

DATED: MAY 9, 1995;

SIGNED BY: RICHARD L. BANGART

William A. Kucharski, Secretary
Department of Environmental Quality
P.O. Box 82263
Baton Rouge, LA 70884-2263

Dear Mr. Kucharski:

This is to transmit the results of the NRC follow-up review and evaluation of the Louisiana radiation control program conducted by Robert Doda, Region IV State Agreements Officer, which was concluded on February 24, 1995. The results of this review were discussed with Gus Von Bodungen, Assistant Secretary, Office of Air Quality and Radiation Protection, Department of Environmental Quality, and William H. Spell, Administrator, Radiation Protection Division.

Following our September 3, 1993, routine review, we withheld findings of adequacy and compatibility for the State's program for regulating agreement materials until improvements were made in the State's sealed source and device (SS&D) evaluation program. The purpose of the follow-up review was to determine the effectiveness of the State's actions to address the recommendations from the 1993 review and to assess the current status of the State's program. The main focus of the follow-up review was to evaluate the adequacy of the State's product evaluation program.

As a result of the follow-up review, we were pleased to find major improvements in the Louisiana program for controlling agreement materials with regard to deficiencies noted during the September 1993 review. The NRC staff determined that the Louisiana program for the regulation of agreement materials is, at this time, adequate to protect the public health and safety and is compatible with the regulatory program of the NRC.

Subsequent to the 1993 program review, staff from the NRC Office of Nuclear Material Safety and Safeguards provided training to Louisiana staff during December 13-15, 1993, on NRC's procedures and guidance for review of SS&D applications. NRC staff has also continued to work closely with Louisiana staff in providing "on-the-job" type training for specific SS&D reviews being completed by the Louisiana staff. A Louisiana staff engineer received training in SS&D procedures during October 17-21, 1994, in the NRC's Headquarters office in Rockville, Maryland. NRC and State staff believe these cooperative technical assistance efforts have been effective in assisting Louisiana staff in gaining broader experience in the review of SS&D applications.

Enclosure 1 contains an explanation of our policies and practices for reviewing Agreement State programs. Enclosure 2 is a summary of the follow-up

William A. Kucharski

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review findings which were discussed with members of the Louisiana Radiation Protection Division during the review.

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

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:

1. Application of "Guidelines for NRC Review of Agreement State Radiation Control Programs"
2. Status of Previous Findings and Summary of Follow-up Review Findings

cc w/encls:

W. H. Spell, Administrator
Louisiana Radiation Protection Division

G. Von Bodungen, Assistant Secretary
Office of Air Quality and Radiation Protection
Department of Environmental Quality

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bcc w/enclosures:

The Chairman
Commissioner Rogers
Commissioner de Planque
Commissioner Jackson

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Application of "Guidelines for NRC Review
of Agreement State Radiation Control Programs"

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

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

It is the NRC's intention to use these categories in the following manner. In reporting findings to State management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety. If one or more significant Category I comments are provided, the State will be notified that the program deficiencies may seriously affect the State's ability to protect the public health and safety. If, following receipt and evaluation, the State's response appears satisfactory in addressing the significant Category I comments, the staff may offer findings of adequacy and compatibility as appropriate or defer such offering until the State's actions are examined and their effectiveness confirmed in a subsequent review. If additional information is needed to evaluate the State's actions, the staff may request the information through follow-up correspondence or perform a follow-up or special, limited review. NRC staff may hold a special meeting with appropriate State representatives. The Commission will be informed of the results of the reviews of the individual Agreement State programs and copies of the review correspondence to the States will be placed in the NRC Public Document Room. Pursuant to Section 274j of the Act, the Commission may terminate or suspend all or part of its agreement with a State if the Commission finds such termination or suspension is required to protect the public health and safety or the State has not complied with one or more requirements of section 274 of the Act.

