

DATED: JAN 27, 1995;

SIGNED BY: RICHARD L. BANGART

Mr. Masten Childers II, Secretary
Cabinet for Human Resources
275 East Main Street
Frankfort, KY 40621-0001

Dear Mr. Childers:

This is to transmit the results of the NRC review and evaluation of the Kentucky radiation control program conducted by Mr. Richard L. Woodruff, NRC Regional State Agreements Officer, which was concluded on Friday, May 13, 1994. The results of the review were discussed with you, Dr. John Volpe, Manager, Radiation Control Branch, and Ms. Vicki D. Jeffs, Supervisor, Materials Section.

As a result of our review of the Kentucky radiation control program and the routine exchange of information between the NRC and the State, we believe that the State's program for regulating agreement materials is, at this time, adequate to protect the public health and safety. However, a finding that the program is compatible with the Commission's program is being withheld because a regulation, which is a matter of compatibility, has not been adopted within the three-year period allowed by the NRC. The regulation for the notification of incidents that became effective on October 15, 1991 and was to be adopted by October 15, 1994 has not been adopted by the State. Mr. Woodruff has received a draft copy of your proposed rule revisions and he will review the rule for compatibility and respond directly to your staff with our comments.

We are pleased with the progress and improvements that have been effected in the Kentucky radiation control program. Specifically, we noted that the State's regulations have been updated and made compatible with the NRC's 10 CFR Part 20, "Standards for Protection Against Radiation," the 10 CFR Part 35 regulations on "Quality Management Program and Misadministrations" were adopted, and the personnel reclassification package was approved.

Please note that there has been a change made 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 is a summary of the review findings where recommendations are made for improvements in the radiation control program. Enclosure 2 contains documentation on the Scope of Review, Conclusion, Status of Program Related to Previous NRC Findings, Current Review Assessments and Recommendations, and Summary Discussions with State Representatives. 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; 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 adequately satisfied the indicator. A written response to the items in Enclosure 3 is not required.

We appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff and the other NRC representatives during the review.

Masten Childers

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Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As stated

cc w/encls:
Rice Leach, M.D., Commissioner
Department for Health Services
John Volpe, Ph.D., Manager
Radiation Control Branch
Department for Health Services
Thomas Bennett, State Liaison Officer

Masten Childers

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

We appreciate your cooperation with this office and the courtesy and cooperation extended by your staff to Mr. Woodruff and the other NRC representatives during the review.

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Richard L. Bangart, Director
Office of State Programs

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Thomas Bennett, State Liaison Officer

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

Distribution: See next page.

* See Previous concurrence

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| OFC | RII:RSAO | RII:DRSS | RA:RII | OSP:SA | OSP:DD | |
| NME | RWoodruff | JStohr | SEbnetter | CMaupin | PLohaus | |
| DTE | 11/17/94 | 11/17/94 | 11/17/94 | 11/28/94* | 11/28/94* | |

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| OFC | NMSS:D | OGC | OSP:D | DEDS | EDO | |
| NME | RBernero | FCameron | RBangart | HLThompson | JMTaylor | |
| DTE | 11/30/94* | 12/2/94* | 12/16/94* | 12/28/94* | 12/28/94* | |

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HNewsome, OGC
RBangart, OSP
PLohaus, OSP
CMaupin, OSP
JStohr, RII
RWoodruff, RII
RTrojanowski, RII
TCombs, OCA
SDroggitis, OSP
Kentucky File

DCD (SP01) PDR (YES)

APPLICATION OF "GUIDELINES FOR NRC REVIEW OF
AGREEMENT STATE RADIATION CONTROL PROGRAMS"

The "Guidelines for NRC Review of Agreement State Radiation Control Programs" were published in the Federal Register on May 28, 1992, as an NRC Policy Statement. The Guidelines provide 30 indicators for evaluating Agreement State program areas. Guidance as to their relative importance to an Agreement State program is provided by categorizing the indicators into two categories. Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety. If significant problems exist in several Category I indicator areas, then the need for improvements may be critical.

Category II indicators address program functions which provide essential technical and administrative support for the primary program functions. Good performance in meeting the guidelines for these indicators is essential in order to avoid the development of problems in one or more of the principal program areas, i.e., those that fall under Category I indicators. Category II indicators frequently can be used to identify underlying problems that are causing, or contributing to, difficulties in Category I indicators.

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

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND RECOMMENDATIONS FOR THE
KENTUCKY RADIATION CONTROL PROGRAM
FOR THE PERIOD
APRIL 17, 1992 TO MAY 13, 1994

SCOPE OF REVIEW

The 28th review of the Kentucky Agreement State program was held during the period of April 24 - May 13, 1994 in Frankfort, Kentucky. The 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 guideline indicators provided in the policy statement.

A questionnaire containing the 30 policy guideline indicators with specific questions addressing each indicator was sent to the State prior to the review. This review included the evaluation of the State's written response to the questionnaire, comparison with previous review information, discussions with the program managers and staff members, review team observations, and licensing and inspection casework file reviews.

