

DATED: AUG 17, 1994;

SIGNED BY RICHARD L. BANGART

Mr. William H. Spell, Administrator
Radiation Protection Division
Office of Air Quality and Radiation Protection
7290 Bluebonnet Road
P.O. Box 82135
Baton Rouge, LA 70884-2135

Dear Mr. Spell:

This is in response to your letter of May 25, 1994, responding to the comments and recommendations from our 1993 review of the Louisiana radiation control program. I would like to respond to some of your most important points first and then address the specifics of your letter.

We agree that NRC took too long to issue the final results of our review and that the communication of our program review concerns in advance of the final report was not satisfactory. At the present time, we are working with the Agreement States to develop program revisions to address a number of issues, one of which is to improve the timeliness of the issuance of review reports. We anticipate that report timeliness will be improved when we implement the program review approach described by the Integrated Materials Performance Evaluation Program, which is now being tested with a pilot program. Additionally, based on your comments and those from other Agreement States, we will conduct follow-up discussions with Agreement State officials before the final report is issued whenever the final program review findings differ from the results described in the exit meeting.

With regard to your statements concerning the withholding of a finding of adequacy based on one indicator, in accordance with the NRC's policy, if significant comments are made in a Category I indicator, the finding of adequacy is withheld. The withholding of findings is used to facilitate improvements in areas which may affect the ability of the State to protect public health and safety before any problems of a serious nature develop. It is not an indication that the State's program is inadequate to protect public health and safety. However, it is an indication of a potential problem area which could lead to a finding of inadequacy if corrective action is not taken in the future. This policy for the withholding of findings has been in place since 1981.

We will determine, as part of our next review of the Louisiana program, scheduled for the January 1995 time frame, the status of the actions taken by the State to address our comments and recommendations. At that time, we will make an overall determination of adequacy and compatibility for the Louisiana program.

You have indicated that training is needed for Louisiana staff in the area of sealed source and device (SS&D) review. The NRC plans to hold a comprehensive workshop on the SS&D evaluation process during 1995. Agreement States will be informed of the dates for this training in the future. In addition, as

discussed in the enclosure, on-the-job training is available to States upon request.

We would like to address concerns expressed in response to our comment 2b that dealt with "...an independent evaluation of the information ..." and "...sufficient documentation on file for an independent determination on the integrity of product designs...." The file should contain sufficient information to permit another reviewer from your program, or a technically qualified auditor, to conduct an independent review of the product using the guidance, regulations, policies and procedures which were in effect when the original review was completed, and reach the same conclusion regarding licensing of the product. An independent review means that your program should not place undue reliance on the accuracy of information or statements supplied by the applicant, instead, your program should critically review the information from the applicant for its technical accuracy, completeness and compliance with regulatory requirements. If the State requires additional technical expertise to perform the review of the material submitted by the applicant, the State should consider obtaining this expertise through contractual assistance. We do not mean to imply that the regulator should always conduct independent reviews of products. However, independent reviews are a useful regulatory approach that you may want to consider. Further clarification of NRC's position on Recommendation No. 2b is provided in the enclosure along with additional responses to the specific items identified in your letter.

Thank you for the support and cooperation extended to our representatives during this review.

Sincerely,

Richard L. Bangart, Director
Office of State Programs

Enclosure:

As stated

cc: Gustave VonBodungen
Assistant Secretary
Office of Air Quality and
Radiation Protection

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Richard L. Bangart, Director
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Assistant Secretary
Office of Air Quality and
Radiation Protection

Distribution: See next page.

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Response to Louisiana's Letter Dated May 25, 1994

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

We recognize the State's actions to amend its radiation control regulations, including the revisions to Louisiana's equivalent 10 CFR Part 20 regulations. We also recognize that continued effort will be needed by the Louisiana program to adopt and implement future changes to regulations. As amendments are prepared, we ask that copies of these amendments be provided to the NRC Region IV office for review.

2. Adequacy of Product Evaluations (Category I Indicator)

Recommendation No. 2a

In response to the State's request for training on sealed source and device (SS&D) reviews, we plan to develop and hold a workshop on SS&D evaluation during 1995. In the interim, we are prepared to provide on-the-job training for your staff at NRC's expense at our offices in Rockville, Maryland. Please let us know if you would be interested in on-the-job training.

Recommendation No. 2b

In regard to adequate documentation and your specific question... "at what point is there `...sufficient documentation on file to provide for an independent determination on the integrity of product designs... ?,'" Louisiana needs to have on file all necessary documentation that was used in the State's review of a product to make a determination that it is acceptable for licensing. This documentation should include a set of drawings of safety related features and components (i.e., dimensions of the source connectors) on file in the agency's office which are associated with the licensed activity. This information should also be sufficient enough that another reviewer using the same "standards and procedures in effect at that time" would agree that, overall, the products are acceptable for licensing.

Although you indicate that drawings are available at the licensee's facility, that State staff has reviewed the drawings and that NRC staff had previously agreed that this was an acceptable practice, we believe that engineering drawings for products should be located in State files, as opposed to licensee files. Drawings are important to assist the State in knowing what they deem acceptable for licensing purposes. Drawings provide the State with information to determine if a proposed change (i.e., welding practice, material substitution, etc) will affect the safety properties of a sealed source or device. The State should be able to quickly identify whether potential generic problems affect any products previously found acceptable for licensing purposes. For example, a manufacturer from another State had a radiography connector fail because of improper heat treatment (excessive hardening). Could a Louisiana manufacturer have products with similar problems?