SUMMARY OF FOLLOW-UP REVIEW OF
THE LOUISIANA RADIATION CONTROL PROGRAM
SEPTEMBER 3, 1993 TO FEBRUARY 24, 1995

SCOPE OF REVIEW

As a result of our routine review of the State's program on September 3, 1993, and the routine exchange of information between the NRC and the State of Louisiana, the staff identified significant deficiencies in a Category I Indicator, Adequacy of Product Evaluations, which was the basis for the withholding of findings that the Louisiana program for the regulation of agreement materials was adequate to protect the public health and safety and compatible with NRC's program for regulation of similar materials. In accordance with NRC policy for the review of Agreement State programs, at that time, if adequacy was withheld, then compatibility was also withheld.

A follow-up review was conducted to evaluate the effectiveness of the State's actions to improve program performance to address comments and recommendations in the Category I Indicator, Adequacy of Product Evaluations, and to determine the current status of the State's program. The review was conducted by Mr. Robert J. Doda, Regional State Agreements Officer, Region IV. We also evaluated Louisiana's actions to address comments and recommendations on three other program indicators made during our September 1993 program review. The follow-up review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs.

The follow-up review with State representatives was held during February 21-24, 1995, in the State's Office in Baton Rouge, Louisiana. The principal purpose of the follow-up review was to evaluate the adequacy of the sealed source and device (SS&D) regulatory program. The detailed results of this review are contained in this enclosure.

The summary meeting for the follow-up review was held on February 23, 1995, with Mr. Gustave Von Bodungen, Assistant Secretary, Office of Air Quality and Radiation Protection, Department of Environmental Quality, and Mr. William H. Spell, Administrator, Louisiana Radiation Protection Division.

CONCLUSION

As a result of our follow-up review of the State's program and the routine exchange of information between the NRC and the State of Louisiana the NRC staff determined that the Louisiana program for the regulation of agreement materials is, at this time, adequate to protect the public health and safety and compatible with the regulatory program of the NRC.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The previous NRC routine review was concluded on September 3, 1993, and comments and recommendations were provided to the State in a letter dated April 11, 1994. At that time, findings of adequate to protect the public health and safety and compatible with the NRC's program for the regulation of similar materials were withheld, due to significant deficiencies in a Category I Indicator, "Adequacy of Product Evaluations."

Comments and recommendations for three other indicators resulting from the previous program review, and the State's responses, were also evaluated during the follow-up. All previous comments and recommendations have been closed out as discussed below:

1. Status and Compatibility of Regulations (Category I Indicator)

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

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 (UMTRCA), as implemented by Part 40.

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

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

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

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

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

Comment

The Division adopted its equivalent of 10 CFR Part 20, "Standards for Protection Against Radiation," on November 20, 1993 and the "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendments (55 FR 843) which were needed for adoption by January 10, 1994 were adopted through an emergency rulemaking on January 1, 1994. In addition, the "Emergency Planning," 10 CFR Parts 30, 40, and 70 amendments that were needed for adoption by April 7, 1993 (54 FR 14061) were adopted as final rules on February 20, 1994.

The State is also in the process of adopting the following compatibility regulations.

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

- "Quality management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 153) which must be adopted by January 27, 1995.
- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) which must be adopted by July 1, 1996.

As a matter separate from this review, we would like to bring to the State's attention other regulations needed for compatibility. These rules are:

- "Licensing Requirements for Land Disposal of Radioactive Wastes," 10 CFR Part 61 (58 FR 33886) which must be adopted by July 22, 1996.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, and 70 (58 FR 39628) which must be adopted by October 25, 1996.

Recommendation from the September 1993 Routine Review

We recommend that the above rules and any others needed for compatibility, be promulgated expeditiously as effective State radiation control regulations.

February 1995 Follow-up Review Status

Based on discussions with staff and review of the State's regulations, the State has adopted the rules needed for a compatibility finding at this time. The "Notification of Incidents" rule has been implemented by the Louisiana Radiation Protection Division (LRPD) through an emergency rulemaking action which became effective on February 1, 1995. The "emergency rule" will remain in effect until a permanent revision is adopted. The "Quality Management Program and Misadministrations" rule was previously adopted by Louisiana in 1992. Other compatibility regulations, due in the future, are being included in draft regulations that are being prepared and processed in accordance with the State's administrative procedures for adopting regulations.