The State was represented by Dr. John A. Volpe, Manager, Radiation Control Branch and his staff. Selected license and compliance files were reviewed by Mr. Richard L. Woodruff, Regional State Agreements Officer. Sealed Source and Device (SS&D) evaluations were reviewed by Mr. John Lubinski and Mr. Douglas Broaddus from the Office of Nuclear Material Safety and Safeguards. A summary meeting regarding the results of the review was held on Friday, May 13, 1994.

CONCLUSION

As a result of our review of the Kentucky radiation control program and the routine exchange of information between the NRC and the State, we believe that the State's program for regulating agreement materials is, at this time, adequate to protect the public health and safety. However, a finding that the program is compatible with the Commission's program is being withheld because a regulation, which is a matter of compatibility, has not been adopted within the three-year period allowed by the NRC. The notification of incidents regulation that became effective on October 15, 1991 and was to be adopted by October 15, 1994 has not been adopted by the State.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The results of the previous review were reported to Mr. Leonard E. Heller, Secretary, Cabinet for Human Resources, in a letter dated June 16, 1992. All of the comments and recommendations following the 1992 review have been resolved except for the recommendation concerning the Staff Continuity Indicator. An additional recommendation on this indicator was offered during this current review. These previous findings and their current status are presented below.

1. Status and Compatibility of Regulations (Category I)

Comment from the 1992 Routine Review

The State's regulations are compatible with the NRC regulations through the 10 CFR Part 20 amendment on National Voluntary Laboratory Accreditation Program (NVLAP) certifications of dosimetry processors that became effective on February 20, 1988.

The State's regulations meet the three-year policy requirement for the adoption of regulations needed for compatibility, except for the "Decommissioning" regulations of 10 CFR Parts 30, 40, and 70 that became effective on July 27, 1988. The program has drafted new regulations that address the "Decommissioning" regulations, and these new State regulations were projected to become effective in September of 1992. A finding of compatibility was offered, contingent upon the adoption of these new State regulations.

The program managers were also reminded that additional regulations are needed for compatibility as follows:

- "Emergency Planning," 10 CFR Parts 30, 40, and 70 amendments that became effective on April 7, 1990.
- "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendments that became effective on January 10, 1991.
- "Standards for Protection Against Radiation," 10 CFR Part 20 amendments that became effective on June 20, 1991.

Program managers related that the above regulations that are needed for compatibility would be drafted later during this calendar year.

Recommendation from the 1992 Routine Review

We recommend that the State give priority to the adoption of regulations that are needed to maintain compatibility.

Current Status

The "Decommissioning" regulations (902 KAR 100:040) became effective on April 21, 1993. The State adopted the "Emergency Planning" regulations (902 KAR 100:041), "Safety Requirements for Radiographic Equipment" regulations (902 KAR 100:100), "Standards for Protection Against Radiation" regulations (902 KAR 100:019), and the "Quality Management Program and Misadministrations" regulations (902 KAR 100:073) on January 14, 1994. However, since the review was conducted another regulation has become due. This regulation is:

"Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) needed by October 15, 1994.

The State has not adopted this regulation. Thus, compatibility will be withheld.

2. Staff Continuity (Category II Indicator)

Comment from the 1992 Routine Review

Salary levels should be adequate to recruit and retain persons of appropriate professional qualifications. The program lost another senior, trained, professional staff member since the last review. We believe that this was directly related to the salary structure and job classification of the Consumer Health Inspector series. During our 1991 review, we recommended that every effort be made to upgrade the salaries to a competitive level with those salaries of other Radiation Specialist and Health Physicists found in other Agreement States and the industry. During 1991, the Program Manager developed a comparative analysis on the program's job classifications and proposed three separate job classifications for the professional staff. However, official action on the proposal was never completed.

Recommendation from the 1992 Routine Review

We recommend that the State take action on the reclassification package for the Radiation Control Branch technical staff, and upgrade the job series classification.

Current Status

The classification package was approved and the "Class Titles" were revised. The Program Manager related that new hires could be offered a beginning salary at the mid point of the salary range. A three percent (3%) cost of living salary increase was received by all State employees in July of 1993.

The program lost one Radioactive Materials Specialist during the review period and the Supervisor related that the principal reason was the salary level.

This recommendation is closed; however, a related recommendation regarding salary level (Staff Continuity) was offered during this current review. (See next section on current review assessments and recommendations.)

3. Administrative Procedures (Category II Indicator)

Comment from the 1992 Routine Review

The radiation control program (RCP) should establish written internal procedures such as enforcement procedures to assure that the staff performs its duties as required and to provide a high degree of uniformity and continuity in regulatory practices. The State developed enforcement procedures. However, during our casework review and the review of the enforcement procedures, we noted that the procedures do not clearly identify when a licensee is to be called into the program office for an "Informal Hearing" to resolve regulatory issues.

