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BOB MILLER
Governor

SCOTT M. CRAIGIE
Director

STATE OF NEVADA

YVONNE SYLVA
Administrator

DONALD S. KWALICK, M.D., MPH
State Health Officer

DEPARTMENT OF HUMAN RESOURCES
HEALTH DIVISION
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OSP

October 19, 1994

Richard L. Bangart, Director
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Bangart,

I am writing in reference to your letter dated September 21, 1994, summarizing the NRC's survey of Nevada's radioactive material program in April 1994. This follow-up visit evaluated the State's response to recommendations from the 1993 NRC audit and assessed Nevada's radiation control program.

Our responses to the follow-up recommendations are addressed in the order cited in enclosure 2 of your letter. Those comments outlined in the visit report which are consistent with Division public health and safety objectives have been reviewed and implemented. The Health Division will continue to monitor radioactive material program activities and implement NRC suggestions where they remain consistent with flexible program management.

Sincerely,

Yvonne Sylva

Yvonne Sylva
Administrator

YS/ll
Enclosure
cc: Darrell W. Rasner, Chief, Bureau of Health Protection Services
Stanley R. Marshall, Supervisor, Radiological Health Section

L-70

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.

Response

A. Review of CRCPD Suggested Procedure E-15 is currently underway and appropriate portions of the procedure may be adopted after review by staff and the Attorney General's office. The Health Division will maintain the right to review each enforcement action on a case-by-case basis in accordance with our existing Policies and Procedures manual. Technical review and recommendations to management is expected to be completed by December 31, 1994.

B. CRCPD Suggested Procedure E-15 will also be reviewed by staff by December 31, 1994 and appropriate sections may be adopted if useful.

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.

Response

A. Concur. Revision of the procedures is anticipated to be completed by December 31, 1994.

B. Completed. Letters have been sent to all Nevada hospitals as well as other all medical licensees to remind them of medical misadministration reporting criteria including dose calculations requirement.

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.

Response

The Health Division is pursuing an improved method to track Agreement material radiation incidents as well as other non-Agreement material incidents. We anticipate addition of a Management Analyst and an upgraded computer system to enhance our data management capability. We will also evaluate the new Nuclear Materials Events Database reporting program including computer software developed by the Nuclear Regulatory Commission as an enhancement to the voluntary exchange of information between our agencies.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 21, 1994

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.

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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,

Original Signed By
RICHARD L. BANGART

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

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.

Enclosure 2

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 Review

Comment

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 Review

Comment

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.

Appendix A

License, Compliance and Incident File Reviews

A. License Files

A total of twelve license files were reviewed.

The following nine files were reviewed in full for the adequacy of the application review, for the technical quality of the licensing action and for adequate documentation. There were no comments.

File No. 1
Licensee: Selco
Location: Las Vegas
License Type: Portable Gauge
Date Terminated: 2/17/93
License No.: 00-11-0308-01
Amendment No.: 1
Type of Action: Termination

File No. 2
Licensee: Animal Medical Specialties, Inc.
Location: Reno
License Type: DVM
Date Terminated: 2/17/93
License No.: 16-12-0277-01
Amendment No.: 1
Type of Action: Termination

File No. 3
Licensee: Transwestern Engineering Corp.
Location: Reno
License Type: Portable Gauge
Date Terminated: 10/6/93
License No.: 00-11-0216-01
Amendment No.: 6
Type of Action: Termination (source impounded)

File No. 4
Licensee: Las Vegas Police Dept.
Location: Las Vegas
License Type: Not available
Date Terminated: 4/8/94
License No.: 03-16-0149-01
Amendment No.: 4
Type of Action: Termination

File No. 5
Licensee: Utah International, Inc.
Location: Imlay
License Type: Fixed Gauge
Date Terminated: 4/5/94
License No.: 14-11-0152-01
Amendment No.: 3
Type of Action: Termination

File No. 6
Licensee: Lockheed Env. Syst. and Tech.
Location: Las Vegas
License Type: Gas Chromatograph
Date Terminated: 2/3/94
License No.: 03-11-0269-02
Amendment No.: 3
Type of Action: Termination

File No. 7
Licensee: Aztec Engr. and Tech. Services — License No.: 00-11-0312-01
Location: Carson City — Amendment No.: 1
License Type: Portable Gauge — Type of Action: Termination
Date Terminated: 7/2/93

File No. 8
Licensee: Desert Radiologists — License No.: 03-12-0327-01
Location: Las Vegas
License Type: Medical — Type of Action: New
Date Issued: 5/6/93

File No. 9
Licensee: Biotech Pharmacy — License No.: 03-11-0332-01
Location: Las Vegas
License Type: Pharmacy — Type of Action: New
Date Issued: 8/17/93

The following three license files were reviewed for the single purpose of determining if the hospitals had committed to performing bio-assays when using I-131 in capsule form.

