

July 3, 2012

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Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

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FROM: Duncan White, Chief */RA LCD for/*
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Division of Materials Safety
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Office of Federal and State Materials
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SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM (IMPEP) REVIEW OF LOUISIANA

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the IMPEP review of the Louisiana Agreement State program. The review was conducted by an interoffice team during the period of April 23-27, 2012. The team issued a draft report to Louisiana on May 23, 2012, for factual comment. Louisiana responded to the findings and conclusions of the review by letter dated June 25, 2012, from Tim B. Knight, Administrator. The Louisiana program commented on the actions taken to address the team's recommendations and also noted a few technical errors which were corrected in this proposed report.

The review team is recommending that Louisiana's performance be found satisfactory for the indicators Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities, and satisfactory, but needs improvement for the Compatibility Requirements, and Sealed Source and Device Evaluation Program performance indicators reviewed. Accordingly, the review team is recommending that Louisiana be found adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission.

The Management Review Board meeting to consider the Louisiana report is scheduled for **Thursday, July 12, 2012, from 1:00 p.m. to 4:00 p.m. (EDT), in OWFN-17B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact Lisa Dimmick at 301-415-0694 or lisa.dimmick@nrc.gov.

Enclosures:

As stated

cc w/ encl: Tim B. Knight, Administrator
Department of Environmental Quality

Judith Schuerman, Manager
Surveillance, Enforcement and Licensing

Earl Fordham, Washington
Organization of Agreement States
Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE LOUISIANA AGREEMENT STATE PROGRAM

APRIL 23-27, 2012

PROPOSED FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program review of the Louisiana Agreement State Program. The review was conducted during the period of April 23-27, 2012, by a review team composed of technical staff members from the U. S. Nuclear Regulatory Commission (NRC) and the State of Florida.

Based on the results of this review, Louisiana's performance was found satisfactory for the indicators Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities, and satisfactory, but needs improvement for the Compatibility Requirements, and Sealed Source and Device Evaluation Program performance indicators reviewed.

The review team made two recommendations: (1) the State should review its processes and develop and implement a methodology to ensure that products issued are of high technical quality and meet the standard expectations, and (2) the State should locate and make readily accessible all of the active sealed source and device registration commitments. Also, a recommendation from the 2008 IMPEP review remains open based on similar issues identified in the Sealed Source and Device Evaluation Program indicator.

Accordingly, the review team recommends that the Louisiana Agreement State Program is adequate to protect public health and safety and is compatible with NRC's program. The review team recommends that the next IMPEP review take place in approximately 4 years and that a periodic meeting be held in 12 to 18 months.

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 April 23-27, 2012, by a review team composed of technical staff members from the U. S. Nuclear Regulatory Commission (NRC) and the State of Florida. 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 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of May 17, 2008, to April 27, 2012, were discussed with Louisiana managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The Louisiana Agreement State Program is administered by the Assessment Division–Radiation (the Division), which is located under the Office of Environmental Compliance within the Department of Environmental Quality (the Department). Organization charts for the Department and the Division are included as Appendix B.

At the time of the review, the Louisiana Agreement State Program regulated 504 specific licenses authorizing possession and use of radioactive materials. 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 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 Department on December 13, 2012. The Department provided its response to the questionnaire on April 5, 2012. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12129A058.

The review team's general approach for conduct of this review consisted of (1) an examination of the Department's response to the questionnaire, (2) review of applicable Louisiana statutes and regulations, (3) analysis of quantitative information from the Department's database, (4) technical review of selected regulatory actions, (5) field accompaniments of five inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicators 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 previous reviews.

Results of the current review of 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.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on May 16, 2008, the review team made two recommendations regarding the Louisiana Agreement State Program's performance. The status of each recommendation is as follows:

1. The review team recommends that the State take measures to evaluate corrective actions of all radioactive material incidents, ensure proper documentation of the review, and appropriately follow up on the corrective actions at subsequent inspections. (Section 3.5 of the 2008 IMPEP Report)

Status: The State has taken measures to evaluate and followup on corrective actions and document review of incidents in subsequent inspection reports. This recommendation is closed.

2. The review team recommends that the State adhere to the document format and content guidance in current version of NUREG-1556, Volume 3. (Section 4.2.2 of the 2008 IMPEP Report)

Status: Similar issues regarding format and content errors were identified during the 2012 review of the Sealed Source and Device Evaluation Program. This recommendation remains open.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review 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

Issues central to the evaluation of this indicator include the Department's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Department's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Department manages the Office of Environmental Compliance which oversees the Division. The Division is composed of the Licensing and Registration Section and the Surveillance and Enforcement Section which are responsible for materials inspection, licensing and compliance activities, and emergency response activities.

At the time of the review, there were 26 technical staff members with various degrees of involvement in the radioactive materials program, totaling approximately 19 full-time equivalents (FTE). Ten staff members left the Department since the last review and nine staff were hired. The Department was recently informed that the position of Senior Technical Staff, vacated November 2011, was eliminated. Department managers are in the process of

identifying, assigning, and performing the duties of this position. No positions were vacant at the time of this review. The review team determined that staffing levels were adequate for the Agreement State program.

The Department had developed a documented training plan for technical staff in response to a recommendation from the 2003 IMPEP. Department management could not provide the actual procedure to the team for review; however, the team determined that it was being implemented. The team discussed the need for a documented procedure for succession planning. The Department managers immediately developed one for the team to review that appeared consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Department's training program is adequate to carry out its regulatory duties and noted that Louisiana management supports the Department training program.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspections of new licenses, (4) timely dispatch of inspection findings to licensees, and (5) performance of reciprocity inspections. The review team's evaluation was based on the Department's questionnaire response relative to this indicator, data gathered from the Department's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that Louisiana's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program." Many of the Department's license categories are inspected at a more frequent inspection schedule than those established in IMC 2800 for similar license types, including nuclear medicine, gauges, and manufacturer/distribution licensees.

The Department conducted approximately 660 higher priority (Priority 1, 2, and 3) inspections during the review period based on the inspection frequencies established in IMC 2800. Nineteen of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Department performed approximately 77 initial inspections during the review period, 6 of which were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The inspections were conducted late due to the military deployment of one inspector for over one year; he has since returned. There were no overdue inspections at the time of the review. Overall, the review team calculated that the Department performed approximately three percent of its inspections overdue during the review period.

