DATED: DECEMBER 26, 1995 SIGNED BY: RICHARD L. BANGART

Ms. Elinor Hall, Administrator
Health Division
Oregon Department of Human Resources
Suite 950
800 NE Oregon Street, #21
Portland, Oregon 97232

Dear Ms. Hall:

This is to transmit the results of the NRC review and evaluation of the Oregon radiation control program. This review, which concluded on July 28, 1995, was conducted by Jack Hornor, State Agreements Officer, Region IV Walnut Creek Field Office. The results of this review were discussed with you and your staff on July 28, 1995.

As a result of our review of the State's program and the routine exchange of information between the NRC and the State of Oregon, the staff determined that, at this time, the Oregon program for the regulation of certain Atomic Energy Act radioactive materials is compatible with the regulatory program of the NRC. However, a finding that the program is adequate to protect the public health and safety is being withheld because of significant deficiencies in three Category I Indicators, "Status of Inspection Program," "Responses to Incidents and Alleged Incidents," and "Enforcement Procedures."

The three Category I Indicator findings are considered significant. First, the backlog of overdue inspections is a serious problem and the need for improvement is critical. At the time of the review, 61 inspections were overdue by more than 25 percent of their scheduled frequency. The number of inspections completed in the two year period prior to this review had dropped to 123 from the 219 completed in approximately the same period prior to the last review. In Enclosure 2, we recommend that every effort be made to eliminate the backlog within the next 18 months. Second, although it appears that the State's initial responses to actual and alleged incidents were suitable, the incident investigations were not always followed through to conclusion or properly closed out. In Enclosure 2, we recommend that procedures be revised to provide increased accountability in the incident closure process. Third, the State has adequate written enforcement procedures; however, during the review period, it was found that the State did not carry out appropriate enforcement action in three separate cases of the 15 cases reviewed. In Enclosure 2, we recommend that actions be taken to assure that appropriate enforcement actions are taken in accordance with the State's procedures.

Please note there has been a change in the format of this letter from our previous review letters. This letter summarizes the findings regarding all 30 program indicators. Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 summarizes our review findings for program indicators where we have identified recommendations for improvements. We request specific responses from the

State on the findings and recommendations in Enclosure 2 within 30 days of this letter. We recognize the delay in our issuance of this letter, and if you require more than 30 days to respond, please let us know. Enclosure 3 presents a summary of the review findings where the State has fully satisfied the indicator. A response to the items in Enclosure 3 is not required.

We were pleased to find your regulations compatible with those of the NRC. Compatible regulations are an important part of the Agreement State Program and the efforts of your staff to successfully adopt compatible regulations necessary at the time of the review are commendable.

In your letter of July 28, 1995, you expressed a strong willingness to correct the problems in the State's program and furnished an action plan to eliminate the inspection backlog. Mr. Hornor has evaluated the plan and has discussed suggested improvements with your staff. We acknowledge that in the July 28 letter the State committed to submitting quarterly progress reports regarding the status of the action plan's implementation and we have received your progress report provided in letter dated November 14, 1995. We will be conducting a follow-up review in 6 to 12 months so that the effectiveness of your corrective actions can be measured.

I appreciate the courtesy and cooperation extended the NRC staff during the review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
1. Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"

2. Status of Previous Findings and Summary of Review Findings and Recommendations for the Oregon Radiation Control Program April 3, 1993, to July 28, 1995

3. Summary Assessment of Indicators Fully Satisfied by the Oregon Radiation Control Program April 3, 1993, to July 28, 1995

cc w/encl:
Ray Paris, Manager
Radiation Protection Services
Oregon Health Division

Thomas W. Johnson, Assistant Administrator
Oregon Health Division

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cc w/encl: See next page.

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cc w/encl:
Ray Paris, Manager
Radiation Protection Services
Oregon Health Division

Thomas W. Johnson, Assistant Administrator
Oregon Health Division

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The Chairman
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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. 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. Comments on Category I indicators that are not significant will not be used as a basis for withholding of findings of adequacy or compatibility.

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. Pursuant to Section 274j of the Act, the Commission may terminate or suspend all or part of its agreement with a State if the Commission finds such termination or suspension is required to protect the public health and safety, or the State has not complied with one or more requirements of section 274 of the Act.

STATUS OF PREVIOUS FINDINGS AND
SUMMARY OF REVIEW FINDINGS AND RECOMMENDATIONS
FOR THE OREGON RADIATION CONTROL PROGRAM
APRIL 2, 1993, TO JULY 28, 1995

SCOPE OF REVIEW

The 29th regulatory program review with Oregon representatives was held during the period July 17-28, 1995, in Portland. This program 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 State's program was reviewed against the 30 program indicators provided in the policy statement. The review included an inspector accompaniment, discussions with program management and staff, technical evaluation of selected license and compliance files, review of the State's policies and procedures, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review.

The State was represented by Ray Paris, Manager, Radiation Protection Services (RPS); Martha Dibblee, Manager, Radioactive Materials, and Nickolas Goevelinger, Manager, Emergency Response.

Selected license and compliance files were reviewed by Jack Hornor, Regional State Agreements Officer, Region IV Walnut Creek Field Office. One field accompaniment of an inspector was made by Mr. Hornor.

CONCLUSION

The State's program for the regulation of Atomic Energy Act radioactive materials is, at this time, compatible with the NRC's program to protect the public health and safety. However, a finding of adequacy is being withheld because of significant deficiencies in three Category I Indicators, "Status of Inspection Program," "Responses to Incidents and Alleged Incidents," and "Enforcement Procedures." There is also need for improvement in one Category II Indicator, "Inspection Reports."

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to the State in a letter to Dr. Michael R. Skeels dated May 21, 1993. The current status of those previous comments is as follows:

1. Administrative Procedures (Category II)

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

a. Comment from the April 1993 Review

Oregon uses the administrative procedures developed by the CRCPD committee as guidance. However, the generic procedures have not been modified to fit Oregon's needs; they have not been approved by management; and they are not followed uniformly by all staff. Deficiencies found in the inspection reports, in particular, emphasize the need for uniform adherence to written procedures.

Recommendation from the April 1993 Review

We recommend that the State adapt the generic procedures to their own needs and, after management approval, require all staff to uniformly follow the procedures.

July 1995 Status

After the 1993 review, program management modified the generic CRCPD procedures to fit the needs of their program. The new procedures have been installed on the local network so that they are easily accessible by staff. Although numerous deficiencies were still found in the inspection reports, the problems appeared to relate to failure to follow the procedures, and not to the procedures themselves. This issue is addressed below in the current findings and recommendations.

The issues addressed in the following comment have been satisfactorily resolved and are considered closed.

b. Comment from the April 1993 Review

The State does not have adequate procedures in place to assure proper recording and tracking of essential program functions, such as incident reporting and escalated enforcement.

- Although the State responded appropriately to all incidents, we found that two incidents meeting NRC reporting requirements were not reported, not entered into the tracking system nor, included in the annual summary. In addition, two leaking sources were not reported to the NRC at the time the State was notified.

- The State's administrative procedures include an inspection policy that assigns points to various levels of severity of items of non-compliance, with escalated enforcement required at a specific point level. The results of the inspections are entered into a computer system designed to track the need for escalated enforcement. However, in a representative sample of eleven compliance files, four cases were found in which errors made on the inspection form or during data entry failed to trigger the escalated enforcement.

Recommendation from the April 1993 Review

The State should revise their tracking system to provide verification that all items are entered properly.

