



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

March 15, 2012

Kathryn Perkins, Assistant Commissioner
Division of Regulatory Services
Texas Department of State Health Services
P.O. Box 149347-Mail Code 2835
Austin, TX 78714-9347

SUBJECT: SUMMARY OF PERIODIC MEETING WITH TEXAS DEPARTMENT OF STATE
HEALTH SERVICES HELD ON FEBRUARY 23, 2012

Dear Ms. Perkins:

A periodic meeting was held with Mr. Richard Ratliff and other members of your staff on February 23, 2012, at the Exchange Building on Wall Street. The purpose of this meeting was to review and discuss the status of the Texas Agreement State Program. The NRC was represented by Dr. Janine Katanic and Mr. Stephan Poy, both of FSME, and me from Region IV. In addition, Mr. Michael Weber, Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs, and his Technical Assistant, Mr. Dan Merzke, observed the exchange of information during the Periodic Meeting. We also appreciated the opportunity to hear from you regarding the highlights of the program, as well as the constraints that you operate under, and the opportunities for our two agencies to work together for the overall national materials program.

We have completed and enclosed a general meeting summary. If you or your staff determines that our conclusions do not accurately summarize the meeting discussion, or if there are any additional remarks or questions regarding the meeting, please contact me at 817-860-8116 or by e-mail at Rachel.Browder@nrc.gov to discuss your concerns. The Special MRB for this Periodic Meeting will be held on April 5, 2012, from 1-3 PM EDT. The NRC may be able to support a videoconference, if requested. Please contact Karen Meyer at 301-415-0113 to coordinate a videoconference for the Special MRB.

Sincerely,

/RA/

Rachel S. Browder, *CHP*
Regional State Agreements Officer

Kathryn Perkins

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Enclosure:

Texas Periodic Meeting Summary

cc w/enclosure:

Richard A. Ratliff, Chief

Radiation Safety Licensing Branch Manager

Division for Regulatory Services

TX Dept. of State Health Services

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TEXAS PERIODIC MEETING SUMMARY

Date of Meeting: February 23, 2012

Attendees

NRC	TEXAS
Rachel Browder, RSAO	Richard A. Ratliff, Manager Radioactive Safety Licensing Branch
Janine Katanic, Ph.D., FSME	Alice Rogers, Manager Radiation Inspections Branch
Stephen Poy, FSME	Barbara Taylor, Manager Radiation PSQA Group
Michael Weber, Deputy EDO	Bob Free, Manager Environmental Monitoring Group
Dan Mertzke, Technical Assistant EDO	Darice Bailey, Manager Radioactive Materials Group
	Ray Fleming, Program Coordinator Industrial Licensing
	Scott Kee, Program Coordinator Medical / Academic
	Lisa M. Nieman Assistant General Counsel
	Charlotte Dokes, Manager Inspection Unit

DISCUSSION:

The Texas Agreement State Program is administered by the Department of State Health Services (DSHS), which regulates approximately 1700 specific licenses authorizing byproduct, source, and certain special nuclear materials (radioactive materials), and the Texas Commission of Environmental Quality (TCEQ), which has regulatory responsibility for uranium recovery and the low-level radioactive waste (LLRW) program in the state. Both, DSHS and TCEQ are granted legal authority through the Texas Radiation Control Act, Chapter 401 of the Texas Health and Safety Code. TCEQ received jurisdiction of the uranium recovery program effective June 2007, just prior to the last IMPEP review. The Texas Radiation Control Act was amended to reflect this change.

The DSHS portion of the Agreement State program is located in the Division for Regulatory Services. The Division for Regulatory Services has two sections: the Health Care Quality Section which implements the licensing and sealed source & device registry (SS&DR) program, and the Environmental and Consumer Safety Section, which implements the inspection, investigation, and policy/standards/quality assurance programs.

Enclosure

The last IMPEP Review was conducted February 22-26, 2010. The review team recommended, and the Management Review Board (MRB) agreed, that the Texas Agreement State Program was found to be satisfactory for all nine performance indicators reviewed. Overall, the Texas Agreement State Program was found to be adequate to protect public health and safety and compatible with NRC's program.

Based on the results of the 2010 IMPEP Review, the MRB concurred that the next full review of the Texas Agreement State Program is to take place in approximately 4 years from the review, and a periodic meeting would be tentatively scheduled for February 2012. The purpose of this periodic meeting is to fulfill that requirement in order to evaluate the overall implementation of the Agreement State Program. The following summary for the periodic meeting with DSHS is one half of the review for the Texas Agreement State Program. A separate periodic meeting was held with TCEQ on February 22, 2012, and a separate summary report was generated. The summary report for TCEQ may be found on the ADAMS website. Both summary reports, for DSHS and TCEQ, will be presented to the Special MRB on April 5, 2012.