The review team evaluated the Department's timeliness in providing inspection findings to licensees. A sampling of 25 inspection reports indicated that none of the inspection findings

were communicated to the licensees beyond the Department's goal of 30 days after the inspection.

During the review period, the Department granted 205 reciprocity permits, all of which were candidate licensees based upon 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 Department exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 25 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 11 Department inspectors and covered inspections of various license types, including academic broad scope, medical institutions with high dose rate remote afterloaders, unsealed radioiodine therapy, permanent or temporary implant brachytherapy, radionuclide production (cyclotron), medical-diagnostic, portable gauges, industrial radiography, self-shielded irradiators, nuclear pharmacy, mobile nuclear medicine, well-logging, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed 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 licensed radiation programs. The review team found that inspection reports were generally thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The majority of the documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Department are generally consistent with the inspection guidance outlined in IMC 2800, including a compliance checklist used by inspectors. An inspection report is completed by the inspector which is then peer reviewed by a second inspector and subsequently emailed to the inspector's supervisor for final review and signature. Supervisory accompaniments were conducted at least annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. All inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Department issues to the licensee a Field Interview Form at the exit meeting of the inspection and, when required, a letter indicating a Notice of Deficiency (NOD), in letter format, which details the results of the inspection. When the Department issues an NOD, the licensee is required to provide a written corrective action plan, based on the

deviations cited, within 30 days. All findings are reviewed by the Enforcement Coordinator and inspection staff.

The review team noted that the Department has an adequate supply of survey instruments to support their inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, were observed to be available. The Department also has a portable multi-channel analyzer for isotope determination of unknown or unidentified radioactive material. Survey instruments are calibrated at least annually, or as needed, by state-licensed calibration services with National Institute of Standards and Technology traceable sources, in the geographic area of each regional office. The Department uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of five Department inspectors were conducted by one IMPEP team member during the week of March 19-23, 2012. The inspectors were accompanied during health and safety inspections of industrial radiography source manufacturing, industrial radiography, medical broad scope including high dose rate remote afterloader therapy, unsealed radioiodine therapy, permanent/ temporary implant brachytherapy, and self-shielded irradiators, PET medical-diagnostic, well-logging, and Increased Controls. The accompaniments are identified 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 and safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 24 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 3 new licenses, 7 renewals, 2 termination actions, and 12 amendments. Files reviewed included a cross-section of license types, including broadscope, medical diagnostic and therapy, gamma knife, industrial radiography, research and development, nuclear pharmacy, gauges, manufacturers, pool and self-shielded irradiators. The casework sample represented work from

four license reviewers. A listing of the licensing casework examined, with case-specific comments is provided in Appendix D.

Overall, the review team found that the licensing actions were generally thorough, complete, consistent, and properly addressed health, safety, and security issues. License reviewers use the NRC NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses. Of the actions reviewed, there were approximately five actions that had deficiencies. The licensing staff addressed and corrected most of the deficiencies prior to the preliminary exit meeting with management. Some of the deficiencies identified included (1) not reviewing a historical authorization of U-235 for shielding in lieu of depleted uranium (DU) as part of a license renewal action, (2) using the American Board of Radiology computer generated results for oral exams only, in lieu of the actual board certificate to document the oral and written exams of a physician authorized user, (3) not listing the Radiation Safety Committee Chair on a broad scope license, and (4) not requiring that the processes used by the Radiation Safety Committee to approve authorized users and designated rooms be submitted during a broad scope license renewal action. The review team determined there was no consistent pattern to the deficiencies identified; however, these deficiencies either did not meet the required technical quality for the review or there was incomplete supporting documentation for the licensing action.

In addition, the review team identified that three medical attestations were not provided as part of the supporting documentation for authorizing a radiation safety officer and two medical physicists. However, the review team determined that the requirements for written attestations are not captured in the current medical regulations for the State of Louisiana, and therefore is not required documentation to support the respective licensing actions. The final medical regulations that were adopted under RATS ID 2007-1 have been submitted to the NRC and are under review at this time.

On June 13, 2003, the NRC issued Orders to all panoramic and underwater irradiator licensees authorized to possess greater than 10,000 curies of byproduct material. One of the licenses issued by the Department authorized an amount of radioactive material in a pool irradiator greater than 10,000 curies and the licensee had received the aforementioned Order. The NRC received information from the licensee in 2003 indicating that, although authorized for greater than 10,000 curies, they possessed quantities significantly below 10,000 curies and, therefore, the specific Order was not applicable. During the review, the Department contacted the licensee and requested a current level of activity in the pool. The review team noted that the current activity corresponded with previous documentation of the activity from 2002 and 2003, with calculated decay correction. Therefore, the pool did not meet the 500 rad/hr at one meter requirement as specified in Chapter 17, "Licensing and Radiation Safety Requirements for Irradiators" under Title 33, Part XV of the Louisiana Code, which is equivalent to Title 10 of the Code of Federal Regulations (CFR) Part 36 requirement. The licensee was implementing the Increased Controls and Fingerprinting Orders as required, for the facility. The Department amended the license during the IMPEP review to reflect an authorized activity well below the 10,000 curie level in order to show that the underwater irradiator Order is not applicable.

Deficiency letters reviewed clearly stated regulatory positions and were used appropriately. In addition to using formal written requests, the staff frequently used telephone or email requests for clarification or to obtain additional information from the licensee or applicant. However, the

review team also identified that some of the requests for additional information were not always documented, which resulted in not being able to ascertain what was authorized in the licensing action. This was especially evident for those requests that were partially authorized or for requests to authorize specific individuals for certain high-risk activities, such as source retrieval. In addition, the Department does not use cover letters for its licensing actions, so there is no formal correspondence to accompany the approved authorization. The Department incorporates the licensee's application date and includes the language "and all subsequent correspondence" as part of the license tie-down condition. The review team discussed the consideration to specifically list documents as part of the tie-down conditions, in order to ascertain what was specifically authorized and in some cases to identify certain individuals that are specifically authorized for high-risk activities, such as source retrieval. Based on discussions with the staff and management, the review team understood that all correspondence from the licensee to the Department is tied-down by the particular license condition. Based on the enforcement actions taken by the Department, it appears that the license and all tie-down conditions are enforceable.

