

DATED: DEC 23, 1994;

SIGNED BY: RICHARD L. BANGART

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

Dear Ms. Belshe:

This is to transmit the results of the Nuclear Regulatory Commission's (NRC) follow-up and the special sealed source and device (SS&D) program reviews and evaluations of the California radiation control program. The NRC follow-up review was conducted by Mr. Jack Hornor, Regional State Agreements Officer, and Ms. Beth Prange, Senior License Reviewer, both from the Walnut Creek Field Office, Region IV, and concluded with discussions with Mr. Ron Joseph, Chief Deputy Director of Operations, Department of Health Services on February 1, 1994. The special SS&D program review was conducted by Mr. Jack Hornor, Mr. John Lubinski, Mechanical Engineer, and Mr. Thomas Rich, Mechanical Engineer, both from the Office of Nuclear Material Safety and Safeguards (NMSS) and concluded on March 3, 1994 with discussions with Mr. Edgar Bailey, Chief, California Radiologic Health Branch, and his staff.

Following our January 1993 routine review, we withheld findings of adequacy for the State's program for regulating agreement materials and compatibility with the regulatory programs of the NRC until the State's regulations had been revised and improvements had been made in the State's inspection program and enforcement procedures. The purpose of the follow-up review was to determine the effectiveness of the State's actions to address the recommendations from the 1993 review and to assess the current status of the State's program. The purpose of the SS&D review was to evaluate the adequacy of the State's product evaluation program.

As a result of the follow-up review, we were pleased to find major improvements in the California program for controlling agreement materials with regard to deficiencies noted during the January 1993 review. The establishment of a special radiation control fund has contributed to solving many of the problems we found during our January 1993 review by enabling the Department to fully staff the radiation control program. In the absence of additional findings that resulted from the special SS&D review conducted in early March, the California program would have been adequate.

However, the finding of compatibility continues to be withheld because of regulations which have not been adopted within the three-year period required by the NRC. Status and Compatibility of Regulations is a Category I Indicator. California, at this time, has four regulations which have not been adopted within the three-year period required by the NRC. These rules are:

- "Decommissioning Rule," 10 CFR Parts 30, 40 and 70 amendments which were to be adopted by July 27, 1991.

- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments which were to be adopted by April 7, 1993.
- "Safety Requirements for Radiographic Equipment (alarming dosimetry requirement)" 10 CFR Part 34 amendment and was to be adopted by January 10, 1994.
- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and was to be adopted by October 15, 1994.

We understand that the decommissioning, the emergency planning, and the radiographic equipment rules have been submitted to the Health and Welfare Agency, the Department of Finance, and the Office of Administrative Law as required by the promulgation procedure. Because uniformity among regulatory agencies is an important part of the Agreement State program, we ask that you follow and expedite the progress of these regulations and advise us when they become effective.

During March 1-3, 1994, a special in-depth review of the California SS&D evaluation program was conducted. From the NRC review, a number of significant findings were noted in the overall SS&D evaluation regulatory program. These findings identified concerns in the evaluation of specific devices and in the general SS&D review process. As a result of this review, we have withheld a finding of adequacy, at this time, and have identified comments and recommendations which are set out in Enclosure 3. We request specific responses from the State on these comments and recommendations, and the development of a plan to address them, as discussed below, within 30 days of this letter. Once we receive and review the plan to address the comments and recommendations in the SS&D regulatory program, and have an opportunity to evaluate the actions taken to implement the plan, the NRC will reevaluate the withholding of adequacy to protect public health and safety. We recognize the delay in our issuance of this letter; if you require more than 30 days to respond, please let us know.

We would like to stress that the withholding of a finding of adequacy is not a finding that the State's program is inadequate to protect the public health and safety. Rather, it is a finding identifying a need to improve performance of a State's program in the areas specified which, if not addressed by the State, could lead to an inadequate program. Therefore, these findings carry potential public health and safety implications, but do not represent an immediate threat to public health and safety.

We recognize that the California staff has identified some special circumstances surrounding the SS&D regulatory program review. As you requested, the NRC staff has informed the Commission of your concerns as addressed below.

First, although different from the recollection of certain NRC staff, California radiation control program staff has indicated that it was told that the special in-depth SS&D program review was only for NRC information gathering purposes and that it was not informed that the results would be used for the determination of program adequacy. In this regard, we note that the normal practice of sending an advance announcement identifying the purpose of the review to the State, was not followed in this case. We acknowledge this may have contributed to a misunderstanding. Second, while the NRC staff believes that the current NRC guidance used in the review was provided to the

State of California in equivalent form on an earlier occasion, California radiation control program staff indicated that the review criteria used by NRC are new and were not provided to the State in advance of the review.

In addition, California radiation control program staff expressed strong disagreement with the significance of the findings. We provided a summary of review findings at the conclusion of the review to radiation control program staff on March 3, 1994. This was followed on April 13, 1994, by a written summary of the factual findings from the SS&D review as requested by the radiation control program staff. This allowed the radiation control program staff an opportunity to provide comment on the review findings. While NRC has not yet received a response, we continue to welcome your written comments.

The safety significance NRC associates with SS&D reviews and the results of similar in-depth evaluations in other Agreement States may add some further perspective to our decision to withhold the finding of adequacy based on the results of this special review. Given the potential for large radiation exposures to workers or members of the public if certain devices containing radioactive materials fail, NRC strengthened its process for the review of such devices over the last several years by supplementing the traditional health physics review with mechanical engineering and material compatibility reviews. This enhanced review approach was described in a training workshop conducted in 1991 for Agreement State reviewers and in the guidance distributed at that workshop. The potential serious consequence of a device failure was underscored in 1992, when a radioactive source wire breakage at Indiana Regional Cancer Center, Indiana, Pennsylvania, initiated a series of events that led to the unfortunate death of a patient receiving high dose rate brachytherapy treatment. Accordingly, NRC initiated a series of in-depth evaluations of Agreement State SS&D review capabilities, that included the review of the California program. Those in-depth evaluations were conducted in six Agreement States; those Agreement States perform approximately 80% of all SS&D reviews conducted by Agreement States. In all of those Agreement State SS&D program evaluations, the findings were linked to NRC's determination of program adequacy. The significant comments generated from the in-depth SS&D evaluations led, or likely will lead, to the withholding of the finding of program adequacy for three Agreement States (including California). In the other Agreement States, the comments generated by NRC reviewers were not judged to be significant, or immediate action was initiated to address program weaknesses, and a determination of program adequacy was made.

Together with our assessment of how we have handled SS&D program in-depth review findings in other Agreement States, we have considered the special circumstances, California's concerns and whether they are of sufficient significance that they should affect our withholding of a finding of adequacy. We also recognize that any in-depth review may have the appearance of using higher standards of performance than in the past. It is unfortunate that the timing of the special SS&D review was such that the program improvements noted in the February follow-up review may receive less recognition. Although these circumstances and concerns have merit, we believe, on balance, that the finding of adequacy should be based on the results of the review, rather than on the special circumstances surrounding the review. This belief primarily results from the safety significance associated with SS&D reviews performed by NRC and Agreement States. Therefore, the finding of program adequacy is being withheld.

