

DATED: MARCH 15, 1996

SIGNED BY: RICHARD L. BANGART

John H. Morse, Secretary  
Cabinet for Human Resources  
275 East Main Street  
Frankfort, KY 40621-001

Dear Mr. Morse:

Enclosed is a copy of the staff report on the results of the visit to your radioactive materials program during the period of August 15-18, 1995. We recognize our delay in the issuance of this report due to completion of our review of Kentucky regulations. The report reflects the status of NRC's comments following the May 13, 1994, review of the Kentucky program, and updated information that was collected during the visit on other selected indicators.

During the 1994 routine review, a compatibility finding was withheld from the Kentucky program because the State had not adopted the "Notification of Incidents," amendments that were needed by October 15, 1994. The 1995 visit confirmed that this regulation, and all regulations needed for compatibility, at this time, had been adopted by the State. Subsequent to the visit, the State's notification of incident regulation and decommissioning regulations were reviewed by NRC staff and were found to be compatible with NRC's regulation. Therefore, the staff has determined that, at this time, the Kentucky program for the regulation of certain Atomic Energy Act materials is compatible with the regulatory program of the NRC.

We have noted that your staff has an action plan to review the remaining sealed source and device (SS&D) sheets, and we are pleased that two of your staff members attended the NRC sponsored workshop on the review and approval of SS&D applications. The information discussed in the workshop will assist in standardizing the SS&D reviews on a national basis, and we will review the actions taken by your staff relative to this indicator during the next review of your radioactive materials program.

Sincerely,

Richard L. Bangart, Director  
Office of State Programs

Enclosure: Staff Report

cc w/encl:

Mark Hooks, Assistant Director  
Division of Environmental Health  
and Community Safety  
John A. Volpe, Ph.D, Supervisor  
Radiation and Toxic Agents Control Section  
Division of Environmental Health and  
Community Safety, State Liaison Officer

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Cabinet for Human Resources  
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Community Safety, State Liaison Officer

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\*See previous concurrence.

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Kentucky File

STAFF REPORT  
KENTUCKY REVIEW VISIT

Visit Dates: August 15-18, 1995  
Last Review Date: May 13, 1994  
Next Review Date: Recommended for April, 1996

SCOPE OF VISIT

A review visit was held with personnel responsible for the Kentucky radiation control program during the period of August 15-18, 1995. The review visit consisted of a follow-up on the status of NRC comments dated January 27, 1995, to the State following our May 13, 1994, program review; the accompaniment of one State inspector; and the status of reviewer selected program elements and indicators derived from observations made during the visit and discussions with program management and program staff.

The following persons were contacted during the meeting:

Dr. Michael W. Easley, DDS, MPH, Director  
Division of Environmental Health & Community Safety  
Department of Health Services  
Cabinet for Human Resources  
Dr. John A. Volpe, Ph.D, Supervisor  
Radiation & Toxic Agents Control Section  
Division of Environmental Health & Community Safety  
Ms. Vicki D. Jeffs, Supervisor, Radioactive Materials Unit  
Radiation & Toxic Agents Control Section  
Ms. Sue Osborne, Radioactive Materials Specialist  
Radioactive Materials Unit  
Mr. Michael Wilcoxson, Radioactive Materials Principal  
Radioactive Materials Unit  
Mr. Michael Cleaver, Radioactive Materials Senior  
Radioactive Materials Unit

STATUS OF COMMENTS AND RECOMMENDATIONS TO MR. MASTEN CHILDERS II, SECRETARY,  
CABINET FOR HUMAN RESOURCES DATED JANUARY 27, 1995

1. Status and Compatibility of Regulations (Category I)

Comment from the May 13, 1994 Review

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 from the May 13, 1994 Review

We recommend that 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.

#### August 18, 1995 Status

All of the regulations that were needed for compatibility, at the time of the visit, had been adopted by the State. Subsequent to the review visit, NRC staff completed a review of the final "Notification of Incidents" rule adopted on April 19, 1995, as 902 KAR 100:040, Section 18; 902 KAR 100:100, Section 23; and 902 KAR 100:142, Section 23. This rule was found to be compatible with NRC's regulation. The staff has determined that, at this time, the Kentucky program for the regulation of certain Atomic Energy Act materials is compatible with the regulatory program of the NRC.

The State notified NRC by letter dated November 30, 1994, that the State does not plan on adopting the "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 rule (58 FR 7715) that became effective on July 1, 1993, and will be due by July 1, 1996, at this time. The State indicated that they will wait until an application for a large irradiator is received, and that appropriate license conditions (incorporating the Part 36 requirements) will be utilized during the interim period for all other type irradiators.

Two regulations needed for future compatibility determination, "Decommissioning Recordkeeping, and License Termination: Documentation Additions" adopted as 902 KAR 100:100, Section 15; and "Self-Guarantee as an Additional Financial Mechanism" adopted as 902 KAR 100:040, Section 17, have been reviewed by NRC staff. The results of this review indicate that these regulations are compatible with those of the NRC.

## 2. Adequacy of Product Evaluations (Category I)

#### Comment from the May 13, 1994 Review

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 Radiation Control Program (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. Also, the background information for a fourth, and the only remaining registration certificate for a generally licensed device issued to Ronan, could not be located. 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&D's 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 from the May 13, 1994 Review

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.

