



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 21 1980

Ref: SA/JOL

Mr. Joseph O. Ward, Chief
Radiologic Health Section
State Department of Health Services
714 P Street
Sacramento, California 95814

Dear Mr. Ward:

We have received Ms. Myers' February 6, 1980 letter reporting steps taken to augment staff, review management and paperwork procedures and improve training opportunities for the radioactive materials program.

Our letter to Ms. Myers on September 17, 1979, which reported our comments following our 1979 review meeting, contained a number of administrative and technical comments. As a result of Ms. Myers' reply, we held follow-up meetings with you and your staff on October 24-26, and November 13, 1979, in Sacramento, to further discuss these items. Although we did not reach full agreement on all the issues, I believe no items were left undiscussed. Summaries of these meetings are enclosed. They include restatements of our comments in light of the follow-up meetings. If you have any further comments on them please let me know.

We are pleased to learn of the steps being taken to strengthen the California radioactive materials program. I appreciate the opportunities provided by you for our staffs to discuss and better define the comments made following the 1979 review meeting.

Sincerely,

G. Wayne Kerr, Assistant Director
for State Agreements Program
Office of State Programs

Enclosure:
As stated

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SPECIAL MEETING WITH CALIFORNIA RADIOLOGIC HEALTH SECTION, OCTOBER 24-26, 1979
(AS SUPPLEMENTED BY NOVEMBER 13, 1979 MEETING)

On October 24-26, 1979, J. McGrath and J. Lubenau conducted a special meeting with the Radiologic Health Section of the California Department of Health Services. The meeting was scheduled following the State's response to Ryan's September 17, 1979, letter to Beverlee A. Myers concerning the 1979 review of the California meeting. The purpose of the meeting was to review and discuss all file reviews made during the August 27-31, 1979, Review Meeting, establish facts relating to the California program and identify areas of agreement and disagreement concerning the performance of the State program. Representing California were Joe Ward, Chief, Radiological Health Section and his senior staff members; Don Honey, Supervisor of the Radioactive Materials Unit; Irv Goldberg, Head, Radioactive Materials Licensing; Gerald Wong, who will shortly become head of radioactive materials licensing; and Chester Mott, Head, Radioactive Materials Compliance and Inspection.

All license and all controversial compliance files reviewed during the regular 1979 review meeting were discussed with cognizant members of the California staff. Two investigation files which resulted in significant comments were discussed with Mott and Honey. (Comments on the remaining investigation files were minor and did not contribute to comments on the California program.) The results of the accompaniments of inspectors were discussed with Mott, and were also included in our discussions on the compliance program. Administrative, staffing and training matters as well as regulations, advisory committee and incident response were explored with all the staff. At the end of the meeting, there were no outstanding items remaining to be covered.

The results of this meeting are as follows:

1. Licensing Actions and Device Evaluations: State and NRC staff did not reach agreement on the health and safety significance of some of the findings we identified as deficiencies in licensing actions. Nonetheless, agreement was reached that improvements in the State's licensing practices are needed to enable the State's practices to conform with current standards and practices. In particular, it was agreed that license guides need to be updated or current NRC license guides should be expanded; additional training would be appropriate; and improved supervisory review (quality control program) is needed. On this point, the staff stated an internal review committee has been established consisting of all license reviewers which will be responsible for conducting formal reviews of proposed major licensing actions.

POOR ORIGINAL

We commented that major problems have been identified on licensing in 1974, 1975, 1976, 1978 and 1979, and there exists a need for a specific and strong commitment to enact improvements.

2. Compliance Activities: We apologized for not discussing the results of the individual compliance file reviews with the staff during the regular 1979 meeting. The results of these reviews were discussed with the State during the August 27-31, 1979 meeting, by way of a summary of the important aspects of the findings and also tied them in with the findings of the accompaniments. We agreed that uniform documentation practices are necessary; that standards for acceptable consistent correspondence practices needs to be established; that the compliance supervisor should conduct regular field evaluations of all inspectors (a two-year cycle to complete field evaluations was agreed upon); and that more careful review of, and insistence by the compliance supervisor that, inspection reports and correspondence conform to acceptance standards is needed. During the November 13 meeting, it was agreed that Mott ~~at~~ the appropriate agency supervisor will accompany all inspectors yearly and Mott will accompany all inspectors at least every two years.

