August 27, 2008

Harold Leggett, Ph.D., Agency Secretary
Louisiana Department of Environmental Quality
602 N. 5th Street
Baton Rouge, Louisiana 70802

Dear Dr. Leggett:

On August 5, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Louisiana Agreement State Program. The MRB found the Louisiana Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 18, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the Louisiana Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for May 2010.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
Louisiana Final IMPEP Report

cc w/encl.: See next page

cc w/encl.: Jeffrey Meyers, Administrator
Louisiana Emergency and
Radiological Services Division

Ann Troxler, Manager
Louisiana Emergency and
Radiological Services Division

Karen Beckley, Nevada
Organization of Agreement States
Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE LOUISIANA AGREEMENT STATE PROGRAM

May 12-16, 2008

FINAL REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the Louisiana Agreement State Program. The review was conducted during the period of May 12-16, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the Commonwealth of Massachusetts and the State of Texas. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of November 1, 2003, to May 16, 2008, were discussed with Louisiana managers on the last day of the review.

A draft of this report was issued to Louisiana for factual comment on June 18, 2008. The State responded by letter on July 1, 2008, from Dr. Harold Leggett, Secretary, Department of Environmental Quality (the Department). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on August 5, 2008, to consider the proposed final report. The MRB found the Louisiana Agreement State Program to be adequate to protect public health and safety and compatible with NRC's program.

The Louisiana Agreement State Program is administered by the Department. The Department Secretary is appointed by and reports directly to the Governor. The Emergency and Radiological Services Division (the Division), within the Department, houses the Surveillance and Enforcement Program and Licensing Program, which comprise the radioactive materials program. Organization charts for the Department and the Division are included as Appendix B.

At the time of the review, the Division regulated 548 specific licenses authorizing the possession and use of byproduct, source and small quantities of special nuclear material. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Louisiana.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Division on April 1, 2008. The Division provided its response to the questionnaire on April 15, 2008. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML081640068.

The review team's general approach for conduct of this review consisted of: (1) examination of the Division's response to the questionnaire, (2) review of applicable Louisiana statutes and regulations, (3) analysis of quantitative information from the Division's database, (4) technical review of selected regulatory actions, (5) six field accompaniments of four Louisiana inspectors, and (6) interviews with staff and managers to answer questions or clarify issues. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Louisiana Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on October 31, 2003, the review team made five recommendations in regard to program performance. The results were transmitted to L. Hall Bohlinger, Secretary, Department of Environmental Quality, on February 3, 2004. The current status of the recommendations is as follows:

1. The review team recommends that the Surveillance Division finalize their training and qualification program of radioactive materials inspectors, including the qualifications required to complete independent inspections of various license types. (Section 3.1 of the 2004 IMPEP report)

   Current Status: The Division established a database program that tracks the training and qualifications for radioactive materials inspectors and includes the qualifications required to complete independent inspections of various license types. This recommendation is closed.

2. The review team recommends that the Department review their existing databases, identify all routine and initial inspections that need to be conducted and complete those inspections. (Section 3.2 of the 2004 IMPEP report)

   Current Status: The Division implemented a database that identifies all routine and initial inspections. On a monthly basis, each regional office is sent an electronic copy of the inspection due list for all the facilities in the respective region. Regional inspectors review the list for accuracy. Any discrepancies are immediately addressed through the database. At the time of the review, the Division had no overdue routine or initial inspections. This recommendation is closed.

3. The review team recommends that the Department develop and implement a process for ensuring that all new licensees receive a timely initial inspection. (Section 3.2 of the 2004 IMPEP report)

   Current Status: After a satisfactory pre-licensing inspection and upon issuance of a license, the new license is placed on the inspection due list as an initial inspection and is given a 6-month inspection due date. The list is reviewed periodically by a supervisor to ensure all new licenses are inspected within 6 months of the license issue date. At the time of the review, the Division had no overdue initial inspections. This recommendation is closed.

4. The review team recommends that the Department inspect implementation of SS&D authorizations during routine inspections. (Section 3.3 of the 2004 IMPEP report)

   Current Status: The Division incorporated the inspection of SS&D authorizations into their inspection protocol for applicable licensees. This recommendation is closed.

5. The review team recommends that the Department develop and implement a process for conducting annual accompaniments of all radiation compliance inspectors by qualified individuals. (Section 3.3 of the 2004 IMPEP report)

   Current Status: A manager or the section technical staff member conducts supervisory accompaniments on an annual or more frequent basis. A copy of the accompaniment evaluation is provided to the inspector and inspection supervisor. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Areas of interest central to the evaluation of this indicator included staffing levels and turnover, in addition to staff technical qualifications and training histories. The review team examined the Division's questionnaire response relative to this indicator; interviewed managers and staff; reviewed job descriptions, training plans, training records and considered possible workload backlogs in evaluating this indicator.

The Division is managed by the Division Administrator from the Central Office located in Baton Rouge. The radioactive materials program, which is housed in the Division, consists of two sections, the Licensing and Surveillance Sections. The Division devotes approximately 16 full-time equivalents (FTE) to the surveillance (i.e., inspection), enforcement, and emergency response programs, including supervisory duties. Thirteen inspection staff members are based out of six regional offices. Inspection staff members also perform other duties, including x-ray and non-radiological inspections. Licensing is performed out of the Central Office. The Division devotes approximately 5 FTE to radioactive materials licensing and approximately 4 FTE to administrative functions.

