DATED: AUGUST 7, 1995

Sandra B. Nichols, M.D., Director Arkansas Department of Health 4815 West Markham Street Little Rock, AR 72205-3867

Dear Dr. Nichols:

This is to transmit the results of the Nuclear Regulatory Commission's (NRC) review and evaluation of the Arkansas radiation control program. This review, which concluded on May 26, 1995, was conducted by Mr. Robert J. Doda, State Agreements Officer, Region IV. The results of this review were discussed with you and Ms. Greta Dicus, Director, Division of Radiation Control and Emergency Management on May 26, 1995. Mr. L. J. Callan, Regional Administrator for NRC's Region IV Office, also attended this meeting.

As a result of our review of the State's program and the routine exchange of information between the NRC and the State, the staff determined that, at this time, the Arkansas program for the regulation of certain Atomic Energy Act radioactive materials, is adequate to protect the public health and safety. However, a finding that the program is compatible with NRC's program is being withheld because certain sections of the State's equivalent of the following regulations are not compatible with the NRC's regulations:

- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendments, which were to be adopted by January 10, 1994;
- "Package Opening Procedures," 10 CFR Part 20 amendments, which were to be adopted by January 1, 1994; and
- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 40, and 70 amendments, which were to be adopted by October 15, 1994.

We recognize that the State addressed some aspects of the notification of incidents rule in a license condition. However, this license condition covers only part of the amended rules. Amendments in the State's regulations are required for the compatibility determination.

In addition to the three regulations above, certain sections of the State's "Quality Management Program and Misadministrations," equivalent to NRC's 10 CFR Part 35 amendments, are not compatible with NRC's regulations. The State's definition of "misadministration" is not compatible with NRC's definition and the State's regulations do not contain definitions of the terms "prescribed dosage," "recordable event," and "written directive." Although the definitions in the State's rule are not compatible with those of the NRC, this will not be used as a basis for the withholding of a finding of compatibility at this time. As part of an NRC evaluation of the regulation of radioactive materials used in the practice of medicine, NRC plans to reassess whether Agreement State adoption of all provisions of this rule will be used as a basis for a determination of compatibility. Upon completion of that Dr. S. B. Nichols -2-

evaluation, we will inform all Agreement States concerning whether the Quality Management (QM) rule promulgation will be a basis for compatibility determination.

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, as opposed to only discussing those indicators where deficiencies were noted.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 summarizes our review findings 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.

Enclosure 3 presents a summary of the review findings where the State has fully satisfied the indicators. A response to the items in Enclosure 3 is not required.

We commend the State on its continued efforts to improve the radiation control program. Specifically, we noted the State's plans to reduce the turnover of technical personnel, and the State's in-house continuing training program. The State's commitment to the training program has facilitated the orientation of new staff. In addition, we noted that the Department of Health (DOH) has no inspection backlog.

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

Sincerely,

Richard L. Bangart, Director Office of State Programs

Enclosures:

- Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"
- Status of Previous Findings and Summary of Review Findings and Recommendations for the Arkansas Radiation Control Program (February 26, 1993, to May 26, 1995)
- 3. Summary Assessment of Indicators Fully Satisfied by the Arkansas Radiation Control Program (February 26, 1993, to May 26, 1995)

cc w/enclosures: G. Dicus, Director Arkansas Division of Radiation Control and Emergency Management Dr. S. B. Nichols

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cc w/enclosures:

G. Dicus, Director Arkansas Division of Radiation Control and Emergency Management

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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 <u>Federal Register</u> 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 a 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 ARKANSAS RADIATION CONTROL PROGRAM FEBRUARY 26, 1993, TO MAY 26, 1995

# SCOPE OF REVIEW

The 26th regulatory program review with Arkansas representatives was held during the period May 22-26, 1995, in Little Rock, Arkansas. This program review was conducted in accordance with the Commission's Policy Statement for Reviewing Agreement State Programs published in the <u>Federal Register</u> 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 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 Ms. Greta Dicus, Director, Division of Radiation Control and Emergency Management; Mr. Bernie Bevill, Supervisor, Emergency Management Section; Mr. Rick Kelley, Supervisor, Compliance Section; and Mr. Jared Thompson, Supervisor, Licensing and Registration Section.

The program review was conducted by Mr. Robert Doda, State Agreements Officer, Region IV, NRC. Mr. Doda visited the Division of Laboratories on May 25, 1995, to observe newly acquired counting equipment. An inspection accompaniment with a State inspector was made at Jefferson Regional Medical Center, Pine Bluff, Arkansas, on March 28, 1995.

# CONCLUSION

The State's program for regulation of certain Atomic Energy Act radioactive materials is, at this time, adequate to protect the public health and safety. However, a finding that the program is compatible with NRC's program is being withheld because sections of the State's equivalent of the following regulations are not compatible with the NRC's regulations:

- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendments, which were to be adopted by January 10, 1994;
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- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 40, and 70 amendments, which were to be adopted by October 15, 1994.

