?

There is no formal frequency established for meetings. The committees are convened as necessary and sinutes are always recorded.

7. What was the date of the last formal meeting of each committee?

The Human Use Advisory Committee last met on March 3, 1981; the Low-Level Waste Committee met September 13, 1985. 8. Are individual committee members contacted for consultation?

Yes.

9. Discuss how each committee is used, the average workload placed on the committee, and the remuneration, if any.

The Human Use Advisory Committee provides medical advice on nuclear medicine procedures, both in routine or investigational use, provides input on legislation and regulations pertaining to the use of radioactive material in nuclear medicine or associated areas and consults on medical aspects of radiation overexposure.

The Low-Level Radioactive Waste Advisory Committee was established for the purposes of providing advisory input and oversight of the development of a low-level waste site in California.

There is no compensation for either committee, but the members are reimbursed actual and necessary expenses incurred in the performance of their committee duties.

II.D Reviewer Assessment:

According to the above responses, the State complies with the NRC guidelines in their use of advisory committees.

III. MANAGEMENT AND ADMINISTRATION

A. Quality of Emergency Planning (Category I)

NRC Guidelines: The State RCP should have a written plan for response to such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

The Plan should define the responsibilities and actions to be taken by State agencies. The Plan should be specific as to persons responsible for initiating response actions, conducting operations and cleanup. Emergency communication procedures should be adequately established with appropriate local, county and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the Plan while in draft form.

The plan should be reviewed annually by Program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Questions:

 Is the RCP responsible for its own emergency plan or are accidents involving radioactive materials incorporated into a comprehensive State plan developed and administered by another State agency? Please provide copies of all applicable plans for review.

The "California Emergency Response Plan" is prepared by the State Office of Emergency Services (OES). The Radiologic Health Branch acts as a technical arm of the OES. The development of the emergency plans and procedures is a combined effort of both agencies. In addition, another OES plan, the "Nuclear Power Emergency Response (NPER) Plan." is directed toward response to emergencies at Rancho Seco, Diablo Canyon and SONGS. Copies of the current plans and procedures have been provided.

2. What written procedures or plans does the RCP use for responding to incidents involving radioactive materials?

The "Plan for Response to Incidents Involving Radioactive Materials" has been distributed and is in use. In addition. we operate under the OES plans.

3. If the plan covers major accidents at nuclear facilities, how does it cover non-catastrophic incidents such as those involving transportation of materials?

The RCP plan is intended to cover all radiation emergencies other than response to nuclear power emergencies.

How does the plan define responsibilities and actions to be taken by all State Agencies (initiating response actions, operations, cleanup, etc.)?

The introduction to the plan defines the jurisdiction and responsibilities of each agency and the licensee.

5. How does the plan provide for notification of and communications with appropriate government agencies?

> An emergency call list has 24-hour telephone numbers for all federal, state and county offices that might be concerned. This list has been provided to the NRC reviewer.

6. How is the response program organized so that qualified individuals are readily available through identifiable channels of communication?

Day and night telephone numbers are listed for all qualified individuals including the Medical Advisory Committee.

7. Has the plan been distributed to all participating agencies?

The Plan has been distributed and the distribution lists have been provided to the NRC reviewer.

8. Has the NRC had opportunity to comment on the plan in draft form?

Yes, the NRC reviewer did provide comments on the final document.

9. Is the plan reviewed annually by the RCP for adequacy and to assure the content is current?

The call list is reviewed quarterly. The plan is expected to undergo substantial revision as we implement the "Nuclear Power Emergency Plan (NPER Plan)".

 Are drills performed periodically to test the plan for radioactive materials emergencies? Explain. for example, how non-routine office hours communications are checked.

The emergency telephone call down system is tested several times per year. The NPER Plan has been revised to facilitate implementation by procedural modules, training and drills. Specific procedural modules are under development for training and an ingestion pathway exercise in October 1987. The NPER Plan is focused on power plants, but also has general applicability to all emergencies as procedural development, training and drilling continue.

4.

III.A Reviewer Assessment:

The State's response plan complies with most of the NRC guidelines. However, the section on transportation requirements is not complete and improvement is needed in the method of distribution of the plan. Contrary to the State's answers, it was found that the regional offices and contracting agencies did not have the latest revisions to the plan although they are often the responding agencies. According to management, the latest revisions were sent just prior to the review meetings, but to make certain all concerned parties received the revisions, discussion of the plan was added to the agenda of the upcoming semi-annual staff meeting with all personnel.

It was also noted the emergency response procedures do not address reviewing incidents against the NRC reporting requirements.

B. Budget (Category II)

NRC Guid:lines: Operating funds should be sufficient to support program needs such as: staff travel necessary to conduct an effective compliance program, including routine inspections. follow-up or special inspections (including pre-licensing visits) and responses to incidents and other emergencies: instrumentation and other equipment to support the RCP; administrative costs in operating the program including rental charges, printing costs, laboratory services, computer and/or word processing support, preparation of correspondence, office equipment, hearing costs, etc., as appropriate. Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Questions:

1. What fiscal year is used by your State?

The State fiscal year runs from July 1 through June 30.

 Indicate the amount for funds obtained from each revenue source (fees, State General funds, HHS, NRC environmental monitoring or transportation surveillance contracts, EPA, FDA and others).

Radioactive materials license fees currently provide \$1.393,463 per year. The balance and costs attributable to fee exempt licenses comes from the State General Fund.

- 3. Show the total amounts assigned to:
 - a. the total radiation control program

1986-1987 - \$4.615.555

28

b. the radioactive materials program

1986-1987 - \$1,682,771

4. What is the change in budget from the previous year and what is the reason for the change (new programs, change in emphasis, statewide reduction, etc.)?

The budget was increased to cover cost of living raises.

 Describe your fee system, if you have one, and give the percentage of cost recovery. Enclose a copy of the fee schedule.

Licensees are assessed an annual fee according to the size of the source. The cost recovery from the licenses is 95 percent. Emergency regulations have been submitted for full cost recovery from fees. This regulation was effective July 7, 1986. A fee schedule is enclosed as Appendix C.

6. Does the RCP administer the fee system?

Yes.

7. What recourse does the RCP have in the event of non-payment?

The RCP may take one or more of the following actions:

- a. Withhold licensing action until payment is made.
- b. Coordinate with other State agencies to deduct the fee due to the RCP from payment due to the licensee.
- c. Refer to the matter to the legal department for fee collection.
- d. Proceed to revoke license.
- Overall, is the funding sufficient to support all of the program needs? If not, specify the problem areas.

Yes.

III.B Reviewer Assessment:

As the State indicated, the RAM program is now required by law to be self supporting, but the funding for the program appears adequate to provide essential program needs and comply with the guidelines.

C. Laboratory Support (Category II)

NRC Guidelines: The RCP should have the laboratory support capability in-house, or readily available through established procedures, to conduct bioassays, analyze environmental samples. analyze samples collected by inspectors, etc., on a priority established by the RCP.

Questions:

1. Are laboratory services readily available in-house or through other departments within the State organization?

The Radiation Laboratory is a branch of the DHS that acts as a support group for the Radiological Health Branch. Although they have their own supervision and budget they are considered in-house because they are part of the DHS.

 If services are provided by other departments, discuss the arrangements, supervision, charges and interdepartmental communications.

Not applicable.

- If laboratory services must be provided by a non-State agency:
 - a. Discuss the contractual arrangements.
 - b. Is the party providing the service a State licensee?
 - c. If a State licensee provides the service or equipment, what are the costs?

None of the above are applicable.

- 4. Describe the capability of the laboratory as follows:
 - a. Can it qualitatively and quantitatively analyze low energy beta emitters?

Yes.

b. Can it qualitatively and quantitatively analyze alpha emitters?

Yes.

c. Can it selectively determine the presence and quantity of gamma emitters?

Yes.

d. Can it handle samples in any physical form - wipes, liquids, solids, gaseous?

Yes.

30

e. Does the lab participate in a periodic quality control program?

Yes, the EPA Safe Drinking Act requires it.

5. How much time does it take to obtain the results from sample analyses on both a routine basis and on an emergency basis?

The routine analyses depends on the lab workload and may take up to two weeks. Emergency samples are analyzed as quickly as the process and transit time permit.

 List the number and types of laboratory instrumentation and services available.

SANITATION & RADIATION LABORATORY INSTRUMENTATION: RADIOCHEMISTRY SECTION

Nuclear Measurement Instruments:

	Make and		Avail
	Model No.	Description	No.
1.	Nuclear Measurement. PCC-117 with DS-3	Internal proportional counter for gross alpha-beta	6
2.	Tennelec, LB 5100	Alpha/beta low background proportional counter with sample changer	2
3.	Beckman Wide-beta II	Low-beta background proportional counter with sample changer	1,
4.	Nuclear Data, ND-6620 with ORTEC (18%) PGT (305)	Ge(L:) gamma spectrometer with 2 Ge(L:) detectors	1
5.	ORTEC, Model 576	Dual detector alpha spectrophotometer	1
6.	Beckman, LS 3801	Liquid scintillation counter	1
7.	Random, SC-5	Radon scintillation counter	2
8.	SRL Const. Radon Counter		1
8.	Nuclear Data, ND-86 with PGT intrinsic detector	Intrinsic Ge detector gamma spectrometer on loan from NRC	1
10.	Scintrex Uranium Analyzer	Laser fluorescence	1

SANITATION AND RADIATION LABORATORY CAPABILITIES: RADIOCHEMISTRY SECTION

- A. Radiochemistry
 - Sequential separation of various radionuclides from a single sample.
 - Purification and determination of approximately. 40 elements and 100 radionuclides from a wide variety of matrices.
- B. Alpha Emitters
 - 1. Gross alpha

Environmental samples, such as, air, water, sewage, soil, vegetation, fish, etc.

2. Alpha pulse height spectrometry

Plutonium -238 and 239-240 and other heavy elements in air. water, fallout, fish, etc.

- 3. Radium -226 by emanation or precipitation methods.
- 4. Uranium in water by radiochemical method.
- Uranium in water by Scintrex Uranium Analyzer, a fast and sensitive method.

C. Beta Emitters

1. Gross beta

Environmental samples as in the alpha counting.

- 2. Strontium -89, 90 in various samples.
- Gross beta-gamma emitters (excluding K-40, Rb-87, Cs-137) in seawater by precipitation method.
- Tritium, C-14 and other beta emitters in water, milk, vegetation, etc.
- 5. Low-level iodine -131 in water, milk.
- 6. Radium -228 in water.
- D. Gamma Emitters

Various environmental samples as gamma scanned as received, such as milk, water in a Marinelli beaker or processed into a solid. The library consisting over 70 radionuclides can identify each radionuclide by their energy peaks, abundance and quantifying the activities corrected for decay.

E. Stable Elements

Uranium by fluorometric method.

III.C Reviewer Assessment:

As indicated in the State's responses. California has a large laboratory with many capabilities and is well within the NRC guidelines.

D. Administrative Procedures (Category II)

NRC Guidelines: The RCP should establish written internal procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies and procedures, decommissioning, and other functions required of the program.

Questions:

 What procedures are established to assure adequate and uniform regulatory practices (e.g., administrative procedures, policy memos, licensing and inspection guides, escalated enforcement procedures, decommissioning procedures, etc.)?

The procedures are contained in the Inspection Policy memos and the Materials memos. An index of these memos have been prepared to facilitate the updating of these memos. The RHB will have all these memos updated, revised and reorganized by September 30, 1987. A new procedure delineating the functions of the RHB, the VSCB and the contracted inspection agencies on the subject of decontamination and decommissioning will be issued after discussion with these parties in the near future.

2. To what extent are the procedures documented?

See answer above.

 If your State has separate licensing and inspection staffs, what are the procedures used to assure adequate communication between the two staffs?

The normal pattern of workload conduct has inspections of major licensees by joint inspector-reviewer teams. Where this is not done (or even if done), compliance input through Form RH 2033 is required on all Priority 1 through 4 (new. renewal or major amendment) licensing actions. For Priority 5 and above, compliance has 15 days to provide input: otherwise the reviewer can act without this input if deemed appropriate. Additionally, each reviewer phones or is phoned by compliance personnel 2 to 5 times per day on matters of mutual concern. Further, for non urgent information Item 23 of the UFI 8/86 is addressed to the reviewer, entitled "License Reviewer Alert".

 How are personnel kept informed of current regulatory policies and practices?

They are notified of changes by mail or in telephone conversations and through discussions at staff meetings.

 If your State collects fees, are fee collection duties assigned to non-technical staff?

Yes.

n.

6. How are contacts with communication media handled?

The media is referred to the State Public Information Office (PIO). The RCP only answers technical questions after they have been cleared by the PIO.

7. What procedures exist to ensure timely release of factual information on matters of interest to the public, the NRC and Agreement States?

