

NRC  
PDR



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION V

1450 MARIA LANE, SUITE 210  
WALNUT CREEK, CALIFORNIA 94596

JAN 11 1984

Mr. Peter C. Rank, Director  
California Department of Health Services  
714. P Street  
Sacramento, California 95814

Dear Mr. Rank:

This is to confirm the discussion Mr. Jack Hornor, Region V State Agreements Representative, Mr. Steve Baggett, Office of Nuclear Material Safety and Safeguards, and Mrs. Kathleen Schneider and Mr. Joel Lubenau, Office of State Programs, held with Ms. Pat Rauscher and your staff following our review and evaluation of the State's radiation control program. The review covered the principal administrative and technical aspects of the program. This included an examination of the program's legislation and regulations, organization, management, administration, personnel, licensing and compliance actions and field evaluations of State inspectors.

Our review was performed in accordance with the NRC policy defined in the "Guidance for NRC Review of Agreement State Radiation Control Programs." These Guidelines were published in the Federal Register on December 4, 1981, and define the 30 indicators that are used for evaluating Agreement State programs. A description of how the indicators are used in reporting the results of program review to State management is enclosed (Enclosure 1).

In the staff's judgement, significant problems exist in three Category I indicators, which under our published guidelines, are of sufficient importance that a recommendation on adequacy and compatibility cannot be made until we have received and evaluated California's response. We wish to bring these to your attention as follows:

Status of inspection program is a Category I indicator. There is a significant deficiency in the California radiation control program's ability to maintain statistics which are adequate to permit management to assess the status of the inspection program on a periodic basis. This has been an ongoing problem we have commented on since 1981.

Status of Regulations, a Category I indicator, specifies that an Agreement State must have regulations that are essentially identical to 10 CFR Parts 19 and 20 and have a high degree of uniformity with other NRC regulations. California's radiation control regulations pertaining to radioactive materials have not been updated in their entirety since 1974. Numerous changes have been made to NRC regulations to reflect changing technology, increased knowledge, recent recommendations of technical advisory groups, and improved regulatory programs. It should be noted that this comment has been made to the State since 1977.

Significant problems exist in Technical Quality of Licensing Actions, a Category I indicator. California is issuing some licenses that are not clear, complete, or accurate as to isotope forms, quantities, authorized uses, and permissive or restrictive conditions. In addition, the essential elements of

8401250514 840111  
PDR STPRG ESGCA  
PDR



Mr. Peter C. Rank, Director

-2-

license applications sufficient to establish the basis for the licensing actions have not always been present or requested.

Staffing level is a Category II indicator. The NRC Guideline is 1.0 to 1.5 staff-years per 100 licenses. California is presently at 0.67 staff-years per 100 licenses or 33% below NRC's guidelines for minimum program maintenance. This has been an ongoing problem since 1974.

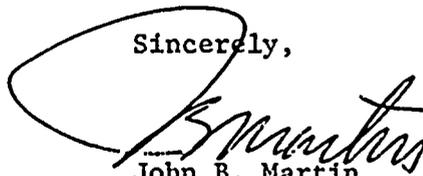
Enclosure 2 contains additional comments regarding the technical aspects of our review of your program. These comments were discussed with Mr. Joe Ward and his staff at our exit meeting with him. Mr. Ward was advised at the time that a response to these findings would be requested.

We would appreciate your review of our comments and recommendations and receiving your specific plans to improve California's radiation control program including milestones and commitment dates such that your progress can be monitored. In addition, a follow-up review will be conducted within six months to assure that the plans are implemented and carried out. At that time we plan to be in a position to consider a finding concerning the adequacy and compatibility of the radiation control program.

We are enclosing a copy of this letter for placement in the State Public Document Room or otherwise to be made available for public review.

We appreciate the courtesy and cooperation you and your staff extended to the NRC staff who conducted the review.