We recognize that the State addressed some aspects of the notification of incidents rule in a license condition. However, this license condition covers only part of the amended rules. Amendments in the State's regulations are required for the compatibility determination.

In addition to the three regulations above, certain sections of the State's "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment regulations are not compatible with NRC's regulations. The State's definition of "misadministration" is not compatible with NRC's definition and the State's regulations do not contain definitions of the terms "prescribed dosage,"

"recordable event," and "written directive." Although the definitions in the State's rule are not compatible with those of the NRC, this will not be used as a basis for the withholding of a finding of compatibility, at this time. As part of an NRC evaluation of the regulation of radioactive materials used in the practice of medicine, NRC plans to reassess whether Agreement State adoption of all provisions of this rule will be used as a basis for a determination of compatibility. Upon completion of that evaluation, we will inform all Agreement States concerning whether the QM rule promulgation will be a basis for compatibility determinations.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous program review were reported to the State in a letter to Dr. Joycelyn Elders, Director, Arkansas Department of Health, dated July 22, 1993. All comments and recommendations made at that time have been satisfactorily addressed and resolved, except for one indicator. The current status of each finding is as follows:

#### 1. Administrative Procedures (Category II Indicator)

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

## Comment from the February 1993 Routine Review

A review of the procedures for response to materials incidents revealed that the telephone lists for contact with media are not complete. Although media organizations were listed, there were only blanks for the telephone numbers. Similar lists attached to procedures for response to fixed nuclear facility emergencies are complete and current.

## Recommendations from the February 1993 Routine Review

The phone lists in the materials response procedures should be completed and regularly checked, or the procedures should be modified to reference similar lists in the fixed nuclear facilities emergency response procedures, if appropriate.

#### May 1995 Status

A review of Attachment III of the State's Emergency Response Manual indicated that the list of telephone numbers for the contact with media is current. The reviewer also noted that this list is routinely updated by the Division.

## 2. <u>Staff Continuity (Category II Indicator)</u>

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

#### Comment from the February 1993 Routine Review

Staff turnover continues to be a problem. In the last 2 years, a total of four individuals have left staff positions in the materials section. Since there are only three staff positions and one supervisory position in the section, this amounts to more than a 100 percent turnover rate in the staff positions. Most of the other problems observed during this review can be

directly or indirectly related to this turnover problem. It is to be noted that some measures have already been taken and other efforts are underway to resolve the major contributing factor in the turnover, the relatively low staff salaries.

#### Recommendation from the February 1993 Routine Review

The program management should continue their current efforts to seek salaries competitive with the salaries paid by other employers which have attracted staff from the Arkansas program.

### May 1995 Status

The Department has been aware of the staff turnover problem for some time. Considerable effort has been devoted into achieving a salary level that should help address the issue of staff turnover. In June 1994, a new salary structure was implemented. This structure provides for substantial raises based upon experience and training. The purpose of the new salary structure is to assist the program in retaining technical staff once they have been trained.

A root cause of staff turnover was the loss of health physicists shortly after they had completed training because salaries were not commensurate with those paid elsewhere for experienced personnel. It is believed that the new salary structure will help to alleviate this problem. Staff turnover during this review period consisted of two technical staff members. The Division has always been able to fill vacancies that occur in a timely manner, and the two new staff members who were recently added to the program are well qualified. 3. Licensing Procedures (Category II Indicator)

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

## Comment from the February 1993 Routine Review

During the review of licensing policies and procedures, a procedure was found which allows a nuclear medicine license applicant to be exempted from the requirement to survey packages containing radiopharmaceuticals if the packages are received from a nuclear pharmacy. The procedure was adopted in 1982, and apparently has not been reviewed or updated since that time. It is noted that a complete review of the program's procedures is planned.

#### Recommendation from the February 1993 Routine Review

This procedure should be repealed, and the planned review of the procedures should be completed as early as possible.

## May 1995 Status

In the Arkansas response to comments contained in our letter dated August 16, 1993, the State disagreed with NRC's recommendation regarding the repeal of the 1982 procedure allowing nuclear medicine licensees to be exempt from the required survey of packages received from a nuclear pharmacy. The Division believed that the procedure was justified, and presented no health and safety risk since it contained guidelines limiting its applicability. Based upon further evaluation of this issue, discussion with Arkansas staff regarding this procedure, and a review of licensing files during the May 1995 review,

the extent to which the Arkansas staff had used the 1982 procedure which allows exceptions to package surveys was not clear. Recent licensing actions did not appear to include this exception on medical licenses as a license condition. In addition, the Arkansas radiation control program (RCP) staff indicated that they cite licensees who do not perform a survey of packages received from nuclear pharmacies in accordance with Arkansas's regulations. This issue will be referred to the State for resolution. (See recommendation below under the indicator "Licensing Procedure" in the section "Current Review Assessments and Recommendations" of this Enclosure.)