July 1995 Status

A new document tracking system was installed along with the new administrative procedures after the previous review. During the file reviews, it was noted that any failures to track incident closure and enforcement actions resulted from not following the prescribed procedure, not from flaws in the procedures.

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

c. Comment from the April 1993 Review

Written procedures have not been revised to meet current regulatory requirements. For example, the medical license application and inspection forms do not reflect recent changes in medical regulations.

Recommendation from the April 1993 Review

The license application guides and inspection forms should be revised to reflect current regulations.

July 1995 Status

During reviews of the regulations and technical procedures, it was verified that the new administrative procedures, licensing guides, and inspection reports conform to the State's regulations.

2. Inspection Reports (Category II)

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

Comment from the April 1993 Review

Although the State's inspection policies and procedures meet the guidelines, the results of the inspections are not adequately documented in the reports. In the representative sampling of eleven inspection reports, seven contained errors or omissions. In four cases, the inspection forms were not fully completed, and in one case an inspector said he conducted a follow-up inspection but did not document it. Other significant findings included:

- dosimetry records entered without specifying units (six cases),
- no reference to inspecting licensee's as low as reasonably achievable (ALARA) commitments (six cases),
- no documentation that previous items of non-compliance were closed out (four cases), and
- no indication of interviews with ancillary workers.

Recommendation from the April 1993 Review

We recommend that all inspection reports be carefully reviewed by the supervisor to ensure the existing policies and procedures are being followed.

July 1995 Status

The quality of the inspection reports showed very little improvement. In the representative sampling of 15 inspection reports, 12 contained errors or omissions. It was noted, however, that with the exception of documenting interviews with ancillary workers, the specific problems listed above did not recur. This continuing problem remains open and is discussed below in the current findings and recommendations.

3. Enforcement Procedures (Category I)

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

Comment from the April 1993 Review

The standard language used in the State's acknowledgement letter to licensee's responses does not indicate whether or not the licensee's corrective actions are satisfactory.

Recommendation from the April 1993 Review

We recommend the standard acknowledgement letter be reworded to advise the licensee of the adequacy of his corrective actions.

July 1995 Status

In was confirmed during review of the State's new procedures that the acknowledgement letter boilerplate and two other forms have been modified to advise the licensee of the adequacy of his corrective actions.

CURRENT REVIEW FINDINGS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 24 of these indicators. Recommendations were made regarding six indicators discussed below, three of which are significant Category I findings. The remaining 24 indicators are discussed in Enclosure 3. A questionnaire containing the 30 indicators with specific questions pertaining to each indicator was sent to the State prior to the review.

The assessments and recommendations below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, review of the State's written procedures and policies, discussions with program managers and staff members, reviewer observations, and licensing and inspection casework file reviews. Specific assessments and recommendations are as follows:

1. Management (Category II)

NRC Guidelines

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

RCP management should periodically assess workload trends, resources and changes in legislative and regulatory responsibilities to forecast needs for increased staff, equipment, services, and funding.

Program management should perform periodic reviews of selected license cases handled by each reviewer and document the results. Complex licenses (major manufacturers, low-level radioactive waste disposal facilities, large scope-Type A Broad, potential for significant releases to the environment) should receive second party review (supervisory, committee, consultant). Supervisory review of inspections, reports, and enforcement actions should also be performed.

For the implementation of very complex licensing actions, such as initial license review, license renewals and licensing actions associated with a low-level radioactive waste disposal facility, there should be an overall Project Manager responsible for the coordination and compilation of the diverse technical reviews necessary for the completion of the licensing action. The Project Manager should have training or experience in one or more of the main disciplines related to the technical reviews which the Project Manager will be coordinating such as health physics, engineering, earth science, or environmental science.

When regional offices or other government agencies are utilized, program management should conduct periodic audits of these offices.

Assessment

The results of this review showed deficiencies in five other program indicators that point to the need for increased management oversight. During discussions with the radiation control program director, the radioactive materials manager, and the emergency response manager, it was noted that communication among the three of them could be improved. Some developing problems had been overlooked:

- Reviews of the files and computer records showed that backlogs were allowed to develop in the radioactive materials licensing and compliance programs.

- Although the records indicated that the State's initial response actions to incidents were satisfactory, over half of the incident investigations were not completed or properly closed out.

- There were no records to indicate that one of the two new inspectors had been accompanied by the compliance supervisor or that annual field evaluations had been conducted for all inspectors.

- Enforcement actions did not always follow the prescribed procedure.

- The quality of the inspection reports was not adequate to meet the guidelines, a finding repeated from the previous review.

During file reviews, it was noted that the Radiation Protection Services manager signs all licenses and escalated enforcement letters. The head of the radioactive materials section reviews and signs off on all licensing actions and inspection reports.

Program management receives monthly computer-generated reports on the status of licensing and compliance actions. Program managers meet once a month; the radioactive materials staff meet daily, and full staff meetings are held

monthly. In reviewing the minutes of 28 staff meetings, however, it was noted that the growing backlogs were never discussed.

In her July 28, 1995, letter to Mr. Bangart, Ms. Hall acknowledged that she and her staff recognize problems exist in the Oregon program and assured the NRC that plans are in place to resolve those problems.

Recommendation

a) We recommend that emphasis be placed on achieving stricter managerial accountability, not only to the commitments made in the July 28 letter for increasing oversight of inspections and incidents, but for overseeing enforcement actions and inspection reports, and for performing inspector accompaniments.

b) We recommend that the program managers implement actions, such as more frequent meetings to discuss current and potential problems, i.e., inspection backlogs, open incidents, and problem cases.

c) We recommend that the program managers more effectively forecast program needs and allocate resources for backlogs in licensing and compliance. This may require changing the formats of the computer reports to place more emphasis on overdue licensing and compliance actions.

2. Status of Inspection Program (Category I)

NRC Guidelines

State RCP should maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. The inspection program in all States should provide for the inspection of licensee's waste generation activities under the State's jurisdiction.

In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should include provisions for pre-operational, operational, and post-operational facility inspections. The inspections should cover all program elements which are relevant at the time of the inspection and be performed independently of any resident inspector program. In addition, inspections should be conducted on a routine basis during the operation of the LLW facility, including inspection of incoming shipments and licensee site activities.

The RCP should maintain statistics which are adequate to permit program management to assess the status of the inspection program on a periodic basis. Information showing the number of inspections conducted, the number overdue, the length of time overdue and the priority categories should be readily available.

At least semiannual inspection planning should be done for the number of inspections to be performed, assignments to senior vs. junior staff, assignments to regions, identification of special needs, and periodic status reports. When backlogs occur, the program should develop and implement a plan to reduce the backlog. The plan should identify priorities for inspections and establish target dates and milestones for assessing progress.

Assessment

Based on review of computer reports, at the time of the review, the State had 61 inspections that were overdue by more than 25 percent of their inspection

frequency. Of these, 12 were initial inspections, 25 were Priority 1, 2, and 3 licenses, and 24 were licenses in Priorities 4 through 7.

From the last review meeting to this one, there was a significant decrease in the number of completed inspections. In the two year period prior to the 1993 review, the State completed 219 inspections. During the two year period prior to this review, the State completed 123 inspections with the same number of FTEs, and basically the same staff. After examining various computer reports, the reviewer projected that, in order to operate without backlogs, the State should perform approximately 100 inspections per year. This figure includes initial and routine inspections. The records show that during the State's Fiscal Year (FY) 93-94, the State completed 60 inspections, during the State's FY 94-95, which ended June 30, 1995, 44 inspections were completed.

As explained previously, it appears management was provided with statistics that should have alerted them to the growing inspection backlog.