There is a long standing agreement between agencies (NRC. OES. DOE, and RHB) to keep each other informed. This is accomplished through verbal and written communications. Matters of public interest are referred to the Branch and Division Chiefs and sent to the Director in the form of a situation alert before being sent to the PIO for press release. Other agreement states are notified of generic issues. Most files of the RHB are considered public records and open to public inspection upon request. Branch staff is available to answer public inquiries.

- 8. If your RCP has regional offices:
 - a. what procedures are in effect to assure the regions have complete copies of the procedures and files?

Copies of procedures are maintained in each regional office together with license files appropriate to the region. Procedures are periodically updated with copy by mail. Copies of all licensing actions are transmitted by mail to the appropriate regional office.

b. how often are periodic staff meetings held with headquarters staff?

We attempt semi-annual meetings.

c. how often are periodic visits/audits made by headquarters staff to regional offices?

34

Once a year as part of the accompaniment program.

d. how is uniformity assured?

By accompaniment and review of inspection and investigation reports.

e. how is supervision handled?

The Compliance Supervisor of the Radiologic Health Branch accompanies the regional inspectors at a frequency of approximately once per inspector per year. Performance of the inspector is evaluated by the observer and discussed with the regional supervisor if applicable. Indirect supervision is accomplished by phone, memo, mail, training and meetings.

III.D Reviewer Assessment:

The State does not satisfactorily meet the guidelines in their administrative procedures and this finding was addressed in the review correspondence. The State has established procedures for most program functions; however, the material is in the form of memos and is not assembled to make the procedures easily accessible to the staff. Also, no method has been developed for maintaining and dispersing material from the NRC such as All Agreement State Letters. IE Notices and Inspection Guides, etc. It was found many procedural memos are incomplete or outdated and do not reflect to current practice. The licensing. emergency response, inspection and enforcement sections of this report identify some of the procedures that need to be added or revised.

E. Management (Category II)

NRC Guidelines: Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs. problem cases, inquiries, regulation revisions). RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services and funding.

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, large scope - Type A Broad, or potential for significant releases to environment) should receive second party review (supervisory, committee, or consultant). Supervisory review of inspections, reports and enforcement actions should also be performed.

Questions:

 How does the staff keep program management abreast of the status of regulatory actions (such as backlog, problem cases, inquiries, and revision of regulations)?
The program staff reports on number of inspections, investigations, pre-license evaluations, reviews and other matters of significance on a monthly basis. Review backlog is established and tracked by means of a computer docketing system. Compliance inspection backlog is tracked bi-weekly, utilizing a computer generated due/overdue listing. Investigations are tracked by generating a monthly computer list of "open" investigations.

2a. Is a periodic statistical tabulation of licenses, licensees, inspections and backlogs prepared by category?

Yes.

b. If so, specify how frequently the tabulation is prepared.

Monthly.

3. How does RCP management assess workload trends and resources in order to determine future needs or the need for program changes?

The Branch uses several techniques for assessment of trends, planning and follow-through for workload; equipment, staff and budget considerations. Periodic reports are prepared to show actual workload against predicted and planned workload. These reports are designed to be used in support of both planning and budgetary activities. Improved output measures are currently under development. A program plan which reviewed workload needs for fiscal year 1987/88 has been drafted and a copy provided to the NRC reviewer.

The State uses specific processes for determination of equipment needs and budgetary changes. Substantial changes to a program are handled through the Budgetary Change Proposal (BCP) process.

4. How does the RCP management keep abreast of changes in legislative and regulatory responsibility?

Legislation is tracked through the Office of Legislative Liaison, which provides the Branch with copies of pertinent legislation impacting the program for analysis and development of the Department's position. Regulations are tracked through the Office of Regulations which follows the Federal Register, and by communication directly with NRC Office of State Programs.

 Discuss the procedures followed by licensing supervision or RCP management to monitor licensing quality.

Staff review and concurrence is required for all Type A licenses and device and sealed source approvals. Supervisors review all Type A authorizations and sealed source and device approvals to assure that these actions conform to staff determinations. Beyond this review, licensing actions are circulated through the staff for peer review as to compliance of regulations, policy and good health physics practice and for review by supervisors.

 Discuss the procedures used for supervisory review of inspection reports.

Investigation and compliance inspection reports receive review by the Compliance Supervisor at RCP Headquarters. Significant questions are referred to supervisors for consultation and resolution. This is done on Form IRR 9/86.

7. What license review practices are followed for unusual or complex license applications?

Complex license applications are reviewed at periodic staff meetings.

 If applicable, discuss the procedures used for supervisory review of work performed by contract agencies or regional offices.

Compliance inspectors in regional offices report directly to the Chief of Compliance in Sacramento. Compliance inspectors in contract agencies report through the agency supervisor to the Chief of Compliance in Sacramento. Inspection and investigation reports are reviewed by the respective supervisors and the Chief of Compliance.

III.E Reviewer Assessment:

During this review period, the RHB management was assisted by other managers from the within the Department of Health Services. As a result, the management problems identified in previous reviews have, for the most part, been resolved and the program now meets the NRC guidelines. This was determined from interviews with program personnel at all levels as well as from observing the improvements in the licensing and compliance programs.

F. Office Equipment and Support Services (Category II)

NRC Guidelines: The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be available to larger (300-400 licenses) programs. Similar services should be available to regional offices, if utilized.

ia. In terms of the person-year/100 censes figure, what level of secretarial/clerical support is provided?

The Radioactive Materials Control Program is supported by 6.5 FTE clerical staff. Three positions are filled presently: namely, Evelyn Darden, (OSSI), Peggy Lorenzo (WPT) and Helen Castleberry (OAII). Two more positions will be filed on April 1. 1987 by Kathy Collins (WPT) and Angela Gregory (WPT). The ratio of clerical FTE per 100 licenses is 0.30/100 California licenses or 0.25/100 NRC equivalent licenses.

b. If your program has regional offices, provide the figures for the support of those offices.

The regional offices which are staffed by contract agencies provide their own support staff.

 Describe the ADP and word processing capabilities available to the RCP.

The Radioactive Materials Control Program is continuing to receive support from the Department's Data Systems Branch (Administration Division) to develop software programs for our microcomputers. Approval for \$30,000 was granted for purchase and lease of additional data processing equipment. This equipment will assist all programs in the Branch. Additionally, \$125,000 of programming staff assistance to develop the Branch's data processing capabilities has been provided by Department administration for the current fiscal year.

IBM microcomputers are available for in-house use. This in-house system has been able to incorporate licensing and compliance data and generate useful reports or lists for management purposes. Some examples of these reports/lists are:

- List of expired licenses
- List for billing of annual fee
- List of completed or open licensing actions
- List of due/overdue inspections
- List of licensees in alphabetical or numerical order plus any additional data stored in the system
- List of open or closed incident investigations
- List of licensees by category

Software programs are being developed to improve the data base and data processing for a comprehensive radiation control management system. Software program for integration of license categories has been completed. Eventually, all programs will be integrated into one comprehensive program so that their functions and data can be inter-linked.

III.F Reviewer Assessment:

During this review period, the secretarial and clerical support provided to the program was not adequate to meet the demand and at times the typing backlog was seriously impeding the licensing and compliance functions. This issue, which had been a problem in previous reviews, was again brought to the attention of Department management during the follow-up review in October 1986. In response to this finding additional clerical support was furnished by assigning overtime and temporary help from other offices, and at the time of the review, the typing and filing backlogs had been eliminated. As noted in the State's response, at the time of the review they had 2181 licenses with only three clerical staff positions filled. This is clearly not adequate to support the program or meet the guidelines; however, additional help had been approved and the new-hires were scheduled to begin work April 1st.

The ADP support continued to improve during this period and is now adequate to support the radiation control program. Some minor flaws were still noted, however. For instance, a listing of the licenses by category apparently had not been updated as licenses were renewed and the expiration date column still showed licenses due to expire as far back as 1984. This is not considered significant because the license expirations are tracked by using another database, but the data should be corrected so as to provide accurate information on all listings. As indicated in the State's answers, improvements are still being made including software for an integrated program for licensing and compliance, and training is planned to provide reviewers and inspectors direct access to the system.

G. Public Information (Category II)

NRC Guidelines: Inspection and licensing files should be available to the public consistent with State administrative procedures. Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws.

Questions:

 Are licensing and inspection files available for inspection by the public?

Yes, license files are considered public documents.

2. Can medical and proprietary data be withheld?

Yes.

3. What other parts, if any, are not available?

Any personal data.

 What written procedures and laws govern this? Please provide reference citations. The Information Practices Act of 1977 (SB 170) and California Public Records Act, Chapter 3.5 of Division 7 of Title of the Government Code.

 For mill States, are opportunities provided for public hearings in accordance with UMTRCA and applicable State administrative procedures and statutes?

Not applicable.

III.G Reviewer Assessment:

According to the above responses the State complies with the NRC guidelines in this program indicator.

IV. PERSONNEL

A. Qualifications of Technical Staff (Category II)

NRC Guidelines: Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel should be commensurate with the type of licenses issued and inspected by the State.

Written job descriptions should be prepared so that professional gualifications needed to fill vacancies can be readily identified.

Questions:

 Do all professional personnel hold a bachelor's degree or have equivalent training in the physical or life sciences?

Professional health physicist personnel are required by the State's classification system to have a bachelor's degree in a physical or life science; this is a requirement which must be met prior to examining to qualify as a health physicist. Additional qualifications include years of experience in health physics or a closely related field.

 What additional training and experience do the senior personnel need to have in radiation protection?

> They must have attended NRC core courses and completed onthe-job training for a minimum of 6 months.

3. What written position descriptions describe the duties, responsibilities and functions of each professional position?

The California State Personnel Board publishes specifications for five levels of Health Physicists. Job descriptions are published which define the responsibilities for each level, the minimum qualifications, and the knowledge and abilities required for each position. Copies of the specifications and job bulletins are available for review.

IV.A Reviewer Assessment:

As indicated by the State's responses, the qualifications of the technical staff comply with the guidelines.

B. <u>Staffing Level</u> (Category II)

NRC Guidelines: Staffing level should be approximately 1-1.5 person-year per 100 licenses in effect. RCP must not have less than two professionals available with training and experience to operate RCP in a way which provides continuous coverage and continuity. For States regulating uranium mills and mill tailings. current indications are that 2-2.75 professional person-years' of effort. including consultants, are needed to process a new mill license (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978. This effort must include expertise in radiological matters, hydrology, geology, and structural engineering.

Questions:

1. Complete a table listing the person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, fraction of time spent and the duty (licensing, inspection, administration, etc.).

Name	Position	FTE%	<u>Area of</u> <u>Effort</u>
Joseph Ward	Chief, Radiologic Health Branch	50	Admin.
Jack McGurk	Chief, Local Environmental Health Services Branch	40	Admin.
Jay Gould	Assistant Chief, Radiologic Health Branch	50	Admin.
Gerard Wong	Supervising Health Physicist	100	Materials Control
Linda Nugent	Health Program Technician I	40	Admin.
Edwin Njoku	Senior Health Physicist	100	Licensing
Dave Wheeler	Associate Health Physicist	100	Licensing
Stuart Rosenberg	Associate Health Physicist	100	Compliance
Ben Kapel	Associate Health Physicist	90 10	Licensing Compliance
Kurt Jackson	Associate Hoalth Thysicist	100	Licensing
Theresa Caron	Associate Health Physicist	100	Licensing
Pete Patel	Associate Health Physicist	100	Licensing
Ken Fury	Associate Health Physicist	100	Licensing
Ollie deLalla	Associate Health Physicist	100	Licensing
Rich McKinley	Associate Health Physicist	100	Licensing

Gordon Stelling	Associate Health Physicist		75 25	Licensing Compliance
				Compliance
Jack Brown	Senior Health Physicist		100	Compliance
Joe Takahashi	Associate Health Physicist Los Angeles		100	Compliance
Donna Sutherland	Associate Health Physicist		75	Licensing
			25	Compliance
Don Honey	Supervising Health Physicist		12	Regulations
Steve Eckberg	Associate Health Physicist		100	Compliance
	CONTRACT AGENCIES			
Department of Indus	strial Relations		:	
Bill Lew	Senior Health Physicist San Francisco		50	Compliance
Lisa Burns	Associate Health Physicist San Francisco		90	Compliance
Mark Gottliet	Associate Health Physicist San Francisco		90	Compliance
Kim Wong	Senior Health Physicist Los Angeles		80	Compliance
Vacant	Associate Health Physicist Los Angeles		90	Compliance
Los Angeles County				;
Jce Karbus	Bead		20	Compliance/ Admin
Al Ferguson	Inspector		90	Compliance
Wm. Don McDougall	Inspector		60	Compliance
Gene Edmonds	Inspector		100	Compliance
Orange County				
James Hartranft	Inspector		50	Compliance
San Diego County				
Frank Bold	Inspector	P	50	Compliance

SUMMARY OF STAFF TIME IN RADIOACTIVE MATERIALS AS OF MARCH 1, 1987:

1

110 0 2 0 2		DIGING		
Professional Staff H	ositions	Authorized	1	Actual
Materials Control Regulations	SUBTOTAL	17.4 (0.12) 17.4		17.8 (0.12) 17.8
Contract Agencies				
DIR Los Angeles County Orange County San Diego County	SUBTOTAL	4.0 2.7 0.5 <u>0.5</u> 7.76		3.1 2.7 0.5 <u>0.5</u> 6.8
	TOTAL	25.1		24.6

Radiologic Health Branch

2. Compute the person-year effort of person-years per 100 licenses (excluding mills and burial sites). Show calculation.

Actual

24.6 person years x 100 = 1.13 person years/100 California 2181 California licenses licenses.