In addition, the evaluation revealed that Arkansas' regulations regarding package surveys are not compatible with NRC's package opening procedures in 10 CFR Part 20. Arkansas did not modify this section of its regulations when the new 10 CFR Part 20 regulations were adopted by the State. (See recommendation below under the indicator "Status and Compatibility of Regulations," in the section "Current Review Assessments and Recommendations" of this Enclosure.)

#### 4. <u>Inspection Reports (Category II Indicator)</u>

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

### Comment from February 1993 Routine Review

The modifications to the inspection report forms for medical and broad scope licensees recommended at the last review have not been completed due, primarily, to the staff turnover.

## Recommendation from February 1993 Routine Review

Program management should consider placing a higher priority on completing the modifications, even before the turnover problem is resolved. The use of complete forms is even more important for relatively inexperienced staff.

#### May 1995 Status

Inspection report forms are available for medical and broad scope licensees. The Division uses NRC inspection report forms as guides for the information that is included on the Division's forms.

## CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 25 of these indicators. Recommendations were made for the five indicators discussed below. None of the comments on Category I indicators, other than the comment on Status and Compatibility of Regulations are considered to be significant, as defined in Enclosure 1. The remaining 25 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, review observations,

licensing and inspection casework file reviews, and accompaniment of the State inspectors. Specific assessments and recommendations are as follows:

## 1. <u>Status and Compatibility of Regulations (Category I)</u>

## NRC GUIDELINE

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 RCP has 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

Arkansas' "Rules and Regulations for Control of Sources of Ionizing Radiation" were updated early for a number of the necessary regulations for purposes of compatibility. However, the review disclosed that certain sections of the State's equivalent of the following regulations were not compatible with NRC's regulations.

• "Safety Requirements for Radiographic Equipment," 10 CFR Part 34, amendments, which were to be adopted by January 10, 1994.

The Arkansas regulations do not include 10 CFR 34.20, "Performance requirements for radiography equipment," and paragraphs (a) and (f) of 10 CFR 34.33, "Personnel Monitoring,"

• "Standards for Protection Against Radiation," 10 CFR Part 20, amendments, which were to be adopted by January 1, 1994.

The Arkansas regulations do not include paragraph (b) of 10 CFR 20.1906, "Procedures for receiving and opening packages."

• "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments, which were to be adopted by October 15, 1994.

The Arkansas regulations do not include 10 CFR 30.50, "Reporting Requirements." In addition, the Arkansas regulations equivalent

to 10 CFR 20.2202, "Notification of incidents," should delete the following statements under paragraph (a):

"(3) A loss of 1 working week or more of the operation of any facilities affected; or

(4) Damage to property in excess of \$200,000."

and the following statements under paragraph (b):

"(3) A loss of 1 day or more of the operation of any facilities affected: or

(4) Damage to property in excess of 2,000."

We do recognize that Arkansas addressed some of the requirements of the incident notification rule in a license condition. However, incorporation into the State's regulations is necessary for compatibility.

In addition, we would like to bring to the State's attention the following regulations that will be needed for compatibility purposes in the future:

- "Licenses and Radiation Safety Requirements for Irradiators,"
  10 CFR Part 36 amendments (59 FR 7715) that became effective on July 1, 1993, and which will need to be adopted by July 1, 1996.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993, and which will need to be adopted by October 25, 1996.
- "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 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 amendments (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 amendments (60 FR 15649) that will become effective March 1, 1998, and which will need to be adopted by March 1, 1998.

## Recommendation

We recommend that the regulations identified above be adopted as soon as possible, and that efforts on upcoming regulation revisions be initiated in order to meet the three-year time limit for compatibility.

## 2. <u>Management (Category II)</u>

## 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.

## <u>Assessment</u>

Based upon an evaluation of the RCP's inspection tracking system, discussions with the RCP staff and the RCP's responses to the NRC routine review questionnaire, the following assessment was made. The RCP has inspection and licensing status data available from the Division's tracking system. Status reports, which are generated from the tracking system, contain current and projected lists of inspections and license review cases that are due for action. These reports provide management with the means to assign priorities.

The Division's radioactive materials program maintains management oversight of license cases with the staff during processing. Staff members bring issues and questions to the Division Director for resolution. The Director also has the opportunity to discuss and review significant licensing actions with the staff prior to approval. All new licenses and renewal applications are reviewed by a section manager. The Division Director meets with Section Supervisors and administration personnel no less than monthly in formal meetings, and on occasion more frequently, based upon needs. Informal meetings with Section Supervisors occur at least weekly (several times weekly, if necessary). Administrative meetings are usually held weekly. Section Heads meet with staff on an asneeded basis, usually weekly.

However, Arkansas' backlog of overdue license renewals had been increasing steadily during the review period. An evaluation of the licensing backlog, and the resources necessary to address this backlog was made. At the time of the review, 65 licenses were in timely renewal. Arkansas has a total of 267 radioactive material licenses. By reviewing the license mix of overdue actions and through discussions with Division staff, it was concluded that this backlog represented over one person year of effort. In addition, there is additional effort necessary to amend most of the State's licensing guides, primarily due to the recent adoption of Part 20-equivalent regulations.