2. Adequacy of Product Evaluations (Category I Indicator)

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

NRC Guidelines

RCP evaluations of manufacturer's or distributor's data on sealed sources and devices outlined in NRC, State or appropriate ANSI Guides should be sufficient to assure integrity and safety for users.

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

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

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

Comment 2a.

Although we determined that the Louisiana staffing and administrative procedures appear adequate to deal with the sealed source and device evaluation workload, at the time of the review, the lead reviewer responsible for the Louisiana SS&D reviews had not been fully trained in current NRC review procedures for licensing and inspection of SS&Ds, or on the standard format and content of a registration sheet. In addition, the reviewer had received signature authority to approve SS&D evaluations without being fully trained. However, subsequent to the program review, staff from the NRC Office of Nuclear Material Safety and Safeguards provided some training to the Louisiana staff on December 13-15, 1993. However, additional training may be needed since it takes from 6 months to 1 year to complete training in SS&D reviews.

Recommendation 2a from the September 1993 Routine Review

We recommend that the State continue to implement NRC guidance on SS&D evaluations received during the recent training session and to contact the NRC if training or technical assistance is needed.

February 1995 Follow-up Review Status

Based on the SS&D file review, the State is implementing NRC guidance on SS&D evaluations.

In addition to the December 1993 training, NRC staff has continued to work closely with Louisiana staff in providing assistance by telephone for specific SS&D reviews being completed by Louisiana staff. This effort has involved NRC staff review and comment on initial State evaluation findings for specific SS&D reviews, review of proposed State catalog sheets prepared based on completed reviews and review and comment on proposed requests for additional information prepared by the Louisiana staff. Also, a Louisiana staff engineer received training in SS&D procedures during October 17-21, 1994, in NRC's Headquarters Office in Rockville, Maryland.

The Louisiana Radiation Protection Division plans to continue using NRC technical assistance, as necessary, in the evaluation of new SS&D applications. For example, Louisiana provided the State's evaluation of a new radiography camera to NRC for review and comment. This registry sheet, for the SPEC Model 150 radiography camera, was subsequently finalized and issued on December 20, 1994. A review of the backup information for this device in the Division's Office indicated that all necessary documentation was in the files. Also, the reviewer checked the proprietary design drawings for an adequate listing of parts, materials specification, and tolerance designations. The proprietary drawings are stored in a secured file cabinet in the Department's confidential file area.

Comment 2b.

There is a need for better documentation on source and device compatibility in SS&D design diagrams. Insufficient documentation was contained in the device review files for the four reviews completed during the past 2 years. The State had accepted vendor data without an independent evaluation of the information and without adequate documentation in SS&D design diagrams.

Recommendation 2b from the September 1993 Routine Review

The State in conjunction with the licensee (SPEC) should develop and implement a plan to revise the source and device registrations in accordance with the NRC standard format and content guide. The State should obtain sufficient documentation on file to provide for an independent determination on the integrity of the product designs and recertify specific SS&D registration sheets.

February 1995 Follow-up Review Status

Based upon review of SS&D files, although the State has not developed a written plan to revise the SS&D registrations, the State has a process in place to adequately address the revision of the registration sheets. The process includes training, guidance documents, confidential files and NRC assistance when necessary. The Louisiana Radiation Protection Division has instituted a process to have source and device drawings maintained in a confidential file in the Department's offices. These detailed design drawings provide staff with necessary references for source and device evaluations for radiological health and safety purposes. Licensees are now required to provide revised drawings to the State whenever changes in these drawings occur. Backup information and State requests for more complete information are now made a part of the evaluation file for each specific product being evaluated. Also, the Division has revised, as of February 21, 1995, the following registry sheets in accordance with current NRC requirements:

- (1) LA-612-S-101-S
- (2) LA-612-S-106-S
- (3) LA-0760-S-102-S

Comment 2c.

The Louisiana-issued Omnitron registration sheet for the Model 2000 device is for a product which has final assembly in Houston, Texas. No formal or informal agreement has been reached with the State of Texas to inspect the Houston facility to determine if the product distributed is in accordance with the information submitted to the State of Louisiana. Louisiana has marginal controls over the distribution of this product from an out-of-state location.