Program Strengths

DSHS is a very large program with approximately 1700 radioactive materials licenses located at approximately 2500 facilities in the state. While the Department has experienced staff losses since the last IMPEP review, they have continued to implement the program across all areas. The program consistently supports and stays involved with NRC working groups, including the revision to NUREG-1556 series. The state has representatives on several organizations, including Advisory Committee on the Medical Uses of Isotopes (ACMUI), Conference of Radiation Control Program Directors (CRCPD), and Organization of Agreement States (OAS.) The Department has integrated the work load to support new programs, including security requirements, National Source Tracking System (NSTS), and Web-based licensing (WBL). The state indicated that the staff members work well together to provide a high level of customer service to their licensees and the Department receives management support to ensure the program is implemented efficiently and effectively.

Program Weaknesses

While the Department has implemented all of the security and verification requirements for licensing and inspection, the Department expressed that the additional requirements continue to be a challenge and strain the radiation control program's resources.

Feedback on NRC's Program

The Department expressed that the Agreement State programs regulate approximately 87 percent of the materials licensees in the country. As a result, NRC should be cognizant of states' constraints and limited financial resources and attempt to balance these against the risks as the NRC develops new requirements. The Department provided several suggestions to allow additional staff members attend the NRC-sponsored medical courses (H-304, Nuclear Medicine; and H-313, Brachytherapy; and Gamma Knife) at the contracted facility in Houston, Texas. It was communicated to the Department that the number of medical courses will be increased to four classes annually for the next 5 years. However, the suggestions that the program provided will be forwarded to the Technical Training Center for consideration. In

addition, the Department suggested that the courses could be video-taped to allow new Agreement State staff to view the material until such time that they could attend the course.

The Department suggested that the NRC review the risk assessment to determine an appropriate reporting requirement for fixed gauge shutter failures. Such failures are reportable under 10 CFR 30.50(b)(2), which requires, in part, a 24-hour notification of an event in which equipment is disabled or fails to function as designed when certain conditions are met. Each licensee who makes a 24-hour notification is required to provide a 30-day written report. The Department questioned whether gauge shutter failures should continue to be a 24-hour reporting requirement since they typically fail in their operating position; therefore, a 30-day reporting requirement may be sufficient.

The TCEQ requested to host the H-308, Transportation of Radioactive Materials course. This was discussed with the Department, who agreed that it would benefit both DSHS and TCEQ for the course to be hosted locally.

The Department suggested that when the NRC changes the priorities agreed to between NRC and the OAS Board, then the agency should communicate with the OAS Board again for consensus.

Staffing and Training

The Department has experienced a number of vacancies as a result of retirements, transfers, promotions. The Department continues to have a strong, experienced staff to implement the program. The Department anticipates additional retirements over the next several years. The Licensing and SS&DR Branch have 10 technical staff, three vacancies and one manager. The Inspection and Investigation Branch have 24 technical staff, six vacancies, and three managers. The Policy/Standards/Quality Assurance Branch has 6 technical staff and one manager, with no vacancies. The Department also utilizes one enforcement coordinator. The Department has reached across branches to support the work as necessary. In addition, the Department is assessing other areas that could support the program. For example, the Department is using the assistance of a staff member from another unit for mechanical engineering reviews to support the SS&DR program. The staff are maintaining qualifications and continuing to receive training courses sponsored by the NRC or other equivalent courses. The senior inspector was performing accompaniments for all of the full-time inspectors.

Program Reorganizations

There has not been a program reorganization since the IMPEP review.

Changes in Program Budget/Funding

The General Revenue appropriation for the Radiation Control Strategy was decreased by approximately 16 percent in the FY 2013-14 biennium, which is approximately \$2.7 million. DSHS is required to evaluate its regulatory programs to determine where new or existing fees can be assessed/increased and identify efficiencies that can reduce the costs within the regulatory program. DSHS subsequently increased the radiation control fees, which became effective on January 1, 2012. Additional revenue from the fee increase will not be fully attained this fiscal year due to the effective date of the rule; however, the revenue may reach a threshold

such that the program's overall general revenue appropriation may be increased. In addition, as part of the required assessment, DSHS will contract for an independent assessment of its regulatory functions. The Department plans to use the assessment to identify and develop recommendations directed at increasing the effectiveness of business operations and administrative processes supporting regulatory activities, maximize consumer safety and public health, and recover the costs of performing regulatory services.