## **Recommendation**

We recommend that the program's management staff examine and take action to reduce the backlog.

## 3. <u>Licensing Procedures (Category II)</u>

#### 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

Based primarily on RCP staff discussions and review of RCP documents, the reviewer determined that the Arkansas program uses internal licensing guides,

checklists, and policy memoranda consistent with current NRC practices. License applicants are furnished copies of applicable guides and regulatory positions. The Division prepares written versions of NRC licensing guides. Some of these need updating due to the new Arkansas regulations equivalent to NRC's Part 20. The staff confers on both license reviews and compliance inspections to assure that the current compliance status of licensees is considered in licensing actions. Preliminary review and screening of applications are normally done within a few days of receipt. Approximately 3 months prior to expiration, licensees are notified that their license is coming up for renewal. A log is kept of these notifications and documented phone contacts are made during the month preceding expiration, if either: (1) an extension has not been made, in writing, or (2) no response has been received from the licensee. The State utilizes timely renewal procedures. Licenses are issued for 5-year periods.

In general, files are maintained in a way to allow accurate retrieval of information and documentation of discussions and visits. The State has a system such that all licensing and compliance documents are filed together in the same folder. Division personnel maintain statistical data regarding the number and types of licenses, inspection of such licenses by category, and furnish such statistical data to the NRC on a timely basis and on special request. The State uses standard license conditions similar to those used by NRC. At the time of the review, there was a significant backlog of renewal license applications. New license applications are given priority and are reviewed immediately, and these are up to date. One renewal application is a complex action that will take an extended amount of time to complete.

As noted in the section, "Status of Program Related to Previous NRC Findings," Arkansas has a 1982 procedure which allows nuclear medicine licensees to be exempt from the required survey of packages received from a nuclear pharmacy. In response to comments contained in our letter dated August 16, 1993, the State disagreed with NRC's recommendation regarding the repeal of the procedure. The Division believed that the procedure was justified, and presented no health and safety risk since it contained guidelines limiting its applicability.

Based upon evaluation of this issue, discussion with Arkansas staff regarding this procedure, and a review of licensing files during the May 1995 review, the extent to which the Arkansas staff had used the 1982 procedure which allows exceptions to package surveys was not clear.

## **Recommendation**

We recommend that the RCP review its medical licenses to clearly determine whether or not the 1982 procedure, which allowed exemption from the required survey of packages received from nuclear pharmacy, has been used. Any license conditions that exempt medical licensees from receipt survey should be deleted to assure that surveys of nuclear pharmacy packages will be conducted.

### 4. <u>Enforcement Procedures (Category I)</u>

# 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 RCP.

## Assessment

In the review of the Division's procedures manuals, it was noted that Arkansas does not have written escalated enforcement procedures. The NRC reviewer supplied an outline of subjects for such procedures. During the review of actual cases involving escalated enforcement actions, the reviewer determined that the State does utilize what it considers to be escalated enforcement measures, such as increased inspection frequency, enforcement conferences, and orders, when warranted. Arkansas has civil penalty authority, but has not issued any civil penalties in recent years.

Arkansas has also adopted the deliberate misconduct rule (even though this regulation is not a matter of compatibility) and has applied it to two recent escalated enforcement cases. One of these cases involves multiple misadministrations and has been referred to the Department's legal counsel for assistance.

### Recommendation

Although Arkansas has and uses escalated enforcement measures, when necessary, we recommend that written escalated enforcement procedures be established so that program managers and staff all become familiar with the options available for achieving regulatory compliance under current State policy.

## 5. <u>Status of Inspection Program (Category I)</u>

#### 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 preoperational, 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 upon discussions with staff, review of inspection status reports, and responses to the NRC routine review questionnaire, it was determined that the State's inspection program is up-to-date. During the period covered by this review, the State performed 216 inspections. As of May 1995, there were no licenses overdue for inspection. The Division has instituted a new system for conducting all inspections (including X-Ray and NORM inspections) on an efficient basis. The Division blocks out small areas of the State and an inspector conducts all inspections in that area on the same trip. This system and the availability of two well qualified inspectors over the last year has resulted in an up-to-date inspection program.

During the review period, 325 reciprocity notices were received and only 6 reciprocity inspections were conducted.

#### **Recommendation**

We recommend that the program consider an increase in number of inspections conducted under reciprocity.

## SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held with Dr. Sandra B. Nichols, Director, Department of Health, on May 26, 1995. The meeting was also attended by Ms. Greta Dicus, Director, Division of Radiation Control and Emergency Management. Mr. L. J. Callan, Regional Administrator, NRC Region IV, was present for the meeting and discussed several aspects of the State's agreement materials program with Dr. Nichols. Mr. Robert Doda also held a separate meeting on May 25, 1995, with Ms. Dicus and Mr. Rick Kelley, Supervisor of the Radioactive Materials Section.

