

DATED: SEPT 21, 1994;

SIGNED BY RICHARD L. BANGART

Ms. Yvonne Sylva, Administrator
Nevada State Health Division
505 East King Street
Carson City, Nevada 89710

Dear Ms. Sylva:

This is to acknowledge receipt of Mr. Stanley R. Marshall's September 13, 1994, letter regarding timeliness of Agreement State program review documentation and to transmit the results of the NRC follow-up review and evaluation of the Nevada radiation control program conducted by Mr. Jack Hornor, NRC Region IV Field Office State Agreements Officer, which was concluded on April 15, 1994. The results of this review were discussed with Mr. Ron Lange, Administrative Health Services Officer, Mr. Darrell Rasner, Chief, Bureau of Health Protection Services, and Mr. Stanley Marshall, Supervisor, Radiologic Health Section.

Following our March 1993 review, a finding of compatibility was withheld since the State had not adopted the decommissioning rule within the three years required by the NRC. Although a finding of adequacy was granted, recommendations for improvement were made relating to the State's enforcement procedures and technical quality of licensing actions. In a letter dated April 16, 1993, which transmitted the results of the March 1993 review, we indicated that these recommendations would be evaluated in a follow-up review within 12 months and that the finding of adequacy would be reconsidered at that time. As indicated in our April 1993 letter, the purpose of this follow-up review was to evaluate the State's actions to address the recommendations and to assess the current status of the State's radiation control program.

As a result of our follow-up review and the routine exchange of information between the NRC and the State, we have determined that Nevada's program for regulating agreement materials, at this time, is adequate to protect the public health and safety and is compatible with the regulatory programs of the NRC.

We were pleased to find that the State has revised all compatibility regulations due through 1994 and has adopted the quality management rule, which was due by January 1995. Uniformity among regulatory agencies is an important part of the Agreement State Program and we appreciate the efforts you and your staff have taken in this area.

We were also pleased with the State's successful efforts to address recommendations in licensing and compliance program areas. However, although the State took appropriate enforcement actions during the review period, the State's written enforcement procedures still need improvement, and the specific guidance for escalated enforcement needs to be expanded.

Yvonne Sylva

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Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the technical issues which were discussed with Mr. Rasner and Mr. Marshall. We request specific responses from the State to the follow-up recommendations in this enclosure within 30 days of this letter. We recognize the delay in our issuance of this letter. If you require more than 30 days to respond, please let us know.

I appreciate the courtesy and cooperation extended the NRC staff during the review. I am looking forward to your staff responses to the Enclosure 2 recommendations.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
Ron Lange, Administrative Health Services Officer,
Nevada State Health Division
Stanley Marshall, Supervisor,
Nevada Radiological Health Section
Robert R. Loux, State Liaison Officer
NRC Public Document Room

Yvonne Sylva

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NRC Public Document Room

Distribution: see next page

**Concurrence by e-mail and phone

*See previous concurrence

OFC	WCFC:SAO	RIV:DRA	OSP:SA	OSP:DD		
NME	JHornor:dr	JMontgomery	CMaupin	PLohaus		
DTE	7/28/94**	7/29/94**	8/29/94*	8/30/94*		
OFC	NMSS:D	OGC	OSP:D	DEDS	EDO	
NME	RBernero	FCameron	RBangart	HLThompson	JMTaylor	
DTE	8/31 /94*	9/8/94*	09/13/94*	05/ /97	05/ /97	

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Yvonne Sylva

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

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DCD (SP01) PDR (YES)
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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.

SUMMARY OF FOLLOW-UP REVIEW OF
THE NEVADA RADIATION CONTROL PROGRAM
MARCH 6, 1993 TO APRIL 15, 1994

SCOPE OF REVIEW

This follow-up 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. As a result of the March 1993 routine program review, the State's program for controlling agreement materials was found to be adequate to protect the public health and safety, but a finding of compatibility was withheld because the State had not adopted the decommissioning rule. Although adequacy was granted, recommendations for improvements were made relating to the State's enforcement procedures, technical quality of licensing actions and three other indicators. This follow-up review concentrated on the five program indicators where recommendations were offered from the 1993 review and the State's procedures for investigating, recording and reporting events were also reviewed.

In a letter dated April 16, 1993, which transmitted the results of the March 1993 review, we indicated that these recommendations would be evaluated in a follow-up review within 12 months and that a finding of adequacy would be reconsidered at that time. As indicated in our April 1993 letter, the purpose of this follow-up review was to evaluate the State's actions to address these recommendations and to assess the current status of the State's radiation control program.