The primary focus of the follow-up review, as noted earlier, was deficiencies from the 1993 routine review in the nuclear materials area. Given the fact that previous reviews did not identify any significant issues, no in-depth review of the California low-level waste program was performed during this follow-up review. The 1994 follow-up review of the California Agreement State program identified deficiencies in one area of the nuclear materials program, the SS&D evaluations. These deficiencies are not associated with the adequacy of the California low-level waste regulatory program. A summary of NRC's previous assessment of the adequacy and compatibility of California's low-level waste regulatory program is contained in the June 11, 1993 letter from Hugh L. Thompson, Jr. to Edward Hastey (Enclosure 4).

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the follow-up review findings which were discussed with members of the California Radiologic Health Branch. The status of the low-level waste program administered by the Environmental Management Branch was also discussed briefly during the follow-up review, see Enclosure 2.

I appreciate the courtesy and cooperation extended to the NRC staff during the review. We view this cooperation as indicative of how the two agencies can work together. While we recognize the different views that exist between the

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State of California and NRC about the SS&D program evaluation, it appears that resolution of the findings will contribute to an improved radiation control program within the State of California.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
Dr. Larry Barrett, Chief
California Food, Drug and Radiation Division
Dr. Harvey Collins, Chief
California Drinking Water and Environmental Management Division
Edgar Bailey, Chief, California Radiologic Health Branch
Charles Imbrecht, California Liaison Officer

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bcc w/encls:
The Chairman
Commissioner Rogers
Commissioner de Planque

Distribution: See next page.

*See previous concurrence ** By telephone G:\CHM\94LETTER.CA2

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NME	JHornor:dr	Montgomery	CMaupin	PLohaus		
DTE	6/6/94* 9/22/94**	6/7/94* 9/27/94*	6/8/94* 6/27/94* 7/20/94* 9/6/94* 9/20/94* 10/13/94* 11/22/94*	06/27/94* 7/25/94* 9/6/94* 9/20/94* 10/15/94* 11/22/94*		
OFC	NMSS:D	OGC	OSP:D	DEDS	EDO	
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor	
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DKunihiro, RIV/WC
DCD (SP01)
California File

PDR (Yes_X__ NO___)

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 May 28, 1992, as an NRC Policy Statement. The Guidelines provide 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 and is compatible with the NRC's program. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety and that the need of improvement in particular program areas is critical. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. No significant items will be left unresolved over a prolonged period. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. If the State program does not improve or if additional significant Category I deficiencies have developed, a staff finding that the program is not adequate will be considered and the NRC may institute proceedings to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended.

Enclosure 1

SUMMARY OF FOLLOW-UP REVIEW OF
THE CALIFORNIA RADIATION CONTROL PROGRAM
JANUARY 29, 1993 TO JANUARY 28, 1994

SCOPE OF REVIEW

As a result of our January 1993 review of the State's radiation control program and the routine exchange of information between the Nuclear Regulatory Commission (NRC) and the State of California, findings of adequacy for the State's program for regulating agreement materials and compatibility with the regulatory programs of the NRC were withheld until improvements were made in three Category I indicators, Status and Compatibility of Regulations, Status of Inspection Program and Enforcement Procedures. A follow-up review was conducted to evaluate the effectiveness of the State's corrective actions in those and six Category II indicators and to determine the current status of the State's program. The review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs.

The follow-up review with State representatives was held during the period January 18, 1994 through February 1, 1994 in Sacramento, California. The State's program was reviewed against the nine program indicators, three Category I indicators and six Category II indicators, found to be deficient during our January 1993 program review. In addition, the follow-up review included visits to two regional offices, inspector field accompaniments and review of the status of the low-level waste program.

Selected license and compliance files were reviewed by Jack Hornor, Regional State Agreements Officer (RSAO), assisted by Beth Prange, Senior License Reviewer, both from the Walnut Creek Field Office, Region IV. Prior to the follow-up meeting, Mr. Hornor visited regional offices in Los Angeles County on November 22, 1993, and in Orange County on November 23-24, 1993. During this period, he accompanied two inspectors during field inspections.

On February 1, 1994, a summary meeting regarding the results of the follow-up review was held with Ron Joseph, Chief Deputy Director of Operations, Department of Health Services.

A special in-depth review of the California SS&D program was conducted during the period March 1-3, 1994. This aspect of the review focused on California's administrative procedures, rules, certificates issued during the last two years, and staffing aspects of the SS&D regulatory program. The purpose of the review was to evaluate the adequacy of the SS&D regulatory program. The detailed results of this review are contained in Enclosure 3.

The review was conducted by Mr. Jack Hornor, Regional State Agreements Officer, Region IV Walnut Creek Office, Mr. John Lubinski, Mechanical Engineer, Office of Nuclear Material Safety and Safeguards (NMSS) and Mr. Thomas Rich, Mechanical Engineer, NMSS.

The summary meeting for the SS&D review was held on March 3, 1994 with Mr. Edgar Bailey, Chief, California Radiologic Health Branch and other members of his staff.

CONCLUSION

As a result of the follow-up review, the special in-depth SS&D review, and the routine exchange of information between the NRC and the State of California, we are withholding, at this time, findings of adequacy to protect the public health and safety and compatibility with NRC's regulatory program. The finding of program adequacy is being withheld because of significant comments in the Category I Indicator, Adequacy of Product Evaluations. A finding of compatibility is being withheld because of regulations which have not been adopted. California, at this time, has four regulations which have not been adopted within the three-year period required by the NRC. Status and Compatibility of Regulations is also a Category I Indicator. The State's rules for decommissioning, emergency planning, and personnel monitoring for radiographers have been submitted to the Health and Welfare Agency, the Department of Finance, and the Office of Administrative Law for final approval, but they have not been adopted. In addition, since the follow-up review was conducted, the regulation concerning the notification of incidents, which was to be adopted by October 15, 1994, has become due.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

1. Status and Compatibility of Regulations (Category I)

The issue addressed in the following comment has not been satisfactorily resolved and remains open.

Guideline Statement

For those regulations deemed a matter of compatibility by the NRC, State regulations should be amended as soon as practicable but no later than three years.

Comment and Recommendation from the 1993 Routine Review

Comment

The review of the State's radiation control regulations disclosed that the State's regulations are compatible with the NRC regulations up to the 10 CFR Parts 30, 40, and 70 amendments on decommissioning that became effective on July 27, 1988. This decommissioning amendment is a matter of compatibility. In a letter dated September 14, 1990, we informed the States that the Commission planned to include a formal comment in its review letters to any State that had not adopted the decommissioning rule by the three year target date, i.e., July 27, 1991.

Recommendation

We understand that the State is awaiting the legislative approval necessary for statutory changes having a financial impact on licensees. We recommend that the State initiate the process of revising regulations with sufficient lead time to meet the required adoption date.

Present Status

The status of the overdue regulation from the 1993 routine review along with other compatibility regulations which have become due since that review were evaluated during the follow-up review.