The State was commended on the continued efforts to improve the program. Particularly noted were the plans to reduce the turnover of technical personnel, and the in-house continuing training program. The State's commitment to the training program has facilitated the orientation of new staff, which in turn has limited the number of problems associated with the lack of staff stability. Dr. Nichols welcomed the recommendations that were discussed, and she believed they would all be addressed as soon as possible. Dr. Nichols affirmed her commitment to continuing Arkansas' cooperative efforts with NRC. She mentioned NRC's proposed reduction in monetary support for State training efforts as a significant loss for the State to overcome.

## SUMMARY OF ASSESSMENT OF INDICATORS FULLY SATISFIED BY THE ARKANSAS RADIATION CONTROL PROGRAM FEBRUARY 26, 1993, TO MAY 26, 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, licensing and inspection casework file reviews, review of the State's policies and procedures, and an inspector accompaniment. The Arkansas Radiation Control Program (RCP) satisfies 25 of the program indicators. These indicators are as follows:

## 1. <u>Legal Authority (Category I)</u>

## 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.<sup>1</sup>

## Assessment

Based upon previous program reviews, discussions with Arkansas staff, review of responses to the NRC routine review questionnaire, and the confirmation of applicable statutes, the following assessment was made.

The currently effective statutory authority for the Arkansas RCP is contained in "Arkansas Code of 1987, Title 20 (Public Health and Safety), Chapter 21 (Radiation Protection) and Title 8 (Environmental Law), Chapter 8 (Interstate Compacts), Sub-Chapter 2 (Central Interstate Low-Level Radioactive Waste Compact)." The State has the authority to (among others):

- a. Apply civil penalties, Arkansas Code of 1987, Annotated (ACA) 20-21-204,
- b. Collect fees, ACA 20-21-201, and
- c. Require performance bonds or sureties for decommissioning licensed facilities, ACA 20-21-207.

<sup>&</sup>lt;sup>1</sup>The level of separation (e.g., separate agencies) should be determined for each State individually.

Discussions with Division staff indicated that no changes have been made in the Division's legal authority, and the State continues to meet the guidelines under this indicator.

## 2. <u>Location of the Radiation Control Program Within the State Organization</u> (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.

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

#### Assessment

Discussions with the Arkansas RCP staff and a review of the State's organizational charts, indicated that the Arkansas RCP is located in the Department of Health (DOH), and is located comparable to other health and safety programs. The Program Director is the Director of the Division of Radiation Control and Emergency Management. Adequate access to appropriate levels of State management is maintained through the Director of the Department of Health.

#### 3. <u>Internal Organization of the RCP (Category II)</u>

## 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 on discussions with staff in the Division and review of organizational charts, the following assessment was made. During the review period, the RCP was reorganized. The Nuclear and Environmental Safety Section has been replaced by the Programs & Emergency Management Section. There is no longer a Radioactive Materials Section and a X-Ray Section. These two sections have been replaced by the Licensing Accreditation and Registration Section, and the Compliance Section. Under the new organization, staff are cross-trained in both X-Ray and radioactive materials, which allows inspectors to perform both X-Ray and RAM inspections.

The Director of the Division of Radiation Control and Emergency Management provides administrative and managerial support to the RCP. Section Supervisors are responsible for the licensing and inspection of radioactive material users. Another Section Supervisor is responsible for the emergency management activities of the Division. There are no regional State offices for radiation control regarding agreement materials.

Given the size of the program, these organizations appear to be adequate for achieving an acceptable degree of staff efficiency and providing specific lines of supervision for program management and execution of program policy.

### 4. <u>Legal Assistance (Category II)</u>

## 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

Based on discussions with staff in DOH and responses to the questionnaire, the following assessment was made. Legal staff is assigned to the DOH and provides legal assistance to the Division. Other legal staff is available from the State Attorney General's office, if the need exists, for escalated enforcement actions. In addition, Department policy is for legal actions to be taken by the Prosecuting Attorney of the county in which the incident occurred for follow-up.

Major areas of legal support have included determining if requested information could be released to the general public; reviewing contracts with consultants; and reviewing regulations, such as regulations equivalent to 10 CFR Part 20. One major escalated enforcement case was ongoing at the time of the review. This case involved multiple misadministrations and has been referred to the Department's legal counsel. Legal assistance has been adequate for the Arkansas RCP.

## 5. <u>Technical Advisory Committees (Category II)</u>

### 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

Based upon discussions with staff and a review of the RCP's responses to the NRC questionnaire, the DOH RCP has a formal Medical Advisory Committee. The Medical Advisory Committee is authorized by Act 8 of the Second Extraordinary Session of 1961 of the Arkansas General Assembly. Members of the Arkansas Chapter of the American College of Radiology (ACR) serve on the committee on a rotating basis; members are appointed by the ACR. Conflicts of interest are avoided by using advisors from institutions not associated with particular cases. In addition, the State has a Low-Level Waste Advisory Committee, a WIPP Shipment Planning Committee, a Nuclear Planning and Response Advisory Committee, and a Mammography Advisory Committee.

The Division also relies on the NRC's Office of State Programs and Region IV personnel for assistance with technically complex licensing or inspection programs. The Division recently worked closely with NRC staff on a sealed source and device review. This device is the Graseby detection cell for an ion mobility spectrometer.