The follow-up meeting with Nevada representatives was held during the period April 11-15, 1994 in Carson City. The State was represented by Stanley Marshall, Supervisor, Radiologic Health Section. The NRC was represented by Jack Hornor, State Agreements Officer, Region IV Field Office. Mr. Hornor reviewed all casework in which comments and recommendations were identified during the previous review and other selected license and compliance files. In accordance with the NRC's efforts to improve the collection of program data, records of incidents and misadministrations were also reviewed with an emphasis on misadministration reporting. Details of the file reviews are contained in Appendix A of this document. A summary meeting regarding the results of the review was held with Ron Lange, Administrative Health Services Officer, on April 15, 1994.

CONCLUSION

As a result of our follow-up review and the routine exchange of information between the NRC and the State, we have determined that Nevada's program for regulating agreement materials, at this time, is adequate to protect the public health and safety and is compatible with the regulatory programs of the NRC.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The comments and recommendations made following our previous review were reported to the State in a letter to Mr. Griepentrog-Carlin dated April 16, 1993. The present status of each of these program indicators is as follows:

1. Status and Compatibility of Regulations (Category I)

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

Comment and Recommendation from the 1993 Routine ReviewComment

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 has not adopted the Decommissioning Rule by the three year target date, i.e., July 27, 1991.

Other regulations have been adopted by NRC that are also matters of compatibility. These regulations are identified below with the Federal Register (FR) notice and the date that the State needs to adopt the regulation to maintain compatibility.

- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70 amendments (54 FR 14051) which was to be adopted by April 7, 1993.
- "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) which was to be adopted by January 1, 1994.
- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) which was to be adopted by January 10, 1994.
- "Notification of Incidents," 10 CFR Parts 20, 31, 34, 39, 40, and 70 amendments (55 FR 40757) which was to be adopted by October 15, 1994.
- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 153) which was to be adopted by January 27, 1995.

Recommendation

During the review meeting, the State presented a plan to adopt all outstanding compatibility regulations by January 1994. We recommend that the State make an effort to exceed that goal by devoting the necessary staff resources to the task. We also suggest that in the future the State initiate the process of revising regulations with sufficient lead time to meet the target date. The State should also consider the use of the Suggested State Regulations to expedite their rulemaking process.

Present Status

All regulations that are currently due as a matter of compatibility have been adopted by the State. The Nevada State Regulations have been amended as follows:

- Decommissioning Rule, 10 CFR Parts 30, 40, and 70: adopted on September 14, 1993; NSR 459.030.
- Emergency Planning Rule, 10 CFR Parts 30, 40, and 70: adopted on September 14, 1993; NSR 459.030.
- Standards for Protection Against Radiation, 10 CFR Part 20: adopted on December 8, 1993; NSR 459.030, 459.070, and 459.201.
- Safety Requirements for Radiographic Equipment, 10 CFR Part 34: adopted on December 8, 1993; NSR 459.030 and 459.070.
- Notification of Incidents, 10 CFR Parts 20, 31, 34, 39, 40, and 70: adopted on December 8, 1993; NSR 459.030, 459.070, and 459.201.

The Quality Management Program and Misadministrations (QM rule), 10 CFR Part 35 amendment needed by January 27, 1995, was completed in draft form on March 21, 1994 and licensee workshops on the rule were held on April 12-14, 1994. The QM rule became effective in June 1994.

2. Enforcement Procedures (Category I)

The issues addressed in the comments B (1), B (2), B (4) and C have been satisfactorily resolved and are closed. The issues addressed in comments A and one aspect of B (3) have not been satisfactorily resolved and remain open.

Comment and Recommendation from the 1993 Routine ReviewComment

- A. Except for low-level waste inspection, the State has no procedures for assigning escalated enforcement actions to various severity levels of violations.
- B. Although the State took appropriate escalated enforcement in some instances, during our review of a representative sample of 11 compliance files, we found the following examples of inadequate enforcement action:
- (1) one case in which a hospital was cited for 16 violations including four repeated from the previous inspection. No escalated enforcement action was taken although the licensee was apparently operating with knowledge of being in violation.
 - (2) one case in which the State took no further escalated enforcement action after a licensee they felt was willfully disregarding regulations failed to show at a scheduled enforcement conference.
 - (3) three other cases in which appropriate escalated enforcement actions were not taken in response to numerous violations, including several repeats.