We commented that the aim of the compliance supervision should be to ensure inspections are complete, quality efforts, properly documented and properly followed by enforcement actions.

3. Administration: It was agreed that improvement is needed in managerial oversight and feedback on program operations. Specific areas for improvement were:
 - a. documenting and tracking work and project assignments;
 - b. program planning (including establishing priorities, benchmarks and targets);
 - c. spotting roadblocks and delays and revising priorities and benchmarks;
 - d. quality assurance (QA);
 - e. automated data processing and retrieval (ADP).

We commented that California is the largest single Agreement State agency and recommended it strive to be the best as well. At the November 13 meeting, Ward indicated he has taken, and will take steps to improve this aspect. Ms. Myers will aid in resolving the ADP problem.

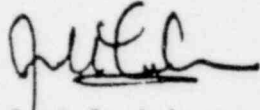
4. Staffing: Inadequate staff has been cited by NRC as a major problem every year since at least 1974 and it has contributed significantly to problems in the California program. There was emphatic agreement on this. Nonetheless, Beverlee Myers' response on this issue was indefinite (and may be dependent upon the Governor's office). Ward agreed and stated he would follow this up with Myers and contact Wayne Kerr prior to Kerr's scheduled meeting with Myers on November 13, 1979. The State staff indicated two additional positions were needed for the radioactive materials program. During the Nov. 13 meeting the State indicated these two were in addition to a current vacancy plus one position to be filled if fees are increased. We questioned the adequacy of this figure pointing out that updating licensing practices will result in more detailed license reviews, and consequently more detailed inspections; other projects including regulation revisions require additional effort; and if unusually complex license applications are received (such as for uranium mills, a possibility), further significant increases in staffing will result. Normal growth also should be planned for. At the Nov. 13 meeting with Myers, Ward stated he would prepare a memorandum on how to achieve a staffing level of 20 as recommended by Kerr.
5. Training: It was agreed that the staff should avail itself of all pertinent short-term training opportunities. However, out-of-state travel restrictions continue to be a severe restraint. When special symposia or workshops are developed on short notice in response to new, rapidly developing needs, the staff are forced to substitute these for previously planned training courses. These restrictions reportedly flow from the Governor's office and Ms. Myers will pursue this matter.
6. Regulations: It was agreed that the regulations need revision. The Radiologic Health Section has been asked by the Budget Section to prepare an economic analysis and Myers, in her letter, requested NRC help. Honey will contact Lubenau with details on their needs. At a minimum, we will provide copies of value impact statements prepared by SD.
7. Technical Advisory Committees and Consultants: Appropriate steps have been taken by California in response to our comments.
8. Incident Responses: The staff stated action was underway to close-out the University of California P-32 incident.

At the conclusion of the meeting, we stated that while some of the comments contained in Ryan's September 17, 1979, letter to Myers needed to be changed or withdrawn, the major portion of them seemed to have been sustained

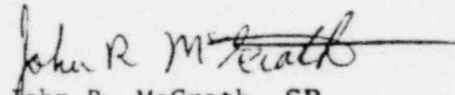
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following this meeting, and that improvements were needed in licensing compliance and management. We stated that additional commitments by the State appeared to be necessary to enact improvements in these areas, including providing adequate ADP services and staffing. Ward responded that staffing will be the key.

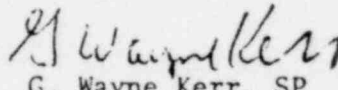
Details of the reviews and discussions held during the meeting are enclosed.



Joel O. Lubenau, SP



John R. McGrath, SP



G. Wayne Kerr, SP

Attachments:

- I. Status of License File Reviews
- II. Status of Comments on Compliance Program
- III. Status of Administration Review
- IV. Status of Other Items

ATTACHMENT I

STATUS OF LICENSE FILE REVIEWS FROM OCTOBER 1979 FOLLOWUP
MEETING & 11/13/79 DISCUSSIONS

General

During Kerr's discussion with California staff on Nov. 13, some generic issues were discussed.