Enclosure 2

- Decommissioning Rule, 10 CFR Parts 30, 40 and 70 amendments, which were to be adopted by July 27, 1991: Because of the potential financial impact, this rule was previously defeated by the California legislature. However, AB 2202 (Conroy, effective January 1, 1994) mandated the Department implement technical and financial criteria for decommissioning licensed nuclear facilities. The Department has submitted a draft regulation package (R-46-93) for emergency adoption. This draft regulation has been submitted for NRC review.
- Emergency Planning Rule, 10 CFR Parts 30, 40, and 70 amendments, which were to be adopted by April 7, 1993: The Emergency Planning rule is included in the R-46-93 package. The following California licensees require contingency plans under the NRC criteria:
 1. General Atomics, Lic. 0145-80
 2. General Electric, Nuclear Energy Division, Lic. 0017-60
 3. Rocketdyne Division of Rockwell International, Lic. 0015-70
 4. Isotope Products Laboratories, Lic. 1509-70

The first three licensees possess both California and NRC licenses with emergency plans which have been accepted by the NRC. The State references the NRC approved emergency plans in the license conditions of the three licensees. It was verified that amendment 78 of the Isotope Products Laboratories requires a contingency plan. However, the company contends that the release of isotopes in a credible accident would not exceed the NRC criteria. California is reviewing the renewal application and will verify the need for the contingency plan before the license is renewed.

- Safety Requirements for Radiographic Equipment, (alarming dosimetry requirement) 10 CFR Part 34 amendment, which was to be adopted by January 10, 1994: In October 1992, the State revised the regulation to conform to 10 CFR § 34.20 "Performance requirements for radiography equipment." However, the 1992 revision of the California regulation omitted the requirements for alarming dosimeters. On December 21, 1993, the State issued Radiation Safety Advisory 93-5 to all industrial radiography licensees, advising them their licenses were being amended to require alarming dosimetry. The NRC reviewer verified that the licenses had been amended by review of the State's license and incident files (See Appendix A, Part II). The State has also drafted an amendment to regulations to incorporate the alarming dosimeters provision. The amendment has been submitted for approval (R-1-94) and is expected to pass without difficulty.

Since the follow-up review was conducted, another regulation has become due. This regulation is:

"Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) that became effective on October 15, 1991 and was to be adopted by October 15, 1994.

In addition, not pertaining to the finding of compatibility for this review, we would like to bring to the State's attention other regulations which will be needed for compatibility. These rules are:

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- "Quality Management Program and Misadministrations", 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992 and will need to be adopted by January 27, 1995.
- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) that became effective on July 1, 1993 and will need to be adopted July 1, 1996.
- "Licensing Requirements for Land Disposal of Radioactive Wastes," 10 CFR Part 61 (58 FR 33886) that became effective on July 22, 1993 and will need to be adopted by July 22, 1996.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 (58 FR 39628) that became effective on October 25, 1993 and will need to be adopted by October 25, 1996.

2. Status of Inspection Program (Category I)

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Guideline Statement

The State Radiation Control Program (RCP) should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. When backlogs occur, management should develop and implement a plan to reduce the backlog.

Comment and Recommendation from the 1993 Routine ReviewComment

Forty-six Priority 1 through 3 and initial inspections were overdue by more than 50% of their inspection frequency as of December 31, 1992. The number of overdue inspections is expected to increase monthly, and the State has no viable plan to eliminate the backlog without additional staff.

Recommendation

Three root causes for the deterioration of the inspection program were considered in making our recommendations:

1. The Radiologic Health Branch (RHB), already below the recommended staffing level, has been operating throughout the past year with 70% of the authorized inspection staff. Three inspector positions are currently vacant. We understand one candidate has accepted an inspector position, but final hiring papers have been waiting several months for Personnel Office processing. We recommend that every effort be made to fill these positions without further delay.
2. Overdue inspections in Los Angeles and San Diego counties accounted for 38 of the 46 total overdue. We recommend that the State re-evaluate the practice of contracting inspections and investigations to county agencies, and if continued, future contracts should hold the counties accountable for work not performed.
3. The State's inspection schedule is planned around the "overdue date" which allows for a grace period of 50% of the scheduled inspection frequency. By basing the inspection schedule on this overdue date, licensees are actually inspected at a rate that is 50% less than the scheduled frequency. Not only is this contrary to the guidelines, inspections can become seriously overdue when circumstances such as those encountered during this review period force the State to fall behind the already extended inspection schedule. We recommend that the State develop inspection schedules which strictly adhere to the established inspection priority frequencies. The plan should establish target dates and milestones for assessing progress.

Present Status

The State has eliminated the overdue inspection backlog. In an outstanding effort to eliminate the backlog, the State conducted 544 inspections in 1993, and at the time of this review, no inspections were

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overdue. All inspector vacancies have been filled and the contracting county agencies have been notified that corrective action must be taken if they fall behind in scheduled inspections. On January 1, 1994, the State changed the "overdue" definition to those inspections overdue by more than 25 percent of the scheduled inspection frequency and expects to be able to operate with no overdue backlog. The compliance supervisor has projected the number of inspections needed to achieve this goal and monitors the progress of the program monthly. Inspection scheduling is normally planned using the routine inspection frequency. If a inspection backlog were to develop, however, the State might use the "overdue date" for planning purposes.

3. Enforcement Procedures (Category I)

The issues addressed in Comments A and B have been satisfactorily resolved and are considered closed.

A. Guideline Statement

Enforcement Procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Written procedures should exist for handling escalated enforcement cases of varying degrees.

Comments and Recommendations from the 1993 Routine Review

Comment 3.A

Although the State took appropriate escalated enforcement actions in several cases, the review team identified a number of cases which did not result in appropriate escalated enforcement action. In these examples, RHB failed to follow their own procedures in dealing with violations.

1. Issues raised during the renewal of a hospital license triggered an inspection in which multiple items of non-compliance were identified. The licensee challenged the enforcement letter and during a subsequent enforcement conference a requirement for independent audits was reduced to a suggestion. There has been no attempt to verify that independent audits are being made of the hospital, and no follow-up inspection is planned. Within a few months, the hospital was cited for losing Ir-192 seeds. No escalated enforcement action was taken.
2. A licensee was cited for unauthorized possession of Xe-133. After promising to comply, the licensee again received Xe-133 twice within days. After documents refuted the licensee's denials of receipt, a second citation was issued. The regional compliance supervisor twice recommended license suspension following the licensee's failure to comply, failure to appear at hearings, and failure to meet the time commitment for hiring an independent auditor as agreed to during the enforcement conference. No further action has been taken against the licensee and no follow-up inspection has been made to re-evaluate the licensee.