Recommendation from the 1992 Routine Review

We recommend that the State's internal procedures on enforcement procedures (Section 301) be revised to clearly identify when a licensee is to be considered for the escalated enforcement procedure "Informal Hearing."

Current Status

The program's enforcement procedures were revised and implemented. A copy of these procedures was received and reviewed during the 1993 review-visit.

For purposes of the above comment and recommendation, this item is closed.

4. Office Equipment and Support Services (Category II Indicator)

Comment from the 1992 Routine Review

The State has an IBM computer in the Division; however, this equipment is not under the administrative control of the program. The Program Manager related that plans were being made to upgrade the computer to a Local Area Network (LAN) type system for use by the program staff. The reviewers had several discussions with the staff and program managers concerning the efficient use of the computer, and information that could be made available to the program for license reviews, inspections, enforcement, and tracking functions. Although the State satisfies the minimum criteria stated in the indicator guideline, the reviewers believe that the computer upgrade is needed for staff efficiency and that State monies will be saved in the long term.

Recommendation from the 1992 Routine Review

We recommend that the State expedite their plans to upgrade the computer system for utilization by the program's staff.

Current Status

The program has nine computer terminals on the LAN system and two modems. For purposes of the above comment and recommendation, this item is closed.

5. Licensing Procedures (Category II Indicator)

Comment from the 1992 Routine Review

During our review of the licensing casework, we noted that two licenses contained conditions which were redundant to specific rules in the regulations. One of these licenses also had seven other minor comments, and this license was identified to the Section Supervisor. The Section Supervisor related that these conditions were incorporated into the license before the rules became effective, and that the license conditions would be revised when the license is renewed in its entirety. The Supervisor also related that all new licenses are transmitted with a cover letter that specifies certain regulatory requirements that are binding on the licensee. This procedure is not always done with "renewals in their entirety."

Recommendation from the 1992 Routine Review

We recommend that the State renew the identified license in its entirety, and that the State's licensing procedures be modified to provide for cover letters on renewal licenses that also specify certain regulatory requirements that need to be brought to the licensee's attention, such as new or revised regulatory requirements.

Current Status

The program renewed the identified license in its entirety and implemented the recommended modifications to their cover letters on renewal licenses.

For purposes of the above comment and recommendation, this item is closed.

6. Inspection Reports (Category II Indicator)

Comment from the 1992 Routine Review

Findings of inspections should be documented in the report clearly describing the scope of the inspection, the scope of the licensee's programs, and substantiating all items of noncompliance. As a rule, items of noncompliance should be documented with "what" requirement was violated, "when" the requirement was violated, and "how" the requirement was violated. One report needed more details describing the scope of the inspection and the scope of the licensee's program. Two other reports needed more documentation clearly describing "how" a requirement was violated.

Recommendation from the 1992 Routine Review

We recommend that the inspection reports clearly document the details of the report that describe the scope of inspection, scope of the licensee's program, and clearly substantiate all items of noncompliance.

Current Status

The program revised their inspection procedures and report forms. The revisions were discussed with the inspectors and implemented. A review of the inspection reports shows that the reports contain the necessary information.

For purposes of the above comment and recommendation, this item is closed.

CURRENT REVIEW ASSESSMENTS AND RECOMMENDATIONS

All 30 indicators were reviewed and the State fully satisfies 24 of these indicators. Deficiencies were identified under six indicators; however, none of the recommendations are considered significant enough to affect the finding of adequacy. A finding of compatibility is being withheld. A questionnaire containing the 30 policy guideline indicators with specific questions addressing 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, discussions with the program managers and staff members, review team observations, a review of the State's policies and procedures, and licensing and inspection casework file reviews. The specific assessments and recommendations are as follows:

1. 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, financial assurances) and those required by the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), as implemented by Part 40. The State should adopt 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

The State was provided a chronology of regulation amendments that are needed for compatibility for comparison with the Kentucky regulations that have been adopted. This chronology was compared with the Kentucky regulations and a cursory review of the regulations adopted since the last review was performed by the reviewer. This review indicated that the following rules have been adopted by the State since the last routine review: the "Decommissioning" regulations (902 KAR 100:040); the "Emergency Planning" regulations (902 KAR 100:041); "Safety Requirements for Radiographic Equipment" regulations (902 KAR 100:100); "Standards for Protection Against Radiation" regulations (902 KAR 100:019); and the "Quality Management Program and Misadministrations" regulations (902 KAR 100:073). These regulations are currently under compatibility review by the NRC. In addition, since the routine review was conducted another regulation has become due. This regulation is:

"Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 40757) needed by October 15, 1994.

In addition, we would like to bring to the State's attention other regulations that will be needed for compatibility. These rules are:

- "Licenses and Radiation Safety Requirements for Irradiators", 10 CFR Part 36 (58 FR 7715) that became effective on July 31, 1993 and will need to be adopted by July 31, 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 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 will be needed to be adopted by January 28, 1997.