24.6 person years x 100 = 0.96 person years/100 NRC equiv. 2574 NRC equiv. licenses* licenses.

Authorized

25.1 person years x 100 = 1.15 person years/100 California 2181 California licenses licenses.

25.1 person years x 100 = 0.98 person years/100 MRC equiv. 2574 NRC equiv. licenses* licenses.

FY 87/88

29.3 person years x 100 = 1.34 person years/100 California 2181 California licenses licenses.

= 1.14 person years/100 NRC equiv. 29.3 person years x 100 2574 NRC equiv. licenses* licenses.

This number of licenses includes a correction factor of times 1.18 license to licensee ratio. The actual number of material licenses in California is 2181 at the time of this review.

3. Is the staffing level adequate to meet normal and special needs and backup?

The overall Materials Control Program is not staffed to the level used as a standard by the NRC. For a program the size of California's, the standard is 32 professional positions. The State and its contractors currently have 25.1 authorized positions. 24.6 are filled as of March 1, 1987.

IV.B Reviewer Assessment:

As indicated in the above figures, California is just under the minimum guideline staffing level; however additional staff has been approved for the next fiscal year. It should be noted that California is a large State with many complex licenses and the staffing level should be at the upper range of the guidelines figure, or approximately 1.5 technical staff person years per 100 licenses, in order to maintain an effective radiation concrol program.

C. Staff Supervision (Category II)

NRC Guidelines: Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel. Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy. Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Questions:

1. Identify the junior and senior personnel.

Only the four new hires are considered junior level personnel. They will be raised to senior level on a case-by-case basis after their probationary period.

2a. What duties are assigned to junior personnel?

Junior personnel work with senior personnel until in the judgment of the supervisor they can work alone. They begin with simpler licensees and eventually work up to the complex.

b. Do they review applications and perform inspections independently?

In simpler cases (gauge licenses) after supervision determines they are sufficiently qualified, they may perform independently. 3a. What duties are assigned to senior personnel?

They are assigned all duties described in the job description, including license reviews, inspection and incident response. Copies of the job descriptions are on file with the RCP and RV NRC office.

b. Do they independently review and monitor the work of junior personnel?

Yes.

 Is there adequate supervisory or senior guidance and direction for junior personnel?

Yes.

 Discuss procedures established to ensure supervisory review of the licensing, inspection and enforcement functions.

With license reviews, there is either peer review or committee review of applications done by junior personnel. With inspection, there is supervisory review when available. For escalated enforcement, input and concurrence is sought from regional supervisor and headquarters.

- 6a. Are RCP staff members allowed to consult or work part time for State licensees?
- b. If so, how are conflicts of interest avoided?

No -- Conflict of Interest Statutes bar acceptance by employees of regulatory agencies of anything of value from persons or organizations regulated.

IV.C Reviewer Assessment:

Overall, the staff supervision is adequate to comply with the guidelines, but the guidance offered junior staff members could be improved. The staff supervisors were all promoted from within the program, and apparently little effort was made to provide them with training in leadership. This was determined from observation of the program and discussion with the supervisors themselves. It is the understanding of the reviewer that management training is available from the State and program management should review the available training and see that each supervisor or senior receives as much help as necessary to develop better supervisory skills.

D. Training (Category II)

NRC Guidelines: Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices and industrial radiography practices. (For mill States, mill training should also be included.) The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology.

Questions:

1. List materials personnel and the training courses they have attended during this review period.

Name	Course	Sponsor	1	Dates
Edwin Njoku	Radiation Protection Engineering	NRC	Nov	1986
Gordon Stelling	Medical Uses of RAM	NRC	Sept	1986
Rich McKinley	Medical Uses of RAM	NRC	March	1986
	Licensing Procedures	NRC	Sept	1986
Ken Fury	Transportation of RAM	NRC	June	1986
Pete Patel	Medical Uses of RAM	NRC	Mar	1986
	Health Physics (5 weeks)	NRC	July	1986
	Licensing Procedures	NRC	Sept	1986
Lisa Burns	Industrial Radiography	NRC	Mar	1986
William Lew	Oil and Gas Well Logging	NRC	Nov	1985
Frank Bold	Inspection Procedures	NRC	Dec	1986
Joe Takahashi	Medical Uses of RAM	NRC	Mar	1985

 How does the RCF utilize short courses and workshops to maintain staff proficiency?

The California RCP uses the NRC courses in the training of staff as available.

IV.D Reviewer Assessment:

As indicated in the above answers, the State meets the training guidelines in that they attend the NRC courses. The staff proficiency could be improved if the Branch developed its own training program in addition to the NRC courses. Suggested courses include orientation of new staff members, State and Branch personnel policies, computer training, forms and documents used by the Branch and State procedures not covered by the NRC. As mentioned previously, management training courses offered by the State should also be utilized.

E. Staff Continuity (Category II)

NRC Guidelines:

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries. Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area. The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Questions:

 Identify the RCP employees who have left the program since the last review and give the reasons for the turnovers. Also state whether the positions are presently vacant, filled (name replacement), abolished or other status.

Don Barr resigned his position; Bill Groteguth retired and Jeff Wong transferred to another position within the Division. All three vacated positions have been filled.

Bill Watson, DOSH-South, transferred to another position within the Division; there has been no replacement yet. Clerical staff members, Suzanne VanKeuren and Susan Pane, transferred to other positions within the State; the vacancies created by the transfers have yet to be filled.

2. List the RCP salary schedule:

Position Title

Annual Salary Range

Chief, Radiologic Health	\$52,188	-	57.432
Supervising Health Physicist	45,120	-	54,516
Senior Health Physicist	39,192	-	47.292
Associate Health Physicist	34,044		41,040
Assistant Health Physicist	29,580	-	35,664
Junior Health Physicist	25,236	-	29,004
Radiation Protection Specialist II	30,264	-	36,480
Radiation Protection Specialist I	26,352	-	31,692
Health Program Advisor II	31,692	-	38,244

The:) pay scales were effective as of July 1, 1986.

 Compare your salary schedule with similar employment alternatives in the same geographical area, such as industrial, medical, academic or other departments within your State.

The salary rate for technical positions, specifically journey level and senior level health physicists, is not comparable to similar employment opportunities in the state. The salary lag is between 10 percent and 20 percent behind selected medical, university, industrial and other governmental employers.

4. What opportunities are there for promotion within the RCP organizational structure without a staff vacancy occurring?

At present, a Junior Health Physicist may promote in place to Assistant Health Physicist and then to Associate Health Physicist (full journey level) without a staff vacancy occurring. Promotions are still based on successful competition in promotional examinations. Promotion: beyond journey level require a position vacancy.

IV.E Reviewer Assessment:

As indicated by the State's answers, the State meets the guidelines for continuity of the technical staff. The transfers and vacancies have adversely affected the continuity of the clerical support staff, however.

V. LICENSING

A. Technical Quality of Licensing Actions (Category I)

NRC Guidelines: The RCP should assure that essential elements of applications have been submitted to the agency, and which meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Pre-licensing visits should be made for complex and major licensing actions. Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions. The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Questions:

1. How many specific licenses are currently in effect?

Number of licenses currently in effect as of December 31, 1986: 2181

2a. How many new licenses (not amendments in entirety) have been issued since the last review?

Number of new licenses issued during (1/1/86 - 12/31/86): 143

b. How many were major licenses?

There were 4 Priority 1, 3 Priority 2, and 34 Priority 3 licenses.

3. How many specific licenses were terminated since last review?

Number of licenses terminated during (1/1/86 - 12/31/86): 134

4. How many amendments were issued during the review period?

Number of amendments issued (1/1/86 - 12/31/86): 1957

 Identify any unusual or complex licenses issued since the last review, including name and license number.

The following includes some of the unusual or complex licenses or amendments issued.

Boothe-Twining2181-56AmendmentNorthrop0006-70Renewal in ProgressFord Aeronutronics0167-30Renewal in ProgressLockheed Missile0169-43Renewal in ProgressGeneral Electric0017-59RenewalRockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressU.S.C.1949-70RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in Progress	Licensee	License #	Description
Northrop0006-70Renewal in ProgressFord Aeronutronics0167-30Renewal in ProgressLockheed Missile0169-43Renewal in ProgressGeneral Electric0017-59RenewalRockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA Technologies0145-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseUS Ecology2873-60Amendment in Progress	Boothe-Twining	2181-56	Amendment
Ford Aeronutronics0167-30Renewal in ProgressLockheed Missile0169-43Renewal in ProgressGeneral Electric0017-59RenewalRockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA Technologies0145-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseWMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Grav2105-30Amendment in Progress	Northrop	0006-70	Renewal in Progress
Lockheed Missile0169-43Renewal in ProgressGeneral Electric0017-59RenewalRockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressGA Technologies0145-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Ford Aeronutronics	0167-30	Renewal in Progress
General Electric0017-59RenewalRockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressGA Technologies0145-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseUS Ecology2873-60Amendment in Progress	Lockheed Missile	0169-43	Renewal in Progress
Rockwell0015-70RenewalRockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA Technologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	General Electric	0017-59	Renewal
Rockwell0021-70Renewal in ProgressJ.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressGA Technologies0145-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Rockwell	0015-70	Renewal
J.L. Shepherd1777-70Renewal in ProgressBeckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA fechnologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Grav2105-30Amendment in Progress	Rockwell	0021-70	Renewal in Progress
Beckman Instruments0441-30RenewalU.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA Technologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	J.L. Shepherd	1777-70	Renewal in Progress
U.C. Davis1334-57Renewal in ProgressU.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA fechnologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Beckman Instruments	0441-30	Renewal
U.C. San Francisco1725-90Renewal in ProgressU.S.C.1949-70Renewal in ProgressCA Technologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	U.C. Davis	1334-57	Renewal in Progress
U.S.C.1949-70Renewal in ProgressGA fechnologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	U.C. San Francisco	1725-90	Renewal in Progress
CA Technologies0145-30RenewalICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	U.S.C.	1949-70	Renewal in Progress
ICN1828-30RenewalIPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	CA Technologies	0145-30	Renewal
IPL1509-70RenewalAerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	ICN	1828-30	Renewal
Aerojet1450-36RenewalBakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	IPL	1509-70	.Renewal
Bakersfield Construction 4742-15New LicenseSmall Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Aerojet	1450-36	Renewal
Small Animal Radiation4640-30New LicenseMMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Bakersfield Construction	4742-15	New License
MMP Quality Inspection4832-70New LicenseUS Ecology2873-60Amendment in ProgressThomas Gray2105-30Amendment in Progress	Small Animal Radiation	4640-30	New License
US Ecology 2873-60 Amendment in Progress Thomas Gray 2105-30 Amendment in Progress	MMP Quality Inspection	4832-70	New License
Thomas Grav 2105-30 Amendment in Progress	US Ecology	2873-60	Amendment in Progress
anomoo or ay baccoo or machinamonic an raction	Thomas Gray	2105-30	Amendment in Progress
Summa Pharmacies 4809-34 New License	Summa Pharmacies	4809-34	New License
Summa Pharmacies 4811-43 New License	Summa Pharmacies	4811-43	New License
Summa Pharmacies 4812-10 New License	Summa Pharmacies	4812-10	New License
Moravek Biochemicals 2960-30 Renewal	Moravek Biochemicals	2960-30	Renewal

 Note any variance in licensing policies and procedures granted since the last review.

None.

7. Do you require license applicants to submit details on their radwaste packaging and shipping procedures?

Yes, waste handling procedures include provisions for clear and distinct segregation of radioactive waste by marking and physical separation from all other waste at locations where radioactive material is utilized.

8a. When do you require licensees to submit contingency plans?

When they exceed the NRC contingency requirements and have not been required to submit plans to the NRC.

List the licensees who have been required to submit contingency plans.