Kerr stated that the regulatory agency's basis for issuing broad licenses is heavily tied to applicant procedures, and applicant criteria for approving users, training, and conducting its radiation safety program. The State generally agreed, particularly for Type A broad licenses but stated that there exists little criteria for training and experience requirements, facility selection criteria and level of detail for procedures. The State also feels a need for some generalized bioassay requirements. Kerr agreed to pursue development of these items with appropriate NRC offices. They also stated that Type B & C broad licenses are tied to regulatory guides. They stated that Type A licensees do need a fairly detailed Radiation Safety manual. They further stated that if broad licensees are authorized to perform specialized activities (e.g., radiography, pool ~~inspections~~, etc.) requirements specific to those operations are imposed on the licensee.

A. X-Ray Products 1878-59

1. The comment regarding the lack of step-by-step procedures remains valid. The State agreed that the applicant should have at least referred to the manufacturer's procedures for handling the equipment.
2. The comment with regard to surveys appears to have been misinterpreted by the State. During the review, no reference to "back-up" surveys was made. Our original comment that there was no discussion in the application of the survey to be performed at the end of each exposure remains valid. The applicant's discussion on surveys was very vague. The State agreed that "greater specificity in operating procedures would have been desirable," but raises a generic question on extent of procedural detail to be required of license applicants.
3. Our comment regarding source exchange should be withdrawn. The licensee stated in his application that devices would be returned to the manufacturer for source exchange.
4. There was no original comment regarding transportation.

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5. Retraining. Although it was true that the applicant did not discuss a retraining program in their application, the State places a condition on all radiography licenses requiring 6-month refresher training. Recent inspections of X-Ray Products confirmed that adequate refresher training was being conducted. Comment withdrawn.
- B. EG&G 0591-59 (Broad License)
1. The State's assertion that "internal approval procedures for users are specified" is correct. However, our original comment was that approval criteria was not specified. The State questions the need for such criteria, assuming that the radiation safety committee will show proper judgment in this area. Kerr agreed with NRC staff comment. State says this is based on knowledge of a small operation, but realizes it authorizes more extensive work. License will be rewritten as a Type B in next few days and tied to License Guide.
 2. Instrument calibration requirements are specified; however, our comment was that procedures were not included. The State feels that the licensees' staff is qualified to perform calibrations and specific procedures are not necessary. Kerr believes procedures need to be detailed if work done by technician level. Also noted judgment on adequacy made by inspector if not covered in license review and therefore less consistency.
 3. Bioassays. Bioassay provisions did not specify frequencies or action levels. The standard tritium condition was on the license and the State did not feel that frequencies or action levels for other isotopes was necessary. State says licensee does ~~coordination~~ coordination work and will be a condition in amended license.
 4. The State's assertion that the licensee planned no liquid effluents was confirmed. Comment withdrawn.
 5. No specific package opening procedures were included in the application; however, a radioactive materials receipt form attached to the application provided guidance. Comment withdrawn.
 6. State agreed that procedures regarding transport were lacking.
 7. State agreed that contamination limits were lacking.
 8. There were no procedures regarding the posting of radiation areas, labeling of containers, storage of waste, and controlling access to restricted areas. State agreed but questioned the significance of this comment since Part 20 type regulation addresses these points. Kerr generally agreed with State except for controlling access but also noted judgment on adequacy then rests on the inspector.

C. Loma Linda University 0060-36 (Broad License)

1. No Pu shipment ban condition on license. State argument not valid.
2. No standard condition limiting human use to physicians. Minor comment, but still holds. Licensee's procedures would limit human use to physicians, but license condition would clarify.
3. Training and experience of committee members was found. Comment withdrawn.
4. State agreed that "approval criteria not well detailed."
5. No frequency of Committee meeting specified. State felt Committee need meet only when necessary, i.e., to review and approve new users and in conjunction with incidents, etc. Broad license committee should meet at least annually. Kerr supported original NRC comment and noted that Committee should periodically review exposures, radiation safety program, etc. State says quarterly meetings may be desirable.
6. Bioassay provisions did not specify frequencies or action levels. (Licensee indicated iodination studies would be performed. Tritium and other isotopes also authorized.) State used same argument as that for EG&G license. (See EG&G introductory comments.)
7. No leak test procedures. State felt that licensee qualified, therefore no need for specific procedures. Kerr believes needed if done by technician. See EG&G comments 2. Reg. Guide 10.5 notes these should be submitted.