During the review period eight staff members, including two managers, left the Department and eight staff were hired. At the time of the review, the Division was in the process of adding a senior technical position to the radioactive materials program.

The review team determined the qualifications of the staff from the Division's response to the

questionnaire, training records, and interviews with personnel. The staff was well qualified from an education and experience standpoint. In general, inspection and licensing staff become qualified to complete x-ray registrations and inspections and, after approximately 1-2 years of experience with x-ray tasks, are then trained to perform radioactive materials licensing and inspections, starting with the least complex and progressing to more complex as experience is gained. The Division has a documented training and qualification program for radioactive materials license reviewers and inspectors that is consistent with the NRC and Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs. The review team noted that the training program consisted of classroom instruction and on-the-job training. Qualification journals were maintained electronically for each technical staff member. Division managers were supportive of and actively identified staff training opportunities. Eleven staff members have attended the NRC's Security Systems and Principles Course and are qualified to perform Increased Controls inspections.

The review team concluded that the Division has an adequate, well-balanced, and adequately trained staff to carry out its regulatory responsibilities. The review team noted that the Department had stable funding during the review period due to dedicated revenue from licensee fees.

Louisiana does not have an active radiation oversight board.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors to review this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Division's questionnaire response relative to this indicator, data gathered from the Division's database, examination of completed inspection casework, and interviews with managers and staff.

The review team verified that the Division's inspection priorities for various license types were at least as frequent as similar license types listed in NRC Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." Seven of the 15 license categories established by the Division were assigned inspection priority codes that resulted in a more frequent inspection schedule than those established in IMC 2800. The Division inspects the following license categories on a more frequent schedule than IMC 2800 describes: industrial radiography, nuclear pharmacy, self-shielded irradiators, academic broad scope, research and development, medical institutions, and portable and fixed nuclear gauges.

The review team determined that the Division conducted approximately 766 high priority (Priority 1, 2, and 3) inspections and 86 initial inspections during the review period. None of these inspections were performed overdue by more than 25 percent of the inspection priorities listed in IMC 2800, nor were any inspections overdue at the time of the review.

To evaluate the Division's timeliness in providing inspection correspondence to licensees, the review team examined 25 inspection reports, covering a cross-section of the staff, and determined that inspection correspondence was generally communicated to licensees within 30 days after the inspection.

Over the review period, the Division granted 87 reciprocity permits that were candidates for inspection based on the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Division exceeded the goal of inspecting 20 percent of all candidate licensees in each of the 4 years covered by the review period.

The review team determined that the Division adequately planned for the initial set of Increased Controls inspections. The review team evaluated the Division's prioritization methodology and found it acceptable. The Division identified 89 licensees subject to the Increased Controls. The review team noted that all initial Increased Controls inspections had been completed at the time of the review. After the initial inspection, the Division performs Increased Controls inspections at the routine inspection interval.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, Status of Materials Inspection Program, was satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed the responsible inspector for 25 inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by nine inspectors and covered a wide variety of inspection types, including: broad scope medical, manufacturers, well logging, industrial radiography, self-shielded irradiators, nuclear pharmacy, Increased Controls, and reciprocity. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensees' radiation safety programs. The review team found that inspection reports were generally thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations, unresolved safety issues, and adequately documented exit interviews.

The inspection procedures utilized by the Division are consistent with the inspection guidance in IMC 2800. The reports and notices are reviewed by the staff scientist reviewer, signed by the radiation section manager and promptly sent to the licensee. Inspection results were clearly stated and documented. The Division requires licensees to respond to violations within 30 days of issuance of a Notice of Violation. The staff scientist reviewer evaluates the licensees' responses for adequacy, with concurrence by the inspector when necessary. The review team also noted that inspection correspondence involving the Increased Controls was appropriately labeled as sensitive information and withheld from public disclosure.

The senior technical staff member or a supervisor conducted supervisory accompaniments at least annually for all inspectors. The review team noted that Increased Controls inspections are included in the supervisory accompaniments.

The review team verified that the Division maintains an adequate supply of appropriately calibrated survey instrumentation to support its inspection program, as well as to respond to incidents and emergencies. The survey instruments are calibrated annually by a qualified contractor. Laboratory support is provided by the Laboratory Services Division in the Office of Environmental Assessment.

The review team accompanied four of the Division's inspectors during the weeks of April 7 and April 23, 2008. The inspectors were accompanied during health and safety inspections of medical, industrial radiography, and portable gauge licensees. The accompaniments are listed in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health, safety, and security at the facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined 20 licensing actions and interviewed the responsible license reviewers. Licensing actions were reviewed for completeness, consistency, proper possession authorization, authorized user qualifications, facility adequacy, equipment, health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, correspondence, reference to appropriate regulations, supporting documentation, enforcement history, pre-licensing visits, peer/supervisory review, and signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period and included six new licenses, four renewals, seven amendments, and three license terminations. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, industrial radiography, portable and fixed gauges, medical broad scope, research and development, and nuclear pharmacies. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

The review team noted that licensing actions were generally thorough, complete, consistent, and of high quality, and properly addressed health, safety, and security. Licensing staff appropriately used the Division's licensing guides and policies. When appropriate, licensees' compliance histories were taken into account during licensing actions. License conditions were clearly

stated and supported by information contained in the license file.