In a letter dated July 28, 1995, the Health Division Administrator provided an action plan to reduce the inspection backlog. The plan, which is signed by the radiation control program director and radioactive materials manager, lists an objective of eight inspections per month for the first 3 months. This plan should prevent more backlogs from accumulating; however, the NRC reviewer estimates that an average of 12 inspections per month should be completed during each of the next 18 months in order to eliminate the backlog. Also, it appears the inspections were scheduled according to location instead of according to priority or inspection due date. Of the first 24 inspections scheduled in 1995, 13 are for Priority 4 to 7 licenses, and six will not become overdue until 1996 or 1997. We are aware of the need to take geography, terrain, and travel time into account when scheduling inspections. However, the list of overdue inspections provided to the reviewer shows several Priority 2 and Priority 3 hospitals within the Portland area that are as much as a year overdue and which are not on the inspection schedule.

The concerns about the adequacy of the plan were discussed by telephone with the radiation control program director and the radioactive materials manager on August 22, 1995. In a letter to Mr. Hornor dated the same day, Mr. Paris explained that the plan would be revised at the end of the first three-month period, and that the revised plan would be sent to the NRC, along with the first quarterly progress report.

Recommendation

We recommend that the State eliminate the backlog of overdue inspections and that the State complete the action plan provided in the July 28, 1995 letter. In addition, we recommend that the action plan be revised to

a) show the inspection priority, due date, and overdue date,

b) schedule staff assignments so as to complete an average of 12 inspections a month so that the backlog can be eliminated by December 1996, and

c) place priority on conducting overdue inspections of licenses with the highest potential hazards of licensed operations, taking into consideration the date the original inspection was due.

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

NRC Guidelines

Inquiries should be promptly made to evaluate the need for onsite investigations.

Onsite investigations should be promptly made of incidents requiring reporting to the agency in less than 30 days (10 CFR 20.403 types).

For those incidents not requiring reporting to the agency in less than 30 days, investigations should be made during the next scheduled inspection.

Onsite investigations should be promptly made of non-reportable incidents which may be of significant public interest and concern, e.g., transportation accidents.

Investigations should include in-depth reviews of circumstances and should be completed on a high priority basis. When appropriate, investigations should include reenactments and time-study measurements (normally within a few days). Investigation (or inspection) results should be documented and enforcement action taken when appropriate.

State licensees and the NRC should be notified of pertinent information about any incident which could be relevant to other licensed operations (e.g., equipment failure, improper operating procedures).

Information on incidents involving failure of equipment should be provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency.

The RCP should have access to medical consultants when needed to diagnose or treat radiation injuries. The RCP should use other technical consultants for special problems when needed.

Assessment

According to the files and incident log, 81 incidents or allegations were reported to the State during the two year review period. Summaries of all 81 events were examined, and six cases were reviewed in depth. There were no therapeutic misadministrations or incidents requiring NRC Abnormal Occurrence Reports. Also, none occurred which appeared to be related to equipment failure or design deficiency.

The records showed that the State responded promptly to most incidents and that the initial investigative efforts were commensurate with potential health and safety significance. However, the follow-up actions were often inadequate. In six out of six cases selected for in depth review, the investigations had not been completed or closed out properly. In one case, the State failed to follow through with an appropriate search for a plutonium (Pu) pacemaker that was apparently discarded as medical waste. In another, no action was taken on an allegation from a former worker at a State licensed facility because the facility is, according to the State, now an EPA Superfund site. In a third case, a licensee was not cited for using an unauthorized user; no action was taken when the licensee failed to follow the State's order to provide a report of the disposition of the source from a damaged gauge; and the incident report was not cross-referenced to the license file, so the incident was not reviewed during the next inspection. Of the remaining three, two were not assigned case numbers or entered in the log. In the sixth case,

the incident was entered in the log, but there was no indication that an incident report had been prepared.

Examination of the log showed that 42 of 81 incident investigations in the incident log remained open. At the time of the review, six of 34 incidents that had been investigated in 1993 remained open, as did 25 of the 40 that were investigated in 1994.

Responsibility for responding to incidents and allegations is divided between the emergency response and radioactive materials programs. In discussions with program managers and staff, it appeared that the lines of responsibility were unclear as to follow-up and reporting responsibilities. As a result, details pertaining to incident investigations were sometimes misplaced or not entered into the tracking system. To further complicate the situation, radioactive materials used two different numbering systems in the incident log, while emergency response used a third. As an example of the less than clear assignment of responsibility, neither manager was aware that someone on the RPS staff had reported the 1994 incidents to the NRC as requested.

In her July 28 letter, Ms. Hall stated that realignment of documentation and assignment responsibilities had already been accomplished and that stricter accountability has been established in the incident oversight portion of the program.

Recommendations

a) We recommend that the procedures for initial incident response assignments, enforcement, tracking, follow-up, cross referencing, reporting, and management review responsibilities be analyzed by management and revised as necessary to provide for adequate follow-up actions on incidents.

b) We also recommend that open incidents be reviewed and the program institute necessary follow-up or close out actions.

4. Inspector's Performance and Capability (Category I)

NRC Guidelines

Inspectors should be competent to evaluate health and safety problems and to determine compliance with State regulations. Inspectors must demonstrate to supervision an understanding of regulations, inspection guides, and policies prior to independently conducting inspections.

For the inspection of complex licensed activities such as permanent low-level radioactive waste disposal facilities, a multidisciplinary team approach is desirable to assure a complete compliance assessment.

The compliance supervisor (may be RCP manager) should conduct annual field evaluations of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

Assessment

On July 20, 1995, the NRC reviewer accompanied a State inspector during an unannounced, routine inspection of a fixed radiography licensee. The inspector was given high marks for the depth of his inspection, his exchange of information with the licensee, and his thorough knowledge of the regulations. The items of non-compliance were correctly identified and the recommendations were appropriate. However, the inspector failed to check his

survey instrument before the inspection or to adequately interview ancillary workers. The exit meeting should have been held at a higher management level, and the inspector should have prioritized his findings for the exit discussion. The results of the accompaniment were discussed with the inspector and his immediate supervisor.

The other two inspectors who perform the majority of the State's inspections have been accompanied by the NRC during previous reviews, and their performance was satisfactory.

There was no documentation that annual field evaluations were conducted by a supervisor during 1993 or 1994. In June 1995, several accompaniments of a new inspector were appropriately documented. However, there is no indication that the emergency response staff member who is now performing independent gauge inspections has been evaluated by the radioactive materials supervisor.

Recommendation

We recommend that the compliance supervisor:

a) accompany each new inspector during an inspection of a licensee typical of the type that will fall within inspector's purview before independent inspections are assigned to the inspector, and

b) conduct annual field evaluations of each inspector to assess performance and to help maintain consistency in the application of the State's policy.

5. Enforcement Procedures (Category I)

NRC Guidelines

Enforcement procedures should be sufficient to provide a substantial deterrent to licensee noncompliance with regulatory requirements. Provisions for the levying of monetary penalties are recommended.

Enforcement letters should be issued within 30 days following inspections and should employ appropriate regulatory language clearly specifying all items of noncompliance and health and safety matters identified during the inspection, and referencing the appropriate regulation or license condition being violated.

Enforcement letters should specify the time period for the licensee to respond, indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). The inspector and compliance supervisor should review licensee responses.

Licensee responses to enforcement letters should be promptly acknowledged as to adequacy and resolution of previously unresolved items.

Written procedures should exist for handling escalated enforcement cases of varying degrees.

Impounding of material should be in accordance with State administrative procedures.