General Electric (Pleasanton), Rockwell International ESG Systems, GA Technologies, and Northrop are the four firms that meet the NRC requirements for contingency plans, and they are all also Federal licensees. They have been required to submit their contingency plans to the NRC, and therefore have not been required to submit duplicate plans to California.

9. How many pre-licensing visits were made during this review period?

Approximately 100 pre-licensing visits were made during the reporting period.

10. What criterion does the State use to determine the need for a pre-licensing visit?

Pre-licensing visits are performed when major changes in the type or level of operations is proposed by a licensee and with new applications proposing potentially hazardous operations. Pre-licensing visits may be performed either at the request of the reviewer, or upon the initiative of the inspection agency.

11. How do you ensure up-to-date information has been submitted prior to a license renewal?

Applicants wishing to renew a radioactive materials license must complete a new application form in detail.

12. Do license files contain all necessary data required to evaluate an application prior to issuing a license?

Yes.

13. Has the State taken any unusual licensing action with respect to licensees operating under multiple jurisdiction?

Yes.

 Prepare a table as below showing the State's major licensees with name, number and type.

INCLUDE:

- Broad (Type A) Licenses
- LLW Disposal Licenses
- LLW Brokers
- Major Manufacturers and Distributors
- Uranium Mills
- Large Irradiators (Pool Type or Other)
- Other Licenses With a Potential Significant Environmental Impact
- Other Licensees You Consider to be "Major" Licensees

	License	
Name	Number	Type
UC Davis, Davis	1334-57	Broad A '
UC Berkeley, Berkeley	1333-62	Broad A
UCSD. La Jolla	1339-80	Broad A
UCLA, Los Angeles	1335-70	Broad A
San Francisco Medical Center		
San Francisco	1725-90	Broad A
Stanford University		
Palo Alto	0676-43	Broad A
Loma Linda University		
Loma Linda	0060-36	Broad A
USC Medical Center		
Los Angeles	1949-70	Broad A
USC Campus, Los Angeles	0382-70	Broad A
GA Technologies, San Diego	0145-80	Broad A
UC Irvine, Irvine	1338-30	Broad A
Northrup, Los Angeles	0006-70	Broad A
General Electric, Pleasanton	0017-60	Broad A
ESG (Rockwell International)		
Canoga Park	0015-71	Broad A
Hughes Aircraft, El Segundo	0039-70	Broad A
Hughes Aircraft, El Segundo	0790-70	Broad A
TRW, Redondo Beach	0816-70	Broad A
U.S. Ecology	2873-60	LLW Broker
Thomas Gray & Associates		
Orange	2105-30	LLW Broker
Environmental Management		
and Control	3546-50	LLW Broker
Pacific West Nuclear, Inc.		
Vista	3622-80	LLW Broker
ICN	1828-30	Mfg/Distributor
Isotope Products, Burbank	1509-70	Mfg/Distributor
J. L. Shepherd, Glendale	1777-70	Mfg/Distributor
Aerojet Ordinance Cowpany		
Compton	2789-70	Mfg/Distributor
NDC Systems, Duarte	1933-70	Mfg/Distributor
Medi Physics, Emeryville	2067-60	Mfg/Distributor
Radiation Sterilizer, Tustin	3390-30	Large Irradiator
International Nutronics, Inc.		
Palo Alto	1822-43	Large Irradiator
Irvine	3911-30	Large Irradiator
Aerojet Ordinance	1450-36	Environmental Impact
Ford Aerospace	0550-43	Environmental Impact
Westinghouse	4346-33	Environmental Impact

V.A. Reviewer Assessment:

The State meets the NRC guidelines for the technical quality of their licenses. This was determined from the answers above and from a comprehensive review of eleven license files. Continued improvement in the quality of the licenses was noted by the reviewers. There were no significant deficiencies or generic issues in the findings. A list of the files reviewed with case-specific comments is contained in Appendix D.

B. Adequacy of Product Evaluations (Category I)

NRC Guidelines: RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC. State. or appropriate ANSI Guides, should be sufficient to assure integrity and safety for users.

The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy. Approval documents for sealed source or device designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Questions:

 How many new and revised evaluations were made of sealed sources and devices during the review period?

Twenty-five

 How many SS&D evaluations have been made for which approval documents have not yet been prepared?

Three.

 How does the RCP evaluate manufacturer's data on SS&D's to ensure integrity and safety for users?

Prior to issuance of a specific license authorizing use of a sealed source or device, the manufacturer is required to file with the Department information completely describing the sealed source or device, supported by such annotated drawings or sketches as are necessary. In some cases this information is required prior to issuance of an authorization to manufacture. Tests to which prototype source capsule/device models have been subjected must be described.

4. Do you determine whether the manufacturer's information on labels and brochures relating to health, safety, assay, and calibration procedures is adequate on all products?

Yes, the information is reviewed.

V.B. Reviewer Assessment:

The following Sealed Source and Device files were reviewed:

CA 378 S 102S Industrial Dynamics Ltd. CA 208 D 106S CPN Corporation CA 384 S 114S Industrial Nuclear Inc. CA 590 D 112S SAIC

In two cases the label description did not indicate dimensions, color or attachment method, but otherwise the registry sheets were prepared in accordance with the applicable regulatory guides and were adequate to meet the NRC guidelines. The new NRC guides and checklists were distributed during the review, and their use should aid in the preparation of the registry sheets in the future.

C. Licensing Procedures (Category II)

NRC Guidelines: The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions. The present compliance status of licensees should be considered in licensing actions. Under the NRC Exchange of Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees and persons exempt from licensing should be submitted to NRC on a timely basis. Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process. Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Questions:

 Has the RCP developed its own licensing procedures or does it use NRC guides? Please provide copies for review.

Guidance for review of applications for new license renewal, renewal and amendment is contained in the Reviewer's Guide. The Reviewer's Guide is organized by category of license and includes material developed by California and the NRC.

 What licensing guides, checklists and policy memoranda are made available to the staff?

All NRC guides, checklists, and standard conditions are made available to the staff. In addition, California developed its own guides and/or checklists on the following:

- 1. Broadscope A
- 2. Broadscope B or C
- 3. Medical Guide
- 4. Lixiscopes (Medical)

- 6. SR-90 Eye Applicator
- 7. Industrial Radiography
- 8. Gas Chromatograph
- 9. Soil Gauges
- 10. Fixed Gauges
- 11. Small Labs
- 12. Large or Medium Labs
- 13. Well Logging
- 14. Large Irradiators

California also has its version of standard conditions. Checklists developed by Texas for industrial gauges and teletherupy are also used for reference. Updated NRC Standard License Conditions, November 24, 1985 are also used.

- 3. What guides and/or regulatory position statements are furnished to license and renewal applicants?
 - "Guide for Applicants for a Radioactive Material License".
 - (2) "Guide for the Preparation of Applications for Medical Programs".
 - (3) "Teletherapy Licensing Guide".
 - (4) "Applicant's Guide Industrial Radiography".
 - (5) "Guide for Applicants for a California License to Manufacture and Distribute Sealed Sources or Devices Containing Radioactive Material".
 - (6) "Guidelines for Applicant Preparation of Draft Registration Sheets".
 - (7) "Special Requirements for Broad Scope Research and Development Radioactive Material Licenses Type A".
 - (8) "Special Requirements for Broad Scope Research and Development Radioactive Material Licenses, Types B and C".
 - (9) Guides for Preparation of Applications for Pacemakers. Portable Gauges and Bone Mineral Analyzers are presently in draft form.
 - (10) Checklists for Research Laboratories, Gauges, Gas Chromatography, Lixiscopes, Bone Mineral Analyzers, Oil and Gas Well Logging, Kr-85 Leak Test Units and Eye Applicators.

 Describe the system for advising classes of licensees of new licensing procedures and regulations.

Rad Safety Advisories are mailed to the licensees. :

5a. How are licensing actions coordinated with the compliance staff?

Regardless of inspection status, compliance input is required on all new or renewal of major amendment actions on Priority 1 through 3 licenses. For Priority 5 and above, the reviewer retains the option of acting without compliance input; however, the decision must be justified.

b. Are licensing actions taken while enforcement action is pending?

No favorable licensing action may be taken with enforcement action pending.

6. For what length of time are various categories of licenses issued?

Licenses are issued for a term of seven years.

- 7a. Does the RCP use standard licensing conditions?
- b. If so, how does the RCP assure they are comparable with those used by NRC?

Standard licensing conditions are utilized and they are based on those used by the NRC.

 Are the licensing conditions on file in the RCP office and with NRC?

Yes.

9. What SS&D sheets, service, distribution and "E" licenses are available for RCP staff use?

A service directory is not available at this time, however one is expected to be received from the NRC soon. Other material is available to the staff.

 Describe your practices for distributing SS&D sheets, as well as GL dist ibution and service licenses, to the NRC.

A cover letter is prepared and they are mailed to the NRC. We rely on the NRC to distribute them to other agreement states.

 Describe your procedures for maintaining the license files (How are files and folders arranged? Are telephone contacts and visits documented? Who is responsible for filing materials in folders?).

The files for licensing, compliance and devices are kept in separate folders and are maintained by the licensing unit. Investigation files are also kept in separate folders and are maintained by the materials control supervisor. Material in the licensing files is arranged as follows: The right side of the folder contains the original license and amendments filed by order of the date. The left side has the notice of expiration as the top document. with other documents and completed correspondence filed under it. Correspondence which requires action, temporary notes and the inspection agency application reviews are kept loose in the folder.

Notes of pertinent telephone conversations are kept and visits are documented.

12. Are there opportunities for license reviewers to accompany inspectors?

RHB-North inspection responsibilities have been taken over by Materials Unit in Sacramento. Reviewers in Sacramento therefore perform part-time inspection of facilities. Reviewers may also accompany inspectors from other contract agencies when the need arises.

V.C. Reviewer Assessment:

The licensing procedures have significantly improved since previous reviews and are now adequate to meet the guidelines. It was noted, however, that procedures establishing the criteria for pre-licensing visits have not been developed. New standard license conditions were finalized and most of the procedural problems that had existed were resolved. As a result, the technical quality of the licensing actions also improved.

VI. COMPLIANCE

A. Status of Inspection Program (Category I)

NRC Guidelines: The State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions.

The RCP should maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.

There should be at least semiannual inspection planning for the number of inspect ins to be performed, assignments to senior vs. junior staff, as wents to regions, identification of special needs and periodic meature reports.

Questions:

 How is statistical information maintained about the inspection program to permit periodic assessment of its status by RCP management?

Statistical summary sheets, DHS 8331 (3/86), accompany each cleared inspection report received by the Sacramento compliance manager. After review, management signs off and gives the report to the computer data staff who enters the data and also signs off in the summary sheet; thereafter the report is filed in the license compliance folder. This data in the computer is then used for the production of due/overdue lists, etc.

The in-house microcomputer is capable of tracking due/overdue inspections, notice of violations and completion of the inspection package.

 Prepare a table as below, indicating the number of inspections made in the review period, by category and priority.

License	Frequency	Number of
Category	Priority	Inspections
Broad A	1	1
	2	2
	3	1
Hospital	2	1
	3	90
	5	2
		10

59

(Cont'd)

License	Frequency	Number of
Category	Priority	Inspections
Private Practice	3	32 :
	5	21
	6	1
Academic	3	3
	5	2
Ind. Radiography	1	36
Misc. Industrial	1	5
	2	6
	3	56
	5	18
	6	25
		:
Services & Consulting	1	2
	3	40
	5	69
	6	11
Government	3	3
	5	21
	3	12
Other	1	1
	5	3
	3	35
	5	7
	6	7
	Total	513

3. Prepare a table (or tables) as below which identify the Priority 1, 2, and 3 licensees with overdue inspections. Include the license category, the due date, and the number of months the inspection is overdue. (If list is extensive, a comprable computer printout is acceptable.)

An accurate, updated computer printout identifying the licensees with overdue inspections has been provided for period ending March 31, 1987 (attachment VI.A.3).

The following is a summary of overdue inspections including those projected to be overdue through the end of March 1987 and those licenses which had not received an initial inspection. It is anticipated the projected overdue inspections will be completed by March 31, 1987.

Inspection	Priority	Priority	Priority	Priority	Priority	
Agency	1	2	3	5	6	Total
					•	
DOSH-North	0	0	0	0	0	0
DOSH-South	0	0	0	2	0	2
RHB-North	0	0	0	0	0	0
RHB-South	0	0	0	0	0	0
OCHCA	0	C	0	0	0	0
LACHD	0	0	0	0	0	0
SDCDHS	1	0	1	0	0	2
TOTALS	1	0	1	2	0	4

 Prepare a table as below indicating the number of overdue license inspections for Priorities 4 through 7.

See computer printout and above table. _

5. How are inspection schedules planned and how are the dates and personnel assignments made?

The Radioactive Materials Control supervisor uses the due/overdue list to assign the inspections to each jurisdiction. The local supervisor makes the specific assignments as to dates and personnel.