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3. In two investigations, the violation points exceeded the level requiring automatic escalated enforcement action. In both cases the escalated enforcement required the licensee to submit to follow-up inspections. The follow-up inspections were not performed.
4. A radiographer inspection conducted in February 1991 resulted in an enforcement letter citing four "serious" violations. The licensee challenged the violations in the response letter; however, the State did not follow up. Following an inspection conducted in March 1992, the State failed to act when the licensee's response to the enforcement letter did not describe corrective actions to be taken. In June 1992 a serious overexposure occurred at the same company. There is no evidence of escalated enforcement although the severity of the incident exceeded the level requiring automatic escalated enforcement.
5. Improvement in the timeliness of escalated enforcement actions is needed. As an example, a hospital technician performing a reinfusion procedure mistakenly injected the wrong patient with blood containing Indium-111. The incident drew a good deal of media attention and the RHB took appropriate enforcement action. However, the escalated action has been pending approval by the Department of Health Services (DHS) Office of Legal Counsel since November 4, 1992.

All escalated enforcement actions appeared to be the sole responsibility of the Senior Health Physicist, Materials Inspection, who was personally required to prepare every escalated enforcement action for referral. In the first two cases above, in particular, responsibility should have been escalated to management level.

RHB has two procedures for escalated enforcement policy, IPM-88-4, dated October 18, 1988, and the enforcement manual entitled, "Radioactive Materials Inspection Procedures Manual," dated September 6, 1991. Although both of these sources supposedly apply to the same enforcement procedure, they offer different guidance to inspectors. For instance, the 1988 version accurately reflects RHB's current category of four "Classes" for civil penalties. The 1991 version, however, described a system of five "Severity Levels" of violations. In addition, there were inconsistent factors assigned to the correlating categories of violations found in these two documents.

Recommendation

We recommend that the State develop a single, uniform policy for managing escalated enforcement actions. Written procedures to implement the policy should contain action levels triggering specific escalated enforcement actions. The procedures should also provide guidance as to when Branch, Division and Department management should become involved in escalated enforcement.

We also recommend that adequate specialized legal support be provided to the Division so that legal cases and administrative penalties receive

Enclosure 2

prompt action and that management become more involved in the escalated enforcement proceedings.

It was noted that some rare but highly significant cases involved willful violation of the State's statutes. It is recommended that inspectors and supervisors be given training on when a criminal investigation is appropriate, the State criminal code as it applies to RCP, and other related training which would provide a general understanding of law enforcement responsibilities.

Present Status

The State challenged our findings in some of the specific cases cited above. On May 24 and June 6, 1993, Mr. Hornor met in Sacramento with Don Bunn, Chief, Compliance and Enforcement, to re-evaluate the cases. It was decided during those meetings that the State's enforcement procedures needed improvement. The NRC review team reviewed the previously identified enforcement cases of concern and found that the State has now taken appropriate action in each of the cases identified above. This issue is now closed. (See Appendix A, Part I.)

The responsibility for escalated enforcement has been elevated from the senior health physicist to the supervising health physicist of the compliance section.

The State's new enforcement procedures which became effective January 1, 1994, were reviewed and found to be satisfactory.

According to discussions with Branch and Division managers, the turnaround time for legal assistance has improved during the past year, so the Division is no longer seeking their own legal staff. Requests for legal assistance now ask for a 30-day deadline for action.

The supervisors and senior staff have attended an investigations class at the University of California, Davis. The State fully meets the enforcement guidelines.

B. Guideline Statement

Enforcement letters should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection. Licensee responses to enforcement letters should be promptly acknowledged as to accuracy and resolution of previously unresolved items.

Comment 3.B

One county agency had changed the regulatory language in the standard acknowledgement letter, omitting required statements pertaining to the adequacy of the licensee's response and future inspections.

Recommendation

We recommend that a more thorough review of enforcement correspondence be performed to prevent unwarranted deviation from procedure.

Present Status

In the twenty compliance files reviewed, the acknowledgement letters were found to have consistent and appropriate regulatory language which was indicative of a more thorough enforcement correspondence review system. (See Appendix A, Part II.) In addition, the new enforcement procedures provide model enforcement and acknowledgement letters to be followed by all staff.

4. Management (Category II)

The issues addressed in Comments A, B and C have been satisfactorily resolved and are considered closed.

A. Guideline Statement

Program management should receive periodic reports from the staff on the status of regulatory actions (backlogs, problem cases, inquiries, and regulation revisions).

Comments and Recommendations from the 1993 Routine ReviewComment 4.A

1. While reviewing enforcement actions, it was determined that RCP headquarters has no tickler file or other method to ensure planned follow-up inspections are conducted.
2. In two cases, more than 30 days elapsed while completed sealed source and device (SS&D) registry sheets were awaiting supervisory signature.

Recommendation

We recommend that a system be developed to track pending follow-up inspections. We also recommend that monthly status reports be submitted to program management by senior staff and supervising health physicists. These reports should describe open investigations, and matters awaiting signature or other action.

Present Status

1. RHB now provides each compliance office a quarterly compliance-enforcement report which lists the status of all enforcement actions. Follow-up inspections are shown as open items until they are closed out, and each supervisor schedules follow-up inspections from this report.
2. The improved computer system now tracks open license cases, including SS&D evaluations. Each senior health physicist tracks open and completed cases from reports generated daily, weekly and monthly.

B. Guideline Statement

Enclosure 2

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Supervisory review of inspections, reports and enforcement actions should also be performed.

Comment 4.B

California's internal procedures require supervisory review of all licensing actions and inspection reports. However, four of the comments made during this review relate directly to the failure to identify and correct problems during supervisory reviews. Fifteen of the 54 representative samples of licensing actions had deficiencies which should have been corrected during appropriate supervisory review. Most supervisory reviews were performed by senior health physicists rather than the supervising health physicist.

Recommendation

We recommend that supervising health physicists be required to perform a specific number of reviews of cases handled by each senior health physicist. The results should be documented and submitted to the Branch Chief.

Present Status

The supervising health physicist in the compliance section reviews and signs all inspections. He also reviews all incidents, allegations and misadministrations.

The supervising health physicist in the licensing section does not routinely review cases which were reviewed by his senior health physicists. He holds weekly meetings with his staff to discuss complex licensing issues. Decisions made in these meetings are documented by written minutes or by log book.

The State's new policy of assigning license casework to groups which specialize in specific types of licenses has improved the quality of the peer and supervisory reviews. This was evidenced by the quality of casework observed during the review of eleven new licensing actions. (See License File Reviews in Appendix A, Part II.)

The State had some concerns regarding our previous findings pertaining to licensing deficiencies and the supervisory review. A review of the nine licensing files in question was conducted and the issues concerning these files were all resolved during this review. (See Appendix A, Part I.)

C. Guideline Statement

The compliance supervisor should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Comment 4.C

During the two-year review period, nine inspector accompaniments were made by the three senior health physicists. No inspector was accompanied more than once and one inspector was not accompanied at all during the two-year interval.

Recommendation

We recommend that each regional supervisor conduct annual accompaniments of each inspector under their supervision. The results of the accompaniments should be submitted periodically to program management.

Present Status

The 1993 annual accompaniments of each inspector by a supervisor, including those in contracting counties, had been completed at the time of this review. The results of the accompaniments were reported to middle management. The State has agreed to establish a tracking method to ensure each inspector is accompanied annually by a supervisor.