Recommendation

We recommend the overdue regulation, and any others approaching the three-year period allowed after NRC adoption, be promulgated as effective State radiation control regulations as soon as possible.

2. 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 on 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 SS&D review consisted of the review of all certificates that were amended since January 1, 1992, for technical quality, accuracy and consistency of the following areas: format, description, labeling, diagram, conditions of use, prototype testing, radiation levels, quality assurance and quality control, limitations of use and the basis for determining that the source or device design was deemed acceptable for licensing purposes. NRC staff reviewed Kentucky's procedures to determine whether the results of the State's evaluations are sufficient to assure the protection of public health and safety, and to determine if a recommended second independent review and concurrence is performed.

The Kentucky RCP amended seven registration certificates during the period covered by the review, and all seven registration certificates and the appropriate background information were reviewed. These registration certificates were issued to Ronan and Ohmart, the only two registrants located in Kentucky, except for registrants of custom devices. The seven registration certificates were for amendments which required radiation safety reviews, such as changes in source strength and shielding. The background information for five of the seven registration certificates was reviewed in its entirety.

The Kentucky RCP issued only one new registration certificate during the period covered by this review. The registration certificate was for a custom device and only authorized use by a Kentucky specific licensee. The State did not evaluate the device since its design was originally evaluated by NRC. Because of the limited use authorized by the registration certificate and the previous NRC review, the review team did not review the evaluation of this device.

In addition to reviewing the amendments issued during the period covered by the review, a registration certificate originally issued by Kentucky to Ronan prior to 1992 for a generally licensed device was also reviewed. The reason for reviewing this certificate was that the three certificates for specific licensed devices issued to Ronan that were amended did not include radiation levels when the device was in the "ON" position. The three background files were very similar to each other and there was a concern that this information may not have been submitted for generally licensed devices as well. As a result of the review of the file for the generally licensed device issued prior to 1992, three other registration files for generally licensed devices issued to Ronan were reviewed for estimated doses to general licensees. No radiation profile information could be located in the files. The background information for a fourth and the only remaining registration certificate for a generally licensed device issued to Ronan could not be located also. The Kentucky staff indicated that this information along with the radiation profile information may have been archived.

The Ohmart Corporation moved their device operation to Kentucky from Ohio (an NRC State) in 1991. All NRC files were transferred to Kentucky at that time, and Kentucky has performed only radiation safety type evaluations of Ohmart device amendments (such as changes in source strength) since the file transfers. However, the Ohmart files that were transferred contained NRC

requests to Ohmart for additional information. Kentucky staff related that they were not aware of these requests for additional information from Ohmart, and that no further action was taken. The NRC staff will follow-up on this issue in a future review.

The staff's experience and qualifications and the overall staffing of the State appears adequate to perform the radiation safety amendments of SS&Ds which were issued during the review period. The current Kentucky staff has never performed a complete SS&D evaluation, which would include an engineering type review. The RCP staff does not have the engineering technical expertise to perform this aspect of an SS&D evaluation. However, during the review, the RCP staff indicated that for the one device currently awaiting SS&D review, they planned to request NRC technical assistance for the engineering aspect of the review as necessary following the completion of their review. In a discussion with the Kentucky staff on December 13, 1994, it was indicated that the review of this device had not been initiated.

The State does have the appropriate documentation, such as ANSI guides, handbooks, reference guides, and NRC course hand-outs, on file to perform a complete SS&D evaluation.

As a result of our review, the RCP management should develop an action plan to address the following concerns:

- A. No current staff member has ever performed a complete device evaluation and the senior members (Branch Chief and Radioactive Materials Supervisor) related that additional training was needed to enable them to perform in-depth device reviews. In response, a current copy of the device evaluation review checklist used by NRC reviewers was provided to the State during the review. Also, technical assistance available from the Office of Nuclear Material Safety and Safeguards (NMSS) was discussed. The State was requested to identify engineers in other State agencies or universities that could be called upon on an as needed basis for assistance with specific engineering issues. Subsequent to the review, NRC committed in an All Agreement States Letter to provide training for a single representative from each Agreement State.
- B. The review team suggested that all older devices (including the 12 Ohmart NRC device reviews and the 8 Ronan devices) should be reviewed by the State to determine if all drawings and evaluation documents (background information) are present to document adequacy of the products. The review team indicated that a one time expenditure of approximately 0.3 person-years from a SS&D trained individual was needed to review these older SS&D devices. In addition, the review team noted that the State is averaging two to three minor amendments per year and currently has one major amendment request and one new device request under consideration. Based upon NRC experience, this average yearly workload will require approximately 0.1 person-year per year from individuals trained in SS&D reviews. The State indicated that they currently do not have staff available for this average yearly workload and the review of the older devices. The review team discussed the need for additional staffing in the SS&D area with the State's radiation control program management. The recommendation regarding staffing for the SS&D program is further discussed under the staffing level indicator below.
- C. Devices that are manufactured for general license (GL) distribution must meet the general license dose requirement equivalent to 10 CFR 32.51(a)(2). Based upon the available file documentation (some of the

older files had been archived), it could not be determined if the devices for GL distribution could meet this requirement.