Licenses and correspondence were created using a standardized format, which included standardized license conditions.

The Division uses a unique license condition in terminated licenses that states “If the Department determines that the information supplied is incorrect or defective, the applicability of a specific license may be reassessed.” The condition holds the former licensee liable if inaccurate information is provided by the licensee in the termination of the license. In such cases, the Department has a right to pursue actions against the former licensee. For example, if radioactive material is found at a facility after the radioactive materials license is terminated, the former licensee is held legally responsible for ensuring proper disposition of the radioactive material. The review team recommended, and the MRB agreed, that use of this standard license condition on terminated licenses is a good practice.

Actions are reviewed by a peer reviewer, the licensing supervisor, the compliance staff, and the departmental manager and are subsequently signed by the Assistant Secretary of the Office of Environmental Compliance. Typically licensing actions are completed within 30 days of receipt.

Deficiency letters reviewed clearly stated regulatory positions and were used appropriately. In addition to using formal written requests, the staff frequently telephones and/or e-mails licensees for clarification or to obtain additional information. Use of these methods promotes timeliness of licensing actions; however, the review team found that telephone conversations are not always captured, which results in disconnects between the licensing request and the final action. The review team discussed this issue and potential resolutions with the licensing supervisor. The licensing supervisor will review this matter with the staff to ensure that all communications with licensees regarding licensing actions are properly recorded.

The review team evaluated the Division’s decommissioning financial assurance program and noted that the Division had identified 14 licensees required to comply with Louisiana’s financial assurance requirements. The original financial instruments are secured and located in the Department of Financial Services. The review team found that terminated licensing actions were well documented and noted that confirmatory surveys were conducted when appropriate.

Division inspectors conduct pre-licensing visits of new applicants, including those that meet the criteria for Increased Controls, to verify compliance with health, safety, and security requirements before a license is issued.

The review team examined the Division’s increased controls licensing practices. The team noted that the Division added legally binding license conditions that met the criteria for implementing the Increased Controls. The review team determined the Division’s methodology for identifying licenses requirng the Increased Controls license condition was thorough and accurate, and that the Division had correctly identified those licenses requiring compliance with the Increased Controls.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana’s performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Division's actions in responding to incidents and allegations, the review team examined the Division's response to the questionnaire relative to this indicator, evaluated all of the incidents reported for Louisiana in the Nuclear Material Events Database (NMED) against those contained in the Division's files, and evaluated the casework for 21 radioactive material incidents. A listing of the incident casework examined can be found in Appendix E. The review team also evaluated the Division's response to ten materials allegations including two that the NRC referred to the State during the review period.

The incidents selected for review included medical events, lost/stolen radioactive material, damaged equipment, and overexposures. When notification of an incident is received, the Division determines the appropriate level of initial response. The review team determined that the response to incidents was complete and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Division dispatched inspectors for on-site investigations in appropriate situations and took suitable enforcement and followup actions, when necessary.

The review team identified 90 byproduct material incidents for Louisiana in NMED that required reporting during the review period. The review team evaluated the Division's timeliness in reporting incidents to the NRC Headquarters Operations Center, and determined that, following notification from the licensee, the Division reported all incidents within the required time frame. Division staff members incorporated incident information into their incident database and provided that information electronically to the NRC's contractor.

The review team found that, following a reported event, the licensees' corrective actions submitted to the Division subsequent to the event were not reviewed during the next routine inspection or were not being documented. The review team recommends that the State take measures to evaluate corrective actions of all radioactive materials incidents, ensure proper documentation of the review, and appropriately follow up on the corrective actions at subsequent inspections.

In evaluating the effectiveness of Louisiana's response to allegations, the review team determined that the Division took prompt and appropriate action in response to all concerns. The allegations were appropriately closed, and affected individuals were notified of the actions taken when possible. The review team noted that Louisiana law requires that public documents be made available upon request. The Division makes every effort to protect an alleger's identity, but cannot guarantee full protection. During initial contact, an alleger is advised that their anonymity cannot be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Louisiana's Agreement does not cover a uranium recovery program, so only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Louisiana became an Agreement State in 1967. The statutory authority for the Louisiana program is found the Radiation Control Law, Chapter 6, R.S. 30:2101-2134. The Department is designated as the State's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Department's regulations for control of radiation, found in Part XV, Radiation Protection, Louisiana Environmental Regulatory Code, apply to all radioactive materials and devices designed to produce radiation.

The review team examined the State's administrative rulemaking process and found that it takes approximately 6 months after preparation of a draft rule to become final. Proposed rules are submitted to the Legislative Fiscal Office for consideration and approval to proceed with public comment. Public notice of proposed rule revisions is made and a 30-45 day public comment period, including a public hearing, is conducted. After resolution of comments and the State Legislative Oversight Committee's approval, final draft rules are sent to the *Louisiana Register* for adoption.

