

DATED: APR 11, 1994; SIGNED BY RICHARD BANGART

Kai David Midboe, Secretary
Department of Environmental Quality
P.O. Box 82263
Baton Rouge, LA 70884-2263

Dear Mr. Midboe:

This is to transmit the results of the NRC review and evaluation of the Louisiana radiation control program conducted by Mr. Robert Doda, Region IV State Agreements Officer, and Raj Kishore, Office of State Programs representative on rotation from the Food and Drug Administration, which was concluded on September 3, 1993. The results of this review were discussed with you, Gus Von Bodungen, Assistant Secretary Department of Environmental Quality, and Hall Bohlinger, Administrator, Radiation Protection Division.

As a result of our review of the State's program and the routine exchange of information between the Nuclear Regulatory Commission and the State of Louisiana, at this time, we are withholding findings of adequacy for the State's program for regulating agreement materials and compatibility with the regulatory programs of the NRC. The findings of adequacy and compatibility are being withheld because of significant deficiencies in a Category I Indicator, Adequacy of Product Evaluations. In accordance with NRC practice for the review of Agreement States, if adequacy is withheld, then compatibility is also withheld.

Adequacy of Product Evaluations is a Category I Indicator. Although the Louisiana staffing and administrative procedures appear adequate to deal with the sealed source and device (SS&D) evaluation workload, the staff was not fully trained in current NRC review procedures for SS&Ds at the time of the review. In addition, Louisiana was accepting vendor data without an independent evaluation of the information and without adequate documentation in SS&D design diagrams. Moreover, we are recommending that the State rescind one of its SS&D sheets and to recertify SS&D sheets identified to the staff during the review.

Subsequent to the program review, staff from the NRC Office of Nuclear Material Safety and Safeguards provided training to Louisiana staff on December 13-15, 1993 on NRC's procedures and guidance on 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 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 State staff. NRC and State staff believe these technical assistance efforts

have been, and will continue to be, effective in assisting Louisiana staff in gaining further SS&D review experience. Based upon NRC staff experience, it will take a minimum of 6 months of on-the-job training with close State management supervision to obtain an acceptable level of training in SS&D reviews.

The difficulties noted above in the SS&D program area, point to a need for closer management attention to changes in the radiation control program. Since the last program review, staff involved in the sealed source and device area changed, resulting in loss of an experienced sealed source and device license reviewer. Less experienced staff continued to perform evaluations without the benefit of adequate training. Management involvement in program changes such as this should have addressed potential weak areas before they became more significant. In addition, when the program is faced with such a case where you have identified a potential weakness, or have identified a specific need for additional training assistance, NRC is prepared to provide assistance to the program, upon your request, such as the training assistance described above.

We commend the State for its prompt adoption of the amendments equivalent to the revised 10 CFR Part 20 which became effective on November 20, 1993 and were implemented on January 1, 1994.

Our review findings were discussed with the Radiation Protection Division staff during the review meeting. An explanation of our policies and practices for reviewing Agreement State programs is attached as Enclosure 1. We request a response to our comments, attached as Enclosure 2, within 30 days of this letter.

Our review disclosed that all other program indicators were within NRC guidelines. Also, a number of other technical matters were discussed with the radiation control staff and resolved during the course of the review meeting.

I appreciate the courtesy and cooperation you and your staff extended to Messrs. Doda and Kishore during the review meeting. Also, I am enclosing a copy of this letter for placement in the State Public Document Room or to otherwise be made available for public review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosures:
As state

cc w/enclosures:
W. H. Spell, Administrator
Louisiana Radiation Protection Division
NRC Public Document Room
State Public Document Room

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Richard L. Bangart, Director
Office of State Programs

Enclosures:

As state

Distribution: See next page.

*See previous concurrence. [g:\chm\93letter.la3]

RIV:SAO	DRA	RA	OSP:SA	OSP:SA:AD	OSP:DD
RDoda/cg	JMontgomery	JMilhoan	CMaupin	JSurmeier	SSchwartz
11/19/93*	11/22/93*	11/22/93*	11/23/93*	11/30/93*	11/30/93*

NMSS:D	OSP:D	OGC	DEDS	EDO
RBernero	RLBangart	FCameron	HLThompson	JMTaylor
12/28 /93*	12/10/93* 01/13/94*	12/29/93*	03/ /94	03/ /94

cc w/enclosures:

W. H. Spell, Administrator
Louisiana Radiation Protection Division
NRC Public Document Room
State Public Document Room

bcc w/enclosures:

The Chairman
Commissioner Rogers
Commissioner Remick
Commissioner de Planque

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DCD (SP01)	SDroggitis
Louisiana File	PLohaus

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 one or more 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 the 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 Category I comments are noted as significant, 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 particular program areas is critical. The NRC would request an immediate response. 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.

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 procedures to suspend or revoke all or part of the Agreement in accordance with Section 274j of the Act, as amended. 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.

ENCLOSURE 1

SUMMARY OF ASSESSMENTS AND COMMENTS
FOR THE LOUISIANA RADIATION CONTROL PROGRAM
AUGUST 23, 1991 TO SEPTEMBER 3, 1993

SCOPE OF REVIEW

This program review was conducted in accordance with the Commission's Policy Statement for reviewing Agreement State Programs published in the Federal Register on May 28, 1992, and the internal procedures established by the Office of State Programs. The State's program was reviewed against the 30 program indicators provided in the Guidelines. The review included inspector accompaniments, discussions with program management and staff, technical evaluation of selected license and compliance files, and the evaluation of the State's responses to an NRC questionnaire that was sent to the State in preparation for the review.