File No. 10
Licensee: St. Mary's Regional Medical Center — License No.: 16-12-0244-01
Location: Carson City — Date Committed to Bioassay: 7/19/93

File No. 11
Licensee: Lake Mead Hosp. and Med. Center — License No.: 03-12-0291-01
Location: North Las Vegas — Date Committed to Bioassay: 6/18/93

File No. 12
Licensee: University Med. Center of So. Nv. — License No.: 03-12-0034-01
Location: Las Vegas — Date Committed to Bioassay: 7/12/93

B. Compliance Files

A total of thirteen compliance files were reviewed. Because of the problems found in the State's enforcement procedures during the previous review, cases selected for this review all required some type of enforcement action. Specific comments follow this list.

The following seven files were new cases which were reviewed in full to verify that the inspection was complete, the report adequately documented the results, exit or management meetings were held at the proper level, appropriate compliance action was taken, enforcement actions were completed in a timely manner, and unresolved issues were pursued to conclusion.

File No.: 1
Licensee: Nevada Minerals Processing License No.: 12-11-0260-01
License Type: Fixed Gauge Priority: 4
Inspection Date: 3/3/94 and 3/17/94

File No.: 2 License No.: 00-11-0094-01
Licensee: Converse Consultants Southwest, Inc.
License Type: Portable Gauge Priority: 3
Inspection Date: 2/17/94

File No.: 3
Licensee: Lockheed Engineering & Sciences License No.: 03-11-0269-01
License Type: Gas Chromatographs (foil) Priority: 4
Inspection Date: 12/3/93

File No.: 4 License No.: 03-11-0269-03
Licensee: Lockheed Environmental Systems and Technologies
License Type: Small Laboratory Priority: 2
Inspection Date: 7/1/93

File No.: 5
Licensee: Clark County Sanitation Dist. License No.: 00-11-0111-01
License Type: Portable Gauge Priority: 3
Inspection Date: 6/4/93

File No.: 6
Licensee: Summit Engineering (Las Vegas) License No.: 00-11-0180-01
License Type: Portable Gauges Priority: 3
Inspection Date: 5/23/93

File No.: 7 License No.: 03-12-0291-01
Licensee: Lake Mead Hospital and Medical Center
License Type: Nuclear Medicine Priority: 2
Inspection Date: 3/26/93

The following five compliance files were found to have problems during the previous review. In all five cases, additional inspections or compliance actions had been taken since the review. These cases were reviewed in full

File No.: 8
Licensee: Desert Radiologists License No.: 03-12-0168-01
License Type: Medical Priority: 2
Inspection Date: 8/4/93

File No.: 9
Licensee: Carson-Tahoe Hospital License No.: 01-12-0032-01
License Type: Medical Priority: 2
Inspection Date: 2/1/94

File No.: 10 License No.: 16-12-0244-01
Licensee: St. Mary's Hospital and Regional Medical Center
License Type: Medical Priority: 2
Inspection Date: 10/8/93

File No.: 11
Licensee: Kleinfelder License No.: 00-11-0278-01
License Type: Industrial Radiography Priority: 1
Inspection Date: 12/2/93

File No.: 12
Licensee: Transwestern Engineering Corp. License No.: 00-11-0216-01
License Type: Portable Gauge Priority: 4
Compliance Action Date: 7/20/93 (source impounded)

The following file was reviewed to determine if corrective action had been taken in response to our previous comment.