All license evaluators were qualified for the respective licensing actions reviewed. The Department performs a peer review, technical review and a supervisory review for all licensing actions. All licensing actions are then routed to the Program Manager and Administrator and are subsequently signed by the Assistant Secretary, Office of Environmental Compliance under the Department of Environmental Quality. Based on the review team's discussions with the staff and management, it was determined that the peer review is primarily administrative in nature to ensure that the license format, amendment number, and dates are correct, whereas the technical review primarily focuses on the specific request and corresponding authorization. Since the review team identified several deficiencies regarding the technical quality and supporting documentation of the licensing actions in addition to identified deficiencies in other products issued by the Department, including sealed source and device registries (see Section 4.2.2), the review team recommends that the Department evaluate its review processes and develop and implement a methodology to ensure that products issued are of high technical quality and meet the standard expectations of the Department.

Once all of the supporting documentation is received for a licensing action, then the Department typically issues the action within 30-days. The results of this metric are provided to the Louisiana legislature on a quarterly basis.

Licenses are initially issued for a five-year period. Prior to the expiration date, the licensee is required to submit a "partial" renewal and attest that their program has not changed or the licensee is required to submit any changes to the program at this time. The license is then issued for a four-year period. Prior to the four-year expiration date, the licensee is required to submit a full license renewal application. In this manner, the license renewals are completed within 10 years and there is an attestation given during the middle of the 10-year period.

On June 21, 2010, the NRC issued RCPD letter RCPD-10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Material Licenses" to all Agreement States and Michigan. The Department has completed the requested action for all increased control licenses and has completed approximately 95 percent of the remaining material licenses. The Department anticipates that all licenses will be completed by the end of 2013.

The Department has access to the National Source Tracking System (NSTS) and utilizes and updates the database, as necessary, when completing certain licensing actions. The Department did not have any licensees with outstanding NSTS reconciliations for 2011. The Department performs pre-licensing checks of all new applicants. The Department's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Department's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls and Fingerprint Orders, as appropriate. The review team analyzed the Department's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Department requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Department's processes for the control of sensitive information. The Department's licensing system is entirely electronic, except for the increased controls supporting documentation. The increased controls license itself is maintained in the electronic system; however there are no markings on the license to indicate it is considered sensitive information. Access to the electronic radiation records is limited to the Radiation Division and those with a need to know. The increased controls sensitive information that is maintained separately from the electronic system is placed in an Increased Controls marked envelope and secured from inadvertent disclosure in a locked file cabinet. The Department recently received approval from their legal counsel that the increased control licenses, which are maintained on the electronic system, may be marked to indicate they are security-related. The Department's legal counsel determined that this action would not alter the State's obligations under the Public Records Act or other applicable rules. The Department indicated that they would be marking the electronic increased control licenses during future amendments and renewals.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Department's actions in responding to incidents and allegations, the review team examined the Department's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Louisiana in the Nuclear Material Events Database (NMED) against those contained in the Department's files, and evaluated the casework for eight radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Department's response to eight allegations involving radioactive materials. There were no allegations referred to the State by the NRC during the review period.

The review team examined the Department's incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Staff Technical Advisor and the Surveillance Supervisor or Program Manager determine the appropriate level of initial response.

The review team identified 64 radioactive material incidents in NMED for Louisiana during the review period. As a policy, the State chose to report all incidents to the NRC through NMED regardless of reportability. The review team selected eight radioactive material incidents for evaluation. The incidents selected for review included the following categories: potential overexposure, medical event, damaged equipment, equipment or procedural failure, and a fire. The review team determined that the Department's 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 Department dispatched inspectors for on-site investigations in all of the cases reviewed and took suitable enforcement and followup actions. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner. The actions taken in response to incidents were documented and filed, and the data were submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

Incidents were addressed in subsequent inspections as recommended from the 2008 IMPEP review. Interviews of inspectors and a sampling of reports for those inspections showed that followup and corrective actions are evaluated and documented. However, the review team noted that the documentation did not give details as to the effectiveness of the corrective actions.

In evaluating the effectiveness of the Department's response to allegations, the review team evaluated the completed casework for eight allegations. The review team concluded that the Department consistently took prompt and appropriate actions in response to concerns raised. The review team noted that the Department documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. When appropriate, the Department notified the concerned individuals of the conclusion of its investigations. The review team determined that the Department adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation (SS&D) Program, (3) Low-Level Radioactive Waste (LLRW) Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with Louisiana does not relinquish regulatory authority for a low level

radioactive waste disposal or uranium recovery program; therefore, only the first two non-common performance indicators applied 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 in Louisiana Administrative Code, Title 33, Part XV, Radiation Protection, and apply to all ionizing radiation. 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 review team evaluated Louisiana's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains. Louisiana's regulation process normally takes approximately two to three months, if the proposed State regulations are identical to Federal regulations, and six months maximum if they are not identical.

During the review period, Louisiana submitted six final regulation amendments, no proposed regulation amendments and one legally binding license condition to the NRC for a compatibility review. Two of the amendments were overdue for State adoption at the time of submission. The NRC's compatibility review resulted in six comments, which will need to be addressed by the State in upcoming rulemaking activities.

The following two amendments were submitted overdue during this review period:

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications", 10 CFR Part 39 amendment (65 FR 20337) that was due for Agreement State adoption on May 17, 2003.
- "Minor Amendments," 10 CFR Parts 20, 32, 35, 40 and 70 amendment (71 FR 15005) that was due for Agreement State adoption on March 27, 2009.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after the effective date of NRC's regulations. At the time of this review, the following 12 amendments have not been reviewed as final regulations and were overdue:

- "Standards for Protection Against Radiation", 10 CFR Part 20 amendment (56 FR 23360) (56 FR 61352) (57 FR 38588) (57 FR 57877) (58 FR 67657) (59 FR 41641) (60 FR 20183) that became effective on January 1, 1991, and was due for Agreement State adoption by January 1, 1994. The review team noted that this amendment had been reviewed as a proposed regulation, but not submitted as a final regulation for NRC review.