D. Alpha Omega 2641-70

State agreed with comments.

E. Gammaceutics Corp. 3416-07 and 3458-07 MD

1. No package description, i.e., shielding of vial, etc. State assertion regarding commitment to DOT requirements not relevant. State should have evaluated package for handling and storage by user as per 10 CFR 32.72 (a)(3).
2. Distribution authorized on manufacturing license. This was not an NRC comment. In any case, distribution was not authorized on the manufacturing license.

F. Southwest Nuclear 2873-60

1. Comment regarding solvent filters was not an NRC comment.
2. Changing of airstream lint filters no radiation problem.
Comment withdrawn.

G. Beverly Hospital 0566-70 (not a broad license)

1. Pacemaker authorization did not specify a user. State agreed.
2. Duties of the Committee not specified. State contends that they may have been "purged" from the file. Also they stated that the application has a parenthetical statement indicating that the composition and duties of the committee are described in the medical licensing guide. This does not appear adequate to tie them to the guide. State agrees.
3. The State agreed that calibration procedures were missing from the files.
4. Information on training of physicians was not in the file. The State said that such information was probably purged. State position is that since users are named, background statements not needed. Ward agreed to that if there is a match against specified criteria, as is normally the case with medical. Kerr stated that description of facilities, description of radiation safety program and description of training and experience are three key elements of license application and therefore preferred to retain T&E in file.
5. The facility description was not in the file.
6. Package opening procedures were not in the application. The State argued that since the regulations require these procedures, it is not necessary that they be included in the application. Kerr noted that 20.205 is specific in some aspects but not on opening procedure.
7. Laboratory rules and emergency procedures were available in the file. However, they did not appear to be part of any application or any particular correspondence so they could not be tied to the license.
8. Survey procedures were inadequate. Surveys of the entire nuclear medicine area were to be performed only every two to three months. State agreed this was probably not adequate.

9. With regard to the use of radium for brachytherapy, it was agreed that complete inventory control procedures were not necessary because sources were obtained from outside on a rental basis. Instructions to nursing personnel were available, but as with the laboratory rules and emergency procedures, they were not a part of an application or any particular correspondence. Kerr and State staff could not determine the mechanism of how material was placed in file but noted it was available therein. In addition, there was no information regarding surveys of patients or patient rooms.

H. Wilshire Oncology Group 0268-70

1. The 1978 renewal application was available in the file.
2. The file did not contain approvals from all hospital administrators (12). The State said that all approvals had been there but were probably purged from the files. Six hospitals were added to this license after June, 1976. Other documentation was in the file going back to 1976 and before. The State's assertion does not appear to be valid. State emphatically stated such authorizations are always obtained.
3. With regard to the teletherapy facility description, the following comments were made: no shielding calculations were provided, no patient viewing system described and no door interlocks described. State says shielding was evaluated in connection with a high energy accelerator application and that these items are a documentation problem.
4. The State agreed that emergency procedures were lacking.
5. Regarding brachytherapy safety procedures, the application was deficient in not indicating the location of the storage room and not providing information on the transport of the sources between hospitals.
6. No leak test procedures were provided. State agreed.
7. The licensee has not yet submitted the initial survey report for the teletherapy facility.

I. LMH, Inc. 3452-07

State agreed with comments.

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J. Nuclear Products 0637-70

1. State misinterpreted NRC comment regarding airborne activity. Comment was: no estimate was made of potential levels of airborne polonium to determine what protective measures would be appropriate.
2. State agreed that surface monitoring could be more frequent.

K. Diagnostic Radiopharmaceuticals 3391-30

1. Daily checks of dose calibrator were discussed. However, full calibrations should have been required.
2. State agreed emergency procedures were lacking.
3. Although all employees are required to monitor shoes, clothing, and hands upon every exit from laboratory, the State should have required surveys of the lab including contamination surveys. The State agreed.