Drawings and supporting documentation also allow the State and the vendor of the product to know exactly what has been approved for licensing purposes and what is expected to be manufactured. Under the review process Louisiana was following at the time of the review, it may have been possible for the manufacturer to change the design of an approved product, possibly because of a defect, without the State being fully apprised of the change. In addition, drawings and design information need to be on file during emergency situations, because the State may not be able to contact the manufacturer for specific information (especially if the manufacturer is out of business). Although we understand that the practice of having drawings located in licensee files was principally established due to concern that proprietary

drawings would not be kept secure, we understand that Louisiana has the capability to withhold certain information from public release but chose in the past not to do so.

You also indicated, in response to the issue of insufficient documentation that some of the sources have been in production for 20 years or more and may be based on other sources designed and used 20 years before that. Please note that the NRC comment and recommendation in this area was not based upon these 20 or more year old sources. Our comment stated, "Insufficient documentation was contained in the device review files for the four reviews completed during the last two years." We do not feel it is necessary for the State to revise all certificates that have been issued. Rather, the comment was directed at certificates that do not contain adequate information.

It is the applicant's responsibility to demonstrate that the product meets safety standards and will maintain its safety properties when used under normal and likely accidental conditions of use. The State must review the applicant's application and supporting documentation, and any other documentation (i.e., incident reports of similar devices) to assure, at a minimum, that the product's design, testing, labeling, quality assurance/quality control, and radiation levels are within acceptable standards, procedures, policies, and regulations. This involves review of supporting drawings and prototype test procedures and results. Louisiana's files did not include enough information for NRC reviewers, who were using guidance, regulations, policies and procedures, which were in effect when the State performed these reviews, to make a finding that the products were acceptable for licensing. The NRC reviewers were unable to make this "independent" determination without accepting the manufacturer's good faith that the products were acceptable for licensing purposes. Louisiana needs to ensure that they agree with the vendor's conclusions about licensing status of a product based on a review of the applicant's submission. This is a similar approach to that used for issuance of a materials license.

In referring to product designs approved 20 years ago, we recognize that many of the certificates previously issued cover products for which the manufacturer is out of business (i.e., Gamma Industries). We further recognize that these certificates should be made inactive, so that reviewers in other States are aware that these products are no longer supported by the manufacturer. Although the certificates are inactive, the products listed on the certificate may still be licensed. Regulators use information in the SS&D certificate and background file to determine if licensing of the products should be continued. Therefore, when transferring a certificate to inactive status, a reasonable attempt should be made to obtain any pertinent information regarding the product that may be missing from the file (i.e., construction, conditions of use, etc.).

We suggest that the State conduct a cursory review of all active certificates issued to ensure that the files contain adequate information. If the files do not contain adequate information, we suggest that the State develop a plan to revise these certificates based on available resources and potential health and safety risk if the product were to fail. At a minimum, we suggest that the State revise the certificates that were reviewed during the 1993 program review.

You indicate that the State's device and source evaluations were reviewed and accepted based on standards and procedures that were in effect at the time of the evaluation and asked that "...judgement of our past evaluations be made only against those standards..." As mentioned earlier, the NRC reviewers

performed their 1993 program review based on standards and procedures in effect as of 1987. NRC staff believes that the State personnel performing the reviews at that time had the available guidance (i.e., Regulatory Guides 10.10, 10.11, ANSI guides, etc.). In addition, NRC staff note that the State was provided an opportunity to comment on the proposed and final NRC rules and regulatory guides, that were put into effect in 1987.

In your letter you also indicated that you will be working with manufacturers in Louisiana to obtain adequate documentation on SS&D design diagrams. You went on to state that you would like assurance that all other manufacturers of similar sources and devices are required to do the same thing, and that this assurance should be given soon. You also stated that it is not fair to single out a single state or NRC licensee for this type of labor-intensive activity. In response to your statements, we can assure you that the review guidance and criteria which were used in the Louisiana SS&D program review are the same as that used in other Agreement State reviews and are used as a minimum in the criteria and guidance applied to NRC licensees. In fact, Louisiana was not the only Agreement State in which deficiencies were noted in the area of adequate documentation. Thus, we can assure you that this requirement for adequate documentation is being required in NRC jurisdictions and is also recommended to Agreement States for implementation in their programs in order to perform an adequate SS&D review.

Finally, you discuss a proposal for submitting source and device evaluation sheets to the Office of Nuclear Material Safety and Safeguards (NMSS) for concurrence prior to distribution, and if that approach is not acceptable, of potentially requesting that NRC conduct all evaluations. In response, NRC is presently examining the issue of whether States may voluntarily turn back to NRC responsibility and authority for performing sealed source and device evaluations and will inform all Agreement States of our conclusions in this area when this evaluation is completed. In the interim, NRC will support the State by conducting sealed source and device reviews, upon your request, and upon a demonstration that the review must be completed expeditiously due to urgent health and safety needs or concerns. Routine concurrence by NRC on State SS&D evaluation sheets will not be performed.

Recommendation No. 2c

We recognize the positive actions taken by the State of Louisiana to inactivate the Omnitron-2000 device sheet and have no objection to the action taken by the State in this matter.

3. Status of Inspection Program (Category I Indicator)

We note the responsive actions Louisiana has taken to assure improved communication between licensing and inspection staff on new licenses and scheduling of initial inspections of new licenses. We plan to review this program at the time of our next review.

4. Status of Inspection Reports (Category II Indicator)

We agree with your conclusion regarding reports for two inspections at SPEC. We have also reviewed your description of measures to ensure that inspection reports are prepared and filed. We believe these measures are appropriate and we will review this area further at the time of the next review.