File No.: 13
Licensee: Leon H. Steinberg, M.D. License No.: 03-12-0307-01
License Type: Nuclear Medicine Priority: 2
Inspection Date: 9/15/92

Specific Comments for Compliance Files

	Comment	File No.
I.	Good follow-up on enforcement, but exit meeting should have been conducted at management level	3,6
II.	There were 3 separate inspections with separate enforcement actions to track not picked up by data base	6
III.	Minutes of enforcement conference held with management not in master file (was obtained by fax from Las Vegas regional office for review)	7
IV.	Three serious items of non-compliance did not trigger escalated enforcement	8
V.	Inspector did not follow through on misadministration which had occurred since last inspection	9

VI. Twelve items of non-compliance found in initial inspection in September 1992. Case was identified as needing escalated enforcement during last review, but State took no further action during this review period. (The licensee has held other State licenses and the State intends to follow through during the next scheduled inspection due this year.) 13

C. Incident Files

The State's incident log lists all events including accidents, lost or abandoned sources, misadministrations and allegations. According to the log, 18 incidents were reported in 1993 and 6 have been reported this year, the majority of which were machine or non-byproduct related. However, during file reviews three events were found that were not listed in the incident log. The following seven cases were reviewed in full.

Case 1
Licensee: Carson-Tahoe Hospital License No.: 01-12-0032-01
Date of Event: 5/2/93 Type of Event: Misadministration
Summary: Patient was given 5.3 mCi of Tc-99m as Hepatolite when Pulmolite was prescribed.
Comment: The hospital furnished dose calculations as required. In their citation letter the State advised the licensee they would follow-up the hospital's corrective actions during the next inspection. The event was not entered in the incident log; correspondence relating to the misadministration was loose in the file; and the inspector did not review the event during the inspection in February 1994.

Case 2
Licensee: Syncor International (Las Vegas) License No.: 03-11-0150-01
Date of Event: 9/23/93 Type of Event: Allegation
Summary: Ex-employee made 14 allegations of misconduct on the part of the licensee.
Comment: The State investigated all 14 allegations and cited the licensee for three items of non-compliance. Two serious discrepancies that involved falsification of records were turned over to the State Board of Pharmacy. Although the incident was closed out in the log, there was no indication in the file of the outcome of the Board of Pharmacy investigation.

Case 3
Licensee: unknown
Date of Event: 6/1/93 Type of Event: Abandoned Radioactive Material
Summary: While dismantling an abandoned mine at Gold Hill, NV, workers discovered a GL gauge with a RAM label, and notified the Radiologic Health Section, who picked it up the same day. After ascertaining it is not registered in Nevada, it was stored with their other radioactive

materials. If unclaimed by the owner, it will be sent to the low-level waste disposal site at Hanford. The State was commended for their prompt response.

Case 4
Licensee: Nevada Power Company License No.: 13-11-0143-01
Date of Event: 5/4/93 Type of Event: Overexposure
Summary: Four employees entered restricted area without shutting down fixed gauge beam. Initial estimated exposure ranged from 0.09 mrem to 980 mrem (worst case). Recalculations estimate approximately 150 mrem.
Comment: Las Vegas office cited licensee for not following procedures and for inadequate posting. Although the incident is closed out in the log, the last acknowledgement letter from the State asks the licensee to notify the State after all corrective actions are complete. If the licensee responded, the response is not in the Carson City file.

In the following three misadministration cases, the hospital did not furnish dose calculations in accordance with Nevada regulations. During the exit meeting with State representatives, they agreed to contact each licensee and require dose calculations.

Case 5
Licensee: Valley Hospital Medical Center License No.: 03-12-01710-01
Date of Event: 9/30/93 Type of Event: Misadministration
Summary: The wrong patient was injected with 5 mCi of Tc-99m.
Comment: The hospital was cited for not verifying the patient's name before the injection. The amount of exposure appears to be small and local; however reporting requirements cannot be precisely determined without dose calculations.

Case 6
Licensee: Lake Mead Hosp. and Med. Center License No.: 03-12-0291-01
Date of Event: 2/16/93 Type of Event: Misadministration
Summary: Incorrect radiopharmaceutical was administered when patient received 5 mCi of Tc-99m MAA instead of 5 mCi of Tc-99m S.C.
Comment: The information pertaining to this misadministration was found during review of the license file. The event was not listed in the incident log nor was it in the incident file in Carson City. It could not be determined if the incident had been closed out by the Las Vegas office.

Case 7
Licensee: Desert Radiologists License No.: 03-12-0178-01
Date of Event: 8/8/91 Type of Event: Misadministration
Summary: Patient given dose of 14 mCi Tc99m-TcO4 for testicular scan when the procedure should have been ultrasound.

Comment: Again, the information pertaining to this misadministration was found during review of the license file. The event was not logged, nor was it in the incident file. The final disposition could not be determined from the Carson City files.