- “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 64980) that became effective on October 15, 1991, and was due for Agreement State adoption by October 15, 1994.
- “Decommissioning Recordkeeping and License Termination: Documentation Additions,” 10 CFR Parts 30 and 40 amendments (58 FR 39628) that became effective on October 25, 1993, and was due for Agreement State adoption by October 25, 1996.
- “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective on June 17, 1996, and was due for Agreement State adoption by June 17, 1999.
- “Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations,” Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective on June 27, 1997, and was due for Agreement State adoption by June 27, 2000.
- “Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 35, and 36 amendments (63 FR 39477, 63 FR 45393) that became effective on October 26, 1998, and was due for Agreement State adoption by October 26, 2001.
- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective on February 16, 2001, and was due for Agreement State adoption on February 16, 2004.
- “Minor Amendments”, 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendments (71 FR 15005) that became effective on March 27, 2006, and was due for Agreement State adoption on March 27, 2009.
- “Medical Use of Byproduct Material – Minor Corrections and Clarifications,” 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207) that became effective on October 29, 2007, and were due for Agreement State adoption on October 29, 2010.
- “Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements,” 10 CFR Parts 30, 31, 32, and 150 amendments (72 FR 58473) that became effective on December 17, 2007, and was due for Agreement State adoption by December 17, 2010.
- “Requirements for Expanded Definition of Byproduct Material,” Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864) that became effective on November 30, 2007, and was due for Agreement State adoption by November 30, 2010.
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendments (72 FR 68043) that became effective February 15, 2008, and was due for Agreement State adoption by February 15, 2011.

The following NRC amendments will need to be addressed in upcoming rulemakings or by adopting alternate legally binding requirements:

- “Medical Use of Byproduct Material – Authorized User Clarification,” 10 CFR Part 35 amendment (74 FR 33901) that became effective on September 28, 2009, and is due for Agreement State adoption by September 28, 2012.
- “Decommissioning Planning”, 10 CFR Parts 20, 30, 40 and 70 (76 FR 35512) that became effective on December 17, 2012, and is due for Agreement State adoption by December 17, 2015.
- “Licenses, Certifications, and Approvals for Materials Licensees”, 10 CFR Parts 30, 36, 39, 40, 70 and 150 (76 FR 56951) that became effective on November 14, 2011, and is due for Agreement State adoption by November 14, 2014.
- “Change of Compatibility of 10 CFR 31.5 and 31.6”, (77 FR 3640) that became effective on January 25, 2012, and is due for Agreement State adoption by January 25, 2015.

As reported in Section 3.1, one of the duties of the vacated Senior Technical Staff position included the development of regulations. The Program Manager is in the process of identifying overdue regulation amendments, submitting them for NRC review, reviewing the NRC comments on the final regulation amendments submitted during this review period, and planning to address the comments in upcoming rulemaking.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana’s performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

4.2 Sealed Source and Device Evaluation Program

In evaluating this indicator, the review team used three sub elements to evaluate the Department’s performance regarding the SS&D Evaluation Program. These subelements include the following: (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 Department’s SS&D evaluation activities, the review team examined the Department’s response to the IMPEP questionnaire on this indicator, performed a search of the SS&D 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 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, one qualified SS&D reviewer left the Department. At the time of the review, the Department had four qualified SS&D reviewers with full signature authority. Two of the qualified reviewers did not perform any reviews during the review period.

The Department completed one new SS&D registration, five SS&D registrations amended in its entirety, and eight SS&D registration inactivations during the review period. Three of the four qualified reviewers with full signature authority each have over 10 years of experience with the Department and the fourth reviewer has five years experience. Each reviewer has obtained either a bachelor's or master's degree in science. All of the reviewers have attended the NRC SS&D workshop. The Department had two pending SS&D evaluations. The review team determined that the staffing level is adequate for the Department's SS&D workload.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Department processed 14 SS&D actions. These actions consist of one new SS&D registration, five SS&D registrations amended in entirety, and eight SS&D registration inactivations. The casework review included one new, five amended in its entirety, and three inactivations to include reviewing all supporting documentation, licensing actions, and inspections. The review team evaluated 9 of these 14 registrations. A listing of the SS&D registrations evaluated, with case-specific comments, can be found in Appendix F.

The review team confirmed that the Department'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 that 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 all nine of the reviewed 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 Department relied upon the format and content from the previously issued registration without checking the NUREG. For example, in four registrations reviewed, each applicant submitted the incorrect use code identified in Appendix C of the NUREG. (This issue was identified during the 2008 IMPEP review.) Also for six registrations reviewed, the date on the registration's first page did not match the dates on the signature page. These formatting issues did not adversely impact the technical quality or content of the reviews; however, because the registrations are used nationally (especially first page information), the documents should be consistent with national standards. The review team recommends that the State adhere to the document format and content guidance in the current version of NUREG-1556, Volume 3.

The registration files do not contain all correspondence, engineering drawings, photographs, radiation profiles, and details of the applicant's quality assurance and quality control program and other commitments made that are incorporated by reference into the registration. For

example, the “Reference Section” of three registrations did not include the standard language indicating that the documents and commitments are incorporated by reference into the registration. Five registrations contain documents that could not be found at the time of the onsite review or documents with incorrect dates. One initial application was superseded by a more recent revision that resulted in deficiency items responses, none of which were incorporated into the registration’s reference section. The SS&D reviewers indicated that they do not review previous documents in the reference section to verify that they are appropriate, need to be changed, or accessible during amendment in its entirety reviews. The Department enforces the requirements of SS&D registrations through conditions made part of specific licenses issued to the manufacturers or distributors of SS&D products by listing the SS&D registrations numbers in a license condition. The license tie-down condition requires the licensee to follow the commitments made in the registration numbers listed in the license condition. None of the SS&D registration commitments listed in the SS&D “Reference Section” are uniquely identified on the license except by the SS&D registration number. The Department may have difficulty enforcing registration commitments or evaluate any product defect issues that may arise if it does not actually possess the commitment documents.

The majority of the documents not available at the time of the review appear to be part of an initial upload into their document imaging system during 2002-2003 when the Department moved to a paperless record keeping system. The recently received documents were located in the document imaging system and the SS&D “Reference Section” did contain a few errors. For example, the reference section indicated a document date, but a review of the document indicated that this date was actually the received date and not the document date.