#### August 18, 1995 Status

In a letter dated March 28, 1995, the State requested technical assistance from NRC concerning the review of a Ronan device application. The assistance was completed and the information was provided to the State on May 19, 1995. The status of the four part (a through d) recommendation above is as follows:

- a) The State's efforts to obtain engineering technical expertise for SS&D reviews on an as needed basis from State agencies and universities were unsuccessful. Currently, the State has not identified any person or contractor to provide engineering expertise to resolve engineering issues that may be encountered during SS&D reviews.
- b) The State developed an action plan for the review of all device sheets. The plan requires the complete review of at least one device each month until all devices have been updated. At the time of the visit, the State had completed review of one of ten Ronan devices, and one of twelve Omart devices. Other device actions were being delayed pending the attendance at the Sealed Source and Device (SS&D) Workshop held September 12-15, 1995, in Gaithersburg, Maryland. Two persons from the Radiation and Toxic Agents Control Section attended this workshop.
- c) The action plan calls for the establishment of documentation concerning dose requirements in the files during the general licensed device reviews. This task has not been completed.
- d) The Omart and the Ronan licenses have been amended in their entirety, and the tie down license conditions were confirmed to contain specific references to drawings and other background information as requested in the recommendation. Under current compatibility procedures, NRC continues to recommend that a rule equivalent to NRC's 10 CFR 30.32(g) be adopted.

This comment remains open and should be evaluated during the next review.



### 3. Staffing Level (Category II)

#### Comment from the May 13, 1994 Review

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 from the May 13, 1994 Review

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.

#### August 18, 1995 Status

There have been no changes in the staffing level for the agreement materials program. Program managers related that the State had a freeze on hiring new personnel. The staffing level remains at approximately 1.0 person per 100 licenses.

The Materials Unit has identified certain steps to make work processing more efficient. The staff has revised the portable gauge licensing guide and review checklist, and has plans for revision of other generic guides and checklists as time permits. The staff also has plans to add standard enforcement paragraphs to the computer data base to make the issuance of enforcement letters more standardized and to more efficiently use resources. The State uses a contractor for providing computerized licensing and inspection data and this tracking system was discussed during the visit. During previous reviews, the managers have related that this contractor report could be eliminated with the efficient use of the in-house computer system and would provide more accurate and timely information for planning and quality

control purposes, and for scheduling license renewals and inspections. The State currently has plans to implement a local area network for use by all personnel.

This comment is closed for the purposes of this review; however, the staffing level should be reevaluated during the next review and after the State's efficiency measures have been fully implemented.

4. Staff Continuity (Category II)

Comment from the May 13, 1994 Review

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 from the May 13, 1994 Review

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.

August 18, 1995 Status

In response to the 1994 review, the State acknowledged that based on the information provided by the NRC, that Kentucky staff salary levels were below those in other States in the Southeast. In addition, the State indicated that they would examine options in order to address staff salaries, which may be impacting staff continuity. During the review visit, it was noted that all State employees had received a 5% increase in salary. At the time of the review visit, there were no further staff turnovers in the materials unit since the May 13, 1994, routine review.

This comment and recommendation are closed.

5. Budget (Category II)

Comment from the May 13, 1994 Review

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 from the May 13, 1994 Review

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.

August 18, 1995 Status

The Section supervisor related that the program had sufficient monies to fund the current program, including the salary increases. The radioactive materials program budget is currently funded by 62.6% of the monies collected from materials license fees. The Section Supervisor of the Radiation & Toxic Agents Control Section indicated that at the present time, as of March 1996, the program continues to be funded at the 62.2% level because the State has not finalized the budget for the program since the reorganization of the radiation control program and other State programs have not been finalized. In addition, the Section Supervisor indicated that the remaining percentage (37.8%) of the budget would be obtained from the radiation control trust fund and a small portion would come from the general fund. (State law requires that all fees collected from the radiation control program activities be used to support the program.)

During the review visit, the Section Supervisor also indicated that a fee increase would be proposed for the next fiscal year. The fiscal year is on a July 1 - June 30 calendar basis.

This comment and recommendation are closed.

6. Licensing Procedures (Category II)

Comment from the May 13, 1994 Review

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.

regulations and SS&D reviews, the supervisors related that sufficient trained staff were now available to conduct the overdue inspections.

4. Response to Incidents and Alleged Incidents (Category I)

Kentucky reported 14 incidents for the calendar year 1994, and summaries of these incidents were provided to the Office of State Programs (OSP) in a letter dated February 27, 1995, from the State.

Only one reportable incident under NRC criteria has occurred so far in 1995, and this brachytherapy incident was provided to OSP by the reviewer in a memo dated February 13, 1995. The State was observed to be maintaining the incidents on file.

CONCLUSION

A informal summary meeting regarding the results of the review visit was held with Dr. John Volpe, Supervisor, Radiation and Toxic Agents Control Section, on August 18, 1995. The status of each comment made following the 1994 review was discussed in general, along with the reviewer's observations concerning the other indicators addressed above.

In reply, Dr. Volpe requested a letter from NRC concerning the status and compatibility of the Kentucky program.

An informal meeting was also held on August 17, 1995, with Dr. Michael W. Easley, Director, Division of Environmental Health and Community Safety. NRC's Agreement State Program was discussed in general, along with the purpose of the visit, since Dr. Easley was hired after the 1994 review. Dr. Easley elaborated on the Division's efforts to reorganize and become more efficient.