Sincerely,



John B. Martin

Regional Administrator

Enclosures:

As stated

cc w/enclosures:

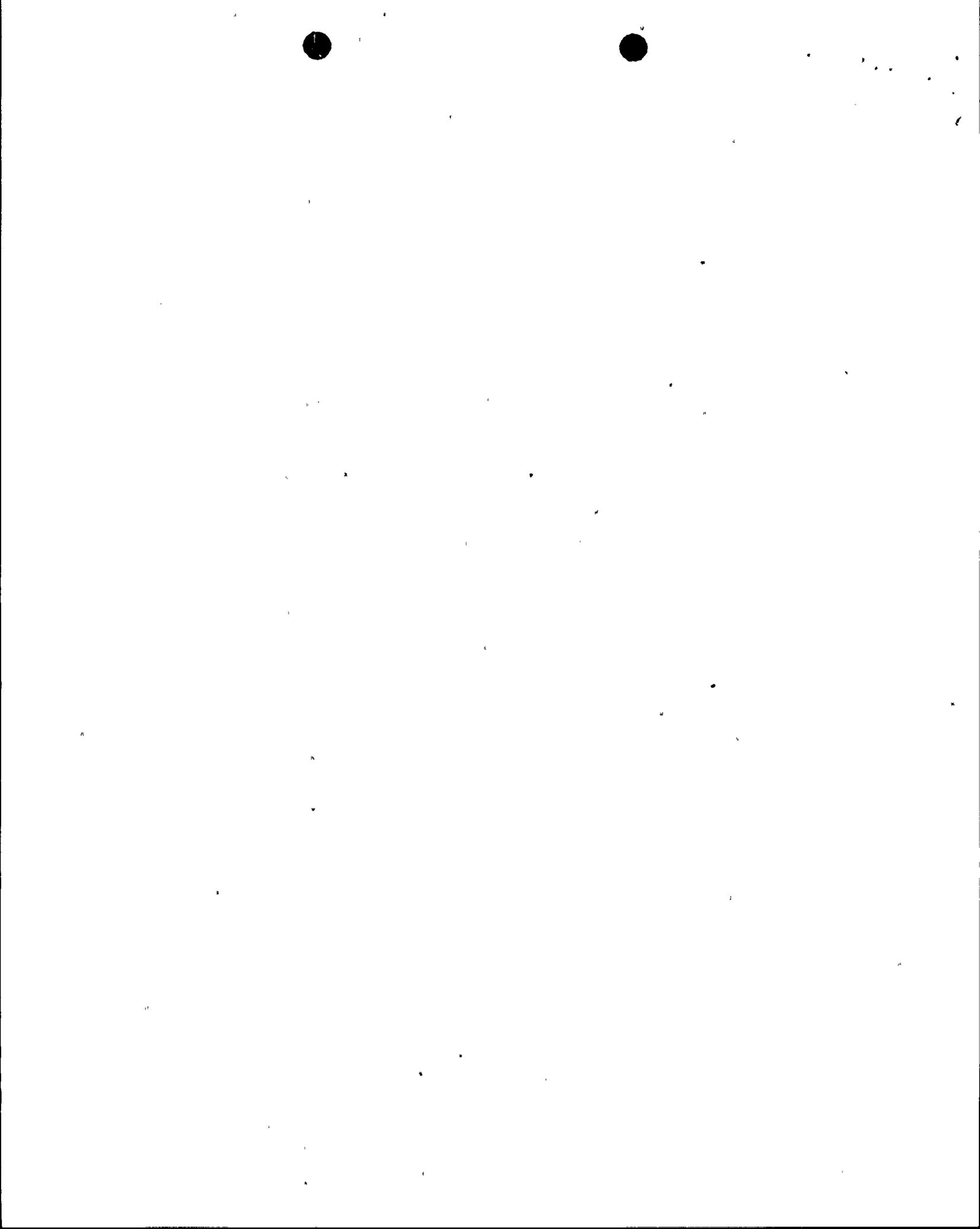
Dr. Harvey Collins, Chief,  
CA Environmental Health Division

Mr. Joe Ward, Chief,  
Radiological Health Branch

State Public Document Room

NRC Public Document Room

G. Wayne Kerr, NRC/OSP



Enclosure 1

Application of "Guidelines for NRC Review  
of Agreement State Radiation Control Programs"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs," were published in the Federal Register on December 4, 1981, as an NRC Policy Statement. The Guide provides 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories.

Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety. If at least one significant Category I comment is provided, the State will be notified that the program deficiency may seriously affect the State's ability to protect the public health and safety and should be addressed on a priority basis. When more than one significant Category I comment is provided, the State will be notified that the need of improvement in the particular program areas is critical. The NRC would request an immediate response, and may perform a followup review of the program within six months. If the State program has not improved or if additional deficiencies have developed, the NRC may institute proceedings to suspend or revoke all or part of the Agreement. Category II comments would concern functions and activities which support the State program and therefore would not be critical to the State's ability to protect the public. The State will be asked to respond to these comments and the State's actions will be evaluated during the next regular program review.