Opportunity for hearings should be provided to assure impartial administration of the radiation control program.

Assessment

Review of the written enforcement procedures confirmed that the State has enforcement procedures that should be sufficient to ensure licensee compliance with regulatory requirements. The enforcement system assigns points equated with the seriousness of the violations and has action levels above which escalated enforcement is required. The radiation control program director explained that although the State has no civil penalties, they achieve the necessary compliance by using the other methods available to them, such as follow-up inspections, management meetings, enforcement conferences, changes to license conditions, confirmatory action letters, orders, and license suspension or revocation. Results of the file reviews indicate the enforcement policy is effective.

The file reviews indicated enforcement and acknowledgement letters were issued promptly. The letters used appropriate regulatory language and were clearly written. The items of concern are clearly differentiated from the items of non-compliance. Licensees are required to respond to enforcement letters within 30 days, and the inspector and program manager review the licensee responses. In the 15 cases sampled, the licensees had responded within the specified time period.

However, during the file reviews it was found that the appropriate enforcement action was not carried out in three separate cases. The failure to cite a licensee for an unauthorized user was discussed above in the assessment for the indicator, "Responses to Incidents and Alleged Incidents." In two instances, the escalated enforcement required by the procedures was not taken. In the first case, the inspector recommended a follow up inspection in three months after the severity level of the violations exceeded the specified number of points. At the time of this review, fifteen months after the inspection, the follow up inspection had not been conducted. In the second case, the inspection report identified a repeat severity level II violation; however, the inspection cover letter to the licensee stated that there were no items of non-compliance and that no action would be necessary.

Recommendation

We recommend that actions be taken, such as increased management oversight of the inspection results and enforcement actions, to assure that appropriate enforcement actions are taken in accordance with the State's enforcement procedures.

6. Inspection Reports (Category II)

NRC Guidelines

Findings of inspections should be documented in a report describing the scope of inspections, substantiating all items of noncompliance and health and safety matters, describing the scope of the licensees' programs, and indicating the substance of discussions with licensee management and licensee's response.

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

Assessment

According to information supplied by the State, 123 inspections were conducted during the review period. Of these, 15 were selected for in-depth casework review. During this review period, five staff members conducted inspections, and the files were selected to evaluate the work of each. Although one of the inspectors is no longer with the program, this inspector's work was included in the sampling to verify the adequacy of the inspection forms and supervisory review. The cases reviewed consisted of licenses in the following categories: academic, portable gauge, type A broad scope industrial, industrial radiography, medical, manufacturing and distribution, mobile nuclear service and nuclear pharmacy.

The overall quality of the inspection reports was not sufficient to meet the guidelines as deficiencies were found in 12 of the 15 inspection reports. Although the compliance supervisor signs off on all inspection reports and enforcement letters, 21 errors or omissions were found during the file reviews.

In some cases, inadequate forms or mistakes in boilerplate letters resulted in deficiencies. The inspection forms have no place to record review of the licensee's incident file. As a result, two cases were identified in which the licensee's corrective actions to prevent further occurrences of similar incidents were not reviewed or documented. In two cases, the enforcement letter boilerplate was inaccurate in describing the point system.

In other cases, deficiencies appeared to be caused by lack of attention to detail in completing the inspection form. In two instances the inspector's independent measurements were not adequately documented. In ten other cases, one of a kind errors or omissions also indicated failure to follow the procedures.

Recommendation

a) We recommend that the inspection forms be revised to include review of the licensee's incident file.

b) We recommend that the program examine the process for preparation, review, and issuance of inspection reports and institute actions to ensure inspection reports are completed and adequately document the results of inspections.

7. Status and Compatibility of Regulations (Category I)

NRC Guidelines

The State must have regulations essentially identical to 10 CFR Part 19, Part 20 (radiation dose standards, effluent limits, waste manifest rule, and certain other parts), Part 61 (technical definitions and requirements, performance objectives, and financial assurances), and those required by UMTRCA, as implemented by Part 40.

The State should adopt other regulations to maintain a high degree of uniformity with NRC regulations.

For those regulations deemed a matter of compatibility by NRC, State regulations should be amended as soon as practicable, but no later than 3 years.

The radiation control program (RCP) should have established procedures for effecting appropriate amendments to State regulations in a timely manner, normally within 3 years of adoption by NRC.

Opportunity should be provided for the public to comment on proposed regulation changes (required by UMTRCA for uranium mill regulation.)

Pursuant to the terms of the Agreement, opportunity should be provided for the NRC to comment on draft changes in State regulations.

Assessment

Oregon has adopted equivalent regulations to all NRC regulations which were deemed matters of compatibility and which needed to be adopted through 1995. Each rule and the accompanying documents and correspondence were reviewed to verify that the State provided drafts of the proposed regulations to the NRC and made the suggested changes before submitting them for final adoption. It was also verified that the public had opportunity for input by reviewing the Public Hearing Officer Comments.

During this review period the following regulations were adopted by the State: "Decommissioning Rule," 10 CFR Parts 30, 40, and 70, amendments which were needed by July 27, 1991, were adopted on May 6, 1994; "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70, amendments which were needed by April 7, 1993, were adopted on May 6, 1994; "Standards for Protection Against Radiation," 10 CFR Part 20, amendment which was needed by January 1, 1994, was adopted on May 6, 1994; "Safety Requirements for Radiographic Equipment," 10 CFR Part 34, amendment which was needed by January 10, 1994, was adopted on April 26, 1995; "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70, which were needed by October 15, 1994, were adopted on May 6, 1994; "Quality Management Program and Misadministrations" 10 CFR Part 35, which was needed by January 27, 1995, was adopted on April 26, 1995; and "Decommissioning Recordkeeping: Documentation Additions" 10 CFR Parts 30, 40, and 70, which are needed by October 25, 1996, was adopted May 6, 1994. The State has no large irradiators and plans to defer adoption of 10 CFR Part 36, "Licensing and Radiation Safety Requirements for Irradiators." The State is reminded of the following NRC regulations that will require equivalent State regulations in order to maintain compatibility:

- "Licenses and Radiation Safety Requirements for Irradiators", 10 CFR Part 36 (58 FR 7715), that became effective on July 1, 1993, and may need to be adopted by July 1, 1996. With respect to this rule, however, State management staff indicated that the State has no licensees that are subject to this rule and they are aware of no plans or current interest in the public or private sector to build a large irradiator. If there are no licensees in the State that would be subject to this rule, it is acceptable to the NRC that the State defer adoption of the rule. To defer adoption, the State is requested to confirm to NRC that there are no facilities subject to the rule and that if an application for an irradiator subject to the rule were to be received, the State would take action to adopt a compatible Part 36 rule, and until such rule became effective, to incorporate the provisions of Part 36 through license conditions.

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70, amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994, and which will be need to be adopted by January 28, 1997.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70, amendments (59 FR 36026) that became effective on August 15, 1994, and which will need to be adopted by August 15, 1997.

- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35, amendments (59 FR 61767, 65243, and 60 FR 322) that became effective on January 1, 1995, and which will need to be adopted by January 1, 1998.

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20, amendment (60 FR 7900) that became effective on March 13, 1995, and which will need to be adopted by March 13, 1998.

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 (60 FR 15649) that becomes effective on March 1, 1998, and which will need to be adopted by March 1, 1998.

Four of the six regulations adopted during the review period required more than 3 years to promulgate. The delay in adoption of regulations during this past review period was due to staffing turn over, several regulations needing adoption since the last review period, and all regulations needing Oregon legislative approval (Oregon legislature meets biannually).