L. J. L. Shepherd 1777-70

1. With regard to expiration, State agreed that with problem licensee, State should require complete renewal before issuing further amendments. State indicated preliminary review of renewal application showed major problems and these have not yet been resolved.
2. With regard to radiography authorization, the State authorized this basically because they have confidence in the licensee's abilities. They agreed that they probably should have at least required him to commit to following equipment manufacturer's procedures. NRC would probably have required much more.
3. With regard to device sheets, State has requested resubmission of information. Essentially agreed with our comments.

M. Kevex Corporation 1655-50

Although there is some disagreement as to the significance of our comment, the State will be issuing a corrected catalog sheet.

ATTACHMENT II

STATUS OF NRC COMMENTS ON COMPLIANCE PROGRAM

NRC Letter (General Comment)

Compliance activities: although the backlog of inspections has been reduced since the last review, our accompaniments of the State inspectors and review of selected compliance files revealed significant deficiencies in the compliance program. In several instances, the inspections are not complete and inspectors are not covering important health and safety items in the inspection (~~see enclosure~~).

CA Response

B. Compliance Activities

We believe that our compliance program is effective and assures the health and safety of workers, patients and the public. Our inspectors are all capable, thoroughly experienced, and conscientious, and we believe the inspections they perform cover all significant matters. There are some weaknesses in report format and documentation which we intend to rectify within the coming months.

Status

Uniform documentation practices are needed. Constant correspondence practices need to be established. Better supervisory review of reports and correspondence and insistence upon adherence to minimum acceptance standards is needed. Accompaniments of all inspectors on a regular basis by the supervisor is needed to verify acceptable performance. There is also a need for improved management oversight perhaps answerable, in part, by an audit program.

NRC

1. Some inspections are not complete. Inspectors have missed important items such as review of many types of health and safety-related records, review of safety committee meeting minutes, and in general safety items were not fully discussed with the licensee.

CA

1. Personnel exposure records are reviewed comprehensively. Other records are examined to the extent called for by the nature of the licensed operations, and we believe that the inspector's judgment may be relied on. Any safety items noted are discussed with the licensee. It would be helpful if the NRC could be more specific about the important items missed and the failure to discuss.

POOR ORIGINAL

Status

Documentation practices are inadequate to show that all important items have been covered or that inspections are complete. State believes all important items are covered by inspectors but independent review of file material by supervisor would be unable to confirm this. This supports the need for more supervisory accompaniments. NRC questioned the adequacy of a one-day inspection of a large broad license (Loma Linda).

NRC

2. Citations not always issued when violations are noted or not recognized as necessary by the inspector.

CA

2. For a period of time in FY 1978-79, Department of Occupational Safety and Health (DOSH) inspectors were attempting to comply with OSHA directives calling for issuance of formal citations only on matters which had a demonstrable direct effect on health and safety. During this period, all health and safety items were noted and specified in requirement correspondence, but use of the formal Notice of Violation was often foregone. All health and safety items were followed-up on just as if they had appeared as formal citations. In order to achieve a desirable degree of program wide uniformity, uniform enforcement procedures were developed and incorporated as terms of the contracts between the Department and the contract inspection agencies which became effective July 1. These procedures require formal citation except under exceptional circumstances. With respect to the asserted failure of an inspector to recognize a violation, we suspect that this may rather be a matter of differing interpretations of regulations between California and the NRC.

Status

The NRC comment reflected one file case. It does not reflect a major problem in this review and should be withdrawn.

NRC

3. Inspectors not following up or are not aware of previous items of noncompliance.

CA

3. We believe that our inspectors do follow-up on significant prior items of noncompliance. Some inspection report formats do not call this out explicitly, however, and we intend to revise them to do so.

Status

The NRC comment stands based in part on one accompaniment and several file reviews. It was agreed that an independent review of file material by supervision would not allow confirmation by supervision that inspectors do pursue these items as State staff indicated is done. Inspectors also need to specifically identify to the licensee that they are following-up and closing out previous violations.

NRC

4. There is some evidence that inspectors are not discussing results of inspection findings with management. Some improvement was noted, however, over past reviews regarding this item.

CA

4. Inspection findings are always discussed with a licensee representative, who may be the Radiation Safety Officer (RSO) rather than a member of management. The RSO, however, is the specified delegate of management for radiation safety. Direct reporting to management would appear unnecessary in many instances, but is invariably done when achievement of compliance appears to require it. In any case, compliance is invariably achieved.