Recommendation 2c from the September 1993 Routine Review

We recommend that the State rescind the sheet for the Omnitron-2000 device until a cooperative arrangement can be made with Texas to inspect the facility, or have Texas issue the device registration sheet, or require the final assembly back under the control of the State of Louisiana.

February 1995 Follow-up Review Status

Based upon SS&D file review, Louisiana inactivated the SS&D registry sheet for the Omnitron-2000 device on April 18, 1994. Subsequent to that time and based on company changes, the manufacture of future devices may occur in a foreign country and be distributed by a supplier in California. A new device registry sheet is planned to be issued by the State of California for this device.

3. Status of Inspection Program (Category I Indicator)

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

NRC Guidelines

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

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

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

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

Comment

The Louisiana Radiation Protection Division completed 402 inspections during the current review period. However, one major inspection was not completed within the required inspection interval. In accordance with Louisiana and NRC inspection policies, initial inspections of licenses in inspection priorities 1 through 5 are to be conducted within 6 months after material is received and operations have begun and inspections of broadscope manufacturing and distribution licenses are to be conducted on an annual basis. However, with Omnitron, License No. LA-6430-L01, there was no 6-month initial inspection and there was no first-year annual inspection accomplished for this licensee. This license was first issued in March 1991 and the initial State inspection of this licensee was conducted on April 12, 1993 after a significant misadministration occurred in November 1992. NRC formed an Incident Investigation Team (IIT) to investigate the incident in Pennsylvania (NUREG-1480, dated February 1993), and Food and Drug Administration (FDA) conducted inspections of the manufacturer in December 1992 and January 1993. Louisiana staff members accompanied the FDA during these inspections.

Recommendation from the September 1993 Routine Review

We recommend the Division institute a quality assurance mechanism to assure that initial inspections and routine inspections of new licenses are accomplished within set inspection priority schedules.

February 1995 Follow-up Review Status

The Louisiana Radiation Protection Division has quality assurance procedures in place to assure that initial and routine inspections are accomplished within the Division's inspection priority schedule. As soon as new licenses are issued, the inspection staff flags them for the initial 6-month inspection. Telephone calls are used to determine when radioactive materials are actually received so that the initial inspection can be performed. This process was demonstrated by the compliance supervisor for observation by the NRC reviewer. In addition, the reviewer verified that the initial 6-month inspections were done by reviewing the inspection status of priority 1 and 2 inspections and the reviewer noted that, at the time of the review, there were no overdue inspections for the Priority 1 and 2 inspections.

4. Inspection Reports (Category II Indicator)

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

NRC Guidelines

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

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

Comment

SPEC, License No. LA-2966-L01. Inspection reports for 1992 and 1993 were missing from the file and could not be found. The Division staff believes that both inspections were accomplished and one, in particular, was remembered as an inspection with a supervisory review by Jay Mason, Radiation Protection Division.

Recommendation from the September 1993 Routine Review

We recommend the Division institute a quality assurance mechanism to assure that inspection reports are written and secured in the proper files.

February 1995 Follow-up Review Status

Based upon discussions with staff and review of files, the concern noted above occurred when certain Division staff transferred to other positions in State government and did not complete their inspection reports before the transfer occurred. The Radiation Protection Division now has a practice in place to require all supervisors to determine that ongoing inspection activities are completed before an employee transfer occurs, or that residual work efforts are taken over by a new staff member. The specific licensee mentioned above, SPEC, License No. LA-2966-L01, has the last two required inspection reports properly filed in the licensing file, as of February 22, 1995.

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held with Mr. Gustave Von Bodungen, Assistant Secretary, Office of Air Quality and Radiation Control, Department of Environmental Quality on February 23, 1995. The scope and findings of the review were discussed. He was informed of the improvements in the Category I findings from the previous review. The follow-up review disclosed that all previous NRC comments and recommendations have been satisfactorily addressed by the State's radiation control program.

In addition, a meeting was held on February 22, 1995, where Robert J. Doda provided current information on NRC's regulatory program for sealed sources and devices, and which included a discussion of Policy Guide No. 2-07, Standard Review Plan for Applications for the Use of Sealed Sources in Portable Gauging Devices, dated October 20, 1994. Several LRPD staff questions were answered at this meeting.