The review team evaluated the Department's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the NRC's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the Office of Federal and State Materials and Environmental Management Programs' State Regulation Status Sheet.

The review team noted that the Department has expended considerable effort in regulation development since the last review in 2003. Since the previous review, the State submitted twelve packages to the NRC for compatibility review.

The review team identified the following regulation as overdue for adoption at the time of the review. The State plans to submit the regulation to the NRC for review by June 2008:

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State adoption by October 1, 2007.

The review team identified the following regulation changes and adoptions that will be needed in the future, and the State related that the regulations would be addressed in upcoming rulemaking or in the adoption of alternate legally binding requirements:

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that is due for Agreement State adoption by March 27, 2009.

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 72 FR 54207), that is due for State adoption by October 29, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for State adoption by November 30, 2010.

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that is due for State adoption by December 17, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for State adoption by February 15, 2011.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, Compatibility Requirements, was satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

In evaluating this indicator, the review team used three subelements to evaluate the Division's performance regarding the SS&D Evaluation Program. These subelements were: (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Division's SS&D evaluation activities, the review team examined the Division's response to the IMPEP questionnaire on this indicator, performed a search of the Sealed Source and Device Registry for registrations issued by Louisiana, and performed NMED searches of manufacturers and distributors identified on SS&D registrations issued by Louisiana. A review of all new, amended, and corrected SS&D evaluations and supporting documents covering the review period was conducted. The review team noted the staff's use of guidance documents and procedures; interviewed managers and staff; and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

During the review period, three qualified SS&D reviewers left the Division and one reviewer was qualified. At the time of the review, the Division had two qualified SS&D reviewers with full signature authority and obtained assistance from another qualified SS&D reviewer from the

NRC. The Division indicated that one additional qualified SS&D reviewer with a position in another division of the Department is also available to perform SS&D reviews but did not perform any reviews during the review period.

The Division completed two new SS&D registrations, one amended SS&D registration, and one corrected SS&D registration during the review period. The Division's two qualified reviewers with full signature authority each have greater than 10 years of experience with the Division, and each have obtained either a bachelor's or master's degree in science. One of the reviewers has attended the NRC SS&D workshop. The other reviewer has reviewed the SS&D workshop manual, has obtained experience by performing SS&D reviews with the qualified NRC SS&D reviewer, and is scheduled to attend the NRC SS&D workshop in September 2008. The Division had one pending SS&D evaluation. The review team determined that the staffing level is adequate for the Division's SS&D workload.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Division processed four SS&D actions. The actions were two new, one amended, and one corrected SS&D registrations. The casework review included all supporting documentation, licensing actions, and inspections. A listing of the SS&D registrations evaluated, with case-specific comments, can be found in Appendix F.

The review team confirmed that the Division's policy is to follow the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses - Applications for Sealed Source and Device Evaluation and Registration."

The review team verified that appropriate review checklists were used to ensure that all relevant materials had been submitted and reviewed. The checklists were retained in the SS&D files along with other documents that clearly identified the responsible reviewer. The review team verified that pertinent American National Standards Institute standards, NRC Regulatory Guides, and applicable references were available and used when performing SS&D reviews.

The review team noted that three out of four registrations did not follow the format and content recommended in NUREG-1556, Volume 3. In cases where the format and content were not followed, the Division relied upon the format and content provided by the applicant without checking the NUREG. For example, in two registrations reviewed, each applicant submitted that the use code was "(V) General Medical Use." A check of Appendix C of the NUREG would have alerted the reviewer that such use code was discontinued in 2002 and that the correct use code for the two registrations is "(AC) Photon-emitting Remote Afterloaders." These formatting issues did not adversely impact the technical quality or content of the reviews; however, because the registrations are used nationally, the documents should be consistent with national standards. The review team recommends that the State adhere to the document format and content guidance in current version NUREG-1556, Volume 3.

The registration files contained all correspondence, engineering drawings, photographs, radiation profiles, and details of the applicant's quality assurance and quality control program. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the products. Deficiency letters clearly stated regulatory

positions and all health and safety issues were properly addressed. The review team found that the evaluations were of good quality. The Division enforces the requirements of SS&D registrations through conditions made part of specific licenses issued to the distributors of SS&D products.

The review team noted that the Division had terminated a specific license associated with SS&D registrations and did not address inactivation of the registrations. The review team also identified that the Division did not address inactivation of two additional SS&D registrations. The review team concluded that no adverse health and safety issues resulted. The review team discussed with the Division managers the benefits of performing inactivations of registrations prior to or in unison with performing license terminations. Division managers agreed to evaluate the need to inactivate the registrations in question and to inactivate the registrations consistent with the guidance in NUREG-1556, as applicable.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Division's response to the questionnaire, interview of Division managers, and the review team's searches of NMED, the review team selected a sample of three incidents and/or equipment failures reported during the review period that occurred in Louisiana or that occurred nationally involving SS&D products registered in Louisiana. The listing of casework examined, with case-specific comments, can be found in Appendix E. The Division reported that there were no allegations received by the Division related to SS&D products registered in Louisiana during the review period.