While most of the registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the products, two of the registrations did not list external radiation limits at the specified distances as required in NUREG-1556, Volume 3. In addition, a new registration did not provide critical information that the brachytherapy sources are delivered non-sterile and provide the maximum temperatures and pressures for sterilization. While a detailed review of this issue showed the source could withstand these temperature and pressures and no health and safety issue existed, this information is important to regulatory agencies in licensing these sources. The review team found that deficiency letters clearly stated regulatory positions and health and safety issues were properly addressed. With the exception of the formatting issues and reference documents missing, the review team found that the majority evaluations were of good quality.

During the onsite review, the team also discovered one registration amended on January 11, 2011, was not transmitted to NRC. This registration was also not included in the Department’s initial response to the questionnaire. A revised questionnaire response was provided to include this registration.

The review team noted that the Department had terminated a specific license associated with multiple SS&D registrations and did not address inactivation of the registrations. The review team also identified that the Department did not address inactivation of one additional SS&D registration. The review team concluded that no adverse health and safety issues resulted and discussed the benefits of performing inactivation of registrations prior to or concurrent with performing license terminations. The SS&D reviewer 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. At the time of the onsite review, the Department has two registration amendments that they are currently reviewing.

The review team found that while the Department has multiple levels of peer, technical and management review of documents that are part of their processes in issuing SS&D registrations and the associated license amendments, these reviews did not identify these issues prior to the SS&D registration being issued. (See recommendation discussed in Section 3.4, Technical Quality of Licensing Actions.)

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Department's response to the questionnaire, interview of Department managers, and the review team's searches of NMED, the review team selected a suspect incident (NMED No. 100251 reported during the review period involving SS&D products registered in Louisiana). NMED No. 100251 was reviewed because the event description described a potential product defect. After reviewing the event with the SS&D reviewer, the review team determined this was event was not related to a product defect. While an NMED text search indicated several industrial radiography events, none was related to a product/equipment defect.

The Department staff indicated that SS&D incidents were reviewed and followed up by the Senior Technical Advisor (DCLB). This individual left the Department in November 2011 and the person who is to assume these duties has not been identified at the time of the onsite review. The Department reported that there were no allegations received by the Department related to SS&D products registered in Louisiana during the review period.

The review team recommends that all of the active sealed source and device registration commitments be located and made readily accessible by the State.

Based on the IMPEP evaluation criteria, the review team recommends that Louisiana's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory, but needs improvement.

4.3 Low-level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory 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. Although the Louisiana Agreement State Program has LLRW disposal authority, the NRC has not required States to have a program for licensing a LLRW 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 review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Louisiana's performance was found satisfactory for five out of the seven performance indicators reviewed, and satisfactory, but needs improvement, for the indicators, Compatibility Requirements, and the SS&D Evaluation Program. The review team made two recommendations regarding program performance by the State and determined that one recommendation from the 2008 IMPEP review should be closed and another should be kept open. Accordingly, the review team recommends that the Louisiana Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately four years and that a periodic meeting be held in 12 to 18 months.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

RECOMMENDATIONS

1. The review team recommends that the Department evaluate its review processes and develop a methodology to ensure that products issued are of high technical quality and meet the standard expectations of the Department. (Section 3.4 and 4.2.2)
2. The review team recommends that all of the active sealed source and device registration commitments be located and made readily accessible by the State. (Section 4.2.2)
3. 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) (Kept open from the 2008 IMPEP review)

LIST OF APPENDICES

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Appendix F	Sealed Source and Device Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Bryan Parker, Region III	Team Leader Technical Quality of Incident and Allegation Activities
Michelle Beardsley, FSME	Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements
Robert Hays, Region III	Technical Quality of Inspections Inspector Accompaniments
Rachel Browder, Region IV	Technical Quality of Licensing Actions
Michael Stephens, Florida	Sealed Source and Device Evaluation Program

APPENDIX B

LOUISIANA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML120960347

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Cardinal Health 414, LLC
Inspection Type: Routine, Announced
Inspection Date: 11/17/11
License No.: LA-5115-L01 (AI# 128228)
Priority: 1
Inspector: JF

File No.: 2
Licensee: Lafayette General Medical Center
Inspection Type: Routine, Announced
Inspection Date: 5/15/08
License No.: LA-5330-L01 (AI# 35788)
Priority: 2
Inspector: JF

File No.: 3
Licensee: Qualitech Services, Inc.
Inspection Type: Routine, Announced
Inspection Date: 9/24/10
License No.: LA-6346-L01 (AI# 102655)
Priority: 1
Inspector: JB

File No.: 4
Licensee: Southern Isotopes
Inspection Type: Routine, Announced
Inspection Date: 3/29/11
License No.: LA-10477-L01 (AI# 91705)
Priority: 1
Inspector: JB

File No.: 5
Licensee: Savoy Technical Services, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 03/27/12
License No.: LA-11235-L01 (AI# 23431)
Priority: 1
Inspector: JR

File No.: 6
Licensee: Abbeville General Hospital
Inspection Type: Routine, Announced
Inspection Date: 4/26/11
License No.: LA-0222-L01 (AI# 1586)
Priority: 2
Inspector: AH

File No.: 7
Licensee: Christus St. Francis Cabrini Hospital
Inspection Type: Routine, Announced
Inspection Date: 2/12/09
License No.: LA-1121-L01 (AI# 55)
Priority: 2
Inspector: JE

File No.: 8
Licensee: Louisiana State University
Inspection Type: Routine, Announced
Inspection Date: 2/17/12
License No.: LA-0001-L01 (AI# 5540)
Priority: 1
Inspectors: MC, JN

File No.: 9

Licensee: H & H X-Ray
Inspection Type: Routine, Unannounced
Inspection Date: 2/29/12

License No.: LA-2970-L01 (AI# 30909)
Priority: 1
Inspector: MC

File No.: 10

Licensee: Rapides Regional Medical Center
Inspection Type: Routine, Announced
Inspection Date: 3/16/09

License No.: LA-0350-L01 (AI# 2971)
Priority: 2
Inspector: JE

File No.: 11

Licensee: Shiloh Contractors, Inc.
Inspection Type: Routine, Announced
Inspection Date: 6/22/09