Status

The NRC comment is withdrawn as not being a current problem. Original comment was based on older inspections. However, it was agreed there is a need to better document such discussions.

NRC

5. Inspectors are not interviewing or observing employees during their performance of duties.

CA

5. Inspectors can hardly carry out an inspection without interviewing or observing employees, and so it is difficult to understand this comment. It might be helpful to have a more specific statement of the alleged shortcoming.

Status

We did not agree with California's response but agreed that it is not evident from present inspection reports that interviews and observations are being done and the supervisor should accompany all inspectors to verify it is being done and in an adequate manner. In November 13 meeting, Kerr explained that we did not doubt that discussions were held with some employees but stressed need to talk to persons handling material. State says this is a documentation problem and Kerr indicated if so, shows need for better supervisory review of reports.

NRC

6. Inspectors need to improve those aspects of their inspections related to licensee implementation of sections 30254 and 30280 of the State's Radiation Regulations, such as checking on licensee instructions to workers, posting of notices to workers, and posting of enforcement correspondence.

CA

6. Since instructions and posting are a normal concern in our inspections, this comment is difficult to interpret, as to what, specifically, was observed and considered inadequate.

Status

The NRC comment stands.

NRC

7. Inspectors not reviewing the licensee's survey instrumentation and calibration procedures for compliance with regulatory requirements.

CA

7. Licensee's survey instrumentation is normally checked for proper functioning by comparison with inspector's instruments. Except for industrial radiography, there is no specific regulatory requirement for calibration. Consideration will be given to the desirability of such a requirement.

Status

The NRC comment is withdrawn as relates to compliance activities. This appears to be related to a problem identified in licensing in that specific procedures are not required at licensing stage.

NRC

8. Necessary enforcement letters are not always being sent to licensee management.

CA

8. Enforcement letters are most often directed to the RSO, but are directed to management when that appears necessary.

Status

The comment stands. NRC practice is direct all enforcement correspondence to management.

NRC

9. In some instances, enforcement language in letters of transmittal is not appropriate.

CA

9. We believe that enforcement language now used is entirely appropriate. We assume this comment is referring to the sometime DOSH practice of expressing requirements without use of formal citation language.

Status

The comment stands in that the desired language is not contained in the transmittal letter but rather in an attachment. The comment does not constitute a major problem area.

NRC

10. Language used in State letters of acknowledgement of licensee response to enforcement letters is not appropriate.

CA

10. If this reference is to the fact that in the past some acknowledgement letters indicated acceptance of the licensee's description of his corrective actions as evidence of actual compliance, our inspection staff has been cautioned in this matter.

Status

The comment stands.

NRC

11. Inspection report format is not adequate as a complete inspection report, especially for complex or broad programs. The format is too brief and we were unable to determine the scope of the inspection or depth of coverage of the inspection for a particular item.

CA

11. The usual practice of an inspection of a large program is to supplement the usual inspection format as necessary.

Status

The comment stands.

ATTACHMENT III

ADMINISTRATION REVIEW

Status of NRC Comments on Administration.

NRC

1. Staff meetings were reported to be conducted. Minutes of such meetings were not available. If assignments are made during such meetings or new policies established, there should be documentation of such items and distributed to appropriate staff.

CA

Administration

1. The licensing staff does meet as a "review committee" for the more complex licensing actions and device reviews. Other technical and administrative matters are also considered at these meetings. The informal nature of these meetings is probably best accounted for by the fact that this is a small group of seven or eight people working in close association with one another in the same office. We do, however, intend to implement the notion of using an annotated agenda as a means of formally recording our conclusions.

Status

The comment stands. Ward agreed there is a need to document decisions and assignments arising out of such meetings and following through on them.

NRC

2. Lines of supervision appear to be broken or not clear. In order to obtain administrative information on the program, our reviewer had to go to several individuals to obtain the information.

CA

2. Management of the review workload has required that supervisor undertake review assignments. Additionally, staff vacancies have created gaps in the management information system. These factors, when coupled with efforts to minimize the impact of NRC review on operations here by directing reviewers to the person having primary responsibility for development of the information requested, may account for the observation with respect to lines of supervision. As a partial remedy, supervisors have been relieved of their review assignments. Further, we are assured that the professional and clerical vacancies in our administrative unit will be filled shortly.