The review team determined that the Division analyzed the events, reviewed the issues, and followed up on the incidents adequately and in accordance with their procedures. One of the events involved both a device and a source failure, and the failures were determined to potentially be generic. The Division notified the appropriate regulatory agencies and locations where the affected products had been distributed. The Division ensured that the sources and the failed component of each device were recalled. The Division identified and documented possible root-causes and continued to investigate. The Division received an application from the source manufacturer to amend the related sealed source registration. The Division anticipated that the device manufacturer may also provide an application to amend the related device registration.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Louisiana's performance with respect to the indicator, SS&D Evaluation Program, was satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Louisiana has such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When

an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a

LLRW disposal facility in Louisiana. Accordingly, the review team did not evaluate the State's performance with respect to this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Louisiana's performance was found satisfactory for all seven performance indicators reviewed. The review team made two recommendations regarding program performance and identified one good practice. Accordingly, the review team recommended, and the MRB agreed, that the Louisiana Agreement State Program was adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State:

1. The review team recommends that the State take measures to evaluate corrective actions of all radioactive materials incidents, ensure proper documentation of the review, and appropriately follow up on the corrective actions at subsequent inspections. (Section 3.5)

2. The review team recommends that the State adhere to the document format and content guidance in current version NUREG-1556, Volume 3. (Section 4.2.2)

Below is the good practice, as mentioned earlier in the report:

> The Division uses a unique license condition in terminated licenses that states "If the Department determines that the information supplied is incorrect or defective, the applicability of a specific license may be reassessed." The condition effectively holds the former licensee liable if inaccurate information is provided by the licensee in the termination of the license. In such cases, the Department has a right to pursue actions against the former licensee. (Section 3.4)

LIST OF APPENDIXES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Donna Janda, Region I	Team Leader Technical Staffing and Training
Eric Skotak, Texas	Status of Materials Inspection Program Technical Quality of Inspections
Toye Simmons, Region III	Technical Quality of Licensing Actions
Linda McLean, Region IV	Technical Quality of Incident and Allegation Activities Compatibility Requirements Inspector Accompaniments
Joshua Daehler, Massachusetts	Sealed Source and Device Evaluation Program
Richard Leonardi, Region IV	Inspector Accompaniments

APPENDIX B

LOUISIANA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML081640072

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Alpha Omega Services — License No.: LA-10025-L01
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 12/21/07 — Inspector: JR

Comment:
Report was issued 59 days after inspection due to preparation for assessment of potential penalties through escalated enforcement.

File No.: 2
Licensee: Source Production & Equipment Co — License No.: LA-2966-L01
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 4/18/07 — Inspector: KJ

File No.: 3
Licensee: QSA Global, Inc. — License No.: LA-5934-L01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 9/27/07 — Inspector: SB

File No.: 4
Licensee: Oncology Systems, Inc. — License No.: LA-11598-L01
Inspection Type: Routine, Announced — Priority: 2
Inspection Dates: 2/26/08 — Inspector: KJ

File No.: 5
Licensee: Sunland Fabricators — License No.: LA-3462-L01
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 1/8/08 — Inspector: SB

File No.: 6
Licensee: Oceaneering International, Inc. — License No.: LA-7396-L01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 8/21/07 — Inspector: SB

File No.: 7
Licensee: Acuren Inspection, Inc. — License No.: LA-7072-L01
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 7/2/07 — Inspector: JR

File No.: 8
Licensee: Acuren Inspection, Inc. License No.: LA-7072-L01
Inspection Type: Field Routine, Unannounced Priority: 1
Inspection Date: 8/28/07 Inspector: JB

File No.: 9
Licensee: Janx Integrity Group License No.: LA-11202-L01
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 9/5/07 Inspector: JG

File No.: 10
Licensee: Petro Chem Inspection Services License No.: LA-10239-L01
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 10/8/07 Inspector: KJ

File No.: 11
Licensee: Energy Wireline, Inc. License No.: LA-4408-L01A
Inspection Type: Routine, Not indicated Priority: 3
Inspection Date: 8/7/06 Inspector: JB

File No.: 12
Licensee: Pathfinder Energy Services License No.: LA-9089-L01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 8/25/05 Inspectors: RC

File No.: 13
Licensee: LSU Health Sciences Center License No.: LA-0005-L01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/24/08 Inspector: JB

File No.: 14
Licensee: Medical Center of LA - New Orleans License No.: LA-1329-L01
Inspection Type: Routine/Special, Announced Priority: 2
Inspection Dates: 3/20/08 Inspector: JN

File No.: 15
Licensee: University Medical Center License No.: LA-0746-L02
Inspection Type: Routine, Not indicated Priority: 3
Inspection Date: 6/6/07 Inspector: JF

File No.: 16
Licensee: Louisiana Regional Medical Center. License No.: LA-7424-L01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/11/06 Inspector: RC

File No.: 17
Licensee: East Jefferson Radiation Oncology
License No.: LA-11456-L01
Inspection Type: Initial, Announced
Priority: 2
Inspection Date: 4/24/07
Inspector: KJ