License No.: LA-10254-L01 (AI# 128921)
Priority: 4
Inspector: JB

File No.: 12

Licensee: ICON-Industrial Control
Inspection Type: Routine, Announced
Inspection Date: 7/23/09

License No.: LA-10631-L01 (AI# 100040)
Priority: 4
Inspector: JG

File No.: 13

Licensee: Women's and Children's Hospital
Inspection Type: Routine, Announced
Inspection Date: 12/08/11

License No.: LA-10698-L01 (AI# 12296)
Priority: 2
Inspector: AH

File No.: 14

Licensee: Pioneer Pharmacy
Inspection Type: Routine, Unannounced
Inspection Date: 05/12/11

License No.: LA-11301-L01 (AI# 174653)
Priority: 1
Inspectors: MM, JR

File No.: 15

Licensee: Scientific Drilling International Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 6/23/10

License No.: LA-10950-L01 (AI# 11373)
Priority: 3
Inspector: JR

File No.: 16

Licensee: Northeast Louisiana Cancer Center
Inspection Type: Routine, Announced
Inspection Date: 4/13/11

License No.: LA-10206-L01 (AI# 36565)
Priority: 2
Inspector: JG

File No.: 17

Licensee: Teche Regional Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 5/18/10

License No.: LA-0571-L01 (AI# 34247)
Priority: 2
Inspector: JB

File No.: 18

Licensee: Acuren Inspection, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 3/08/12

License No.: LA- 7072-L01 (AI# 126755)
Priority: 1
Inspector: JR

File No.: 19

Licensee: Combined Technical Services
Inspection Type: Routine, Unannounced
Inspection Date: 9/15/10

License No.: LA-7125-L01A (AI# 39006)
Priority: 3
Inspector: KJ

File No.: 20

Licensee: Slidell Memorial Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 2/24/10

License No.: LA-0783-L02 (AI# 2970)
Priority: 2
Inspector: MM

File No.: 21

Licensee: Southern Valve Service, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 11/29/11

License No.: LA-10608-L01 (AI # 12340)
Priority: 4
Inspector: JR

File No.: 22

Licensee: Alliance Imaging, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 5/15/09

License No.: LA-10598-L01 (AI# 86657)
Priority: 1
Inspector: KJ

File No.: 23

Licensee: Southeastern Louisiana University
Inspection Type: Routine, Announced
Inspection Date: 1/06/11

License No.: LA-2574-L01 (AI# 5101)
Priority: 3
Inspector: MM

File No.: 24

Licensee: Gamma-Tron Services, Inc.
Inspection Type: Initial, Unannounced
Inspection Date: 10/31/08

License No.: LA-4895-L01 (AI# 38912)
Priority: 2
Inspector: RC

File No.: 25

Licensee: Louisiana State University
Inspection Type: Special, Announced
Inspection Date: 2/14/12

License No.: LA-0001-L01 (AI# 5540)
Priority: 1
Inspectors: MC, JN

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Ochsner Clinic Foundation
Inspection Type: Routine, Announced/Special
Inspection Date: 3/19/12

License No.: LA-0002-L01 (AI # 3043)
Priority: 1
Inspector: GM

Accompaniment No.: 2

Licensee: Source Production and Equipment Co.
Inspection Type: Routine, Announced
Inspection Date: 3/20/12

License No.: LA-2966-L01 (AI# 38844)
Priority: 1
Inspector: KJ

Accompaniment No.: 3

Licensee: Open Air MRI of Cen-LA
Inspection Type: Routine, Announced
Inspection Date: 3/21/12

License No.: LA-10218-L01 (AI# 156084)
Priority: 3
Inspector: JE

Accompaniment No.: 4

Licensee: Capitol Ultrasonics
Inspection Type: Routine, Unannounced/Special
Inspection Date: 3/22/12

License No.: LA-5838-L01 (AI# 12540)
Priority: 1
Inspector: RC

Accompaniment No.: 5

Licensee: Weatherford
Inspection Type: Routine, Announced
Inspection Date: 3/23/12

License No.: LA-4413-L01 (AI# 127801)
Priority: 3
Inspector: JF

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Code Inspection & Testing Co. South
Type of Action: New
Date Issued: 2/13/09
License No.: LA-12071-L01
Amendment No.: 0
License Reviewer: JR

File No.: 2
Licensee: Desert Industrial X-Ray, LP
Type of Action: New
Date Issued: 4/26/10
License No.: LA-12285-L01
Amendment No.: 0
License Reviewer: MB

File No.: 3
Licensee: Waggoner Services, Inc.
Type of Action: New
Date Issued: 3/5/09
License No.: LA-11860-L01
Amendment No.: 0
License Reviewer: BS

File No.: 4
Licensee: Louisiana State University
Type of Action: Amendment
Date Issued: 4/14/10
License No.: LA-0001-L01
Amendment No.: 37
License Reviewer: MB

File No.: 5
Licensee: Tulane University Health Sciences Center
Type of Action: Renewal
Date Issued: 12/16/11
License No.: LA-0004-L01
Amendment No.: 53
License Reviewer: KR

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

File No.: 6
Licensee: LSU Health Sciences Center/Shreveport
Type of Action: Renewal
Date Issued: 12/6/11
License No.: LA-0005-L01
Amendment No.: 120
License Reviewer: KR

Comment:
Radiation Safety Committee Chair was not authorized.

File No.: 7

Licensee: Cardinal Health 414, Inc.
Type of Action: Renewal
Date Issued: 4/24/08

License No.: LA-10217-L01
Amendment No.: 24
License Reviewer: BS

Comment:

Authorized U-235 in lieu of depleted uranium for shielding.

File No.: 8

Licensee: PETNET Solutions, Inc.
Type of Action: Renewal
Date Issued: 10/22/09

License No.: LA-10505-L01
Amendment No.: 22
License Reviewer: KR

File No.: 9

Licensee: Touro Infirmary
Type of Action: Amendment
Date Issued: 8/5/11

License No.: LA-1198-L01
Amendment No.: 36
License Reviewer: KR

File No.: 10

Licensee: Terrebonne General Medical Center
Type of Action: Amendment
Date Issued: 1/29/10

License No.: LA-2762-L01
Amendment No.: 52
License Reviewer: KR

File No.: 11

Licensee: Loyola University
Type of Action: Termination
Date Issued: 10/16/08

License No.: LA-0014-L01
Amendment No.: 26
License Reviewer: BS

File No.: 12

Licensee: Source Production & Equipment Company, Inc.
Type of Action: Amendment
Date Issued: 2/8/11

License No.: LA-2966-L01
Amendment No.: 59
License Reviewer: JR

Comment:

File contained insufficient information to follow reviewer's determination process for authorizing the licensing action.