VI.A Reviewer Assessment:

As indicated by the above figures, the backlog of overdue inspections has virtually been eliminated and the status of the California inspection program is now within the NRC guidelines.

B. Inspection Frequency (Category I)

NRC Guidelines: The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, broad licensees, and industrial radiographers should be inspected approximately annually --- smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency should be consistent with the NRC system.

Questions:

1. Enclose a copy of the State's priority system.

This is attached as Appendix E.

2. Who assigns licenses to the priority categories?

The reviewers assign the license priority in accordance with the table in Appendix E. Any exceptions are authorized by the Supervisor of the Radioactive Material Unit. Discuss any significant variances in the State's priorities from the NRC priority system.

They are the same as the NRC priority system.

4. Is the inspection priority system designed to assure that the more hazardous and/or complex operations are inspected at an appropriate frequency?

Yes, see priority system.

 Describe the State's policy for unannounced inspections and exceptions to the policy.

About half of the inspections are unannounced depending on the inspector's discretion.

 Describe the State's policy for conducting follow-up inspections.

> Follow-up inspections are conducted to verify corrective action where the issues are complex or serious and in situations where experience or the licensee's response suggests that corrective action will be ineffective or delayed.

7.a. Does the RCP inspect out-of-state firms working in the State under reciprocity or under State licensure?

Yes, the "Notices of Reciprocal Recognition" are conditioned to provide the inspection agency with timely information permitting inspection on a sampling basis.

b. How many reciprocity notices were received?

Sixty-six were received in calendar year 1986.

c. How many were inspected since the last review?

In the calendar year 1986 about 20 were inspected.

VI.B Reviewer Assessment:

As indicated in the State's answers, their priority system is the same as that used by the NRC and thus complies with the guidelines.

C. Inspector's Performance and Capability (Category I)

NRC Guidelines: Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections. The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Questions:

1a. Does the senior inspector or supervisor periodically accompany the inspectors?

Yes.

b. Are these accompaniments documented?

Yes.

 List the number of supervisory accompaniments of inspectors since the last review meeting and identify the persons accompanied and the supervisors.

			PERSON	LICENSEE	LICENSE
0	BSERVER	DATE	ACCOMPANIED	INSPECTED	NUMBER
J.	Brown	11/17/86	Jim Hartranft	Signa Health	4619
J.	Brown	11/18/86	Kim Wong	Decisive Test	1836
J.	Brown	11/19/86	Gene Edmunds	Whittier Hosp.	1989
J.	Brown	11/20/86	Joe Takahashi	Riverside Gen.	0901
J.	Brown	12/18/86	Frank Bold	Coronado Hosp.	2856
J.	Brown	1/7/87	Mark Gottleib	CA Almond	3896
J.	Brown	1/9/87	Lisa Burns	Smith Emery	3789
J.	Brown	3/11/87	Stu Rosenberg	Stockton Diag. Radiology	4107
J.	Brown	3/12/87	Steve Eckberg	Horizon Labs.	4317

IV.C Reviewer Assessment:

Seven field accompaniments and evaluations of inspectors were conducted by Jack Hornor during the program review:

INS	SPECTOR	AGENCY	DATE	LICENSEE	LICENSE TYPE
F.	Bold	San Diego Co.	2/17	Palomar Hosp.	Nuclear Med.
J.	Hartranft	Orange County	2/23	St. Joseph Hosp.	Medical
J.	Takahashi	RHB - South	2/24	San Antonio	Nuclear Med/
				Community Hosp.	Brachy Th.
G.	Edmunds	L.A. County	2/26	L.A. Commun. Hosp.	Nuclear Med.
Κ.	Wong	DIR	2/27	Continental Testing	IR
S.	Rosenberg	RHB - North	3/17	Fremont Med. Center	Medical
s.	Eckberg	RHB - North	3/18	Auburn Faith Hosp.	Medical

It was found the quality of the inspections was very good and overall the inspectors' performance meets the guidelines. In most cases, the inspectors were commended on their professional performance and adherence to proper regulatory practices. In one case, however, the inspector had

not allowed sufficient time to review a large medical program and also did not clearly differentiate between recommendations and items of noncompliance in the exit interview. This was discussed with him and the compliance supervisor. It was suggested this inspector accompany some of the more experienced inspectors as well as receive high priority on the list for NRC training courses.

As noted in the State's answers, the compliance supervisor is making field accompaniments of all inspectors and is documenting the results.

D. Responses to Incidents and Alleged Incidents (Category I)

NRC Guidelines: Inquiries should be promptly made to evaluate the need for onsite investigations. Onsite investigations should be promptly made of incidents requiring reporting to the Agency in less than 30 days (10 CFR 20.403 types). For those incidents not requiring reporting to the Agency in less than 30 days, investigations should be made during the next scheduled inspection. Onsite investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern. e.g., transportation accidents. Investigations should include indepth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate. State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures). Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency. The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Questions:

1. How does the RCP respond to incidents and alleged incidents?

Inquiries and complaints are promptly evaluated to determine the need for onsite investigation. Onsite investigations are conducted where review discloses Class A or B (immediate or 24-hour notice required) overexposure.

 Are major incidents (10 CFR 20.403 types requiring reporting in less than 30 days) investigated on a priority basis?

Yes, the priority is as follows:

(Continued next page)

	Time First Notice Due to	Time Period in which Agency is to initiate <u>Investigation</u>		
Type of Occurrence	Dept./Agency			
Type C overexposure or release 17CAC 30297	15 days	15 days		
Type B overexposure, release or loss of use 17CAC 30295(b)	1 working day	3 working days		
Type A overexposure, release or loss of use 17CAC 30295(a)	Immediately by phone. notice within one working day	3 working days		
Lost or stolen source 17CAC 30294	Immediately by phone notice within one working day	3 working days		
Complaint-violation of radiation safety and health requirements	1 working day	3 working days		

3. Are other incidents followed up in the next scheduled inspection?

Yes.

4. Are non-reportable incidents that may be of significant public interest and concern promptly investigated?

Yes.

5. How many incident investigations were conducted during the review period?

During 1986, 216 investigations were initiated. Of these 216 investigations, 123 were closed. In addition, 46 investigations initiated in 1985 were closed. As of March 3, 1987, there are a total of 119 open investigations (1985-86).

6. Attach as an appendix a summary of each incident investigated. Include documentation of investigation results, enforcement action when appropriate, any reenactment and time motion studies, as well as notification of the NRC and state licensees of incident information that may have been relevant to other licensed operations.

> All incidents investigated during 1986 and 1987 are listed in the computer. These lists indicate the nature of the incident (transport, loss/theft, leak/malfunction, presumed overexposure and loss of control/use). In addition a

computer list of all 1985, 1986, and 1987 investigations which remain open as of March 3, 1987 is available. (Copy furnished to NRC.)

Below is a listing of the incidents which this Departing and the NRC consider significant. These incidents are ident 'ied relative to status (open/closed). In depth details of incidents/investigations are available for review at the Radiologic Health Branch Office.

- a. <u>California Bionuclear (File # 011786)</u> Investigation initiated as a result of a complaint by the Los Angeles County Hazardous Material Unit. Investigation indicated a loss of control over the use of radioactive material, inclusive of unauthorized disposal of radioactive material and extensive contamination. This facility was "raided" by Los Angeles County Hazardous Material Unit. Following the removal of all explosives and flammables, this facility underwent a thorough decontamination of radioactive materials. A notice of violation was issued and this investigation remains opened.
- b. U.C.S.F. (File # 042286) - During the course of a brachytherapy procedure a resident physician from the radiation oncology department was unable to distinguish the difference between the radioactive source and the source applicator. Because of a medical emergency it was necessary for the resident to remove the sources. Since the resident physician was unable to distinguish the source from the applicator, the resident placed the source applicator (source placement rod) in the shielded lead pig. After stabilizing the patient the resident removed the remaining source applicator (which still contained approximately 44 mg. Ra eq. CS-137). the resident carried the applicator and unshielded sources in his hand for approximately 15 minutes. Estimated extremity dose is approximately 70 Rem. This investigation is still opened - licensee's corrective actions have been received and are presently being reviewed. A notice of violation will be issued.
- c. <u>International Nutronics (File # 090986)</u> Winch motor failure at this industrial sterilizer facility sources remained in the pool. This investigation is still opened and the NRC was informed by phone and mail of this incident. This incident is not thought to be due to a generic problem.
- d. <u>Frederick George, DPM (File # 090986)</u> NRC reported a leaking 125 I source was received from Dr. George at Lixiscope Corporation in Illinois. The leak resulted in significant thyroid uptake to NRC personnel and lixiscope personnel. An investigation and site visit

was immediately conducted. No evidence of contamination or thyroid uptake was detected at Dr. George's facility. This Department found no violation of regulations or license condition and closed this investigation. All investigation material was forwarded to NRC for further determinations.

- e. <u>Boothe-Twining (File # 091586)</u> During the course of a radiographic procedure a radiographer's survey instrument malfunctioned. When he approached the camera no radioactivity was detected and the radiographer incorrectly assumed the source was retracted and he continued his work. This incident resulted in a 2.7 Rem whole body exposure to the radiographer. This investigation is still open and a Notice of Violation was issued.
- f. <u>Industrial Nuclear Company (File #092086)</u> -Incompatibility between INC Model IR-100 W/Model 32 pigtail and source changer supplied by INC - This investigation is open and has been determined not to be a generic problem.
- g. <u>ICN Radiochemicals (File #102386, 122986, 021887)</u> -Several incidents of ICN shipping radioactive materials to individuals not holding authorization from the appropriate regulatory agencies (NRC and California) -Their investigations are still open.
- h. <u>United States Testing Company (File #110786)</u> Theft of 70 curies of IR-192 (sealed radiographic source). Source subsequently recovered. A Notice of Violation was issued. This investigation is considered closed.
- i. <u>International Nutronics (File # 012887)</u> Source hoist rounding bolts sheered during source travel at this industrial sterilizer facility - This investigation is closed and the NRC was informed by phone and mail of this incident. No Notice of Violation was issued.
- 7. Were any incidents attributed to generic-type equipment failure?

No.

8. What action was or would be taken by the RCP pertaining to incidents attributable to generic equipment failures in regard to notification of the NRC, other licensees and the regulatory agency which approved the device?

If the failure occurred in California the NRC would be notified, then the NRC would notify other regulatory programs. California may also notify the other State and Federal programs directly for purposes of expediency.

- If a failure should occur in equipment manufactured by a State licensee, what action would be taken to:
 - a. stop the manufacture or force changes in design?

With respect to California licensees, the Department has authority to suspend or modify licenses and by order require retrofit of existing devices or prohibit use of such devices by California licensees.

b. assure retrofit of existing devices?

Information regarding a Department order requiring retrofit and prohibiting use of the device would be transmitted to other agencies by copy of the order.

10. When are other State licensees and the NRC notified of pertinent information about an incident?

Investigations involving equipment failures or malfunctions always include review to determine whether the failure is generic or specific. If review discloses a possible generic failure the NRC is notified along with the regulatory agency which approved the device and California licensees possessing the device.

11a. Are medical consultants available and used when necessary?

Yes, our principal medical consultant participates in review of investigations where expert medical consultation is required.

b. Is the State aware of the availability of medical consultants from NRC?

Yes, the State is aware of the NRC resources.

 Explain any use of other technical consultants for special problems encountered in incident investigations.

There were none necessary in this review period. We would call on the NRC if needed.

 Were there any incidents since the last review meeting that met Abnormal Occurrence Report (AOR) criteria?

No.

VI.D Reviewer Assessment:

The State's incident response program complies with the essential elements of the NRC guidelines. Twenty-five incident files were selected from the computer listing and reviewed in depth. In each case the correct action was taken promptly. It was pointed out that the emergency response procedures do not address reviewing incidents against the NRC reporting requirements. However, in reviewing the files, no instances were found in which the NRC was not properly notified.

E. Enforcement Procedures (Category I)

NRC Guidelines: Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended. Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated. Enforcement letters should specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses. Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items. Written procedures should exist for handling escalated enforcement cases of varying degrees. Impounding of material should be in accordance with State administrative procedures. Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Questions:

1. Describe the State's enforcement procedures.

Briefly, the procedure is as follows: Violations and items of noncompliance are defined as to seriousness based on guidelines of the NRC. Items of noncompliance that are aggravated by repetitiveness, appear to be willful, are accompanied by a large number of other forms of noncompliance, or that have not been corrected in a reasonable time may be raised in the level of seriousness. A Class IV item of noncompliance (no unnecessary exposure or unnecessary risk) requires a letter calling the licensee's attention to the matter. In the event of a more serious violation, a letter is sent with a Notice of Violation which calls for a reasonable date for reply. A response which, although technically inadequate, indicates the desire to come into compliance calls for no unusual enforcement action, but simply requires further correspondence between the inspector and the licensee. In the occasional instance of a very tardy, incomplete, argumentative, or otherwise negative response, the case is handled by management and the license may be revoked.