File No.: 18
Licensee: Shreveport Nuclear Pharmacy
License No.: LA-3751-L01
Inspection Type: Routine, Announced
Priority: 2
Inspection Date: 1/25/07
Inspector: JB

File No.: 19
Licensee: Medi-Physics Inc./GE Healthcare
License No.: LA-5470-L01
Inspection Type: Routine, Announced
Priority: 2
Inspection Date: 3/19/08
Inspector: KJ

File No.: 20
Licensee: Hematology-Oncology Associates of Baton Rouge
License No.: LA-11314-L01
Inspection Type: Initial, Announced
Priority: 3
Inspection Date: 6/22/06
Inspector: JN

File No.: 21
Licensee: Northeast Louisiana Cancer Institute
License No.: LA-10206-L01
Inspection Type: Routine, Announced
Priority: 2
Inspection Date: 4/17/07
Inspector: JG

File No.: 22
Licensee: Sunland Fabricators
License No.: LA-3462-L01
Inspection Type: Field, Unannounced
Priority: 1
Inspection Date: 1/8/08
Inspector: SB

File No.: 23
Licensee: Marco Inspection Services
License No.: TX-L06072
Inspection Type: Reciprocity
Priority: 1
Inspection Date: 3/27/08
Inspector: MC

File No.: 24
Licensee: AITEC, USA
License No.: TX-L00578
Inspection Type: Reciprocity
Priority: 1
Inspection Date: 11/21/06
Inspector: KJ

File No.: 25
Licensee: CIS-US, Inc.
License No.: MA-20-9734
Inspection Type: Reciprocity
Priority: 3
Inspection Date: 3/14/08
Inspector: JB

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1
Licensee: Winn Parish Medical Center License No.: LA-6544-L01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 4/8/08 Inspector: JE

Accompaniment No.: 2
Licensee: Balar Associates, Inc. License No.: LA-10969-L01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 4/8/08 Inspector: MC

Accompaniment No.: 3
Licensee: Willis Knighton Medical Center License No.: LA-1194-L01
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 4/7/08 Inspector: MC

Accompaniment No.: 4
Licensee: David G. Baker, M.D. License No.: LA-10913-L01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/23/08 Inspector: JF

Accompaniment No.: 5
Licensee: Cardiovascular Institute of the South License No.: LA-5851-L01
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 4/23/08 Inspector: JF

Accompaniment No.: 6
Licensee: Turner Specialty Services, LLC License No.: LA-10185-L-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 4/22/08 Inspector: JR

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: LSU Bogalusa Medical Center — License No.: LA-0037-L02
Type of Action: Renewal — Amendment No.: 23
Date Issued: 11/03/04 — License Reviewer: JR

File No.: 2
Licensee: Ochsner Clinic Foundation — License No.: LA-0002-L01
Type of Action: Renewal — Amendment No.: 48
Date Issued: 5/24/04 — License Reviewer: MH

File No.: 3
Licensee: RADS S.L., Inc. — License No.: LA-5093-L01
Type of Action: Termination — Amendment No.: 27
Date Issued: 9/19/03 — License Reviewer: MH

File No.: 4
Licensee: Gramercy Alumina LLC — License No.: LA-0673-L01
Type of Action: Renewal — Amendment No.: 34
Date Issued: 4/14/05 — License Reviewer: JR

Comment:
File contained insufficient information to follow reviewer's logic for the licensing action.

File No.: 5
Licensee: Tommy Causey, M.D. — License No.: LA-11437-L01
Type of Action: New — Amendment No.: 0
Date Issued: 7/14/06 — License Reviewer: KR

File No.: 6
Licensee: Foti Nuclear Pharmacy Services — License No.: LA-6165-L01
Type of Action: Amendment — Amendment No.: 24
Date Issued: 8/30/06 — License Reviewer: KR

File No.: 7
Licensee: Honeywell International — License No.: LA-10814-L01
Type of Action: Renewal — Amendment No.: ??
Date Issued: 5/7/07 — License Reviewer: BS

File No.: 8
Licensee: Denton-James, LLC — License No.: LA-11586-L01A
Type of Action: New — Amendment No.: 0
Date Issued: 5/27/07 — License Reviewer: BS

File No.: 9
Licensee: Cembele Industries Inc. License No.: LA-11671-L01
Type of Action: New Amendment No.: 0
Date Issued: 7/17/07 License Reviewer: BS

File No.: 10
Licensee: Saraj Tampera, M.D. License No.: LA-10998-L01
Type of Action: Termination Amendment No.: 2
Date Issued: 8/14/07 License Reviewer: KR

File No.: 11
Licensee: Lafayette Arthritis & Endocrine Clinic License No.: LA-4845-L01
Type of Action: New Amendment No.: 0
Date Issued: 8/31/07 License Reviewer: KR

Comment:
File contained insufficient information to follow reviewer's logic for the licensing action.