- D. The State does not have regulations equivalent to the NRC 10 CFR 30.32(g), which is a Division II compatibility requirement and 10 CFR 32.210, which is a Division III matter of compatibility. 10 CFR 30.32(g) provides that an application for a specific license to use byproduct material in a sealed source or a device must either (1) identify the source or device by manufacturer and model number as registered with the Commission or with an Agreement State or (2) contain the information identified in 32.210(c). Information to be included in an application for a sealed source or a device approval for use is outlined in 10 CFR 32.210(c). This regulation provides that SS&D applications include information on the design, manufacture, prototype testing, leak testing, labeling, proposed uses, and quality control program, and for a device, the application must also include sufficient information on installation, service and maintenance, operating and safety instructions, and its potential hazards.

Recommendation

We recommend improvements of the SS&D evaluation program as follows:

(a) obtain engineering technical expertise for SS&D reviews, such as through contractual agreements or through State agencies or universities, that could be called upon as needed for resolution of specific engineering issues that may be encountered during SS&D reviews; (b) develop an action plan for the review of all device sheets to assure that the files contain all current background information and drawings applicable to the device safety review; (c) establish documentation in the files which show that the generally licensed (GL) devices will meet the dose requirements; and (d) the amendment of the State's regulations to adopt requirements equivalent to those in 10 CFR 30.32(g) and 32.210(c), or amend the SS&D licenses with conditions that specifically tie the respective devices, drawings, and background information to the license.

3. 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 three-four professional technical person-years (in addition to the two professionals for the basic RCP). 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 low-level radioactive waste 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

Based upon the data provided in the questionnaire, interviews with staff, and observations made during the review, we believe that additional staff is needed to maintain a fully adequate and compatible program. Currently the materials program has three technical staff persons and one first line supervisor for the regulation of 391 specific licenses (including 20 major licenses), environmental radiation surveys, response to radiation incidents, and the technical updating of regulations. This staffing was calculated to be equivalent to 0.9 person-years per 100 licenses, which is below the NRC recommended staffing level of 1.0 to 1.5 per 100 licenses. As discussed under the indicator above (Adequacy of Product Evaluations), additional effort is needed for the SS&D evaluations. Also, we noted that the numbers of specific licenses and major licenses are increasing annually. We noted that the Materials Section Supervisor also performs numerous inspection and licensing activities (because of the workload) that are in addition to the supervision and training of junior staff members. We have observed that under optimum training and working conditions, from one to two years of training is needed for the development of an entry level employee into a health physicist capable of independent license reviews and compliance inspections.

In addition, we noted that updating of regulations places additional administrative burden on the technical staff in addition to the technical evaluation of the proposed regulations. We discussed with senior management, the possibility of obtaining administrative assistance on an interim basis, to assist the technical staff in updating and codification of amended regulations.

Recommendation

We recommend that the technical staffing level be increased to the 1.5 persons per 100 licenses ratio, or that contractual support or support from other State agencies be obtained, to accommodate the additional workload needed for SS&D reviews and other major license actions. If additional staffing or outside support is not obtained, the RCP should identify work processing efficiency gains that could be implemented to alternatively address the staffing shortfall. Also, we recommend that provisions be made for the utilization of additional administrative staff as needed for the updating of the radioactive material regulations.

4. 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

All state employees received a three percent (3%) increase in salaries on July 1, 1993. The reclassification package for the radiation control positions was approved and all of the radioactive materials positions were reclassified. However, this reclassification was not accompanied by any

salary increases for all of the technical staff, only the entry level, technical hiring positions were increased. The Materials Section lost one fully trained person reportedly due to the lack of promotion and salary potentials during the review period. This continues to be a chronic problem with the program, in that at least five, fully trained, senior personnel have left the program during the time span of the last several program reviews.

The reviewer compared Kentucky's radioactive material classifications (Specialist, Section Chief, and Program Manager) salary ranges with similar classification salary ranges utilized in other Agreement States in the Southeast area. This comparison showed that Kentucky salary ranges for the radioactive materials classifications are the lowest in the Southeast for similar type positions in other States.

Recommendation

We recommend that the salary ranges for the program staff and management positions be evaluated to assess whether they are adequate to retain qualified staff.

5. Budget (Category II)

NRC Guidelines

Operating funds should be sufficient to support program needs such as staff travel necessary to conduct 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 low-level radioactive waste facility's 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 the budget information provided by the State in the questionnaire, discussions with program managers, and previous review information, it was determined that the budget would not support the hiring of additional technical personnel, or the upgrading of technical salaries, if found to be necessary by the State of Kentucky. The program evaluated their monetary needs based upon their current level of State appropriations and increased the fees by 25% for materials licenses. These monies are paid into an agency fund. However, the monies received from State appropriations were then reduced to offset the increase in fees, which left the materials program funding from fees to be about 94%.