Materials Inspection Program

At the time of this periodic meeting, the Department reported that there were no overdue inspections. The security inspections were being performed in conjunction with the health and safety inspections and the pre-licensing security inspections were being performed. In addition, the Department performed at least 30 percent of the reciprocity inspections. The inspection program has one inspector vacancy in the Corpus Christi region; however, other regional inspectors have been covering inspections in the vacant region as necessary.

Materials Licensing Program

As a result of the vacancies in the licensing program, the Department indicated that they were prioritizing the licensing actions such that amendment requests, new applications, and emergent health and safety issues were being addressed. Licensing actions that were in timely renewal were being worked as needed. The Department stated that the industrial, advanced technology, and general licensing actions were being processed within 30 days. The medical and academic licensing actions were being processed in approximately 60-90 days. There were approximately 125 renewals that were in timely renewal for approximately 1 year and approximately 45 in timely renewal over 2 years. The Department recognizes the impact that the vacancies have had on the licensing branch and are working to resolve the backlog before it gets overwhelming. Some of the recommendations include cross-training other staff members to assist in the licensing branch.

The Department is maintaining NSTS and is working toward having the licensing staff credentialed to ensure the database is being maintained as required.

The Department maintains the Radiography Certification Program, which is available on the website at: <http://www.dshs.state.tx.us/radiation/ir.shtm>. The program is responsible for testing approximately 900 radiographers a year in Texas and provides tests and grading services for an additional 1100 tests taken in other states. The program certifies approximately 1200 radiographer trainees, 500 radiographers, and 150 radiographer trainers a year in Texas, plus an additional 250 radiographers and 150 radiographer trainees under reciprocity.

Regulations and Legislative Changes

The State is up to date on all regulation amendments currently required for compatibility. The Department has a process in place to address the final comments for six regulatory packages that include: (RATS ID 2002-2), (RATS ID 2004-1), (RATS ID 2006-1), (RATS ID 2007-2), (RATS ID 2007-3), and 10 CFR 34 and 39 Not Associated with a Specific RATS package. The Department's process includes the submittal of the final regulations to address the respective comments.

The comments identified for (RATS ID 2001-1) concerns generally licensed devices (GLDs). This regulation review has been held in abeyance as a result of the proposed rule on GLDs. However, as discussed during the periodic meeting and as documented in FSME letter 12-016, there was a change in compatibility of 10 CFR 31.5 and 31.6 in the withdrawal of the proposed rule and closure of Petition For Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control. As a result, the Department should submit their regulations equivalent to 10 CFR 31.5 and 31.6 by letter, and the NRC will review (RATS ID 2001-1) and (RATS ID 2012-1). The new date for State adoption is January 25, 2015.

The following amendments will need to be addressed by the Department in future rulemakings or by adopting alternate generic legally binding requirements:

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 amendment (76 FR 35512) that is due for Agreement State adoption by December 17, 2015
- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 40, 70, and 150 (76 FR 56951) that is due for Agreement State adoption by November 14, 2014

All Texas agencies are subject to sunset review by the Texas Sunset Commission. The Department was last reviewed in 2000. The next sunset review has been deferred to 2014.

Event Reporting, Including Follow-up and Closure Information in NMED

At the time of the periodic meeting, the Department had reported 116 events to the Nuclear Material Events Database (NMED) since the 2010 IMPEP review. This value is approximately 0.07 percent for the number of licenses issued by the Department. In addition, approximately 30 of the events involved a stuck shutter for a fixed gauge, which typically failed in the operating position and did not impact the health and safety at the facility. Based on the events reviewed and discussed throughout the review period, the events were appropriately reported to the NRC and were properly entered into, updated, and closed within NMED.

Response to Incidents and Allegations

The Department continues to be responsive to notifications of incidents and allegations. Incidents are quickly reviewed for their affect on public health and safety. The Department provides input for Abnormal Occurrence (AO) reports and IAEA INES Level reporting, in a timely manner to support the NRC's reporting requirements. During the review period, there were three significant incidents which the Department investigated. One was a medical event that involved two separate therapeutic administrations of P-32, the second event involved a stolen radiography camera that contained Category 2 material and has not been recovered, and the third event involved an extremity exposure in excess of the regulatory limits to a radiographer trainee, which resulted in a radiation burn to the hand. The Department is continuing to investigate the third event. The two other significant events have been closed. The Department issued violations in all three cases.

Status of Allegations and Concerns Referred by the NRC for Action

NRC referred five allegations to the Department during the review period. The Department investigated and closed four of the allegations in accordance with their procedure. One of the allegations is continuing to be investigated. The Department closes the concern with the individual or provides the closure letter to the NRC for those cases in which the concerned individual does not want their contact information provided to the Agreement State program.