## 6. <u>Contractual Assistance (Category II)</u>

### 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

This indicator is not applicable as the State does not regulate the disposal of low-level radioactive waste.

## 7. <u>Quality of Emergency Planning (Category I)</u>

## 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

Based upon discussions with the RCP staff and the RCP's responses to the NRC routine review questionnaire, the following assessment was made. DOH has the lead responsibility in Arkansas for response to radiological incidents not involving a nuclear reactor. The Arkansas RCP, as required by Act 511 of 1973, as amended, uses the Arkansas Emergency Operations Plan (EOP). The EOP comprehensive State plan for responding to emergencies was developed and is administered by the Arkansas Office of Emergency Services. The radiation emergency operations annexes are: Annex N, Radiation Protection Systems and Annex V, Radiological Emergency Response Plan Arkansas Nuclear One (nuclear power plant).

Notification procedures provide for notification and communication with appropriate government agencies and are organized so that qualified individuals are readily available through channels of communication. The plan also identifies responsibilities and actions to be taken by State agencies.

The State's emergency plan is a comprehensive one, which is intended to cover major accidents at nuclear facilities, but Annex N also adequately covers noncatastrophic incidents. The plan is reviewed periodically to assure it is kept current. The most recent revision did not change the agreement materials aspects of the plan. The next revision of the plan is scheduled for later in 1995. A health physics drill occurred on December 7, 1994, that tested radiation monitoring and communication procedures. The emergency call list was found to be current and a copy was obtained for the Region IV State files.

Personnel in all program areas are members of the State Radiological Emergency Response Team and collect environmental samples. The Section Manager for Emergency Management coordinates all activities for the State's emergency response teams.

# 8. <u>Budget (Category II)</u>

#### 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 responses 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

Based upon discussions with the RCP staff and the RCP's responses to the NRC routine review questionnaire, the following assessment was made. The Division's funding is sufficient to support the Atomic Energy Act materials program. The program managers stated that there are no impediments to travel, equipment purchase, or administrative support. All of the Division's license fees are specifically earmarked for the Division of Radiation Control and Emergency Management in the DOH. Approximately 30 percent of operating revenues for DOH's materials program are covered by license fees.

However, the RCP staff did indicate that funding was insufficient to support the total RCP activities. These activities include naturally occurring radioactive material (NORM) licensing and remediation activities; Mammography Quality Standard Act (MQSA) responsibilities for an accrediting body; and the ever-expanding use of radioactive materials in medical and industrial applications.

#### 9. <u>Laboratory Support (Category II)</u>

#### 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.

#### <u>Assessments</u>

Based upon an evaluation of laboratory capability during this review, discussions with RCP staff, and the RCP's responses to the NRC routine review questionnaire, the following assessment was made. The radiochemistry laboratory is available within the Arkansas Department of Health, Division of Public Health Laboratories. The time lag between sample submission and receipt of a final report may vary from one day to 3 weeks, depending on workload, sample type, and equipment condition. The average time required to receive a formal report on routine samples is on the order of 3-4 weeks. Emergency samples, including wipes taken during inspections, are counted quickly; with a preliminary report available in a few hours (depending on counting time). The State has purchased a new liquid scintillation counter with alpha capabilities. The lab participates in an ongoing Environmental Protection Agency (EPA) intercomparison program in addition to audits by the EPA. In addition to the radioactive materials program, the lab carries out a reactor environmental surveillance program, and an environmental monitoring program.

## 10. Administrative Procedures (Category II)

## NRC Guidelines

The RCP should establish written internal procedures to assure that the staff performs its duties 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

A review of the Division's administrative procedures manual indicated that written administrative procedures have been established and are in use by personnel. The procedures are located in the radioactive materials manual, the administrative procedures manual, the emergency response manual, and in policy memoranda. Procedures exist for preparation of licenses, license termination, license fee tracking, reciprocity actions, media communications, NRC exchange of information, and other functions required of the program. These procedures manuals are updated frequently to reflect the most up-to-date information.

#### 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 the RCP staff and responses to the NRC routine review questionnaire, adequate equipment and support services are being supplied within the RCP. RCP has word processing (Work Perfect 6.0 and Word Perfect for Windows), data processing and spread sheet programs (Lotus 123, Dbase IV, and Quattro Pro) services available. There are four full-time secretaries assigned to provide clerical support to the RCP. The Nuclear Planning and Response office (Russellville) employs two clerical people, both of whom provide support to the offsite Arkansas Nuclear One emergency preparedness program.