## ENCLOSURE 2

### Comments and Recommendations for the California Radiation Control Program for Agreement Materials

#### Legislation and Regulations

Status of Regulations is a Category I indicator. The following item of major significance was noted.

#### Comment

California's radiation control regulations pertaining to radioactive materials have not been updated in their entirety since 1974. Examples of some of the recent significant changes relating to radiation safety that have not been incorporated in California's regulations are as follows:

1. Requirements to perform surveys of patients to confirm the radioactive source implants have been removed;
2. Special requirements for controlling areas in which very high radiation levels exist (i.e., excess of 500 rem/hr);
3. ALARA requirements;
4. MPC values;
5. Modification of transportation requirements;
6. Defacing of radioactive material labels prior to disposal.

#### Recommendation

We recommend that priority attention be given to the updating of California's radioactive materials regulations. We suggest that California make use of NRC's value impact statements to support the regulation justification.

#### Management and Administration

- A. Budget is a Category II indicator.

#### Comment

Some operating funds to operate specific portions of the California radiation control program are apparently unavailable for use by the program management. Specific instances include automatic data processing support, funding necessary for filling of existing vacancies, and staff training.



Recommendation

We recommend that the Radiation Control Program management be given the ability to spend the appropriated funds necessary for the operation of the program. Some low-cost recommendations to immediately assist the program include:

1. Consultant support for automatic data processing;
  2. Filling of the three authorized vacancies;
  3. Transferring the vacancy for compliance supervisor from Berkeley to Sacramento;
  4. Hiring of Radiation Control Program retirees as consultants to assist with the adoption of regulations;
  5. Staff training for new employees.
- B. Management is a Category II indicator

Comment

It was noted that a quality assurance system exists for program management to perform periodic reviews of selected license cases handled by each reviewer. The system is presently not being used according to internal procedures which include documentation.

Recommendation

We recommend that the State follow its procedures for performing quality assurance of licensing action, including documentation.

Personnel

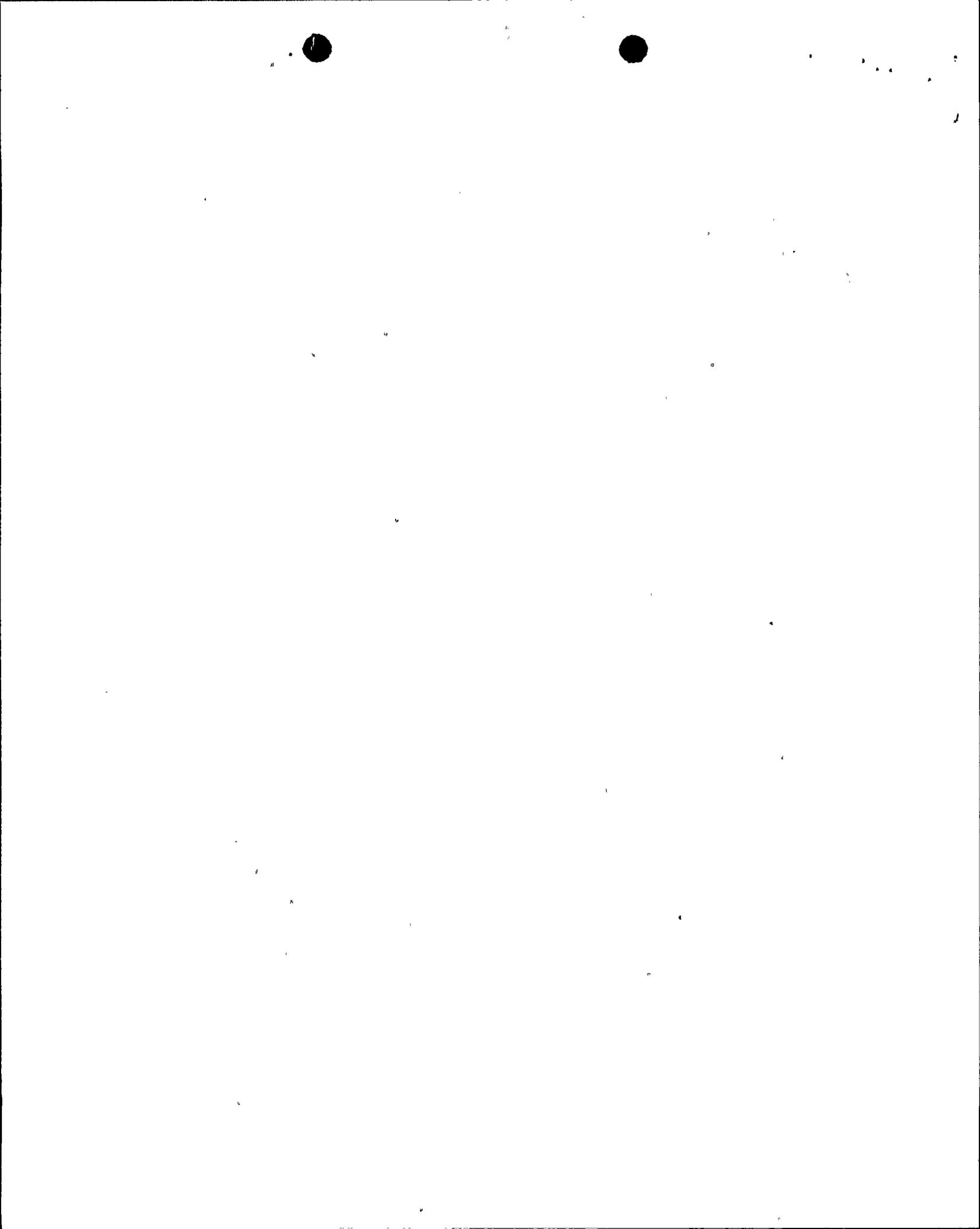
- A. Staffing Level is a Category II indicator.