File No.: 13

Licensee: Source Production & Equipment Company, Inc.
Type of Action: Amendment
Date Issued: 3/11/11

License No.: LA-2966-L01
Amendment No.: 61
License Reviewer: JR

File No.: 14

Licensee: Ochsner Medical Center Baton Rouge
Type of Action: Amendment
Date Issued: 10/14/10

License No.: LA-5088-L01
Amendment No.: 29
License Reviewer: KR

File No.: 15

Licensee: Ochsner Medical Center - Kenner, LLC
Type of Action: Amendment
Date Issued: 3/9/10

License No.: LA-5162-L01
Amendment No.: 35
License Reviewer: KR

File No.: 16

Licensee: Sterling Sugars, Inc.
Type of Action: Amendment
Date Issued: 5/20/10

License No.: LA-4665-L01
Amendment No.: 11
License Reviewer: BS

File No.: 17

Licensee: Mary Bird Perkins Cancer Center
Type of Action: Amendment
Date Issued: 7/5/11

License No.: LA-2651-L01
Amendment No.: 89
License Reviewer: KR

Comment:

Authorized two medical physicists based on ABR computer generated oral board results
in lieu of the ABR board certificate.

File No.: 18

Licensee: Women's Hospital Foundation
Type of Action: Amendment
Date Issued: 8/16/10

License No.: LA-2338-L01
Amendment No.: 27
License Reviewer: MB

File No.: 19

Licensee: Mary Bird Perkins Cancer Center
Type of Action: Amendment
Date Issued: 11/1/11

License No.: LA-2651-L01
Amendment No.: 90
License Reviewer: KR

File No.: 20

Licensee: Lake Charles Memorial Hospital
Type of Action: Renewal
Date Issued: 6/24/10

License No.: LA-0575-L01
Amendment No.: 68
License Reviewer: MB

File No.: 21

Licensee: Warrior Energy Services Corp.
Type of Action: Renewal
Date Issued: 3/31/10

License No.: LA-10011-L01
Amendment No.: 16
License Reviewer: BS

File No.: 22

Licensee: BioLab Facility
Type of Action: Renewal
Date Issued: 3/4/09

License No.: LA-10387-L01
Amendment No.: 4
License Reviewer: BS

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License Casework Reviews

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File No.: 23

Licensee: Kiewit Louisiana Company

Type of Action: Amendment

Date Issued: 11/4/10

License No.: LA-12214-L01

Amendment No.: 1

License Reviewer: MB

File No.: 24

Licensee: Seaboard Wireline, Inc.

Type of Action: Termination

Date Issued: 2/20/09

License No.: LA-11728-L01

Amendment No.: 3

License Reviewer: BS

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Mary Bird Perkins Cancer Center
Date of Incident: 12/23/08
Investigation Date: 1/15/09

License No.: LA-2651-L01
NMED No.: 090094
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2

Licensee: Hill Brothers Construction
Date of Incident: 3/26/09
Investigation Date: 3/31/09

License No.: MS-520-01
NMED No.: 090407
Type of Incident: Damaged Portable Gauge
Type of Investigation: Site

File No.: 3

Licensee: Cameron Valves & Measurement
Date of Incident: 7/28/09
Investigation Date: 7/31/09

License No.: LA-7095-L01
NMED No.: 090689
Type of Incident: Radiography Source Disconnect
Type of Investigation: Site

File No.: 4

Licensee: Accurate NDE & Inspection
Date of Incident: 7/31/09
Investigation Date: 9/25/09

License No.: LA-10207-L01
NMED No.: 090751
Type of Incident: Personnel Overexposure
Type of Investigation: Site

File No.: 5

Licensee: Westlake Polymers, LLC
Date of Incident: 12/07/09
Investigation Date: 12/10/09

License No.: LA-5404-L01
NMED No.: 100043
Type of Incident: Fixed Gauge Shutter Failure
Type of Investigation: Site

File No.: 6

Licensee: Mary Bird Perkins Cancer Center
Date of Incident: 3/12/10
Investigation Date: 5/28/10

License No.: LA-2651-L01
NMED No.: 100219
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 7

Licensee: Accurate NDE & Inspection
Date of Incident: 12/01/11
Investigation Date: 3/05/12

License No.: LA-10207-L01
NMED No.: 120154
Type of Incident: High Dosimeter Result
Type of Investigation: Site

File No.: 8

Licensee: Shaw Sunland Fabricators, Inc.
Date of Incident: 3/15/12
Investigation Date: 3/16/12

License No.: LA-3462-L01
NMED No.: 120184
Type of Incident: Facility Fire
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

File No: 1

Registry No: LA-612-D-114-S

SS&D Type: (A) Industrial Radiography

Date Issued: 11/25/09

Type of Action: Amendment

Distributor: Source Production & Equipment Company, Inc.

Reviewers: JP, JR

Type of Device: Industrial Radiography Source Assembly

Model Number: G-80 Series, G-80 548 Series, G-80 741 Series

Comments:

- a) Review and concurrence date 11/25/09 does not agree with Page 1 date of 10/26/09 as the format described in NUREG 1556 Vol 3 Rev.1 Appendix D.
- b) Leak test frequency on Page 1 indicates testing "During fabrication final inspection, then every six months" instead of "Six months." Does not follow format described in NUREG 1556 Vol 3 and comments regarding leak testing during the manufacturing process belong in the Quality Control and Quality Assurance Section.
- c) Document dated 1/24/2000 in reference section could not be located.
- d) Document listed in the reference section as "letter dated September 29, 2009" is actually dated 9/28/09. The document was received on 9/29/09.

File No: 2

Registry No: LA-0612-D-111-S

SS&D Type: (A) Industrial Radiography

Date Issued: 1/11/11

Type of Action: Amendment

Distributor: Source Production & Equipment Company, Inc.