5. Office Equipment and Support Services (Category II)

The issues addressed in Comments A and B have been satisfactorily resolved and are considered closed.

A. Guideline Statement

The RCP should have adequate secretarial and clerical support.

Comments and Recommendations from the 1993 Routine Review

Comment 5.A

According to staff interviews and observations of the review team, typing backlogs have delayed licensing actions and other program functions. At one time during the review period there were over 100 licensing documents waiting to be typed. Personal computers are in the process of being purchased for all technical staff.

Recommendation

We recommend the use of pre-typed templates for different types of licenses, SS&D sheets, and compliance documents to make more efficient use of staff resources. Clerical vacancies should also be filled promptly.

Present Status

All technical staff now have personal computers, and the staff are using updated software, boilerplate documents, and templates to make more efficient use of resources. All but one of the clerical vacancies have been filled, and the typing backlog has been virtually eliminated.

B. Guideline Statement

States should have a license document management system that is capable of organizing the volume and diversity of materials associated with licensing and inspection of radioactive materials.

Comment 5.B

The review team found several problems in the licensing and compliance tracking systems.

1. In two cases licenses had been allowed to expire while apparently still possessing and using radioactive material. Their reinstatement and renewal cost the program lost fees and extra staff effort.
2. The most current RHB tracking report reflected 62 open investigations. However, a spot check of eight incident files disclosed that two open cases had actually been closed. Also, two cases were closed through investigations of subsequent, related complaints but remained in the "open" file. As minor as the problem seems, it is an indicator of a weak tracking and reporting system.
3. Previous data in the licensee data base are deleted each time a new licensing or compliance action is entered. This makes it impossible to study historical trends.
4. RHB has no computer system for tracking or triggering follow-up inspections.

Recommendation

We recommend that the document control problems cited above be addressed in the new computer system presently being designed by RHB staff.

Present Status

The computer document control system is still being upgraded; however, significant improvements were found in the system for tracking licensing and compliance actions.

1. Two months prior to expiration of a license the system generates a notice of expiration which is sent with an renewal application package and termination form to the licensee. If the notice is ignored, the need for action appears on the "open issues" report generated for the senior license reviewers.
2. The computer document control system generates a list of open investigations monthly for management review. Management reviews the list and directs action on any open investigations. The tracking system is updated at the time the investigation is closed. The review of incident and compliance files revealed that investigations are now being adequately closed out. (See Appendix A, Part II.)

3. System analysts are working to change the system to improve the retention of information needed for tracking past compliance histories and trends.
4. Follow-up inspections are triggered by the quarterly enforcement report sent to each agency and regional compliance supervisor.

6. Staffing Level (Category II)

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Guideline Statement

The professional staffing level should be approximately 1 to 1.5 person-years per 100 licenses in effect.

Comment and Recommendation from the 1993 Routine Review

Comment

Throughout the two-year review period, the professional staffing level has been below the minimum guidelines, with the staff/license ratio averaging approximately 0.94. The current figure is 0.92, and if all vacancies were filled, the ratio would be 1.3. The State has been unable to maintain an adequate inspection program, and serious backlogs have developed in the licensing program where 322 renewals are now awaiting action. The review team noted that many deficiencies found in other program indicators related directly to the State's failure to maintain an adequate technical staffing level.

Recommendation

First, we understand candidates have accepted offers for four of the seven open positions, but final hiring has been delayed by the Personnel Office. We recommend that hiring procedures be changed to allow prompt action in filling vacancies.

Second, California is a large State with many complex licenses and sealed source and device evaluations, and thus the higher end of the suggested staffing range, 1.5 person-years per 100 licenses, may be needed to properly administer the program. We recommend that the State staff at the upper limit of the suggested staffing level.

Present Status

Since funds became available on July 1, 1993, the State has been able to successfully correct the staffing problem which had adversely affected their regulatory program. All previously vacant positions were filled as a total of 18 FTEs were hired into technical positions in the RHB and contracting counties. The present radioactive materials staff has 28.5 health physicists or 1.25 FTEs per 100 licenses.

7. Licensing Procedures (Category II)

The issues addressed in Comments A, B and C have been satisfactorily resolved and are considered closed.

Guideline Statement

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice. Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process.

Comments and Recommendations from the 1993 Routine Review

Comment 7.A

California's standard license conditions do not include the NRC condition requiring sealed source physical inventories in medical and radiopharmacy licenses.

Recommendation

We recommend that the State add this requirement as a standard condition.

Present Status

California's standard license conditions now include the following condition, which is added to medical and radiopharmacy licenses as they are renewed or amended:

"The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection."

It was verified by the review of six medical license files that the reviewers are including this condition. (See Appendix A, Part II.) However the senior reviewers were urged to expedite completing the new model licenses containing this condition.

Comment 7.B

In some cases, the final disposition of radioactive material could not be determined in terminated license files. Form 2558 (Request to Terminate Radioactive Material License) was found in some files, but not in others. The State's written termination procedures do not reference this form nor provide instructions on its use. This form, when properly used, ensures that the State is aware of the final disposition of all radioactive material.

Recommendation

We recommend that the procedures be revised to provide guidance for using the form.

Present Status

The termination procedures have been revised to include the use of the termination form, RH2558, "Request to Terminate Radioactive Materials License."

The files of five licenses terminated since January 1994 were reviewed, and all were found to be properly closed out. (Appendix A, Part I.)

Comment 7.C

Although timeliness is not specifically addressed in the guidelines, 48 timely renewals had been pending in-house for two years or more. This comment was noted in our past review and the backlog has increased since that time.

Recommendation

We recommend that supervisors set specific goals for eliminating this backlog, discuss the priorities with the licensing staff and develop a system to track backlogged casework.

Present Status

The licensing backlog has been greatly reduced. No applications for new licenses or amendments are overdue for action and the number of licenses awaiting timely renewal have been reduced from 322 to approximately half. Of the 48 timely renewals that were pending for more than two years during the 1993 routine review, only seven timely renewals were in this category during the follow-up review. These figures include cases awaiting action by the licensee. The new tracking system advises each senior staff person of the current status of each license under his or her charge.

8. Inspection Procedures (Category II)

The issue addressed in Comment B has been satisfactorily resolved and is considered closed. Comment A remains open.

A. Guideline Statement

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.

Comments and Recommendations from the 1993 Routine Review

Comment 8.A

The forms used to inspect nuclear pharmacies are designed for medical licenses. These forms do not cover some elements of pharmacy licenses such as transportation practices. The Northern California regional office adds their own pharmacy supplement to the medical form, but this practice is not uniform. Again, the need to add the transportation element to pharmacy inspections was not identified in supervisory review.

Recommendation

We recommend that specific pharmacy inspection forms be developed and used uniformly.

Present Status

At the time of the review, the State had not added a pharmacy supplement to their inspection forms. Of the three pharmacy inspection reports examined during this review, two omitted the transportation element. (Appendix A, Part II.) The State made a commitment to develop a pharmacy supplement to the medical inspection form during the next full staff meeting and to implement the pharmacy supplement as soon as possible thereafter.