Sealed Source and Device Registry

The SS&DR is an active program in the Department that manages 211 active SS&D registrations. This includes 132 registrants under Texas licensure and 16 under non-Texas licensure. In addition, there are 63 registrations that are pending inactivation because the companies are no longer in business. After the last IMPEP review, the state initiated a biennial fee for all active registrants, which has encouraged registrants to inactivate their device registry if they are no longer being used. This has allowed the Department to retire a significant number of registries over the past couple of years. As a result of the biennial fee, the Department anticipates approximately 50 percent of the remaining 148 active registrations will request termination of their registries.

The Department utilizes four industrial reviewers, two medical reviewers, and one mechanical engineer from another unit in support of the SS&DR review program. The mechanical engineer supports the reviews as requested and does not have specific SS&DR training. The vacancies in the Licensing Branch have impacted the SS&DR staffing; however, the Department is using the assistance from another unit (i.e., mechanical engineer) and has continued to implement the program consistent with the Department's policies and procedures.

Emerging Technologies

The Department received two unique inquiries, which would be considered new emerging technologies, as summarized below.

Request to use irradiated Yttrium Barium Copper Oxide (YBCO) crystals for use as super conducting magnets cooled with liquid nitrogen for use in motors for a research project conducted by the applicants for the U.S. Navy. If successful, it is proposed that this technology may also be used in other magnet and motor technologies such as in MRI machines. The proposal indicates that, after the irradiated crystal/magnets have decayed for a couple of years, they are approximately 100 mrem/hr on contact.

An applicant requested a radiopharmaceutical license as a supplier of Sr-82 for Rb-82 generators, to either replace columns in existing Bracco Cardiogen-82s or perhaps manufacture their own generators in the future. The principle investigator documented the technology while at Los Alamos Labs.

Large, Complicated, or Unusual Authorizations for use of Radioactive Materials

The Department has coordinated with two different licensees to obtain financial assurance instruments for major decommissioning activities. One licensee established a \$37 million dollar instrument for remediation of a former rare earth processing plant that involves uranium, thorium, and progeny in equipment, soil, and ponds. The second licensee holds a letter of

credit for decommissioning a linear accelerator and cyclotron facility that is no longer operational, which has been complicated by the sale of the facility to a separate unlicensed company, who is indecisive about its future use.

Current State Initiatives

The Department is granted legal authority through the Texas Radiation Control Act, Chapter 401 of the Texas Health and Safety Code to regulate shipping and transportation of LLRW to the Texas disposal facility. As a result, the Department is responsible for registering shippers (e.g., licensee or broker) and transporters of LLRW to the Texas LLRW disposal facility. Shippers are required to register with DSHS, provide their emergency plan for responding to an accident or incident involving shipment of radioactive waste, and provide a list of shipping containers along with their certificates of compliance or other certifying documents. If the shipper manufactures their own containers, then they must submit their quality assurance procedures. The shippers are charged \$10 per cubic foot and will be billed by DSHS after the shipment is completed. Transporters are required to provide their emergency plan and proof of financial responsibility to comply with U.S. Department of Transportation requirements. The DSHS indicated that nine applications have been received and five registrants have been issued. The fees are collected in a perpetual care fund such that the charge may be reduced as long as the fund maintains \$500,000.

State's Mechanisms to Evaluate Performance

The Department uses management review of inspection reports and licensing actions to ensure the quality of regulatory products. In addition, a quality assurance review is performed on all radioactive material inspection reports. Reports are generated routinely to ensure that inspections are completed by the due date. The Department's inspection and licensing information have been fully migrated into the new VERSA computer system and is used for generating reports to assess metrics for the program.

Current NRC Initiatives

NRC staff discussed ongoing Office of Federal and State Materials and Environmental Management Programs (FSME) initiatives with the Texas representatives. This included a review of strategic FSME and RCPD letters, as well as proposed rulemaking and Regulatory Issues Summaries.

CONCLUSION

The Texas Agreement State Program remains a very active, strong, stable program with excellent management support. Staffing and budget constraints continue to be a high priority which the Department is addressing by raising fees, shuffling resources, using resources from other business units, and contracting for an independent assessment of its regulatory functions. The DSHS Assistant Commissioner indicated that they will continue to support the program and work to address the budget and staffing issues within their processes; however, the unfunded requirements will continue to be a challenge. The Department continues to support the IMPEP program, NRC working groups, OAS, and CRCPD and has a state representative on the ACMUI.

Schedule for the Next IMPEP Review

NRC staff recommends that the next IMPEP review be held, as currently scheduled, in FY 2014.