(4) three "items of concern" identified in enforcement letters should have been cited as items of noncompliance.

C. A computer listing of inspections performed since the April 1991 review showed that of 48 enforcement letters sent, seven letters failed to be sent within the 30 day timeframe following the inspection; in fact, six exceeded 60 days and one exceeded 90 days.

Recommendations

- We recommend that increased management oversight be provided to the enforcement program.
- We recommend that the State develop and implement written enforcement procedures which specify actions to be taken at various levels of severity. The Conference of Radiation Control Program Directors, Inc.'s E.15 procedures provide guidance in developing these procedures.
- We recommend that the State consider various methods of escalated enforcement actions used by other States without civil penalties. These could include follow-up inspections, enforcement conferences which require top management attendance in the Carson City office, license restrictions, or requirements for independent audits by outside consultants.
- We recommend that internal procedures be changed to ensure enforcement letters are sent within 30 days after the inspection.

Present Status

- A. Although the State's written enforcement procedures prescribe escalated actions in general terms, they do not directly address serious first-time violations and lack specific action levels for violations of varying degrees of severity. In their July 14, 1993, response to our April 16 letter, the State indicated they felt their written procedures were adequate and subsequently made no changes. Based on the current review, the State has, however agreed to strengthen their written procedures for escalated enforcement. They indicated that during this process they will study the need for severity levels and the feasibility of implementing civil penalties. This item remains open.
- B. The previous cases cited in the 1993 review were resolved as follows:
- (1) The State performed two follow-up inspections and held a management conference during 1993. As a result of these activities, the State found that the licensee was making steady progress in resolving previous areas of non-compliance. During the next routine inspection in February 1994, the hospital was found to have no items of non-compliance.
 - (2) After sending several letters and notices to the licensee, the State terminated the license and impounded the radioactive material in July 1993.
 - (3) Two of the three licensees have had subsequent inspections and the items of non-compliance have been corrected. In the third case,

the State plans to follow up on the violations during the next routine inspection. This item remains open.

- (4) In the review of eleven new inspection reports, all items of non-compliance were properly cited in that no items of noncompliance were mischaracterized as an "item of concern."

- C. Sixty-seven enforcement letters were sent during the review period and all were within the appropriate time frame. The State's corrective action in response to this comment was excellent.

Follow-up Recommendation

We recommend that the enforcement procedures be strengthened by adding:

- A. The requirement for escalated enforcement if the licensee has one or more serious violations directly relating to occupational or public health or safety, and
- B. specific actions to be taken for violations of various levels of severity.

In addition, we suggest that the State obtain assistance in this area from the Conference of Radiation Control Program Directors, Inc., (CRCPD) by using their E.15 enforcement procedures as guidance in developing the Nevada radiation control program's enforcement procedures.

3. Technical Quality of Licensing Actions (Category I)

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

Comment and Recommendation from the 1993 Routine Review

Comment

Both the Nevada Medical Policy Document, dated January 1989, and NRC's Regulatory Guide 10.8 require bioassay for administrations of I-131 in any form. Contrary to their own policy, the State does not require bioassays for capsule use of the isotope.

Recommendation

We recommend that the State follow their own policy in requiring bioassays for all forms of I-131.

Present Status

The Nevada Medical Policy Document which contains the requirement for bioassays for administrations of I-131 in any form has been added as a license condition to all Nevada medical licenses. However, the State had not been requiring the use of bioassays. Subsequent to our 1993 review comment, the State sent notices to all medical licensees on June 14, 1993, informing them of the bioassay requirement. The notice also contained a form letter with a commitment statement on the use of bioassays for I-131 applications which licensees were to sign and return to the radiation control program. Thus, all medical licensees are now being required to commit to the bioassay

requirement. The files of three licenses authorizing the use of I-131 in capsule form were reviewed and all licensees had formally committed to the bioassay requirement by the submission of the signed form letter. (See Appendix A for details.)

The State took appropriate action in response to our comment and this issue is closed.

4. Administrative Procedures (Category II)

The comments in this indicator from the 1993 review have been satisfactorily resolved and are closed. However, additional comments are offered under this indicator during the follow-up review.