The 22nd Regulatory Program Review meeting with Louisiana representatives was held during the period of August 30 through September 3, 1993, in Baton Rouge, Louisiana. The State was represented by Hall Bohlinger, Administrator, Radiation Protection Division, and Michael Henry, Program Manager, Inspection and Enforcement Section, and Stan Shaw, Program Manager, Emergency Response and Planning Section. The NRC was represented by Robert Doda, Region IV State Agreements Officer, and Raj Kishore, Office of State Programs representative on rotation from the Food and Drug Administration (FDA). A review of selected license and compliance files was conducted during August 30-31, 1993. A review of legislation and regulations, organization, management and administration, and personnel was conducted on August 31, 1993. Steven Baggett and Thomas Rich of NRC's Office of Nuclear Material Safety and Safeguards conducted reviews of Louisiana's program for sealed source and device evaluations during August 30-31, 1993. A summary meeting regarding results of the regulatory program review was held with Mr. Kai David Midboe, Secretary, Department of Environmental Quality, on September 3, 1993.

In addition to the routine program review, an accompaniment inspection was made at a Louisiana medical licensee: Riverview General Hospital, Baton Rouge, Louisiana, Licensee Number LA-5456-L01.

CONCLUSION

As a result of our review of the State's program 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 are the basis for the withholding of findings that the Louisiana program for the regulation of agreement materials is adequate to

ENCLOSURE 2

protect the public health and safety and compatible with NRC's program for regulation of similar materials. The finding of adequacy is being withheld until improvements have been made in the Adequacy of Product Evaluations Category I Indicator. In accordance with NRC policy for the review of Agreement States, if adequacy is withheld, then compatibility would also be withheld.

STATUS OF PROGRAM RELATED TO PREVIOUS NRC FINDINGS

The previous NRC program review was concluded on August 23, 1991, and comments and recommendations were sent to the State in a letter dated October 18, 1991. At that time, the program was found to be adequate to protect the public health and safety; however, a finding that the program was compatible with the NRC's program for the regulation of similar materials was not made due to several overdue regulations. These regulations were included in a revision to the State's regulations that was sent to NRC in January 1992. As a result, NRC was able to make a finding that the Louisiana agreement materials program was adequate and fully compatible with the NRC's program for radiation control in a letter dated February 21, 1992.

Other comments and recommendations from the previous program review were followed up and the State's responses were evaluated for adequacy. All previous comments and recommendations have been closed out.

CURRENT REVIEW COMMENTS AND RECOMMENDATIONS

The Louisiana radiation control program satisfies the Guidelines in 29 of 30 indicators. The State did not meet the Guidelines in a Category I Indicators, Adequacy of Product Evaluations. In addition, comments and recommendations are provided in three other indicators.

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

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 progress 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.

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:

- "Licenses and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 (58 FR 7715) which must be adopted by July 1, 1996.
- "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

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

2. Adequacy of Product Evaluations (Category I Indicator)

We reviewed the registration sheets and the background files for technical quality and consistency in the following areas: format, description, labeling, diagrams, conditions of use, prototype testing, radiation levels, quality assurance and quality control, limitations of use and the bases for determining that the sources or device designs are deemed acceptable for licensing purposes. The following registry sheets were reviewed:

1. SPEC..... LA-612-S-101-U
2. SPEC..... LA-612-S-106-U
3. Omnitron... LA-0760-D-101-S
4. Omnitron... LA-0760-S-102-S

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 one year to complete training in SS&D reviews.

Recommendation 2a.

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.

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 last two 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.

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.

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.

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.

3. Status of Inspection Program (Category I Indicator)

Comment

The 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 six 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 six-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 FDA conducted inspections of the manufacturer in December 1992 and January 1993. Louisiana staff members accompanied the FDA during these inspections.

Recommendation

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.

4. Inspection Reports (Category II Indicator)

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

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

SUMMARY DISCUSSION WITH STATE REPRESENTATIVES

A summary meeting to present the results of the regulatory program review was held with Mr. Kai David Midboe, Secretary, Department of Environmental Quality on September 3, 1993. The scope and findings of the review were discussed. He was informed of the significance of the Category I finding regarding the one amendment that had not been adopted by Louisiana within the three year period provided by the NRC for States to adopt compatible regulations, the emergency planning rule. Messrs. Midboe and Bohlinger decided that the Division could address this problem most efficiently by adopting the compatibility requirement in the next revision of the State's radiation control regulations. The other Category I comment, Adequacy of Product Evaluations and Status of Inspection Program, were accepted by the State officials as program areas that need improvement, and they believed that the problems could be solved quickly by the Division.

Mr. Midboe expressed the State's appreciation for past NRC assistance and training for the Division's staff. He said the Department will continue to support the radiation control program, any NRC-sponsored training courses, and cooperative efforts with the NRC and other Agreement State programs.

A closeout discussion with the radiation control program technical staff was conducted on September 2, 1993. The State was represented by Hall Bohlinger and his radiation control staff. Several general and specific questions were raised by the State representatives. The review guidelines and the State's responses were discussed in detail. In addition, the results of the license and compliance casework reviews were provided to the staff for discussion. An instructional phase was included to reinforce the proper methods to be used by State personnel when notifying NRC of incidents, when using the Sealed Source and Device Registry, and when sending information on enforcement actions to the NRC.

In addition, a meeting was held on August 31, 1993, where Steven Baggett and Thomas Rich of NRC's Office of Nuclear Material Safety and Safeguards, provided current information on NRC's regulatory program for sealed sources and devices, and which included other information on the Sealed Source and Device Registry. Several State questions were answered at this meeting.