File No.: 12
Licensee: Morehouse General Hospital License No.: LA-1155-L02
Type of Action: Amendment Amendment No.: 18
Date Issued: 10/19/07 License Reviewer: KR

File No.: 13
Licensee: Cardiology Associates of Central Louisiana License No.: LA-11746-L01
Type of Action: New Amendment No.: 0
Date Issued: 10/24/07 License Reviewer: KR

File No.: 14
Licensee: Seaboard Wireline License No.: LA-11728-L01
Type of Action: New Amendment No.: 0
Date Issued: 10/30/07 License Reviewer: BS

File No.: 15
Licensee: Conoco Phillip Company License No.: LA-5199-L01
Type of Action: Amendment Amendment No.: 26
Date Issued: 10/30/07 License Reviewer: BS

Comment:
File contained insufficient information to follow reviewer's logic for the licensing action.

File No.: 16
Licensee: MDS Pharma Services (US), Inc. License No.: LA-4095-L01
Type of Action: Termination Amendment No.: 36
Date Issued: 1/09/08 License Reviewer: KR

File No.: 17
Licensee: Qualitech Services
License No.: LA-6346-L01
Type of Action: Amendment
Amendment No.: 26
Date Issued: 1/28/08
License Reviewer: BS

File No.: 18
Licensee: Gonzales Industrial Xray, Inc.
License No.: LA-4611-L01A
Type of Action: Amendment
Amendment No.: 4
Date Issued: 1/28/08
License Reviewer: JW

File No.: 19
Licensee: Tulane University Health Science Center
License No.: LA-0004-L01
Type of Action: Amendment
Amendment No.: 52
Date Issued: 4/18/08
License Reviewer: MB

File No.: 20
Licensee: Southern Isotope
License No.: LA-10477-L01
Type of Action: Amendment
Amendment No.: ??
Date Issued: 4/28/08
License Reviewer: KR

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Bayou Inspection Services, Inc. — License No.: LA-7112-L01
Date of Incident: 12/03/03 — NMED No.: 030974
Investigation Date: 12/5/03 — Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 2
Licensee: Global X-Ray & Services, Corp. — License No.: LA-0577-L01
Date of Incident: 1/23/04 — NMED No.: 040163
Investigation Date: 2/2/04 — Type of Incident: Equipment failure
Type of Investigation: Site

File No.: 3
Licensee: Cardinal Health — License No.: LA-7096-L01
Date of Incident: 2/27/04 — NMED No.: 04049
Investigation Date: 3/31/04 — Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 4
Licensee: Tulane University — License No.: LA-0004-L01
Date of Incident: 10/10/04 — NMED No.: 040742
Investigation Date: 10/11/04 — Type of Incident: Medical event
Type of Investigation: Written report

File No.: 5
Licensee: Schlumberger — License No.: NR (TX License)
Date of Incident: 7/26/05 — NMED No.: 050498
Investigation Date: 7/27/05 — Type of Incident: Lost RAM
Type of Investigation: Telephone

File No.: 6
Licensee: D & S Wireline — License No.: LA-7657-L01
Date of Incident: 7/21/05 — NMED No.: 050510
Investigation Date: 2/26/05 — Type of Incident: Abandoned source
Type of Investigation: Written report

File No.: 7
Licensee: Team Industrial Services — License No.: LA-5601-L01
Date of Incident: 6/1/06 — NMED No.: 060375
Investigation Date: 6/7/06 — Type of Incident: Overexposure
Type of Investigation: Site

File No.: 8
Licensee: Owensby & Kritikos, Inc.
Date of Incident: 1/10/05
Investigation Date: 1/30/06
License No.: LA-2234-L0
NMED No.: 060086
Type of Incident: Overexposure
Type of Investigation: Site

File No.: 9
Licensee: Cardinal Health Nuclear Pharmacy
Date of Incident: 5/22/06
Investigation Date: None
License No.: LA-9089-L01
NMED No.: 060378
Type of Incident: Loss of control of RAM
Type of Investigation: Written report

File No.: 10
Licensee: Lafayette General Medical Center
Date of Incident: 4/4/07
Investigation Date: 4/4/07
License No.: LA-0581-L01
NMED No.: 070206
Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 11
Licensee: Nondestructive & Visual Inspection
Date of Incident: 3/9/06
Investigation Date: 3/27/06
License No.: LA-5601-L01
NMED No.: 060257
Type of Incident: Equipment damage
Type of Investigation: Written report

File No.: 12
Licensee: Nondestructive & Visual Inspection
Date of Incident: 2/16/06
Investigation Date: 3/15/06
License No.: LA-5601-L01
NMED No.: 060135
Type of Incident: Overexposure
Type of Investigation: Site

File No.: 13
Licensee: Mary Bird Perkins Cancer Center
Date of Incident: 11/22/05
Investigation Date: None
License No.: LA-2651-L01
NMED No.: 060046
Type of Incident: Medical event
Type of Investigation: Written report

File No.: 14
Licensee: Schlumberger
Date of Incident: 7/15/05
Investigation Date: 7/21/05
License No.: LA-2789-L01
NMED No.: 050498
Type of Incident: Lost RAM
Type of Investigation: Not recorded

File No.: 15
Licensee: Global X-Ray & Testing Corp.
Date of Incident: 7/14/05
Investigation Date: Not recorded
License No.: LA-0577-L01
NMED No.: 050462
Type of Incident: Equipment failure
Type of Investigation: Not recorded