B. Guideline Statement

For States with separate licensing and inspection staffs, procedures should be established for feedback of information to license reviewers.

Comments and Recommendations from the 1993 Routine ReviewComment 8.B

In four compliance files, the review team found no indication in the file that the inspector had notified licensing staff of changes in the licensee's status.

Recommendation

Although the current procedures require inspectors to notify licensing staff when changes are found, a system should be developed to ensure the necessary forms are received and processed by the licensing staff. Also, omissions such as this should be corrected during the supervisory review.

Present Status

The State believes their existing procedures are sufficient to ensure that license reviewers are notified of changes found in the licensee's status during inspections. A copy of Form 2033 is forwarded to the licensing staff at the time of the inspection, and another copy is included in the inspection package sent to the compliance chief. The NRC reviewers agree that the procedures are adequate when used as written, and these documents may have been missing from the files because of the staff shortage and filing backlog that existed during the last review. No concerns of this type were identified during review of the license and compliance files. (Appendix A, Part II.)

9. Inspection Reports (Category II)

The issue addressed in the following comment has been satisfactorily resolved and is considered closed.

Guideline Statement

Reports should uniformly and adequately document the results of inspections including confirmatory measurements and status of previous noncompliance items and identify areas of the licensee's program which should receive special attention at the next inspection.

Comment and Recommendation from the 1993 Routine ReviewComment

Inspection forms are not used correctly and uniformly by all agencies and inspectors. The following deficiencies in the inspection reports resulted from the incorrect or incomplete use of the inspection form.

1. In three cases, there was inadequate documentation that previous items of non-compliance had been closed out. This is a repeat finding.
2. In two cases, there was no evidence that incidents that had occurred since the previous inspection had been reviewed during the inspection. This is a repeat finding.
3. In two cases, violations cited in the enforcement letter were not included in the inspection report.

Apparently none of these deficiencies were identified during supervisory review.

Recommendation

Supervisors should require all inspectors to use the forms in the manner prescribed in the procedures.

Present Status

The review of twenty new compliance files showed marked improvement in the quality of the inspection reports. With the exception of the pharmacy inspection reports discussed above, no problems were found. Previous items of non-compliance and previous violations had been properly closed out, and the enforcement letters agreed with the inspection reports. It was apparent that the inspectors are making a real effort to improve the quality of the reports.

ADDITIONAL REVIEW ACTIVITIES

In addition to evaluating changes made in response to our previous comments and recommendations, portions of the following program indicators were reviewed because of recent changes in policy, personnel, or procedures.

1. Budget

In 1992, the Governor signed Assembly Bill 3626 (Felando), establishing a separate radiation control fund. This bill, which became effective July 1, 1993, mandates fees collected by RHB be used only to support its activities. This special fund is adequate to cover all expenditures

Enclosure 2

necessary to administer the radiation control program and is not subject to the hiring freezes and resource reductions affecting agencies dependent on monies from the General Fund.

The most obvious benefit of this act was RHB's ability to fill staff vacancies and provide a staffing level adequate to successfully maintain the regulatory program. In addition, the availability of independent funds has resulted in improvements in other areas. For example, personal computers have been provided to the technical staff, outdated software has been replaced, and new document control systems continue to be developed; emergency monitoring equipment, protective clothing and respirators have been provided to field staff; field office and key headquarters staff have been supplied pagers or cellular phones for better communication.

2. Technical Quality of Licensing Actions

Eleven additional new license cases were reviewed. The quality of the licenses was very good and no significant deficiencies were found. These findings were discussed with the individual reviewers as well as with management.

3. Inspectors' Performance and Capability

On November 22, 1993, Mr. Jack Hornor, NRC RSAO, accompanied a new Los Angeles County inspector, Barbara Hamrick, during an inspection of Bellwood General Hospital (Lic. No. 1522-70). On November 23 and 24, 1993, he accompanied Orange County inspector, Suzie Kent, during an inspection of St. Jude Hospital, Fullerton, (Lic. No. 0507-30). Both inspectors were thorough, professional, observant, and knowledgeable about regulations and good health and safety practices. The entrance and exit interviews were conducted appropriately and with the highest possible level of management. Ms. Hamrick used good judgement and tact to convince the licensee to voluntarily sign a "User Declaration" to cease the unsafe use of radioactive material in conjunction with afterloading brachytherapy. The inspectors' performances were discussed with their respective supervisors and with the compliance chief.

4. Response to Incidents and Alleged Incidents

The State's 1993 incident log was reviewed, and seven complex cases were selected and reviewed in depth. The State took appropriate action in each case and met the NRC guideline criteria for the reporting and handling of incidents, alleged incidents, and misadministrations. The State promptly evaluated the need for on-site investigations and documented the results. In addition, the State notified its licensees and the NRC of pertinent information about any incident which could be relevant to other licensed operations.

The State's written procedures for handling allegations, incidents, and misadministrations were reviewed. The procedures are contained in the Radioactive Materials Inspection Procedures Manual and are supplemented by a February 11, 1993, memorandum from Don Bunn, Supervising Health Physicist, Enforcement and Compliance, instructing the staff to follow the procedures in the NRC All Agreement States Letter SP-92-165 for data entry, tracking investigations, reporting and closure. Allegations are

treated as incidents and the written procedures provide details on when to investigate, the depth of investigation, the follow through on enforcement when needed, and closeout. Each reported misadministration is evaluated and those exceeding NRC's new criteria specified in the QM rule are investigated immediately if necessary, or at the next inspection. The decision to investigate is determined by the senior health physicist and the supervisor, based on the potential harm to the patient. (All incorrect blood injections or re-use of syringes are immediately investigated.)

5. Low-Level Waste Program Update

On January 18, 1994, Mr. Hornor met with Dr. Harvey Collins, Chief, Division of Drinking Water and Environmental Management, and on January 24 and 27, 1994, he met with Mr. Jack S. McGurk, Chief, Environmental Management Branch, to discuss the status of the State's low-level waste program. The Branch is awaiting the results of lawsuits filed against the Department and the decision of the U.S. Department of Interior regarding transfer of Bureau of Land Management (BLM) land to State ownership before proceeding with program development.

Meanwhile, the low-level waste unit has been kept intact. Due to the reduction in workload caused by Secretary Babbitt's decision not to proceed with the land transfer, personnel have been given assignments to assist other division programs, as time allows. Their primary function, however, is to work on low-level waste issues and to assist in resolving the lawsuits. After the land for the facility is transferred to State ownership, construction of the facility is expected to take approximately a year to complete. The Department plans to use this interim period to hire and train the additional personnel needed for on-site inspection at the facility during its operational phase and conducting point-of-origin inspections at generators' facilities. These personnel will be ready to begin performing their respective duties before the facility begins to receive waste shipments. In addition, the State could also use contractors to assist in the regulatory review of the facility. Although monies have not been designated for contractual assistance, monies could be advanced from the Department of Health's sixteen billion dollar budget.