Recommendation

We recommend that additional monies be provided for the hiring of needed additional technical staff for the Materials Section, and for salary upgrades, if needed to maintain staff continuity. Budget increases for technical contractual assistance should also be considered.

6. 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 and persons exempt from licensing 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

Twenty-three licensing files were reviewed for technical adequacy of application review, significant errors and omissions, utilization of licensing procedures and standard conditions, and documentation. Based upon this review, the following assessment was made.

The program essentially utilizes NRC policy guidance and procedures for the evaluation of applications and the writing of the license document. Standard licensing guides have been developed and are available for the applicant's use. The State acknowledged the receipt of the draft Licensing Guide for Remote Afterloading Devices. Standard license conditions are also utilized for uniformity. Copies of NRC's standard licensing conditions, and license review checklists were provided to the program on diskettes for their information.

As noted in the above NRC Guideline, standard license conditions should be used to expedite and provide uniformity in the licensing process. A standard license condition is needed on nuclear pharmacy licenses that require "an authorized user to be physically present whenever licensed material is used." License reviewers need to confirm that industrial radiography licensees and portable gauge licensees have specific procedures concerning the control of device keys for devices being stored and/or transported.

Recommendation

We recommend that a standard license condition requiring that "an authorized user be physically present whenever licensed material is used" be added to all nuclear pharmacy licenses, and that licensing procedures require verification that industrial radiography and portable gauge licensees have adequate control of device keys when the devices are being stored and transported.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A preliminary meeting with Mr. Fontaine Banks, Jr., Acting Secretary, Cabinet for Human Resources, Dr. Rice Leach, Commissioner, Department for Health Services, and Dr. John Volpe was held on April 29, 1994 to discuss the scope

of the review and to arrange for a summary meeting with the new Secretary, Mr. Masten Childers, II.

A final summary meeting to present the results of the regulatory program review was held on Friday, May 13, 1994, with Mr. Masten Childers, II, Secretary, Cabinet for Human Resources, Dr. John Volpe, Manager, Radiation Control Branch, and Ms. Vicki D. Jeffs, Supervisor, Radioactive Materials Section.

The reviewer provided background information to Secretary Childers on the Agreement State program and the Kentucky review, and discussed the scope of the review and the indicators with comments. The organizational changes in the Office of State Programs were discussed, and the Secretary was informed that the reviewer would recommend findings of adequacy and compatibility, and that a letter confirming the review would be forthcoming from the Director, Office of State Programs.

In reply, Secretary Childers related that he would continue to support the program, and that he appreciated our comments and recommendations, and the opportunity to discuss the radiation control program.

SUMMARY OF ASSESSMENT OF INDICATORS ADEQUATELY SATISFIED
BY THE KENTUCKY RADIATION CONTROL PROGRAM
FOR THE PERIOD
APRIL 17, 1992 TO MAY 13, 1994

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, review team observations, review of the State's policies and procedures, and review of licensing and inspection casework files. The State fully satisfies the following 24 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 radioactive 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.

Assessment

Clear statutory authority exists (Kentucky Radiation Control Act of 1978, KRS 211.842 to 211.852) which designates the Kentucky "Cabinet for Human Resources" as the State radiation control agency with authority for evaluation and control of hazards associated with the use of sources of ionizing, non-ionizing, and electronic product radiation. The Act provides for promulgation of regulations, licensing, fees, inspections, financial sureties, and enforcement. A copy of this Act, complete to December 1, 1992 is on file, and program managers related that there had been no additional changes to the Act. The Act was not reviewed since there were no changes from the previous review.

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

Assessment

The organizational chart depicting the program relative to other health and safety programs was reviewed. The RCP is located in the State organization parallel to other health and safety programs. The Secretary, Cabinet for Human Resources, is appointed by the Governor and reports to the Governor's Office through the Secretary of the Executive Cabinet. The Cabinet has seven

Divisions, one of which is the Division of Environmental Health and Community Safety that contains six Branches including the Radiation Control Branch.

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

The internal organizational chart was reviewed and the organizational structure was discussed with the Program Director. There have been no changes in the internal organization of the RCP since the last review. In general, the program is organized to place emphasis on major program functions, and provides specific lines of supervision for execution of program policy through three separate sections. These sections are the Radiation/Environmental Monitoring Section, the Radiation Producing Machines and Operator Certification Section, and the Radioactive Materials Section.

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, statutes, and regulations.

Assessment

The RCP has adequate legal assistance and support from the Department of Law, which also reports to Secretary Childers. The RCP has utilized legal assistance as needed for enforcement cases, and issues concerning regulations, fees, and financial assurance issues.