Recommendation

Oregon management should examine their rule procedures and should adopt compatible regulations within the three year time frame.

SUMMARY OF DISCUSSIONS WITH STATE REPRESENTATIVES

A summary meeting regarding the results of the review was held with Ms. Hall on July 28, 1995. The meeting was also attended by Mr. Paris and Thomas Johnson, Assistant Administrator, Center for Environment and Health Systems.

The State was thanked for their cooperation and congratulated on adopting compatible regulations. The history of the Agreement State Program and the review process was briefly reviewed with Ms. Hall. It was explained to Ms. Hall that the NRC had always had an excellent working relationship with the State of Oregon. All parties agreed that a good working relationship between the State and the NRC continues to be important. The NRC IMPEP program was also explained and discussed.

Mr. Hornor then pointed out that the results of the review showed weaknesses in the radioactive materials program, that if allowed to continue, could jeopardize the State's ability to protect public health and safety. The problems in each of the program indicators above were discussed at length.

Ms. Hall and Mr. Paris voiced their concerns about the findings and committed to start action to address the findings immediately. Ms. Hall outlined her preliminary plans to address the findings in a letter to Richard Bangart dated July 28, 1995. A copy of that letter and enclosures are enclosed with this report along with a letter dated August 22, 1995, from Mr. Paris to Mr. Hornor, which clarified the action plan to reduce inspection backlogs.

Mr. Hornor advised the State representatives that the final determination of the findings of adequacy and compatibility will be made by NRC management. It was pointed out that the State's willingness to take immediate steps to address the findings would be taken into consideration.

Ms. Hall and her staff thanked Mr. Hornor for his review and suggestions. They asked for a follow-up review after approximately 6 to 12 months so that they could demonstrate to the NRC that they are committed to conducting a first-rate radiation control program.

SUMMARY OF ASSESSMENT OF INDICATORS FULLY SATISFIED
BY THE OREGON RADIATION CONTROL PROGRAM
APRIL 2, 1993, TO JULY 28, 1995

The assessments below are based upon the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the program managers and staff members, reviewer observations, review of the State's policies and procedures, and licensing and inspection casework file reviews. The State fully satisfies the following indicators:

1. Legal Authority (Category I)

NRC Guidelines

Clear statutory authority should exist, designating a State radiation control agency and providing for promulgation of regulations, licensing, inspection, and enforcement.

States regulating uranium or thorium recovery and associated wastes pursuant to the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) must have statutes enacted to establish clear authority for the State to carry out the requirements of UMTRCA.

States regulating the disposal of low-level radioactive waste in permanent disposal facilities must have statutes that provide authority for the issuance of regulations for low-level waste management and disposal. The statutes should also provide regulatory program authority and provide for a system of checks to demonstrate that conflicts of interest between the regulatory function and the developmental and operational functions shall not occur.[1]

Assessment

The Oregon Health Division is designated as the State radiation control agency by the Oregon Revised Statutes (ORS) 453.605 to 453.755. The implementing rules are contained in the Oregon Administrative Rules (OAR), Chapter 333, Divisions 100 to 199. Copies of the enabling statutes and the rules have been provided to the NRC Region IV Walnut Creek Field Office and were reviewed.

Oregon has no agreement to regulate primary uranium recovery operations. Because the State is a member of the Northwest Compact, which utilizes the Hanford, Washington low-level radioactive disposal facility, there has been no need to provide for the promulgation of low-level waste disposal regulations.

2. Location of the Radiation Control Program Within the State Organization (Category II)

NRC Guidelines

The RCP should be located in a State organization parallel with comparable health and safety programs. The Program Director should have access to appropriate levels of State management.

[1]The level of separation (e.g., separate agencies) should be determined for each State individually.

Where regulatory responsibilities are divided between State agencies, clear understandings should exist as to division of responsibilities and requirements for coordination.

Assessment

The radiation control program is administered by Radiation Protection Services (RPS), a section of the Center for Environmental and Health Systems within the Oregon Health Division (OHD). The Health Division is one of six divisions of the Department of Human Resources whose Director reports directly to the Governor.

The reviewer was furnished copies of interagency agreements which are in place between RPS and the Oregon Departments of Environmental Quality, Energy, Occupational Safety and Health, and the Metropolitan Tri-County Government Agency to provide certain monitoring, cleanup, disposal, and emergency response functions. The RPS Section, however, has the primary responsibility for radiation control.

From discussions and review of documents, the reviewer was satisfied that the RCP director has access to the appropriate levels of State management.

3. Internal Organization of the RCP (Category II)

NRC Guidelines

The RCP should be organized with the view toward achieving an acceptable degree of staff efficiency, place appropriate emphasis on major program functions, and provide specific lines of supervision from program management for the execution of program policy.

Where regional offices or other government agencies are utilized, the lines of communication and administrative control between these offices and the central office (Program Director) should be clearly drawn to provide uniformity in licensing and inspection policies, procedures, and supervision.

Assessment

Based upon discussions and review, Radiation Protection Services is divided into three programs. Radioactive Materials handles licensing and compliance for all radioactive materials, including general licenses and NARM. Emergency Response, in addition to emergency response and incident tracking, coordinates all rulemaking. Electronic Products is responsible for regulating x-ray and tanning machines. At the time of this review, a fourth program, Environmental Surveillance, had recently been discontinued because of budget cuts, and some of the duties and staff had been transferred to the remaining programs.

The small size of the program necessitates frequent cross-over staff assignments. For example, some gauge inspections are performed by the Emergency Response staff, and the Radioactive Material staff respond to incidents. Unclear specific lines of responsibility among program managers appeared to create problems in tracking and reporting incidents. These problems are discussed in Enclosure 2.

4. Legal Assistance (Category II)

NRC Guidelines

Legal staff should be assigned to assist the RCP, or procedures should exist to obtain legal assistance expeditiously. Legal staff should be knowledgeable regarding the RCP program, statutes, and regulations.

Assessment

Oregon policy requires each program to pay the costs of legal assistance out of operating funds. During the 1993 summary meeting with management, we expressed our concern that perhaps this practice may discourage the use of appropriate legal assistance and strongly recommended that legal assistance be provided to the radioactive materials program without reducing funds available for licensing and inspection. In their response, State management explained that they had found the cost of obtaining legal services had no negative impact on program functions. They also explained that if unexpected legal costs were incurred, funds are available from other sources.

According to figures supplied by program management, RPS spent approximately $55,000 for legal services in 1994. Legal assistance was provided for such diverse issues as setting the radioactive materials fee structure, collecting outstanding fees, the ongoing Precision Castparts Corporation enforcement case, preparing legislative bills, and reviewing Federal rules. After discussing the issue with the RCP and examining several recent invoices prepared by the Department of Justice, the reviewer concluded that this method of providing legal assistance is satisfactory.

5. Technical Advisory Committees (Category II)

NRC Guidelines

Technical committees, federal agencies, and other resource organizations should be used to extend staff capabilities for unique or technically complex problems.

A State Medical Advisory Committee should be used to provide broad guidance on the uses of radioactive drugs in or on humans. The Committee should represent a wide spectrum of medical disciplines. The Committee should advise the RCP on policy matters and regulations related to use of radioisotopes in or on humans.

Procedures should be developed to avoid conflict of interest, even though Committees are advisory. This does not mean that representatives of the regulated community should not serve on advisory committees or not be used as consultants.