The Branch furnished the reviewer a written report of the current status of the siting activities.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

On February 1, 1994, Mr. Hornor and Mr. Ross Scarano, both of the NRC, met with Mr. Joseph to discuss the results of the follow-up review. The meeting was also attended by George Rutherford, M.D., Deputy Director Prevention Services; Larry Barrett, DVM, Acting Chief, Food, Drug and Radiation Safety Division; Dr. Collins, and Edgar Bailey, Chief, Radiologic Health Branch.

The State representatives were congratulated on the many improvements found in the radiation control program. The corrective actions accomplished in each program indicator were discussed; however, the State was reminded of the importance of compatible regulations among regulating agencies. Mr. Hornor, with Mr. Scarano concurring, explained that although decisions regarding adequacy and compatibility rest with NRC upper management, he would recommend

the State be granted adequacy. However, because several compatibility regulations had not yet been adopted, a finding of compatibility would continue to be withheld until the NRC is notified the revised regulations are in place.

Mr. Joseph thanked the NRC for their effort to improve the State's program. He indicated he was pleased with the progress his staff had made and that our findings reflected these efforts. He further said the Department is committed to a first-rate radiation control program, and that his staff would work closely with the RHB to ensure that high quality is maintained. He agreed to place more emphasis on promulgating regulations within the three-year time frame. He feels the new computer system that is being developed will improve their methods of identifying problems and projecting program needs.

SUMMARY OF THE SPECIAL SEALED SOURCE AND DEVICE REVIEW OF THE
CALIFORNIA RADIATION CONTROL PROGRAM
MARCH 1-3, 1994

SCOPE OF REVIEW

The special in-depth sealed source and device (SS&D) regulatory program review was conducted during the period March 1-3, 1994. This aspect of the review focused on California's administrative procedures, rules, certificates issued during the last two years, and staffing aspects of the SS&D regulatory program. The purpose of the review was to evaluate the adequacy of the SS&D regulatory program.

The review was conducted by Mr. Jack Hornor, Regional State Agreements Officer, Region IV Walnut Creek Office, Mr. John Lubinski, Mechanical Engineer, Office of Nuclear Material Safety and Safeguards (NMSS) and Mr. Thomas Rich, Mechanical Engineer, NMSS.

The summary meeting for the SS&D review was held on March 3, 1994 with Mr. Edgar Bailey, Chief, California Radiologic Health Branch and other members of his staff.

CONCLUSION

As a result of the special in-depth SS&D review, we are withholding, at this time, the finding of adequacy to protect the public health and safety. The finding of program adequacy is being withheld because of significant comments in the Category I Indicator, Adequacy of Product Evaluations. We would like to stress that the withholding of a finding of adequacy is not a finding that the State's program is inadequate to protect the public health and safety. Rather, it is a finding identifying a need to improve performance of a State's program in the areas specified which, if not addressed by the State, could lead to an inadequate program. Therefore, these findings carry potential public health and safety implications, but do not represent an immediate threat to public health and safety.

STATUS OF PROGRAM

Adequacy of Product Evaluations (Category I)

NRC Guidelines

- A. Radiation Control Program (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.
- B. The RCP should review manufacturer's information on labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.
- C. Approval documents for SS&D designs should be clear, complete and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Comment

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This review focused on California's administrative procedures, rules, certificates issued during the last two years, and staffing aspects of the SS&D regulatory program. The purpose of the review was to evaluate the adequacy of the SS&D regulatory program. A representative sample of new and amended registration certificates issued in the last two years were reviewed for technical quality, accuracy and consistency in the following areas: format, description, labeling, diagram, conditions of use, prototype testing, radiation levels, quality assurance and quality control, limitations of use and the basis for determining that the source or device design(s) was deemed acceptable for licensing purposes. We reviewed State procedures for assurance that the results of the evaluations are consistent and that a second independent review and concurrence are performed. Based on our review of State files and discussions with the staff, the following specific comments are provided for each identified registration certificate(s).

1. CA-380-D-101-G May 10, 1993 CINDI Model N-002

Guidelines A and B above were not met. The specific details are as follows:

- Details of the case design are needed. (Guideline A)
- Fire or accident conditions were not examined. (Guideline A)
- No prototype testing or verification that the device will survive the proposed temperatures it would be subjected too. The ANSI N538 low temperature condition classification contained in the certificate falls outside of the temperature to be tested for the classification of 3. (Guideline A)
- There are discrepancies in the general licensee dose calculations. Using the most conservative radiation measurements taken around the device (2.5 millirem/hr at 30 centimeters, page 9 of registration certificate), the estimated dose to a user could be 600 millirem in one year (60 hours/quarter x 4 quarters x 2.5 millirem/hour). This estimate far exceeds the dose estimate using the neutron flux calculation which is included in the background file. (Guideline A)
- The dose calculations for the device do not include the estimated doses to workers when the device is in storage. This estimate is required by the regulations. (Guideline A)
- There was very little quality assurance (QA) information submitted. (Guideline B)
- The described manufacturing method is questionable. The source is soldered-sealed in lead and then melted into polyethylene. There is a question concerning whether the melting process would have any detrimental effects on the source or the shielding (lead source holder) of the source. (Guideline B)
- This device should be re-evaluated to determine whether it is appropriate to be used under a general license. This is necessary because the design of the device is fragile (polyethylene encasement), the dose rate information appears to indicate that the dose to a general

Enclosure 3

licensee may exceed regulatory limits, the device is portable and it is not equipped with a shutter mechanism. (Guideline A)

2.	CA-510-S-102-S	August 10, 1992	IND1050-1099
	CA-510-S-103-S	August 10, 1992	IND1100-1049
	CA-510-S-104-S	August 10, 1992	IND1150-1199

Guidelines A, B and C above were not met. The specific details are as follows:

- Because of the large range of isotopes in the series, the internal design may be different than just using spacers but this is not reflected in the submittal. An example of such a change may be the capsule having a smaller inner diameter or a different shaped spacer to account for the larger diameter metallic elements. (Guideline A)
- Prototype testing was not performed on the extreme designs of each series of sources nor was there a justification of why the extreme designs would pass the prototype testing. The information submitted concerning prototype testing did not include dimensions of the sources tested. However, the certificate states that the smallest and largest source dimensions would be the lowest and highest model number respectively. The model numbers of the prototype sources were not the smallest and largest sources listed in the series. (Guideline A and C)
- The leak test procedure used to test the prototype sources is only valid if there is sufficient void space within the capsule (see ANSI N542-1977). However, manufacturer provided no indication of the size of the void space for the capsules. (Guideline B)
- Complete drawings of the source design were not provided. Critical dimensions are missing. For example, the diameter of the plug and the clearance between the plug and capsule is not specified. (Guideline A and C)
- The quality control (QC) information in the document states that the activity will be between -10 and +20%, but does not indicate that 100 mCi is not to be exceeded. (Guideline C)
- The certificate did not indicate that the device is to be leak tested using techniques capable of detecting 0.005 microcuries of removable contamination. (Guideline C)