 If the RCP can apply civil penalties, explain the procedures for keying monetary penalties to violations. Current law provides that willful or grossly negligent violation of radiation statutes, orders, or regulations is punishable by imposition of a civil penalty not to exceed \$5,000 per day per violation. The presiding judge' determines the penalty amount.

3. Describe the State's provisions for criminal penalties.

The Health and Safety Code provides that violations of the Radiation Control Law and Regulations are punishable as misdemeanors with penalty not to exceed \$1000 and 6 months in jail for each count.

 Describe the policies in effect for issuing field forms equivalent to NRC form 591 or letters for enforcement action.

California issues a short form for de minimis violations correctable on the spot where the licensee expresses a willingness to correct.

 Are there written procedures for handling escalated enforcement cases? Please provide copies for review.

Yes.

6. Can the State issue Orders; including Emergency Orders?

Yes, the Branch Chief, Radiologic Health Branch, Department of Health Services is now authorized to sign Emergency Orders.

7. Can the RCP impound radioactive material?

The Radiation Control Program has the authority in the Health and Safety Code to impound radioactive material in an emergency. Example, Universal Testing/MMP, two IR projectors yellow tagged by DOSH-SO on 9/25/86.

 Bo State administrative procedures permit the opportunity for hearings in major enforcement cases?

Enforcement actions are reviewable informally within the Department and formally at administrative hearings and in Superior Court.

9. If during the review period the State has issued orders, applied civil penalties, sought criminal penalties, impounded sources, or held formal enforcement hearings, identify these cases and describe the State's enforcement action.

Name	License Number	Type of Enforcement	Date of <u>Action</u>	Current Status
UC San Francisco	1725	Office Comp. Conference	1/14/86	Continuing
Boothe Twining	2181	Civil Penalty (\$5,000)	3/13/86	Continuing
Universal Testing	3573	Compliance Conference	4/4/86	License Terminated
Industrial Marine	2799	Compliance Conference	7/9/86	Resolved
Rosechem	1494	Cease/Desist Order	8/1/86	Legal Action Contemplated
Universal Testing and MMP	3573	Impounded IR Sources (Yellow Tagged)	9/25/86	Resolved
CA Portland Cement	3670	Compliance Conference	12/17/86	Liconse in Termination
CA Bionuclear Corp.	2476	Criminal Charges	3/20/87	Convicted, Fined and Sentenced
Alarm Concepts Te	rminated	Criminal Charges	4/86	Convicted, Fined and Sentenced
USC	1949	Criminal Charges	3/87	Continuing
International Nutronics, Inc.	1822 & 3911	License Revocation	Not Set Yet	Waiting for Advice from Legal Office

10. Are enforcement letters issued within 30 days of the inspection?

Enforcement actions are normally taken within 30 days of the inspection.

11. Are enforcement letters written in regulatory language and reference regulations and license conditions?

A form notice of violation is used and required reference to regulations and license conditions as appropriate.

12. Do the enforcement letters clearly differentiate between noncompliance items and health and safety recommendations?

Yes, enforcement procedures require that health and safety recommendations must not be included in the Notice of Violation but instead are discussed in a cover letter.

71
13. If applicable, do the letters separate actions subject to the State radiation control act and State OSHA regulations?

The form only addresses violations of Title 17 (CAC) and not CAL-OSHA regulations.

14a. Are enforcement letters issued by inspectors or supervisors?

By inspectors.

b. If issued by inspectors, do they undergo supervisory review prior to dispatch?

Prior review of enforcement letters is not required except in cases where the inspector judges the matter to be serious and to require supervisory input.

15. Do enforcement letters require the licensee to respond within a stated time period? Note the period.

Licensees responses to Notices of Violation are normally required within 30 days and may be escalated for serious violations.

- 16a. Are licensee's responses to enforcement letters reviewed by the inspector and the supervisor?
 - b. Are they acknowledged?

They are reviewed and acknowledged by the inspector and are reviewed by the supervisor as part of the package submitted to the Program by the contractors or regional offices.

17. Has the State taken escalated enforcement action against licensees who operate in multiple jurisdictions.

Yes.

VI.E Reviewer Assessment:

Although the enforcement actions taken by the State during this review period comply with the guidelines, the written procedures are not complete and should be updated to reflect the current practice. For example, there are no clear-cut policies for such measures as follow-up inspections or shortened inspection frequencies when numerous or repeated violations are observed. Also, there are no written procedures to clearly define the action levels for escalated enforcement.

As indicated in the State's replies, they have recently taken a very strong enforcement stand against several recalcitrant licensees.

The State briefly explained that two industrial radiography projectors were "yellow tagged"" by the DOSH office in Southern California. The sources originally belonged to Universal Testing Company. The owner of that company had refused to comply with regulations and had been threatened with suspension of his license so he disposed of the sources. Upon investigation, the inspector determined the sources had been sold to an unlicensed company, MNP Quality Inspections. He located the new company and yellow tagged the sources. Since that time, the MMP radiographers have been licensed and the seals removed. The Universal Testing license has been terminated.

F. Inspection Procedures (Category II)

NRC Guidelines: Inspection guides, consistent with current NRC guidance, should be used by inspectors to assure uniform and complete inspection practices and provide technical guidance in the inspection of licensed programs. The NRC Agreement States Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc. Written inspection policies should be issued to establish a policy for conducting unannounced inspections. obtaining corrective action, following up and closing out previous violations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems. Procedures should be established for maintaining licensees' compliance histories. Oral briefing of supervision or the senior inspector should be performed upon return from nonroutine inspections. For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Questions:

 Has the RCP developed its own inspection guides or does it use NRC guides?

California has developed its own guides.

 Are current copies of the internal inspection forms and guides on file in the RCP office and with NRC? Attach revisions or new guides developed since the last review.

Region V has copies of all existing forms and guides. However, licensing and inspection policies are being revised and will be available for the next audit.

3. Are inspectors furnished copies of inspection guides?

Yes.

[&]quot;The State uses the term, "yellow-tagged," to refer to impounded sources. A yellow-tagged source is not physically removed from the owner's premises. Instead, the sources are tagged and sealed to prevent use.

 Discuss the use or non-use of inspection policy memoranda, interpretations, etc., to supplement inspection guides.

In addition to the guides, we use inspection procedures and inspection policy memos to address such issues as enforcement criteria, contamination limits, cleanliness surveys, etc.

- 5. Are there written procedures establishing policy for:
 - a. unannounced inspections?

No.

b. obtaining corrective action?

Yes.

c. following-up and closing out previous citations of violations?

Yes.

d. exit interviews with management?

Yes.

e. issuing notices of violations and findings of health and safety problems?

Yes.

f. categorizing the seriousness of violations?

Yes.

Please provide copies of these procedures for review.

6. What procedures have been established for maintaining licensees' compliance histories?

The compliance histories have been maintained by a summary sheet in the compliance folder. They will be part of the licensee data base in the new ADP system.

7. Does the senior inspector or supervisor orally debrief the inspector upon return from inspections?

Yes, when there is a local supervisor.

 What procedures are there for providing feedback from inspectors to licensing?

Response and commitments to citations or recommendations which significantly upgrade a licensee's radiation safety

program are forwarded to licensing with a recommendation for amendment action so that the commitments are enforceable as license conditions. In addition, licensing is advised to clear the record with respect to acceptance of corrective action following a notice of violation.

VI.F Reviewer Avessment:

The State essentially meets the NRC guidelines in their inspection procedures, but some elements still need to be added. There are no written procedures regarding announcing inspections or making confirmatory measurements. As noted in the enforcement section, there are no written policies for follow-up inspections or shortened inspection frequencies when numerous or repeated violations are observed. These issues were discussed with management and are addressed in the review correspondence.

G. Inspection Reports (Category II)

NRC Guidelines: Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of licensees' programs, and indicating the substance of discussions with licensee management and licensee's response. Reports should uniformly and adequately document the results of inspections and identify areas of the licensee's program which should receive special attention at the next inspection. Reports should show the status of previous noncompliance and the independent physical measurements made by the inspector.

Questions:

 How do inspection reports document the inspection that was conducted and the inspection findings? Explain how the reports substantiate noncompliance and health and mafety matters and describe the scope of the licensee's program.

The inspection reports are done on comprehensive forms that document the licensee's performance in pertinent matters of health and safety. The reports serve as checklists to ensure all areas of the program are covered and the results are summarized. The last page of the report lists the items of noncompliance, the findings and discussion, and the basis for close-out. The scope of the program is described both in the report and on the cover sheet.

- 2. Do the reports
 - a. relate the discussions held with license management and interviews with workers?

Yes.

b. include independent measurements conducted by the inspector?

Yes, the measurements are documented.

c. document follow-up of previous citations of violations made by the inspector?

The entrance interview is documented in the report and that has a section for a review of citations from prior inspections as well as a review of corrective actions described by the licensee complete with closeout.

d. identify areas of the licensee's program needing special attention at the next inspection?

The exit report section indicates the preliminary findings and enforcement actions available or which will be considered.

3. Are inspectors routinely inspecting radwaste package preparation and shipping practices and do the reports document the results?

Yes, the report evaluates complete and clear written instructions for package pickup and receiving, security and adequacy of temporary storage when necessary, clear written internal delivery and transfer procedures, adequate package survey and opening procedures, records or receipt and survey of packages, record of use and transfer of material, use of authorized chipping containers and adequate packing and shipping procedures.

VI.G Reviewer Assessment:

Twelve compliance files were reviewed and the results indicate that for the most part the inspections appeared to be adequate to comply with the guidelines, but improvements are needed in the inspection form. Items such as the inspector's observation of the licensee's handling of radioactive material and interviews with ancillary workers are not included in the current report form and were not documented in several reports. Also, only one standard inspection form is currently being used for all types of licensees and it is not always adequate to describe the scope of the inspection. A list of the files that were reviewed and the comments specific to each file are contained in Appendix F.

H. Independent Measurements (Category II)

NRC Guidelines:

Independent measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samplers, lab counting equipment for smears, identification of isotopes, etc.).

GM Survey Meter: 0-20 mr/hr Ion Chamber Survey Meter: several r/hr Neutron Survey Meter: Fast & Thermal Alrha Survey Meter: 0-100,000 c/m Air Samplers: Hi and Low Volume Lab Counters: Detect 0.001 uc/wipe Velometers Smoke tubes Lapel Air Samplers

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service contract. Exceptions for other State Agencies. e.g., a State University, may be made. Agency instruments should be calibrated at intervals not greater than that required to licensees being inspected.

Questions:

 Discuss the State's policy for conducting independent measurements as a part of each inspection (e.g., air samples, wipe samples, air flows, dose rates). Are these measurements documented in the inspection report?

It is our policy to conduct independent measurements as part of each inspection. Radiation levels are checked in controlled and uncontrolled areas, contamination levels are measured in the vicinity of the workplaces and effluents to the environments are measured when appropriate. The inspection reports verify that these levels are in compliance.

 List the instrumentation that is readily available to the RCP for surveying licensed operations and conducting appropriate independent measurements.

Each inspector can take wipes, has a GM and ion chamber instrument and can measure alpha, beta and gamma radiation.

Each office has, in addition, airflow measurement and air sampling capability. The program has neutron measuring capability.

 Describe the method used for calibrating survey instruments and the frequency of calibration.

See the Uniform Calibration Protocol, previously provided, which the contract agencies have agreed to follow.

VI.H Reviewer Assessment:

As mentioned above, the State has no written procedures for making confirmatory measurements, although it is included in the inspection forms and the inspectors appear to be making the proper measurements. According to the above responses and our findings during the review, the State complies with the NRC guidelines in their independent measurements.

:

A. Non-Agreement Sources of Radiation

Questions:

 Are the licensing and inspection procedures for NARM the same as for agreement materials?

California has a comprehensive Radiation Control Program. The procedures for licensing and inspection of NARM are identical to the procedures established for agreement materials.

 Give the number of X-ray machine (or tube) and accelerator registrants by category, e.g., dental, medical, industrial, etc.

There are 45,665 X-ray tubes registered with the State's Xradiation control program. Machines are in the following categories:

- (a) Priority I 14,565 tubes These are high workload medical machines, primarily radiographic and fluoroscopic used in hospitals and radiologist offices. Approximately 300 of these are high energy accelerators used for medical therapy. There are less than 50 high priority industrial use tubes which are mainly field radiography X-ray machines.
- (b) Priority II 8,280 tubes These are low workload medical, veterinary, and industrial (cabinet) machines. Approximately 15% or 1,400 of these are industrial and analytical tubes.
- (c) Priority III 22,820 tubes These are all dental machines.
- 3. How many machine and accelerator inspections were made in the last year (or other appropriate interval)?