Assessment

ORS 453.645 establishes the State's Radiation Advisory Committee and assigns the selection of the eight members to the OHD administrator. Members are to be selected on the basis of their technical qualifications. The list of members provided by the State in the questionnaire shows that members offer a broad range of expertise from the medical community, academia, and industry. Although no formal conflict of interest procedures have been developed, according to program management, advisory committee members are not asked for technical assistance in any case where a conflict of interest may be involved. Recommendations from the Committee are not binding, nor is the RPS required to implement any recommendations from the Committee.

6. Contractual Assistance (Category II)

NRC Guidelines

Because of the diversity and complexity of low-level radioactive waste disposal licensing and regulation, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have procedures and mechanisms in place for acquisition of technical and vendor services necessary to support these functions that are not otherwise available within the RCP.

The RCP should avoid the selection of contractors which have been selected to provide services associated with the LLW facility development or operations.

Assessment

Oregon is in the Northwestern Compact and will not be regulating a low-level waste disposal site in the near future. The guidelines under this indicator are not applicable.

7. Quality of Emergency Planning (Category I)

NRC Guidelines

The State RCP should have a written plan in response to incidents at licensee facilities which takes into account such incidents as spills, overexposures, transportation accidents, fire or explosion, theft, etc.

The plan should define the responsibilities and actions to be taken by State agencies. The plan should be specific as to persons responsible for initiating response actions, conducting operations, and cleanup.

Emergency communication procedures should be adequately established with appropriate local, county, and State agencies. Plans should be distributed to appropriate persons and agencies. NRC should be provided the opportunity to comment on the plan while in draft form.

The plan should be reviewed annually by program staff for adequacy and to determine that content is current. Periodic drills should be performed to test the plan.

Assessment

The radioactive materials emergency plan, "Oregon State Health Division Emergency Response," is a section of the statewide emergency plan, "State of Oregon Emergency Operations Plan." A copy of the plan is kept in the NRC Walnut Creek Field Office. The emergency communications list, which was last updated in February 1995, lists the RPS managers and technical staff as first responders to be called in case of an emergency. It also lists the support agencies and defines their roles.

The plan was evaluated and updated in December 1994; however, the changes were not significant. The last major revision was in February 1993, and because it was evaluated by the NRC at that time, it was not reviewed in depth during this review.

Two table-top scenarios were conducted by the reviewer to test the effectiveness of the emergency plan and the preparedness of the primary responders. In the first scenario, a transportation accident caused an industrial radiography source to come out of its shield, and in the second, I-131 was found on a bus. The emergency response manager and one of his

responders participated in the scenarios and both indicated they would take the appropriate response actions. Even though periodic drills were not conducted, the table-top scenario exercises indicated the State could adequately respond to emergencies.

8. Budget (Category II)

NRC Guidelines

Operating funds should be sufficient to support program needs, such as staff travel necessary to the conduct of an effective compliance program, including routine inspections; follow-up or special inspections (including pre-licensing visits) and response to incidents and other emergencies; instrumentation and other equipment to support the RCP; administrative costs in operating the program, including rental charges, printing costs, laboratory services, computer and/or word processing support; preparation of correspondence; office equipment; hearing costs; etc., as appropriate. States regulating the disposal of low-level radioactive waste facilities should have adequate budgetary resources to allow for changes in funding needs during the LLW facility life cycle. After appropriations, the sources of program funding should be stable and protected from competition from, or invasion by, other State programs.

Principal operating funds should be from sources which provide continuity and reliability, i.e., general tax, license fees, etc. Supplemental funds may be obtained through contracts, cash grants, etc.

Assessment

The total amount allotted to the radioactive materials program for the current biennial budget is $869,310. Based on the State's response to the questions and interviews with program managers, the operating budget is sufficient to meet program needs.

The program is 100 percent fee supported, with fees established by the legislature. The last fee adjustment was effective July 1, 1995.

9. Laboratory Support (Category, II)

NRC Guidelines

The RCP should have laboratory support capability in house, or readily available through established procedures, to conduct bioassays, analyze environmental samples, analyze samples collected by inspectors, etc., on a priority established by the RCP.

In addition, States regulating the disposal of low-level radioactive waste in permanent disposal facilities should have access to laboratory support for radiological and non-radiological analyses associated with the licensing and regulation of low-level waste disposal, including soils testing; testing of environmental media; testing of engineering properties of waste packages and waste forms; and testing of other engineering materials used in the disposal of low-level radioactive waste. Access to laboratory support should be available on an "as needed" basis for nonradiological analyses to confirm licensees' and applicants' programs and conditions for nonradiological testing should be prescribed in plans or procedures.

Assessment

The laboratory was formerly part of the Environmental Surveillance Program. Because that program was eliminated by budget cuts, the laboratory is now operated by the Radioactive Materials Program, and the radiochemist has been transferred to the materials staff.

According to information provided by the State, the lab can handle samples in any form, providing they are in the proper counting geometry containers. They do not have the ability to take bulk material and proportion it into counting geometry containers or to do chemical analyses or separation. The lab uses a Packard Tricarb Liquid Scintillation System to analyze low-energy beta emitters. A Tennelec Low Background (LB5110) System is used for alpha and other beta emitters. A Nuclear Measurement Corporation Proportional Counter (PC-5) is also available. A Nuclear Data 9900 System is used for quantitative analysis of gamma emitters. Two intrinsic GeLi detectors are tied to this system. The laboratory also uses a Harshaw 4000 TLD system. If the need exists for a particular type of analysis beyond the scope of the lab's capability, the State seeks the assistance of other laboratories, such as the Oregon State University Laboratory. All contractor laboratories must meet strict quality assurance and quality control requirements.

Also, according to information provided by the State, the lab participates in the Las Vegas EPA Gamma Cross-Check radionuclide verification program and the Northeast Environmental Measurement Laboratory Cross-Check program out of New York. Additionally, any contractor lab that is used in lieu of their own analysis must meet the same QA standards for the particular nuclide being analyzed.

10. Administrative Procedures (Category II)

NRC Guidelines

The RCP should establish written internal policy and administrative procedures to assure that program functions are carried out as required and to provide a high degree of uniformity and continuity in regulatory practices. These procedures should address internal processing of license applications, inspection policies, decommissioning and license termination, fee collection, contacts with communication media, conflict of interest policies for employees, exchange-of-information, and other functions required of the program. Administrative procedures are in addition to the technical procedures utilized in licensing, and inspection and enforcement.

Assessment

After the last review, the State developed a complete set of administrative and technical procedures, based on the CRCPD suggested procedures. The new procedures have been installed on the local network so that they are easily accessible by staff. Seventeen separate sets of administrative and technical procedures were reviewed in depth during this review. All procedures identified in the guideline above were included in this review and found to be satisfactory.

11. Office Equipment and Support Services (Category II)

NRC Guidelines

The RCP should have adequate secretarial and clerical support. Automatic typing and Automatic Data Processing and retrieval capability should be

available to larger (greater than 300-400 licenses) programs. Similar services should be available to regional offices, if utilized.

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.

Professional licensing, inspection, and enforcement staff should not be used for fee collection and other clerical duties.

Assessment

Based upon discussions with management and staff, the clerical support is adequate to meet the needs of the program. Temporary help is available when needed.

The office equipment and computer system also meet the program needs. The staff demonstrated the effectiveness of the computer system for the reviewer by producing several ad hoc reports. The system tracks licensing actions, including soon-to-expire licenses; licensee compliance history; allegations and incident investigations; completed, due, and overdue inspections; and enforcement actions including correspondence and escalated enforcement. All technical staff have access to personal computers. The Division plans to change to a Unix-based operating system in late 1995.

Fee collection and other fiscal duties are handled by the clerical staff within the RPS section, and not by the technical staff.