3.	CA-510-S-119-S	March 13, 1992	IND1603
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Guideline C above was not met. The specific details are as follows:

- No drawing was provided. (Guideline C)
- Letters dated 10/14/91 and 7/3/91 were not tied down on the certificate. (Guideline C)

4.	CA-305-D-103-S	April 20, 1993	1200SL
	CA-305-D-104-S	June 21, 1993	CB

Guidelines A and C above were not met. The specific details are as follows:

- The information submitted does not clearly show how the device operates. (Guideline A)
 - Neither the drawings nor a materials list were included in the files. (Guideline A and C)
 - Extreme temperatures are stated but the device was not tested to these levels. (Guideline A)
 - Only the ANSI N538 prototype testing was performed, no vibration or other extreme condition tests were performed. (Guideline A)
 - A users manual specific to the device is needed to verify that the device does not conflict with the regulations or with user safety. (Guideline C)
 - The Frontier source does not meet the ANSI classification listed in the certificate. It only meets ANSI classification C66344; it does not meet classifications C64545 or C64444. (Guideline A)
5. CA471D102B June 3, 1992 Model 101, 102, 103, 104, 108, 200, 210, and 220

Guidelines A and C above were not met. The specific details are as follows:

- The differences/similarities between different model numbers need to be defined. (Guideline C)
 - The reference section in the registration certificate did not reference any documents or letters containing information for review and approval of Models 200, 210, or 200 although these models were approved on the certificate. (Guideline C)
 - It is recommended that the manufacturer perform drop tests on these types of devices, because they are generally licensed devices. (Guideline A)
 - The results of prototype tests were not available. (Guideline A)
 - There was a lack of information on the materials of construction and/or detailed drawings for safety related items for the device. (Guideline A and C)
6. CA471D103B October 27, 1993 Model 104P/104PD

Guidelines A, B, and C above were not met. The specific details are as follows:

- Manuals for Model 104PD are needed. (Guideline B)
- It is recommended that the manufacturer perform drop tests on these types of devices, since they are generally licensed. (Guideline A)

- The prototype tests and results or engineering analysis are needed. (Guideline A)
 - It is not clear how the Model 104PD is used. The drawing for the head indicates that the head is attached to another component. This raises concerns about installation and handling of the device (i.e., Is the general licensee allowed to install and handle the device? Are the radiation doses received during installation and handling within applicable limits?). (Guideline B and C)
 - There is a lack of information on the materials of construction and/or detailed drawings for safety related items. The current drawing does not reflect description (i.e., description specifies slip ring, which was not shown on the drawing). (Guideline A)
7. CA384S177S January 26, 1993 Model 22
CA384S116S November 9, 1993 88

Guidelines A and C above were not met. The specific details are as follows:

- The dimensions for the female connector should be in the file especially the hole diameter, and distance from hole to end of connector so that compatibility comparisons can be made. (Guideline A and C)
 - For dimensional changes, both the old and new dimensions of the source should be described on the sheet along with information on why the changes were initiated. The old sources may have been distributed and may still be in use. (Guideline C)
8. CA384D109S September 27, 1993 Model IR-100

Guidelines A, B, and C above were not met. The specific details are as follows:

- The reference section in the registration certificate did not reference all letters used to make their determination. For example, letter dated September 30, 1993 was not listed under the reference section in the certificate. (Guideline C)
- More detailed drawings and list of materials for the device and accessories are needed. For example, these drawings are required to determine if the ANSI requirements were met, whether the female connector on the drive cable fits the male connector on the approved sources and whether there is protection from the uranium shield contacting the steel casing (i.e., prevent steel/uranium interface). (Guideline A & C)
- More detailed drawings and list of materials for the device and accessories are needed. (Guideline C)
- External radiation levels should be for maximum activity stated on the certificate (i.e., 120 curies). The extrapolate radiation levels appear to exceed the ANSI guide and transportation levels (> 200 mr/hr). (Guideline C)

- Under prototype testing, the certificate states that, "All radiography devices (IR-100) and sealed sources meet all the requirements listed in 10 CFR 34.20." Only the prototype products meet the requirements (i.e., 20,000 cycle test). (Guideline C)

9. CA406S106S 4/21/93 Model GF-XXXD Series

Guideline C above was not met. The specific details are as follows:

- Two letters providing information were not tied down to the certificate. (Guideline C)

10. CA406S112S 12/12/92 Model LAN Series, Act Series, and XFB Series

Guidelines A and C above were not met. The specific details are as follows:

- There was no reference listed for amendment. (Guideline C)
- There was no information provided on the safety analysis. (Guideline A)
- There were no signatures or dates for amendment. (Guideline C)

Recommendations

1. We recommend that the State ensure that the proper prototype testing or engineering analysis has been performed on the SS&D by the manufacturer for the intended use. In addition, the manufacturer should certify that the tests were performed and that the SS&D passed the test. ANSI guides should be used as the minimum set of prototype tests for sealed sources and the ANSI guide for devices should be supplemented with appropriate prototype tests for the devices intended uses.
2. The State should request and review complete operations manuals and users manual for device and source installations, service, maintenance, and emergency procedures to determine if any proposed activity would compromise worker safety, device integrity, or put the licensee in non-compliance.
3. The State should request detailed drawings and lists of materials from manufacturers/distributors of SS&D for all safety related components. This information is necessary to check if the manufacturer's device/sealed source design will withstand the proposed uses. In addition this information is required for an overall understanding of how the safety features operate and to determine if components from one manufacturer are acceptable for use in another manufacturer's design (i.e., radiography - sealed source and camera compatibility).
4. The staff should re-evaluate the general licensing of the neutron gauge (Model N-002, CA380D101G). It appears that the external radiation levels may exceed the prescribed dose limits for generally licensed

devices (>500 mrem/yr). In addition, the gauge did not appear to be adequately prototype tested.

5. The State should ensure that the staff receives appropriate training in SS&D reviews. This training should include, but not be limited to, how to read blueprints, training on the utility of the registry system, and the necessity of performing independent evaluations of source and device designs. The staff should also review all appropriate ANSI guides.
6. All staff performing SS&D reviews should be provided copies of all documents, guides, and information pertaining to SS&D review.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

On March 3, 1994, Mr. Jack Hornor, Mr. John Lubinski, and Mr. Thomas Rich met with Mr. Edgar Bailey to discuss the results of the SS&D review. The meeting was also attended by Mr. Ben Kapel, Mr. Pete Patel, Mr. Robert Reyes, Mr. Fred Toyama, Mr. David Wesley, and Mr. Gerard Wong. During the meeting, NRC staff discussed the need for the State to ensure that the proper prototype testing analysis has been performed on the SS&D by the manufacturer for the intended use; the use of ANSI guides as the minimum set of prototype tests for sealed sources; the usefulness of reviewing complete operations manuals and users manual for device and source installations, service, maintenance, and emergency procedures; the need to obtain detailed drawings and list of materials from manufacturers/distributors of SS&D for all safety related components; and that the State should consider re-evaluating the general licensing of the neutron gauge.

7ENDFIELD