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

The State has never had a formal technical advisory committee and the State relies upon the NRC, EPA, DOE, FDA and other Federal and sister State agencies for technical resources if needed. Members of an informal advisory committee of medical licensees and health physics specialists were utilized for evaluation of a medical license applicant's training during this routine review period. The State uses this informal advisory committee on an infrequent basis. This approach has been found to be acceptable.

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 low-level radioactive waste facility development or operations.

Assessment

This guideline was not evaluated because the State, at present, does not have a low-level radioactive waste disposal regulatory program.

7. Quality of Emergency Planning (Category I)

NRC Guidelines

The State RCP should have a written plan for response to 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 RCP has a written emergency response plan. The plan was tested in 1991 utilizing other State agencies, and the NRC and FEMA participated. The Radiation Control Branch (RCB) has updated the telephone listing for emergency response, and made distribution as appropriate. Two incidents occurred during the review, and the plan was observed by the reviewer to work as intended, and the State's response was excellent. The emergency communication listing was updated in March of 1994.

8. Laboratory Support (Category II)

NRC Guidelines

The RCP should have the 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 facilities 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 radioactive 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

Based upon the reviewer's knowledge of the laboratory and discussions with RCP management, the program has a state of the art laboratory, capable of analyzing a wide variety of radionuclides and all types of environmental media. Environmental samples are also collected and analyzed from the Maxey Flats site and the Martha Oil Field property. The casework establishes that environmental media samples and contamination smears are collected by the inspectors during inspections and incident evaluations for evaluation in the laboratory. Quality Control has been established through the analysis of samples shared with the EPA laboratory in Montgomery, Alabama.

9. 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

The internal procedures developed by the program since the last review were reviewed and discussed with the supervisors and the technical staff. Special attention also was given to the review of the procedures for handling proprietary information, allegations, incident tracking, misadministrations, and enforcement procedures. The State has established procedures that address administrative, licensing, and inspection and enforcement topics. A review of the casework and the reviewer's discussions with the staff indicated that the level of the program's uniformity and continuity in regulatory practices is appropriate.

10. 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 fundings. 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, and those which have the 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 Materials Section Supervisor prepares monthly reports on the status of licensing and enforcement actions, and misadministrations. The current monthly report was reviewed. Discussions with program staff revealed that staff meetings are held at least weekly with the section supervisor and on an as needed basis. File documentation indicates that all licensing actions,

inspection reports and enforcement cases receive supervisory review. Documentation reviewed also showed that all inspectors are accompanied at least annually.

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 (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 staff should not be used for fee collection and other clerical duties.

Assessment

The program's computer system has been upgraded to a local area network (LAN) and the system has modem capability to link with the Internet System. Licenses are generated and stored via the computer, and enforcement letters are computerized. The program currently utilizes a contractor for generation of licensing/inspection data for quarterly reports; however, the State has plans to phase out this contract and for the transfer of this data system to the LAN. Each Section has an administrative person (Secretary) for administrative support and the program has it's own facsimile machine and copy machine for daily use. Larger reproduction jobs and tasks are available from the other divisions as needed.

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 operates under an "open records" law which requires files to be available to the public. Proprietary information can be withheld as appropriate and administrative procedures have been developed for the management of this type of information. The procedures were reviewed.

13. Qualifications of Technical Staff (Category II)

NRC Guidelines

Professional staff should have a 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. 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

The qualifications of the technical staff were reviewed and all technical staff members have at least a Bachelor of Science degree in the physical and/or life sciences. They are also attending the NRC sponsored training courses as the courses become available. All of the technical staff meet the requirements of the guideline.

14. 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

A review of the training and experience of the senior personnel and first line supervisors indicates that these personnel are adequate to provide guidance to junior and senior personnel. Discussions with staff and the review of casework indicates that the supervisor reviews the work of all personnel, and projects and tasks are assigned appropriately to the staff.

15. 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 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

All of the senior personnel and most of the junior personnel have attended the NRC core courses. One staff member attended the Oak Ridge Institute for Science and Technology five-week Health Physics course in July of 1994. The RCB also utilizes short courses and workshops sponsored by other agencies to the extent possible.

16. 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 which 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, Kentucky had 389 specific licenses in effect. During the review period, a total of 23 new licenses were issued; 26 licenses were terminated; 430 renewals were issued; 323 amendments were issued and 26 terminations were completed. Twenty-three license files were selected for casework review. Based upon the review of these files, the following assessment was made.

The program currently has 19 major licenses and the review sample included major licenses that have never been reviewed previously by the NRC reviewer and those having major amendments. The sample contained 12 of the 19 major licenses (five manufacturing, two distribution, two nuclear pharmacies, one broad academic, one broad medical, and one processor). The remainder of the sample contained three industrial radiography, two well logging, two portable gauge, three institutional medical, and one private medical license. The technical quality of the licensing actions was determined to meet all of the criteria listed in the above guideline, and only minor, isolated comments were noted. The program does not have a licensing backlog, and pre-licensing visits to the major licenses are conducted as needed.