# 12. <u>Public Information (Category II)</u>

# 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.

## <u>Assessment</u>

Based upon discussions with the RCP staff and responses to the NRC routine review questionnaire, the following assessment was made. The RCP uses a DOH procedure to issue public information notices. Paragraph RH-4040 of the Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation contains the Agency's regulation specific to the RCP and its licensees and registrants. In addition, the Arkansas DOH policy and procedure concerning public records is incorporated in the Agency's Administrative Policies and Procedures Manual. All agency files, including licensing and inspection files, are open and available to the public subject to limitation of the open records statutes. As a general rule, only the following categories of information contained in licensing and inspection files are not open records: (a) medical records, (b) proprietary information, and (c) files on active investigations where disclosure would jeopardize the outcome of the investigation. One case was reviewed, the Graseby sealed source and device review. It was concluded that this file was open for public inspection because the licensee did not claim proprietary interest in any of the product's design drawings.

# 13. <u>Qualifications of Technical Staff (Category II)</u>

# <u>NRC Guidelines</u>

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.<sup>2</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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).

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

## <u>Assessment</u>

Based upon discussions with the RCP staff and responses to the NRC routine review questionnaire, the following assessment was made. RCP technical staff members all have bachelor degrees in the physical and life sciences and have specific training in the use of radioactive materials. Resumes of new employees were also obtained during this review and were found to meet the guideline.

The Division's managers and staff have attended numerous technical training courses and have considerable experience with radiation safety programs. The Arkansas Office of Personnel Management job descriptions for Health Physicist Supervisor, Health Physicist II, and Health Physicist I were provided to NRC during past reviews.

#### 14. <u>Staffing Level (Category II)</u>

#### 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.

### Assessment

A review of the Arkansas RCP's staffing levels disclosed that the current staffing level is 1.18 persons per 100 licenses which is within NRC's recommended range of 1.0 to 1.5 person-years per 100 licenses. Arkansas has a total of 266 radioactive material licenses and has 3.10 person staffing level.

## 15. <u>Staff Supervision (Category II)</u>

#### 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

Based upon discussions with the RCP staff and responses to the NRC routine review questionnaire, the following assessment was made. In the RCP, the Division Director and the Section Manager provide licensing and inspection guidance to junior personnel. Currently, all inspection letters and licensing actions are reviewed and signed by management. Senior level personnel in the Division review licensee documents, make necessary changes if any, and sign licenses. Senior personnel are responsible for ensuring that the licensing activities are appropriate and in accordance with Division policy. Inspectors' work is monitored by review of their inspection preparation, debriefing upon return, and review of inspection reports and letters. License reviewers' work is monitored by supervisory review of checklists, deficiency letters, and licensing documents.

#### 16. <u>Training (Category II)</u>

#### 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 are consistent with the needs of the program.

#### Assessment

Based upon discussions with the RCP staff and responses to the NRC routine review questionnaire, the following assessment was made. The DOH has senior staff that are well qualified and have attended many radiation safety training courses over the years. All of the senior personnel in the RCP have attended the NRC core courses. The State emphasizes the NRC core courses for basic program training for their staff members and some new staff members are presently scheduled for these courses. Initial training of new employees usually involves informal (on-the-job) training, including working under the close supervision of senior personnel in conducting materials inspections and reviewing simple licensing actions.

## 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

Based upon discussions with the RCP staff and responses to the NRC routine review questionnaire, the following assessment was made. The Arkansas agreement materials program had two personnel leave the program during this period. This is a definite improvement over previous reviews. The Division was able to fill these two positions in a timely manner with well qualified individuals.

Based upon previous reviews, the Department has had a staff turnover problem in the past. Considerable effort has been devoted into achieving a salary level that should help address the issue of staff turnover. In June 1994, a new salary structure was implemented. This structure provides for substantial raises based upon experience and training. The purpose of the new salary structure is to assist the program in retaining technical staff once they have been trained.

A root cause of staff turnover was the loss of health physicists shortly after they had completed training because salaries were not commensurate with those paid elsewhere for experienced personnel. Arkansas has instituted a system whereby new staff members receive automatic salary increases when certain NRC courses have been satisfactorily completed. This is an effort to retain staff after they have achieved a higher level of training. It is believed that the new salary increases will help to alleviate staff turnover.

## 18. <u>Technical Quality of Licensing Actions (Category I)</u>

#### 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

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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 routine review, the Arkansas RCP had 267 material licenses in effect. During the 1994 calendar year, 16 new licenses were issued; 8 licenses were terminated; 10 licenses were renewed; and 330 amendments were issued. A review of 12 selected license files was performed during the routine review. In general, the essential elements of applications were found to be sufficient to establish a basis for licensing action. The State performed 11 prelicensing visits since the last program review. The staff stated that prelicensing visits are made to most new licensees with offices in Arkansas. Exceptions are made for small industrial licensees. Also, a "relicense" visit may be made prior to issuing an amendment which substantially changes a licensee's program. Applicants must provide a complete new application with all new supporting information (except for preceptor statements) before a license may be renewed.

#### 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

The Division staff stated that one sealed source and device evaluation was performed since the previous review. This was for the Graseby detection cell for an ion mobility spectrometer. The device review was coordinated closely with NRC staff before the Sealed Source and Device (SS&D) registry sheet was finalized. An examination of the Graseby file indicated all necessary design drawings were available for the review process.