File No.: 16
Licensee: Christus Saint Francis Cabrini Hospital
Date of Incident: 6/29/07
Investigation Date: 7/9/07
License No.: LA-070403
NMED No.: 1121-L01
Type of Incident: Medical event
Type of Investigation: Site

File No.: 17
Licensee: Alpha Omega Services
Date of Incident: 7/11/07
Investigation Date: 7/11/07
License No.: LA-10025-L01
NMED No.: 070426
Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 18
Licensee: Eustis Engineering
Date of Incident: 11/15/07
Investigation Date: None
License No.: LA-2922-L01
NMED No.: 070762
Type of Incident: Damaged equipment
Type of Investigation: N/A

File No.: 19
Licensee: Team Industrial Services, Inc.
Date of Incident: 1/25/08
Investigation Date: 3/7/08
License No.: LA-9098-L01
NMED No.: 080135
Type of Incident: Overexposure
Type of Investigation: Site

File No.: 20
Licensee: Metco Nondestructive Testing
Date of Incident: 5/24/06
Investigation Date: None
License No.: LA-8043-L01
NMED No.: 060427
Type of Incident: Equipment failure
Type of Investigation: N/A

File No.: 21
Licensee: Gilchrist Construction
Date of Incident: 7/20/06
Investigation Date: 7/21/06
License No.: LA-7890-L01
NMED No.: 060468
Type of Incident: Stolen Gauge
Type of Investigation: Site

SEALED SOURCE AND DEVICE INCIDENT CASEWORK REVIEWS

File No.: 22
Licensee: Oncology Systems, Inc.
License No.: LA-11598-L01
Date of Incident: 2/9/08
NMED No.: 080087
Investigation Date: 2/26/08
Type of Incident: Equipment failure
Type of Investigation: Site

Comments:
a) The Division did not provide NMED with any updates between the initial report submitted February 11, 2008, and May 15, 2008. The Division provided a substantial update to NMED on May 15, 2008.
b) At the time of the review, the Division continued to investigate the incident and, therefore, the incident was not closed in NMED.

File No.: 23
Licensee: Central Testing Co.
License No.: LA-2393-L01
Date of Incident: 11/17/04
NMED No.: 050003
Investigation Date: 11/29/04
Type of Incident: Equipment failure
Type of Investigation: Site

File No.: 24
Licensee: Savoy Technical Services
License No.: LA-11235-L01
Date of Incident: 7/23/2007
NMED No.: 070473
Investigation Date: 8/1/2007
Type of Incident: Equipment failure
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Registry No.: LA-0612-D-102-U — SS&D Use Code: (A) Industrial Radiography
Applicant's Name: Source Production & Equipment Co. — Type of Action: Amended registration
Date Issued: 5/5/08 — SS&D Reviewers: JP, AT

Comments:
a) The first page information section of the registration did not contain any use code letter. The use code letter should be "A."
b) The header section of the registration incorrectly indicated "U" for unknown. The header should instead indicate "S" to acknowledge use of the device for only specific licensees.
c) The issuing agency section of the registration indicated "Prepared By". The issuing agency should acknowledge the "Reviewer" instead of the preparer of the registration.
d) The diagrams section of the registration referred to an appendix without specificity to the list or number of pages attached. The attachments should be numbered (e.g. Attachment 1 of X) and include the header information.

File No.: 2
Registry No.: LA-0760-S-102-S — SS&D Use Code: (V) General Medical Use
Applicant's Name: Alpha-Omega Services, Inc. — Type of Action: Corrected registration
Date Issued: 11/19/03 — SS&D Reviewer: MH

File No.: 3
Registry No.: LA-1281-D-101-S — SS&D Use Code: (V) General Medical Use
Applicant's Name: Oncology Systems — Type of Action: New registration
Date Issued: 8/7/07 — SS&D Reviewers: TH, AT

Comments:
a) The first page information section of the registration incorrectly indicated the use code as "(V) General Medical Use". Such use code was discontinued in 2002. The use code should be "(AC) Photon-emitting Remote Afterloaders."
b) The FDA Approval Summary was not included in the registration.

File No.: 4
Registry No.: LA-0612-S-115-S SS&D Use Code: (V) General Medical Use
Applicant's Name: Source Production & Equipment Co. Type of Action: New registration
Date Issued: 8/7/07 SS&D Reviewers: JP, AT

Comments:

a) The first page information section of the registration incorrectly indicated the use code as "(V) General Medical Use". Such use code was discontinued in 2002. The use code should be "(AC) Photon-emitting Remote Afterloaders."
b) The FDA Approval Summary was not included in the.
c) The header section of the registration indicates "Safety Evaluation of a Device". The header should instead indicate "Safety Evaluation of a Sealed Source."
d) The diagrams section of the registration identifies diagrams which were made part of the pages of the registration instead of as attachments to the registration. Attachments should be numbered (e.g. Attachment 1 of X) and be included after the pages of the registration.

ATTACHMENT

July 1, 2008, Letter from Harold Leggett
Louisiana's Response to Draft IMPEP Report

ADAMS Accession No.: ML082040290