17. Status of Inspection Program (Category I)

NRC Guidelines

The 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 low-level radioactive waste 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. There should

be at least semiannual inspection planning for the number of inspections to be performed, assignments to senior versus 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

The computerized inspection tracking system was reviewed. The program does not have any inspections that are overdue for inspection. The status of the inspection program is assessed monthly and on a quarterly basis, and the inspection due listing is generated on a semi-annual basis. A review of the casework and the system indicates that licenses and inspections are coded properly and the information is properly entered into the tracking system.

18. 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, 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 for initial inspections should be no less than the NRC system.

Assessment

A comparison was made of the inspection frequencies utilized by the State and those utilized by NRC. The State utilizes the same inspection frequencies as those of the NRC.

19. 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

All State inspectors have been accompanied by supervisors since the last review, and the junior inspectors train with the senior inspectors on team inspections. All inspectors have been accompanied by the reviewer within the past three years except for one person who is still in training. This inspector attended the five-week Health Physics course in July of 1994, and will be accompanied during the next review-visit. Documentation reviewed also showed that all inspectors are accompanied at least annually.

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

NRC Guidelines

Inquiries should be promptly made to evaluate the need for on-site investigations. On-site 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. On-site 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

All of the incident files for the 1992 and 1993 calendar years have been distributed to the Office of State Programs. The incidents for 1993 were reviewed by Richard L. Woodruff including the file and data systems utilized by the State, and the regulations related to incident reporting requirements. The State's incident reporting system, with emphasis on medical misadministrations, was discussed with the program managers. The program maintains logs of misadministrations, complaints, allegations, and events along with the summary forms that are used for file documentation. The procedures for handling complaints, misadministrations, and allegations have been updated and reviewed without comments.

The files indicate that 26 events occurred during the 1993 calendar year. No events would be considered misadministrations under NRC regulations. The State performed 16 on-site investigations in 1993. The program has been very responsive in responding and evaluating incidents and alleged incidents as they occur.

21. 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

The State's regulations (902 KAR 100:170) contain provisions that are taken in regard to violations of receipt, use, and transfer of radioactive materials. These "regulations" provide for Notice of Violations, Enforcement, Orders, Informal Hearings, and Formal Hearings. The State can assess monetary penalties for violations of State regulations through the State court system.

The program has issued orders to three licensees since the previous review, and six informal hearings have been held to resolve compliance issues. The State has also utilized increased inspection frequency on one licensee to monitor compliance with regulatory requirements. The enforcement procedures and practices were reviewed during the casework reviews and the results indicate that the procedures along with the regulations provide a substantial deterrent to licensee noncompliance.

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

Assessment

All of the materials inspectors have attended the NRC Inspection Procedures Course, and the program utilizes the Inspection Guidance and Procedures provided by NRC Inspection Manual, Inspection Procedure 87100 and Manual Chapter 2800. Updated copies of the these chapters were provided on diskette to the program managers during the review for implementation. The State procedures, guides, and the casework reviews that were performed indicate that the inspection procedures are consistent with NRC guidance, and are adequate to provide complete and uniform technical guidance to the staff inspectors.

23. 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 licensees' programs, and indicating the substance of discussions with licensee's management and licensee's response. Reports should uniformly and adequately document the results of inspections 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 independent physical measurements made by the inspector.

Assessment

Twenty-one compliance files were selected for the casework review. This sample included casework from each compliance inspector. The casework consisted of one nuclear pharmacy, one processor, five manufacturing, two distribution, four industrial radiography, one broad medical, one broad academic, two institutional medical, one private medical, two well logging, and one portable gauge licenses. The reports uniformly documented

inspections, which included documentation of independent measurements made by the inspectors.

Only minor, isolated comments were developed from the casework reviews. These comments were discussed with the technical staff at the conclusion of the review and were not indicative of any generic problems associated with the inspection reports.

24. 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 and 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 samplers, 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: up to several R/hr
- Neutron Survey Meter: Fast & Thermal
- Alpha Survey Meter: 0-100,000 c/m
- Air Samplers: Hi and Low Volume
- Lab Counters: Detect 0.001 μ Ci/wipe
- Velometers
- Smoke Tubes
- 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.

(Note: Additional types of instrumentation that are highly desirable are thin window plastic or NaI detectors for low energy gammas and "micro-R" meters with audio signal for searching for lost gamma emitter sources.)

Assessment

The inspection reports were reviewed for documentation concerning confirmatory measurements and independent measurements, and were found to be consistent with NRC practices and sufficient to document licensee performance. The program utilizes a Nashville based commercial calibration facility for the routine calibration of portable instrumentation. The program also has purchased a portable multichannel analyzer for use. The listing of portable instrumentation was reviewed, and the operability and calibration was checked on a sampling of instruments.