Reviewers: JP, AT

Type of Source: Radiographic Exposure Device.

Model Number: SPEC 150

Comments:

- a) Issuance date of 1/18/11 on signature page 10 does not agree with the page 1 date of 1/11/11 as described in NUREG 1556 Vol 3 Rev.1 Appendix D.
- b) Document listed in the reference section as "letter dated November 04, 2010" is actually dated 10/4/10. The document was received on 11/4/10.
- c) NRC SS&D website does not list this 1/11/11 revision. This revision was not identified on the IMPEP questionnaire.

File No: 3

Registry No: LA-0612-S-116-S

SS&D Type: (AA) Manual Brachytherapy

Date Issued: 6/25/09

Type of Action: NEW

Applicants Name: Source Production & Equipment Company, Inc.

Reviewers: JR, JP

Type of Device: Brachytherapy Source

Model Number: SPEC Model M-31

Comments:

- a) Issuance and concurrence date 6/29/09 does not agree with Page 1 date of 6/25/09 as the format described in NUREG 1556 Vol 3 Rev.1 Appendix D.
- b) Limitations section use uses the word "should" in items 3, 5, 6, and 7 instead of "shall" which places the limitation on the use.
- c) A statement that the sources are sent as non-sterile needs to be added to the "Limitations" section along with a statement to that they shall follow the manufacturer's instructions for sterilization and list with the maximum temperature and pressure.
- d) The reference section does not include the phrase that "The following supportive documents are hereby incorporated by reference and are made part of this registry document." As described in NUREG 1556 Vol 3 Rev.1 Appendix D.
- e) Details not provided on the manufacturer's instrumentation used, its calibration or procedures followed to determine the activity of Ytterbium 169.

File No: 4

Registry No: LA-1281-D-801-S

SS&D Type: (AC) Photon-emitting Remote Afterloader

Date Issued: 7/21/09

Type of Action: Inactive Amendment

Distributor: Oncology Systems

Reviewers: JR, AT

Type of Device: Remote Afterloading Brachytherapy Unit

Model Number: AccuSource 1000

Comment:

The first page information section of the registration incorrectly indicates the use as "(V) General Medical" instead of "(AC) Photon-emitting Remote Afterloaders" and the FDA Approval Summary was not included in the registration.

File No: 5

Registry No: LA-612-D-106-S

SS&D Type: (A) Industrial Radiography

Date Issued: 10/21/10

Type of Action: Amendment

Distributor: Source Production & Equipment Company, Inc.

Reviewers: JR, JP

Type of Device: Industrial Radiography Source Assembly

Model Number: "T" Series

Comments:

- a) Concurrence date 11/16/10 is past the 10/21/09 date identified on Page 1 and the signature page.

- b) The first page information section of the registration incorrectly indicates the use as “Industrial Radiography” instead of “(A) Industrial Radiography” as required by NUREG 1556 Vol 3 Rev. 1.
- c) The External Radiation Level Section does not provide measured or calculated radiation levels of a for each isotope with the maximum activity allowed at distances of 0, 5, 30 and 100 centimeters as described in NUREG 1556 Vol 3 Rev.1.
- d) Multiple documents between 1988 and 1994 listed in the reference section that are incorporated by reference could not be located.

File No: 6

Registry No: LA-612-D-105-S

SS&D Type: (A) Industrial Radiography

Date Issued: 10/21/10

Type of Action: Amendment

Distributor: Source Production & Equipment Company, Inc.

Reviewers: JR, JP

Type of Device: Industrial Radiography Source Assembly

Model Number: “G” Series

Comments:

- a) Issuance date of 10/21/10 on signature page 6 does not agree with the page 1 date of 10/18/10 as described in NUREG 1556 Vol 3 Rev.1 Appendix D.
- b) The concurrence date 11/16/10 is past the issuance date 10/21/10 on page 1.
- c) The External Radiation Level Section does not provide measured or calculated radiation levels of a for each isotope with the maximum activity allowed at distances of 0, 5, 30 and 100 centimeters as described in NUREG 1556 Vol 3 Rev.1.
- d) Multiple documents between 1979 and 1995 listed in the reference section that are incorporated by reference, to include the original application and deficiency replies could not be located.
- e) Applicant submitted the following revisions that were reviewed and approved but were not added to the Reference Section. Registration Application Revision (1) dated 10/1/96, letter dated 3/25/97. The amendment in its entirety did not incorporate changes and remove outdated procedures as required by NUREG 1556 Vol 3 Rev. 1.

File No: 7

Registry No: LA-0577-S-802-S

SS&D Type: (AA) Manual Brachytherapy

Date Issued: 6/10/08

Type of Action: Inactivation Amendment

Distributor: RADS S.L., Inc.

Reviewers: JP, AT

Type of Source: Brachytherapy Source

Model Number: SL-77HS

Comment:

- a) The first page information section of the registration still incorrectly indicates the use as “(V) General Medical” instead of “(AA) Manual Brachytherapy.” While this is an inactivation, NUREG 1556 Vol 3 Rev.1 requires inactivation to formatted to standards and contain the most current and correct information.
- b) Page 1 list the isotope as “Iridium-I 92” instead “Iridium-192.”

ATTACHMENT(S)

June 25, 2012 Letter from Tim B. Knight
Louisiana Response to the Draft Report
ADAMS Accession No.: ML12178A015

Agenda for Management Review Board Meeting
July 12, 2012, 1:00 p.m. – 4:00 p.m. (EDT), OWFN-17-B4

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other participants.
3. Consideration of the Louisiana IMPEP Report.
 - A. Presentation of Findings Regarding Louisiana's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - Sealed Source and Device Evaluation Program
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Louisiana representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees:	Michael Weber, DEDMRT	Cynthia Carpenter, FSME
	Bradley Jones, OGC	Brian McDermott, FSME
	Mark Satorius, FSME	Duncan White, FSME
	David Lew, RI	Lisa Dimmick, FSME
	Earl Fordham, WA	Michelle Beardsley, FSME
	Bryan Parker, RI	Karen Meyer, FSME
	Rachel Browder, RIV	Daniel Merzke, OEDO
	Bob Hays, RIII	Tim Knight, LA
	Mike Stephens, FL	