The following X-ray machine inspection and accident investigations were completed for the period January 1 -December 31, 1986.

- (a) Priority I 3,146 tubes inspected approximately 50 were therapy accelerator type.
- (b) Priority II 686 tubes inspected approximately 20 were industrial cabinet type.
- (c) Priority III 2.122 dental tubes were inspected.

79

- (d) Investigations 136 accidents or complaints involving X-ray machines were completed. There were no Type A, two Type B, and seven Type C overexposures caused by Xray machines for the period. One of the Type B overexposures was caused by a diffraction machine located at a university campus laboratory. The other Type B was to an X-ray technician employed at a small medical office.
- Does the State license X-ray or nuclear medicine technologists?

Yes, X-ray Technicians must be certified by the Department of Health Services and Nuclear Medicine Technologists will be certified when regulations are adopted.

B. Environmental Monitoring Program

Questions:

- To indicate the scope of the environmental monitoring program, describe:
 - a. types of media sampled
 - b. the number and locations of stations sampled
 - c. the frequency of sample collection
 - d. the analyses run on each type of sample

These data are included in the 1986 contract report NRC-05-077-105 Environmental Surveillance Report. This report has previously been provided.

 Is a copy of the latest environmental surveillance report available for review?

Yes.

C. Other Areas

This section of the review is for the use of either the reviewer or the RCP to address issues pertaining only to the individual State, to new areas of concern, or to generic or State-specific issues raised by NRC staff.

1. Other Generic Issues

Questions:

a. For radiography inspections, to what extent do you make inspections at temporary job sites?

Temporary job site inspections for IR are required to close out inspections in California when the company has field operations ongoing. b. Are you finding Ir-192 contamination on radiographic equipment?

> No, the California inspectors have been instructed to survey the guide tubes for contamination with a GM survey meter as part of their inspection. California will again remind the inspectors to perform this survey, and to document the results.

c. What are the State's plans to adopt the low-level waste (LLW) manifest rule (if not already adopted)?

The State has adopted the low-level waste manifest rule (10 CFR 20.311) and it is currently in effect.

d. For State with LLW disposal sites, what are the State's plans to implement 10 CFR 61?

The State is proposing to develop a low-level waste site as soon as possible and has already adopted 10 CFR 61 which is now in effect.

e. Will your State have access to a LLW disposal site after January, 1986? If not, what contingency plans are there for after January, 1986?

> The State did not have the low-level site operating by January 1, 1986, and has negotiated a special agreement with the State of Washington to use their low-level waste site until California's is available.

f. Have copies of 10 CFR 61 and NRC technical positions on waste form and classification been distributed to State licensees? If there has been feedback please provide documentation.

Copies of 10 CFR 61, but not all of the NRC technical position on waste, have been mailed to all State licensees. There has been no feedback from any licensee on 10 CFR 61.

g. Have there been any applications or approvals for incineration, compacting or disposal?

> There have been non-commercial applications and approvals for incineration, compacting and disposal (not shallow land burial); the major one currently being reviewed is Stanford University. We have received two applications for compacting/disposal of wastes on a commercial basis; the requests are under review.

h.

What use is being made of IE information notices?

NRC IE information notices are distributed to license reviewers and inspectors but not to California licensees. If the information needs to be distributed to licensees, California puts out a Radiation Safety Advisory to all licensees.

i. Identify any group of materials licensees for which the State has increased the frequency of inspection due to problems with the general category. Please discuss the nature of those problems.

Many field radiography licensees were inspected on an accelerated frequency when serious or repeat violations were found.

j. With respect to medical licensees, is the State making any effort during inspections of nuclear pharmacies to determine whether the licensee is actually conducting the required molybdenum breakthrough tests, i.e., what is the State doing in addition to record reviews to establish compliance or noncompliance with the requirement?

Molybdenum breakthrough is inspected during every routine inspection of medical and pharmacy licensees. Inspectors will show up in early morning hours to observe actual procedures at nuclear pharmacies.

k. Is the State mounting any special effort to look at the possibility of reconcentration of radionuclides in sanitary sewers and sewage treatment plants as part of the regular inspection program? If so, please describe.

The State reviewed the All Agreement State letter addressing the sewage reconcentration problem and could not find any situations where it could be a problem. California has, in the past, run a sewage sludge sampling program (under EPA) and found no problems.

1

Has the State received applications from NRC licensed reactors requesting approval for disposal by burial of low-level radioactive waste? If so, please identify the reactor operator and the date of the application.

No such applications were received.

VIII. LOW-LEVEL WASTE

The reviewer held a day-long meeting on March 16. 1987, with the staff of the Low-Level Waste Section of the Vector Surveillance and Control Branch (VSCB). the Branch of the Environmental Health Division recently assigned the responsibility for the development, licensing and regulation of the California low-level radioactive waste site. Following is an outline of the items discussed and the current status of the program.

1. Legislation and Regulations

California has already adopted regulations equivalent to 10 CFR 61.

2. Organization

As indicated above, the low-level waste program has been assigned to a Branch within the Division that is not headed by the radiation control program director. The reviewer discussed the Agreement State program and provided copies of the background statement to the program management. It was explained to the State that pursuant to the guidelines, when regulatory responsibilities are divided between agencies as in this case. MOU's or equivalent understandings must exist to clearly determine the division of responsibilities and requirements for coordination. It was also explained that the NRC will expect that one agency, logically the RHB, be designated to interface with the NRC and be named the lead agency for regulating agreement material. The Division expects to reorganize and rename the Branches in the near future and the new organization and its effect on the program will be followed up in the next review.

3. Budget

The current annual budget is \$250,000, paid by the designated licensee. Once the site is operating, the State will receive a 10 percent disposal charge in addition to the annual license fee of \$250,000. These funds are expected to support the State's regulation of the site.

4. Administrative Procedures

The program has not reached the stage at which procedures will be established. Management is aware of the need for addressing such items as RCRA responsibility, topical reports, HIC evaluations, etc. They are gathering as much information as possible in the form of regulations, reg guides, NUREGS, licenses and SOP's from the NRC, existing sites and other participating state and Federal Agencies. The reviewer pointed out several items for consideration by the State such as setting policies for special exemptions, containers, compacting, incineration, mixed waste, and storage.

5. Personnel

The program is headed by Don J. Womeldorf. Branch Chief and Program Manager, and now has two technical staff members: Rueben Junkert. Senior Waste Management Engineer, and Fred Toyama, Health Physicist. The reviewer interviewed the staff and reviewed the job descriptions and resumés. It was found the qualifications of the technical staff are all satisfactory and within the NRC guidelines. The program will be hiring additional staff and using consultants as the development process continues.

6. Training

The training available from the NRC was discussed and staff member's have already been assigned to upcoming training courses.

7. Licensing

US Ecology has been selected as the designated licensee. A preliminary license application is expected in the Spring or Summer of 1988 and the final application and EIR/EIS in late 1989. The State plans to use technical assistance from the NRC and consulting firms in writing the license.

8. Site Selection and Development

The site development program and preliminary schedule submitted by US Ecology is attached as Appendix G. The schedule has three phases, site selection, site characterization and environmental review and licensing. At the time of the review, the site selection phase was still in progress. Eighteen desert basins had been studied, and using siting criteria developed from public comments as well as technical and regulatory requirements the State and US Ecology had narrowed sixteen candidate siting areas to three primary and two backup sites. The plan is now to enter Phase 2, in which the three primary sites will be characterized by detailed studies for one year, after which the final site will be chosen. Construction is expected to begin in late 1989 after completion of the environmental review and final approval of the license application.

9. Sureties

The licensee designee has posted a \$1,000,000 performance bond with the State. Sureties for decommissioning and long term care and maintenance after closure are to come from monies collected by the ten percent disposal charges. The amounts have yet to be established and the State plans to form an analysis and evaluation group that would use the services of an economist and a budget analyst to determine the necessary amounts.

10. Compliance

Although compliance procedures have not been developed, the need for adequate inspection and enforcement procedures was discussed. Presently, the State plans to have at least one onsite inspector with possible additional oversight from the selected county. Items that need policies established include enforcement severity levels, escalated enforcement and the disposition of incoming waste that does not meet requirements.

LIST OF APPENDICES

- A. California State Organization Charts
- B. Radiologic Health Branch Organization Chart
- C. License Fee Schedule
- D License File Review
- E. Inspection Priority Schedule
- F. Compliance File Review
- G. Low Level Radioactive Waste Disposal Facility Development Program and Preliminary Schedule

CALIFORNIA DEPARTMENT OF HEALTH SERVICES





APPENDIX A



BAR (C)

APPENDIX A

Page 3

	the product of the pr			8 (1) 10 (1)	No. 10.10 No. 10.10 No. 10.10 No. 10.10	int in man Duart I mus a statut	INT IN Management Management Management Jury J	(11) be nary were a new Britari bergalik Witchik antari	NULLER TRATEGO NULLER TRATEGO TRATEGO NULLER NULLER PLAN	
				ULL IN IN IN IN IN IN IN IN IN IN IN IN IN IN IN	PUBLIC (AN UNIT) PUBLIC (AN UNIT) PUBLIC (AN UNIT) PUBLIC (AN UNIT) PUBLIC (AN UNIT)	Access Sources and Access and Access	March 1 and	J.K. et it. B.K. et it. 1. et al. et al. B.K. et al. et al. B.K. et al.	Annual and annual a	
			All Date of the second	Mark International International International International Internation	All H100(kc)1 All H100(kc)1 Barton All Anorea Barton F10 Mar	(11) BUIGHTONES (11) BUIGHTONE	NU LG 	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1		
ENER			MICLINE CONTRACTOR		Concertion for the manual of the concertion of t	MATTERIA (MATTERIA) MATTERIA MATTERIA MATTERIA MATTERIA MATTERIA MATTERIA	Berrar and Long and Long and Long	NATION IN WARRANT NATIONAL Nat	Internet in the second	
ANCH	And the second s	Particular Pricio Asprime Pricio Asprime Prime Lance Prime Second	Section and Dates and Dates an	BUTTAL BUTTAL BUTTAL BUTTAL BUTTAL BUTTAL	and the second s	Pratriata de Centration - La Lande France Drive	Mitality (e. e. e	an e una una una una una una una una	Contraction and President and President Conservations and President and Pre President and President	
	Participant and an and an	Lill Lill Lill Lill Lill Lill Lill Lill		NEW YOR NUTREE NEWTHER NUTREE New York NUTLE (New York NUTLE NUTLE NUTLE						
COLUMN INA			And	A second se	Province of the second	maan maan maan maan maan maan maan maan	the processes	131) 131)		
		berins a menen bereins berins	Add Add - And Address Barris 1948 Barris and Barris and Barris and Barris 1940 Barris 1940 Barri 1940		an unitaria provincia de la construcción de la cons	Annua Annua				
	но со	(ALC) ACCESSION ACCE	An of Contract States		No. 40 (1914) In March 1990 (1914) In March 1990 (1	Internet Neuropana Neuropa	and interview of the second se		The second secon	
	The second secon	References (IN RE Constitution Constitution Note: Note	anter tra anter a	RETURN F RETURN F RETURN F RETURN F RETURN R R R R R R R R R R R R R R R R R R	and a second sec	a need	Marine B Marine	A LICITED ALLERGY ALLE	and a second sec	
	www.ri Contraction of the second seco	International In	A CONTRACT OF A	Mark and Annexyment Sectors from the formation for the formation of the fo						
	and the second sec	THE COMPARENCE OF COMPARENCE O	IN THE REAL OF CARDINATION OF THE REAL OF	A state	REAL OF A	ALL	A TAN TAN	INTER INTERIOR	and the form	Provide a supervision of the sup
	Manager Manager Manager Manager Mana Manager Manager M Manager Manager M	A PROV A PROVA A PROVA	And Andrews		MARTINE MULTINE MULTIN	Lines and Lines	A DOMINICA	A DATE AND	A Mayoan of A	A manufacture of the second se



APPENDIX D

LICENSE FILE REVIEW

Eleven pre-selected license files were reviewed. License applications were reviewed for completeness and for proper signatures. Casework was reviewed for timeliness of State actions, adherence to good health physics practices, reference to appropriate regulations, supporting documentation, consideration of enforcement history on renewals, pre-licensing visits, and peer or supervisory review as indicated. Licenses were reviewed for accuracy. appropriateness of the license and of its conditions and tie-down conditions and overall technical quality. The files were checked for orderliness and retention of necessary documents and supporting data.

Overall the licenses were well drafted and no major deficiencies or generic issues were noted. It was obvious from reviewing the files that the reviewers are making an effort to improve the quality of the licenses and during the staff exit they were commended on the improvement.