## 20. <u>Inspection Frequency (Category I)</u>

## 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, broad licensees, 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

Based upon discussions with staff, review of the RCP's inspection procedures, inspection schedules, and responses to the NRC routine review questionnaire, it was determined that the inspection priority systems in the Arkansas RCP call for inspections at intervals at least as frequent as those required by the NRC inspection priority system. The Division inspects more frequently than the NRC for several categories of licensees.

Inspections are generally unannounced. The inspection priorities are listed in a schedule and are updated as NRC Manual Chapter 2800 is modified. Inspection frequencies may be temporarily reduced or extended based on licensee performance, as allowed by NRC Manual Chapter 2800.

#### 21. <u>Inspector's Performance and Capability (Category I)</u>

## 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

Based upon previous inspector accompaniments and an accompaniment of an inspector during this review, the reviewer determined that the Arkansas radioactive materials inspectors are competent to evaluate health and safety problems and to determine compliance with State regulations and requirements. An inspection manual is used by the RCP, which details training and inspection activities required for inspectors in the program. Prior to receiving authorization to perform independent inspections, new inspection personnel are accompanied by the Section Supervisor. All inspectors are accompanied by the Section Supervisor annually. An inspector was accompanied on an inspection of a medical program by the Region IV State Agreements Officer. The March 28, 1995, accompaniment was Jefferson Regional Medical Center (License No. ARK-623-BP-RA-10-96). The inspector's performance was deemed to meet the guidelines for this indicator. The inspector used an appropriate checklist for the inspection and verified the licensee's handling operations for radioactive materials by discussions with workers, observations of the use of equipment, and a review of records required by the license and the regulations. The inspector reviewed past incidents and misadministrations. All necessary records were found to be complete, by the inspector, except for daily survey records for therapeutic administrations of radionuclides. The inspector adequately evaluated radiation safety and determined compliance with the license conditions and the State's regulations.

#### 22. 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

A review of the Division's incident/event file (45 reported events during 1994) revealed that the agency was timely in responding to reported incidents/events and dispatched personnel as appropriate. Incident/event reports were comprehensive in scope and investigation findings were supported by backup documentation, when necessary. During the last year, only two incidents needed to be reported to NRC and five incidents received on-site

inspections. Incident details and response actions are discussed with the Regional State Agreements Officer in certain cases. Telephone inquiries are made to determine the need for an immediate onsite investigation. Medical consultants are available and used when necessary, including medical consultation through the NRC. Often individuals telephoning the Division with allegations do not provide their names. If this is the case, no effort is made to obtain the names(s). If an individual provides his or her name and requests non-disclosure, every effort is made to provide that protection. The Division responds to all allegations; this includes allegations where the alleger is not identified.

### 23. <u>Inspection Procedures (Category II)</u>

## 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.

### <u>Assessment</u>

Based upon discussions with the RCP management and the review of sample information from the RCP's computer tracking system, along with the review of inspection and licensing files, the following assessment was made.

The Division has improved the quality of its inspections by hiring additional staff, providing training, and providing supervisory oversight. An inspection manual is used as a guide and a training tool for all radioactive materials inspectors. It also includes several Inspection Report Forms. These are used by all materials inspectors to perform inspections and document inspection findings while still in the field. The report forms address every type of inspection performed in Arkansas.

The RCP utilizes NRC inspection guidance as contained in Manual Chapter 2800 and Inspection Procedure 87100. Inspection policy memoranda or information notices are used to inform licensees of new compliance requirements or changes in policy. Staff personnel are informed of inspection policy changes in staff meetings and/or training sessions. Inspectors are also given copies of these memoranda for review and comment.

## 24. 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

Based upon discussions with individual inspectors, responses to the NRC routine review questionnaire, and a review of selected compliance files, the following assessment was made.

For the Arkansas RCP, findings of inspections are documented satisfactorily in the inspection reports which also describe the scope of the inspections, as well as all noncompliance items and any health and safety matters. The reports reviewed (8 inspection reports) were comprehensive in scope, detailed in discussions of inspection findings, and included program areas that should be reviewed in detail at the next scheduled inspection. At the end of each section of the report, there is an area to list items of noncompliance, recommendations, or comments. There is also a page at the end of the report for a summary in each of the above areas. Each section of the form also contains a narrative subsection where the inspector can explain in more detail pertinent aspects of the inspection or items not included on the form. Arkansas radioactive material inspection reports, which were reviewed, indicated that the reports meet NRC guidelines.

#### 25. <u>Confirmatory measurements (Category II)</u>

## 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 uC/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

Based upon discussions with inspectors, an inspection accompaniment, and a review of compliance files, it was determined that inspectors are making and documenting appropriate radiological measurements during inspections. An inventory of the radiation survey instruments and laboratory equipment that is available to the staff is adequate for the scope of this agreement materials program.

The Arkansas RCP has a policy for calibration of all of the instruments used for radiation surveys. These instruments are calibrated at frequencies equivalent to those required for licensees. Calibrations are performed in the Division's own calibration facility. This facility was visited by the NRC reviewer during the program review.

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