Comment and Recommendation from the 1993 Routine Review

Comment

- a. The State's written termination procedures fail to include essential requirements necessary to prevent the abandonment or misuse of radioactive material after licenses are terminated. In one instance, a license was terminated while the licensee still possessed radioactive material.
- b. Under the exchange-of-information program with the NRC, Agreement States are asked to periodically supply copies of all new and amended licenses to the Office of State Programs. Our examination of the State's licenses prior to a program review helps ensure that the State's licenses are technically well-drafted, do not purport to regulate areas reserved by the Commission, and are consistent and compatible with those issued by the NRC and other Agreement States. Although Nevada has provided these documents in the past, we found that none had been submitted during this review period.

Recommendations

- (1) We recommend that:
 - C. the written termination procedures be revised to include the license termination requirements in the Nevada regulations,
 - D. the State use a check list to verify the final disposition of all radioactive material, and
 - E. certification of disposal or transfer should be required when receipts cannot be obtained from the new recipient.
- (2) We ask the State to resume the practice of sending copies of these documents to State Programs.

Present Status

- a. The State's termination procedures have been rewritten to prevent the abandonment or misuse of radioactive material after licenses are terminated, and checklists are now being retained in the termination files. Seven terminated license files were reviewed and no problems were indicated. (See Appendix A.)

- b. The NRC Office of State Programs has discontinued the practice of asking Agreement States to supply copies of all licensing actions.

1994 Follow-up Comment

Administrative procedures should be sufficient to assure all program functions are carried out as required. Recent regulatory emphasis has been placed on the importance of accurate and timely misadministration reporting under the exchange-of-information program between the NRC and the Agreement States. Nevada hospitals are required by regulation to provide dose calculations when reporting misadministrations to the State so that each event may be analyzed and reported as necessary. However, in three misadministration cases calculations were not provided; thus the events could not be evaluated against the reporting criteria.

The State agreed to require the three hospitals to provide dose calculations without delay for the past misadministrations. The State also agreed to transmit any necessary misadministration reports to the NRC after the data have been received and analyzed.

Follow-up Recommendation

- a. We recommend that the State's administrative procedures be revised to improve instructions for evaluating, following and reporting misadministrations.
- b. We recommend that letters be sent to all Nevada hospitals reminding them of the misadministration reporting criteria, including the requirement for dose-calculation.

5. Staffing Level (Category II)

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

Comment and Recommendation from the 1993 Routine Review

Comment

Although the State has been able to meet the minimum staffing level requirements suggested in the guidelines, an authorized and funded professional staff vacancy which exists in the Carson City office has not been filled due to a hiring freeze. We feel that the increasing complexity of the Nevada radioactive materials licenses, coupled with the anticipated staff effort which will be needed to implement the upcoming regulatory changes in radiation protection standards, will require additional staff.

Recommendation

We recommend this position be filled as soon as possible.

Present Status

This position has been filled with a person experienced in X-ray, but not in materials. The State expects to provide the new staff member two years of on-

the-job training supplemented by NRC sponsored training courses and other training courses.

ADDITIONAL FOLLOW-UP REVIEW AREA

A comment in the category listed below was not offered during the 1993 routine review.

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

1994 Follow-up Comment

The following findings were identified based on a review of the State's system for tracking incidents and misadministrations.

- a. Incidents and misadministrations are not tracked by computer, and the incident log was incomplete.
- b. Some incidents shown as closed in the incident log lacked documentation in the files justifying closure.
- c. In some cases, copies of correspondence were found in the Las Vegas regional Office on events handled by that office but were not in the headquarters office files in Carson City. According to the Nevada procedures, these events files should have been in the headquarter's files also.

Follow-up Recommendation

We recommend that the State improve their events tracking system to ensure complete incident logs, to ensure that all open items are properly documented before closure and to ensure proper dissemination of regional event correspondence to headquarters files.

SUMMARY DISCUSSIONS WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held with Mr. Ron Lange, Administrative Health Services Officer on April 15, 1993. The meeting was also attended by Mr. Stanley Marshall, Supervisor, Radiologic Health Section and Darrell Rasner, Chief, Bureau of Health Protection Services.

The State's corrective actions in response to each of our previous comments were discussed, and the State was commended on their efforts to correct the problems. The need for effective escalated enforcement procedures was discussed at length, and as indicated above, the State agreed to revise and strengthen their procedures. The importance of accurate and timely event reporting was also discussed, and management agreed to establish better methods of collecting and recording misadministration and incident data.

The State thanked the NRC for their suggestions and assistance. Mr. Lange explained that Mr. Griepentrog-Carlin is no longer with the Nevada program. Correspondence formerly sent to him should now be directed to Ms. Yvonne Sylva, Administrator, Nevada State Health Division.