The licenses reviewed are listed below and are followed by a list of comments specific to each case. These comments were discussed with the applicable reviewer.

Case # 1 Licensee: Kaiser Permamente Medical Group Lic. No.: 1802-60 Amendment No.: 26 Location: Hayward, CA Type of License: Group Medical Type of Action: Renewal Date of Action: August 26, 1986 Case # 2 Licensee: City of Hope National Medical Center Lic. No.: 0307-70 Amendment No.: 86 Location: Duarte. CA Type of License: Group Medical. Teletherapy, R&D. Irradiator (self-shielded) Date of Action: May 8, 1986 Type of Action: Renewal Case # 3 Lic. No.: 1471-70 Licensee: Temple Community Hospital Amendment No.: 28 Location: Los Angeles, CA Type of License: Group Medical Type of Action: Renewal Date of Action: September 4, 1986 Case # 4 Licensee: Becton-Dickinson Monoclonal Center, Inc. Lic. No.: 3404-43 Location: Mountain View. CA Amendment No.: 14 Type of License: Tracer Studies, Self-shielded Irradiator Date of Action: November 7, 1986 Type of Action: Renewal

Case # 5 Licensee: Isotope Products Laborator es Lic. No.: 1509-70 Amendment No.: 64 Location: Burbank, CA Type of License: Source Manufacturing/Distribution Date of Action: March 13, 1986 Type of Action: Renewal Case # 6 Lic. No.: 4809-34 Licensee: Summa Pharmacy of Sacramento Location: Sacramento, CA Type of License: Nuclear Pharmacy Type of Action: New License Date of Action: September 11, 1986 Case # 7 Lic. No.: 2181-56 Licensee: Boothe-Twining, Inc. Amendment No.: 49 Location: Oxnard, CA Type of License: Industrial Radiography Type of Action: Special amendment to Date of Action: July 1, 1986 enact enforcement agreement Case # 8 Lic. No.: 0144-56 Licensee: Schlumberger Well Services Amendment No.: 49 Location: Houston, TX Type of License: Well Logging Date of Action: May 12, 1986 Type of Action: Renewal Case # 9 Lic. No.: 2074-43 Licensee: Tracor X-ray, Inc. Location: Mountain View, CA Amendment No.: 35 Type of License: Manufacture of X-ray Fluorescence Analyzers Date of Action: February 3, 1986 Type of Action: Renewal Case # 10 Lic. No.: 0015-70 Licensee: Rocketdyne Division Location: Canoga Park, CA Amendment No.: 75 Type of License: R&D, IR, Irradiator, Hot Cell Operations, Fabrication of Fuel Assemblies, Decontamination Service - Type of Action: Renewal Date of Action: August 29, 1986 Case # 11 Licensee: Nuclear Theory & Technologies Lic. No.: 4722-70 Mineral Division Location: Woodland Hills, CA Type of License: Activation in gemstones Type of Action: New Date of Action: May 22. 1986 Comment File No. 1. Bioassay condition not on license 1.10 2. License condition included that did not apply to 1,2 licensee's facilities or use of RAM 3. No central point for ordering RAM 1

4.	File not orderly	2.5.10
5.	Ambiguous authorized user condition	. 2.9
6.	Leak test conditions did not cover all sealed sources	2.3
7.	Application unclear on adequate facilities or instrumentation: reviewer did not follow up	3,5,6
8.	Security not addressed	4
9.	Users listed for all uses, but not trained in all uses	4.5.9
10.	Record keeping not adequately addressed in application	5
11.	Shipping procedures not adequately addressed	5
12.	High range survey instrument needed but not listed in application	6
13.	No source changers listed for IR's	7,10
14.	RAM handling procedures missing	8

APPENDIX E

INSPECTION PRIORITIES

ANGUSCI IGA		Medical/Medical Related			
Priority	Type of License	Priority	Type of License		
6 .	DU Shielding ,	6	DU Shielding		
6	Gas Chromatographs	5	Lixiscopes (medical)		
6	Fixed Gauges	5	Bone Densitometers		
6	Small Sealed Sources (∠100 uCi)	5	Sr-90 eve applicators		
6	EPA Sponsored Water Labs	3 or 5(b)	Groups 1 - 12		
5	Portable Moist/Dens. Gauges .	2	Broad Scope A		
5	Lixiscopes (industrial)	2	Nuclear Pharmacies		
5	X-ray Fluoroscopy	2	Mobile Services		
5	Small Irrad. (Cat. I, II, III) .	3	Veterinary Medicine-Therapy		
5	Small Lab (10 mCi)	5	Veterinary Medicine-Sr-90		
3	Med/Large Lab	3	Brachytherapy Source Suppliers		
3	Well Logging/Tracers	5	RIA Testing only		
3	Tubular Inspection		the second bury		
3	Kr-85 Units		Academic		
Ĵ	Irradiated Electronics < 10 mCi		No an al annual de las de		
3	Irradiated Electronics >10 mCi	3.4.or 6(c)	Specific license		
3	Manufacturing Devices	3 or 5(c)	Broad C		
3	Manufacturing RIA Kits	3	Broad B		
• 3	Broad A and B	2	Broad A		
5	Broad C				
1,2,3(a)	Manufacturing Sealed Sources		Services		
1,2.3(a)	Manufacturing Unsealed RAM				
1.2.3(8)	Manufacturing Source Material	3	Demonstration		
3	Research and Development	3	Leak Test Service		
1	Industrial Radiography	3	Calibration of Instruments		
1	Large Irradiators (Cat IV)	3	Gauge Service		
		3	Film Badge/TLD's		
		3	Calibration of Diagnostic Inc.		
		2	Waste Broker		

Distribution - Same priority as associated manufacturing license.

Others - Depends on type of license. See the Chief, Radioactive Materials Management Section.

2

Decon and Decommissioning

Notes:

Industrial

- a. As these types of licenses vary with respect to scope of operations, priorities 1, 2, or 3 may apply. If the licensee is a major processor/distributor, the priority is 1. If activities are more limited, priorities 2 or 3 may be assigned. Verify proper priority assignment with the Chief, Radioactive Materials Management Section.
- b. Priority assignment for nuclear medicine/therapy depends on possession limit. These are priority 3 unless the possession limit is less than 100 millicuries.
- c. Specific or Broad C Academic licenses occassionally have significant Subiters which make them a priority 3. In other cases, such as use of a small irradiator or gas chromatograph, the priority would be 5 or 6 respectively.

Priority	1	2	3	5	6
Initial (months) 1/	6	6	6	6	12
Follow-Up					
Due Frequency (yr-1)	1	0.5	0.33	0.20	non routine
Due (months) 2/	12	24	36	60	
Overdue (months) 2/	16	36	54	90	· "

INSPECTION FREQUENCIES

1/ From Date of Issuance

2/ From Date of Last Inspection

ter

Ŧ

APPENDIX F

COMPLIANCE FILE REVIEW

Twelve compliance files were reviewed to verify that the inspection reports uniformly and adequately documented the scope and results of a proper inspection, that appropriate compliance action was taken, that enforcement letters were written in appropriate regulatory language, that enforcement actions, responses and acknowledgements were completed in a timely manner, that unresolved issues were pursued to conclusion and that compliance actions and inspection reports had proper supervisory review. The files were also checked for orderliness and retention of necessary supporting data.

Although the inspection reports and files reflected the fact that the inspectors are performing thorough inspections and taking the appropriate enforcement actions promptly, improvement needs to be made in the inspection forms. The RCP has revised the uniform inspection form several times in the past months, and each office was using a different version. The form still needs to be revised to include the inspector's observations of the licensee's operations and interviews with ancillary workers. Also only one standard inspection form is currently being used for all types of licensees and it is not always adequate to describe the scope of the inspection.

Case	* 1	
	Licensee: Cigna Health Plans	Lic. No.: 4619
	Location: Westminster, CA	Priority: 3
	Type of Licensee/Facility: Medical	
	Reason for Inspection: Initial	
	Inspection Date: 11/17/86	Enforcement Letter Date: 11/19/86
Case	\$ 2	
	Licensee: Mast Immunosystems. Ltd.	Lic. No.: 3906
	Location: Mountain View, CA	Priority: 3
	Type of Licensee/Facility: Bio Laborat	ory Manufacturing & Distribution
	Reason for Inspection: Routine	•
	Inspection Date: 7/2/86	Enforcement Letter Date: 8/13/86
Case	# 3	
	Licensee: John Muir Memorial Hospital	Lic. No.: 2207
	Location: Walnut Creek, CA	Priority: 3
	Type of Licensee/Facility: Medical	
	Reason for Inspection: Routine	
	Inspection Date: 7/9/86	Enforcement Letter Date: 7/25/86
Case	\$ 4	
	Licensee: SIBIA, Inc.	Lic. No.: 4437
	Location: La Jolla, CA	Priority: 3
	Type of Licensee/Facility: R&D Laborat	ory
	Reason for Inspection: Initial	
	Inspection Date: 6/11/86	Enforcement Letter Date: 8/26/86

Case # 5 Licensee: Friendly Hills Medical Group Location: La Habra CA Type of Licensee/Facility: Medical - Private Practice Reason for Inspection: Initial Inspection Date: 1/15/87 Enforcement Letter 1	Lic. No.: 4139 Priority: 3
Case # 6 Licensee: Los Angeles Dept. of Water and Power Location: Los Angeles. CA Type of Licensee/Facility: Gas Chromatograph Reason for Inspection: Initial	Lic. No.: 3665 Priority: 5
Inspection Date: 12/9/86 Enforcement Let Case # 7	ter Date: 12/15/86
Licensee: Needles-Desert Communities Hospital Location: Needles. CA Type of Licensee/Facility: Medical Reason for Inspection: Initial	Lic. No.: 3520 Priority: 2
Inspection Date: 8/19/86 Enforcement L	etter Date: 9/2/86
Case # 8 Licensee: Bud Antel, Inc. Location: Salinas Type of Licensee/Facility: R&D Laboratory Reason for Inspection: Routine Inspection Date: 7/25/86 Enforcement Letter D	Lic. No.: 2593 Priority: 3 Mate: Not Required
Case # 9 Licensee: Western Industrial X-ray Location: Richmond. CA Type of Licensee/Facility: Industrial Radiography Reason for Inspection: Routine Inspection Date: 5/19/86 & 7/31/86 (Field) Enforcement Letter Date: 8/19/86	Lic. No.: 2851 Priority: 1
Case # 10 Licensee: Richardson X-ray Location: Alhambra, CA Type of Licensee/Facility: Industrial Radiography Reason for Inspection: Routine Inspection Date: 11/4/86 Enforcement Let	Lic. No.: 0373 Priority: 1 ter Date: 11/6/86
Case # 11 Licensee: City of Hope Location: Duarte, CA Type of Licensee/Facility: Nuclear Medicine, Teletherapy Group 9 Labs, Brachytherapy Reason for Inspection: Routine Inspection Date: 11/10-12/86 Enforcement Let	Lic. No.: 0307 Priority: 3 by. tter Date: 11/20/86

-

Case	<pre># 12 Licensee: Canoga Park Hospital Location: Canoga Park.CA Type of Licensee/Facility: Medical Reason for Inspection: Routine Inspection Date: 10/6/86 Enforcement</pre>	Lic. No.: 1809 Priority: 3 Letter Date: 10/17/86
Comm	ent	File No.
1.	No documentation of inspector observance of licensee operations	1.2.11.12
2.	No documentation of inspector interviews of ancillary workers	1.2.5.7.11.12
3.	No description of scope of licensee operation	2
4.	Exit meeting not with appropriate level of manageme	ent 2
5.	Enforcement letter late	4
6.	Incorrect use of short form (2514) for enforcement	5
7.	No licensee response: no follow-up by State	5
8.	Exit meeting documentation not clear	5
9.	Dosimetry review data on form not completed	5
10.	Items of non-compliance unclear; no license condit or regulations cited	ions 5
11.	No indication of independent measurements by inspe-	ctor 5
12.	No attendance record of exit meeting	, 7
13.	Inspector did not use uniform inspection format	8
14.	File not in order	11
15.	Inspector recommended follow-up inspection; no recommended follow-up inspection; no reco	ord 12

U.S. ECOLOGY LOW LEVEL RADIOACTIVE WASTE DISPOSAL FACILITY DEVELOPMENT PROGRAM AND PRELIMINARY SCHEDULE







U.S. ECOLOGY LOW LEVEL RADIOACTIVE WASTE DISPOSAL FACILITY DEVELOPMENT PROGRAM AND PRELIMINARY SCHEDULE





U.S. ECOLOGY LOW LEVEL RADIOACTIVE WASTE DISPOSAL FACILITY DEVELOPMENT PROGRAM AND PRELIMINARY SCHEDULE



0 01

.

.



•