Status

State does not feel NRC comment was applicable to any health and safety matters, but rather to administrative matters such as staffing, budgeting, etc. NRC followup review of 10/24-26 indicates original comment was mis-stated and should have related to lack of tracking systems, feedback and followup procedures. Ward will implement procedures to correct this.

NRC

3. Supervisors from the Sacramento office have not accompanied any inspectors since the last review.

CA

3. Inspection accompaniments are made by inspection agency supervisors and by the RHS supervisor of compliance from the Berkeley office.

Status

The comment is incorrect. Mott has accompanied ^{one} Health Department inspectors; one from the L.A. County Health Dept. and one from DIR. It was agreed that Mott or the appropriate agency supervisor will accompany all inspectors yearly and Mott will accompany all inspectors at least every two years.

NRC

4. The use of the computer for storing and retrieving program information is not being fully used. For a complex program such as California, we believe data processing capability would be very beneficial to the management and staff. Information can be retrieved for issuing renewal notices, scheduling inspections, follow-up on compliance cases, and distributing technical and regulatory information to selected groups on an as needed basis.

CA

4. We agree.

Status

California's response did not indicate any corrective action. The State's computer service is not adequate. Reportedly high personnel turnover has had a serious adverse impact upon the quality of the service. This item requires further response from California. During the Nov. 13 meeting Ms. Myers agreed to pursue this matter with appropriate State offices.

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NRC

5. Written procedures are unavailable for calibrating survey instruments and recording results of these calibrations.

CA

5. The compliance inspection reporting format will be amended to require identification by make, model number, and date of last calibration for every instrument used for radiation measurements. A uniform procedure for instrument calibrations and records thereof will be established by January 1, 1980.

Status

State has responded satisfactorily.

NRC

6. Timely license renewal procedures are in use; they are, however, verbal rather than written.

CA

6. Administrative procedures for timely license renewal are working rather smoothly as has been the case since their adoption in 1962. Written procedures are included in the clerical procedures manual.

Status

The comment was not warranted and is withdrawn.

NRC

7. Supervisors need to perform thorough reviews of staff licensing evaluations and inspection reports to assure that the license reviewers and inspectors are covering all important aspects of the licensee's program by using State guidelines. All but one of the compliance files selected for review indicated no supervisory review. We recognize the staff efforts towards improving licensing activities through the use of a "committee review" of complex licensing actions and territorial assignments of licensing reviews to staff members.

CA

7. Inspection reports are reviewed by both inspection agency supervisors and the RRS compliance supervisor. Clearer identification of such review will be made on future reports. Licensing actions will receive more frequent re-review of applications and subsequent license documents by supervisors in addition to the current editorial review as part of our

quality assurance program. We also expect that the recently adopted requirement for "committee review" of all authorizations for Type A quantities will sharpen our hazard evaluations of these applications.

Status

It was agreed better supervisory review and insistence upon reports and correspondence meeting acceptance criteria is needed. New contracts with the contract agencies permit the Radiologic Health Section to withhold payment for unacceptable reports. Record-keeping practices to show supervisory review have been started. An audit program of licenses issued will be initiated. The "committee review" will consist of all license reviewers meeting to review proposed major licensing actions in which the license review must defend his decision to recommend issuance of the license. In addition to Type A quantity licenses, source and device evaluations, broad licenses and other major licenses will be included. A sampling of other license issuances will be reviewed by Honey and the Licensing Supervisor.

NRC

8. U. S. Nuclear Regulatory Commission correspondence to the department requesting agreement material information is many times unanswered. Nine such requests dating from 1977 still remain unanswered.

CA

8. We have adopted an internal correspondence tracking system which should prevent recurrence of this difficulty. We would appreciate copies of unanswered correspondence where such material is still relevant.

Status

A copy of all the unanswered correspondence was given to Ward and replies will be prepared.