Comment

California is presently at 0.67 staff-years per 100 licenses or 33% below the minimum NRC recommended guideline of 1.0 to 1.5 staff-years per 100 licenses.

Recommendation

1. Priority should be given to filling the authorized vacancies which would raise the program staff level to approximately 0.8 staff-years per 100 licenses.
2. Effort should be spent in obtaining authorization for new positions to enable the program staff to meet NRC's recommended guidelines.



B. Training is a Category II indicator.

Comment

- . During the accompaniments of the compliance staff, it was noted that one inspector had not attended any NRC courses in inspection procedures, radiography or well logging.

Recommendation

We recommend that the inspector be sent to the inspection procedure course and the other mentioned courses as soon as possible.

Licensing

A. Technical Quality of Licensing is a Category I indicator. The following item of major significance was noted.

1. Comment

Since the last review, California is issuing medical licenses that are not clear, complete or accurate as to isotope forms, quantities, authorized uses, and permissive or restrictive conditions.

Recommendations

As per discussions with the staff, we recommend that California issue medical licenses that are clear, complete and accurate.

2. Comment

During the review of selected license files, we noted that:

- a. In some instances, Xenon 133 was authorized without supporting documentation by the applicant or evaluation by RCP staff.
- b. Evaluation of the proposed waste handling procedures are inadequate.
- c. No requests are being made of applicants for ALARA program commitments.
- d. Applicants' procedures for preparing packages for shipment and for transportation of radioactive materials were frequently inadequate and sometimes out-of-date.

Recommendation

We recommend that licensing checklists be used and maintained with the licensing file to assure all aspects of an application are evaluated.

B. Adequacy of Product Evaluation is a Category I indicator. The following minor comment was observed.



Comment

It was noted during the review of 27 sealed source and device (SSD) evaluations that in many instances the supporting documentation was inadequate. This included sample labels, drawings, and manufacturer's data for safe use. In addition, the SSD sheets are not always clear, consistent and accurate.

Recommendation

We recommend that the State require all manufacturer's data and documentation of staff evaluation be retained in the file prior to issuance of the Registry Sheet. In addition, we recommend the use of checklists to maintain consistency between sheets.

Compliance

Status of Inspection Program is a Category I indicator. The following item of major significance was noted.

Comment

The California RCP cannot use the computer to update the Compliance program data base. Management has not had an updated status of the inspection program report since February of 1983. NRC guidelines require management to be able to assess the status of the inspection program on a periodic basis. During past reviews, California committed to a quarterly review of information showing the number of inspections performed, number of inspections overdue by priority, and length overdue.

Recommendation

The California RCP should bring in a consultant to make the existing data processing system operable and then train several users on how to access and update the system for the short term. Long range plans can then be studied for a better system at some future date.



\_\_\_\_\_