12. Public Information (Category II)

NRC Guidelines

Inspection and licensing files should be available to the public consistent with State administrative procedures. It is desirable, however, that there be provisions for protecting from public disclosure proprietary information and information of a clearly personal nature.

Opportunity for public hearings should be provided in accordance with UMTRCA and applicable State administrative procedure laws during the process of major licensing actions associated with UMTRCA and low-level radioactive waste in permanent disposal facilities.

Assessment

The State's public information policy is described under "Media Relations" in the Health Division Policy and Procedure Manual (OHD Policy # 01-01-06).

According to the manual provisions, licensing and inspection files are available for inspection by the public within the guidelines of statutes, rules, and policy. Confidential information may, if necessary, be withheld.

13. Qualifications of Technical Staff (Category II)

NRC Guidelines

Professional staff should have bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel, including the director of the radiation protection program, should be commensurate with the type of licenses issued and inspected by the State. For States regulating uranium mills and

mill tailings, staff training and experience should also include hydrology, geology, and structural engineering.[2] For programs which regulate the disposal of low-level radioactive waste in permanent facilities, staff training and experience should include civil or mechanical engineering, geology, hydrology, and other earth science, and environmental science. In both types of materials, staff training and experience guidelines apply to available contractors and resources in State agencies other than the RCP.

Written job descriptions should be prepared so that professional qualifications needed to fill vacancies can be readily identified.

Assessment

In previous reviews it was found that all professional staff in the radioactive materials program have bachelor's degrees or equivalent training and experience. Of the two new staff members, one holds a degree in public health and was formerly the North Dakota radioactive materials program manager; the other transferred from the environmental surveillance laboratory to the materials program and holds a degree in chemistry.

The written job descriptions were not reviewed during this meeting because they were satisfactory at the time of the previous review, and they have not been changed.

14. Staffing Level (Category II)

NRC Guidelines

Professional staffing level should be approximately 1-1.5 person-years per 100 licenses in effect. The RCP must not have less than two professionals available with training and experience to operate the RCP in a way which provides continuous coverage and continuity. The two professionals available to operate the RCP should not be supervisory or management personnel.

For States regulating uranium mills and mill tailings, current indications are that 2-2.75 professional person-years of effort, including consultants, are needed to process a new mill license (including in situ mills) or major renewal, to meet requirements of Uranium Mill Tailings Radiation Control Act of 1978.

States which regulate the disposal of low-level radioactive waste in permanent disposal facilities should allow a baseline RCP staff effort of 3-4 professional technical person-years (in addition to the two professionals for the basic RCP indicated in the first bullet of this indicator). However, in some cases, the level of site activity may be such that a lower level is adequate, particularly if contractor support is on call. In any event, staff resources should be adequate to conduct inspections on a routine basis during operations of the LLW facility, including inspection of incoming shipments and licensee site activities and to respond to emergencies associated with the site. During periods of peak activity additional staff or specialty consultants should be available on a timely basis.

[2] Additional guidance is provided in the Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement (46 FR 7540, 36969 and 48 FR 33376).

Assessment

Calculations show that the present professional staffing level is 1.5 FTEs per 100 specific licenses. This number, however, includes the new staff member who recently transferred from environmental surveillance and is not trained. Throughout the review period, the figure was closer to 1.2 FTEs per 100 specific licenses.

15. Staff Supervision (Category II)

NRC Guidelines

Supervisory personnel should be adequate to provide guidance and review the work of senior and junior personnel.

Senior personnel should review applications and inspect licenses independently, monitor work of junior personnel, and participate in the establishment of policy.

Junior personnel should be initially limited to reviewing license applications and inspecting small programs under close supervision.

Assessment

According to information provided by the State, supervision is adequate to senior and junior staff. Three of the four staff members in the radioactive materials program are considered to be senior personnel because of their experience and training. At the time of the review, the junior staff member had recently been transferred from the environmental surveillance program. According to program management, the new staff member will be monitored by the senior staff during her training period.

16. Training (Category II)

NRC Guidelines

Senior personnel should have attended NRC core courses in licensing orientation, inspection procedures, medical practices, and industrial radiography practices.

The RCP should have a program to utilize specific short courses and workshops to maintain an appropriate level of staff technical competence in areas of changing technology.

The RCP staff should be afforded opportunities for training that is consistent with the needs of the program.

Assessment

The training records of the technical staff were provided by the State. All three senior personnel have attended the NRC core courses, except for one inspector who has not attended the licensing orientation course. Experience has shown that Oregon takes excellent advantage of opportunities for NRC training and can be counted on to send representatives to attend workshops and meetings to keep abreast of current issues.

The training records also showed that the RCP makes good use of training offered by other Federal agencies, such as FEMA and DOE, and staff members

actively participate in Hazmat training. It was also noted that staff attend computer training classes to keep abreast of the changing technology.

Because the new radioactive materials staff member had just been transferred at the time of this review, she has not worked with senior personnel, nor has she taken any of the NRC courses. The emergency response staff member has taken the NRC 5-week health physics course, but none of the core courses. Based on the extent of on-the-job training provided for the emergency response staff member, RCP management determined he was qualified to conduct portable gauge inspections. The State and the NRC are aware of the need to expedite training for the new staff member. (The emergency response staff member is no longer with the agreement materials program.)

The member of the emergency response program who has been assigned to inspect portable gauges accompanied senior staff members during two inspections and has performed one portable gauge inspection independently. Although he is experienced in emergency response, he is still considered to be a junior inspector.

17. Staff Continuity (Category II)

NRC Guidelines

Staff turnover should be minimized by combinations of opportunities for training, promotions, and competitive salaries.

Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. Salaries should be comparable to similar employment in the geographical area.

The RCP organization structure should be such that staff turnover is minimized and program continuity maintained through opportunities for promotion. Promotion opportunities should exist from junior level to senior level or supervisory positions. There also should be opportunity for periodic salary increases compatible with experience and responsibility.

Assessment

One technical staff member left the program to start his own consulting service after he obtained his health physics certification. His position was filled from within the RPS.

Program management feels the salary schedule is adequate to recruit and retain staff. Also, according to program management, State salaries are lower than the private sector. However, with the closure of Trojan and the heavy reductions in force occurring in the Hanford area, State salaries are competitive. The RCP staff indicated that the State also typically provides better job security and better benefits than the private sector.

The lack of turnover indicates there is no problem with staff continuity.

18. Technical Quality of Licensing Actions (Category I)

NRC Guidelines

The RCP should assure that essential elements of applications have been submitted to the agency and that these elements meet current regulatory guidance for describing the isotopes and quantities to be used, qualifications of persons who will use material, facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions.

Additionally, in States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should assure that essential elements of waste disposal applications meet State licensing requirements for waste product and volume, qualifications of personnel, facilities and equipment, operating and emergency procedures, financial qualifications and assurances, closure and decommissioning procedures and institutional arrangements in a manner sufficient to establish a basis for licensing action. Licensing activities should be adequately documented including safety evaluation reports, product certifications, or similar documentation of the license review and approval process.

Prelicensing visits should be made for complex and major licensing actions.

Licenses should be clear, complete, and accurate as to isotopes, forms, quantities, authorized uses, and permissive or restrictive conditions.

The RCP should have procedures for reviewing licenses prior to renewal to assure that supporting information in the file reflects the current scope of the licensed program.