ATTACHMENT IV

OTHER ITEMS REVIEWED AND DISCUSSED

NRC comments, the State's response, and the present status of items other than licensing, compliance and administration follow:

NRC

4. The number of technical personnel administering the agreement materials program, in terms of staff years, was reported to be 15.3 staff years. Based upon the number of agreement materials licenses this is equivalent to 0.8 staff year per 100 licenses. The NRC recommended value is on the order of 1 to 1.5 staff years per 100 licenses for an average size program. In comparison with the other Agreement States, California is one of the larger programs with above average numbers of complex licensing actions and facilities within a large geographical area. The present staff effort represents a decrease compared to last year's reported value of 17.5 staff years and 0.95 staff years per 100 licenses.

CA

Item 4. Staffing

With regard to your recommendations on staffing, I regret that your workload data is rather subjective and fails, therefore, to suffice for our program design base. We do agree that additional staff is necessary and are in the process of obtaining approval.

Status

The State staff felt additional guidance is needed from NRC on how to account for time to be charged to the radioactive materials program; lacking such guidance, staffing figures are inexact. Nonetheless, NRC staff feels the program is seriously understaffed, especially in licensing. The staffing figure is probably understated since no adjustment made for California's practice of issuing only single licenses to licensees (as a result of the fee system).

Nonetheless, the Radiologic Health Section staff agreed that more professional staff is needed. Indeed, Ward concluded, at the end of the October 24-26 meeting that increased staff in the key, in his opinion, to enacted improvements he agrees are needed in the radioactive materials program. During the Nov. 13 meeting Kerr stated the State needs a minimum of 20 professional person years in the materials program. Ward is to prepare a paper for Ms. Myers to take to the Finance Dept. to address the staffing problem and possible ways of funding new positions which will likely involve adjustments to the fee program.

NRC

5. Training: Based upon a program effort of 15 staff years, the level of formal technical training was found to be about 0.03 staff years. This level of training is significantly below the NRC-recommended level of 5 to 10% of the program effort, i.e., 0.75 to 1.5 staff years.

CA

Item 5. Training

I agree additional training would improve the program. We are sending personnel to your courses for such training. The lack of training you cite was due, in part, to vacancies in the program.

Status

Out-of-State travel restrictions also affect the State's ability to take advantage of training opportunity and this needs to be addressed. When special workshops and symposia are developed on short notice that are pertinent to the program, the State must substitute attendance at these in place of attended scheduled courses. In view of today's fast-changing regulatory scene for radioactive materials (e.g., uranium mill tailings, radioactive wastes) this policy has a serious, adverse impact upon the training for the staff.

Ms. Myers will address the problem of out-of-State travel restrictions with other State officials. Kerr was given other suggestions on alternatives to the current NRC training program.

NRC

6. Regulations: The State's Radiation Protection Regulations were last updated in 1974, except for the section equivalent to the NRC's Part 19 which became effective in 1976. Our review this year finds that additional effort is needed for completing the revision.

CA

Item 6. Regulations

Regulations have been drafted for some time now. The Section staff has been asked by the Budget Section to make an economic analysis of these proposed regulations. This analysis will be complete by December 1, 1979. If your staff has completed a similar analysis, we would greatly appreciate your help.

Status

We will provide the State with examples of SD value impact statements for proposed rule changes. Honey is to also provide details on this request and we will try to respond.

NRC

7. Technical Advisory Committees and Consultants: Although the staff informed the reviewers that the members of the Medical Advisory Committee have been reappointed as recommended in the last review, the staff advised that the Committee has not held any formal meetings since the last review nor has it been used as a Committee. We understand that the staff does consult with individual members and that a consultant has been appointed as an adviser to the staff on medical matters.

CA

Item 7. Advisory Committee

We agree that it is appropriate to convene a meeting of the Medical Advisory Committee, recently reappointed. Applications and guidance for medical uses need updating. That meeting will be set for the current year, as the availability of the members dictates.

Status

The State has taken satisfactory action on this.

NRC

8. Incident Responses: From the files reviewed, the response to incidents in general appear to be handled in an appropriate manner. One incident, however, involving the contamination of a student with phosphorous 32 at the University of California remains open.

CA

Item 8. Incident Response

We have again contacted the University of California for the information needed to close the file with which you are concerned. We are promised the matter will be resolved shortly.

Status

The staff stated positive steps are being taken to close this matter and they are not waiting upon a promise.