Assessment

At the time of the review, Oregon had 268 specific licenses. During the 24 months prior to the review, 38 new licenses were issued, 68 licenses were terminated, 57 were renewed in entirety, and 588 other amendments were issued. Fifteen licensing files were selected for casework review, including the two new major licenses. Licensing actions selected included three new licenses, three renewals in entirety, eight terminations, and one other amendment. Types of licenses included: two academic, two fixed and portable gauges, one type A broad scope industrial, three institutional medical, two manufacturing and distribution, two nuclear pharmacy, two R&D, and one service license.

The overall quality of the licensing actions was very good, and for the most part, met all of the guideline criteria. Only three minor errors were found, and they were corrected during the review.

19. Adequacy of Product Evaluations (Category I)

NRC Guidelines

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.

The RCP should review manufacturer's information in labels and brochures relating to radiation health and safety, assay, and calibration procedures for adequacy.

Approval documents for sealed source or device designs should be clear, complete, and accurate as to isotopes, forms, quantities, uses, drawing identifications, and permissive or restrictive conditions.

Approval documents for radioactive waste packages, solidification and stabilization media, or other vendor products used to treat radioactive waste for disposal should be complete and accurate as to the use, capabilities, limitations, and site specific restrictions associated with each product.

Assessment

No SS&D registry sheets were issued by Oregon during the review period. The State would use NRC guidance if an application is received.

20. Licensing Procedures (Category II)

NRC Guidelines

The RCP should have internal licensing guides, checklists, and policy memoranda consistent with current NRC practice.

In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, the RCP should have program specific licensing guides, plans, and procedures for license review; and policy memoranda which relate to specific aspects of waste disposal. The program should include the preparation of safety evaluation reports, product certifications, or similar documentation of license review and approval process.

License applicants (including applicants for renewals) should be furnished copies of applicable guides and regulatory positions.

The present compliance status of licensees should be considered in licensing actions.

Under the NRC Exchange-of-Information program, evaluation sheets, service licenses, and licenses authorizing distribution to general licensees should be submitted to NRC on a timely basis.

Standard license conditions comparable with current NRC standard license conditions should be used to expedite and provide uniformity in the licensing process.

Files should be maintained in an orderly fashion to allow fast, accurate retrieval of information and documentation of discussions and visits.

Assessment

Oregon's licensing guides were compared to the NRC's and found to be consistent with current NRC practice. The reviewer determined from the review that the guides, checklists, and sample licenses are closely modeled after those used by the NRC. The State's standard license conditions were also compared with the NRC's and found to be comparable.

The technical licensing procedures are part of the administrative and technical procedures that were reviewed in depth and discussed in Section 11 above. These procedures are kept online to enable the reviewers to quickly locate the appropriate information. The procedures offer step-by-step instructions on reviewing applications, corresponding with the licensee, and issuing licensing documents.

It was verified that the package furnished to applicants for new licenses and renewals contains the appropriate guides and regulatory positions.

According to the information provided by the State, no evaluation sheets, service licenses, or licenses authorizing distribution to general licensees were issued during this review period. However, procedures are in place to ensure such documents are appropriately distributed to the NRC.

The licenses and inspection reports are filed in the same file folder, making the compliance records readily available to the reviewer. Procedures require the licensee's compliance history be taken into account in renewals and amendments. The files were all found to be orderly and the computer tracking system efficient in tracking licensing actions.

21. Inspection Frequency (Category I)

NRC Guidelines

The RCP should establish an inspection priority system. The specific frequency of inspections should be based upon the potential hazards of licensed operations, e.g., major processors, and industrial radiographers should be inspected approximately annually. Smaller or less hazardous operations may be inspected less frequently. The minimum inspection frequency, including initial inspections, should be no less than the NRC system.

Assessment

Review of the priority schedule shows that Oregon's inspection frequency is comparable to the NRC's system, except for a limited number of licenses that are inspected more frequently. Program management explained that Oregon's inspection frequencies are tied to the fee schedule and can only be changed by legislation. The next opportunity for change, if needed, will be when the legislature meets in 1997.

22. Inspection Procedures (Category II)

NRC Guidelines

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. NRC Guides may be used if properly supplemented by policy memoranda, agency interpretations, etc.

Written inspection policies should be issued to establish a policy for conducting unannounced inspections, obtaining corrective action, following up and closing out previous violations, interviewing workers and observing operations, assuring exit interviews with management, and issuing appropriate notification of violations of health and safety problems.

Procedures should be established for maintaining licensees' compliance histories.

Oral briefing of supervisors or the senior inspector should be performed upon return from non-routine inspections.

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

Assessment

The State's inspection procedures were among the 17 sets of procedures that were reviewed in depth. These procedures, like the others, are based on the CRCPD recommended procedures, and meet all criteria listed in the guideline above. The State also keeps a current copy of the NRC Inspection Procedures Manual and supplements their own procedures with the NRC's when needed for unusual circumstances.

The need to add a section on the inspection forms for review of licensee's incident records was addressed in Enclosure 2 in the inspection reports section.

According to the written procedures, routine inspections within the Portland area are not announced in advance. To insure the availability of the licensee, out-of-town inspections are announced unless the licensee's inspection history indicates the need for an unannounced inspection. All licensing and compliance documents are filed in the same folder, including past inspections, and the compliance history is also in the database. There is no formal procedure for providing feedback of information to the license reviewer; however, because of the small size of the program, licensing and compliance duties are somewhat intermingled, and information is exchanged verbally as needed. There was no indication in the casework that this is not satisfactory. The radioactive materials supervisor is debriefed after each inspection and the results are documented.

23. Confirmatory Measurements (Category II)

NRC Guidelines

Confirmatory measurements should be sufficient in number and type to ensure the licensee's control of materials and to validate the licensee's measurements. In States which regulate the disposal of low-level radioactive waste in permanent disposal facilities, access to testing should be available on an "as needed" basis for confirming licensees' and applicants' programs for measurements related to nonradiological aspects of facility operations, such as soils and materials testing, environmental sampling and analysis to demonstrate compliance with 10 CFR Part 61 or compatible Agreement State regulations, and ensure facility performance. Conditions for nonradiological testing should be prescribed in plans or procedures.

RCP instrumentation should be adequate for surveying license operations (e.g., survey meters, air samples, lab counting equipment for smears, identification of isotopes, etc).

RCP instrumentation should include the following types: GM Survey Meter, 0-50 mR/hr; Ion Chamber Survey Meter, several R/hr; micro-R-Survey meter; Neutron Survey Meter, Fast and Thermal; Alpha Survey Meter, 0-1,000,000 c/m; Air Samplers, Hi and Lo Volume; Lab Counters, Detect 0.001 u/wipe; Velometers; Smoke Tubes; and Lapel Air samplers.

Instrument calibration services or facilities should be readily available and appropriate for instrumentation used. Licensee equipment and facilities should not be used unless under a service contract. Exceptions for other State Agencies, e.g., a State University, may be made.

Agency instruments used for surveys and confirmatory measurements should be calibrated within the same time interval as required of the licensee being inspected.

Assessment

The NRC reviewer confirmed that the inspectors are making and documenting appropriate measurements by reviewing the compliance files, by observing a field accompaniment, and by conducting interviews with the inspectors. The inspection reports documented that wipes are taken and analyzed for all licensees with soft beta sources, such as H-3 and C-14. Procedures require that other wipes be taken whenever meter surveys indicate surface contaminants.

According to information provided by the State and review of the calibration procedures, survey instruments are calibrated annually by Oregon State University Radiation Center. An instrument database identifies instrument kits coming due for calibration. Kit calibrations are staggered throughout the year to ensure that there are an adequate numbers of calibrated instruments at any time if there were an emergency.

Examination of the instruments showed that all required instruments are available to the staff and are properly calibrated.