



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

April 12, 2016

Charlotte Sullivan, M.S.A., B.S.N
Acting Radiation Control Program Director
Division for Regulatory Services
Texas Department of State Health Services
P.O. Box 149347, Mail Code 2835
Austin, TX 78714-9347

Dear Ms. Sullivan,

A periodic meeting with you and your staff was held on February 10, 2016. The purpose of this meeting was to review and discuss the status of the Texas Agreement State Program. The scope of the meeting was limited to activities conducted by the Texas Department of State Health Services. A separate meeting was held with the Texas Commission on Environmental Quality on February 11, 2016. The U.S. Nuclear Regulatory Commission (NRC) was represented by Mark Shaffer, Duncan White and me.

I have completed and enclosed a general meeting summary, including any specific actions resulting from the discussions. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting has been scheduled for June 16, 2016 at 1:00 pm (EDT). Call in information for the MRB will be provided in a separate transmission.

If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (817) 200-1143 or via e-mail at Randy.Erickson@nrc.gov to discuss your concerns.

Sincerely,

/RA/

Randy Erickson
State Agreements Officer
Division of Nuclear Materials Safety

Enclosure:
Periodic Meeting Summary

Charlotte Sullivan, M.S.A., B.S.N
Acting Radiation Control Program Director
Division for Regulatory Services
Texas Department of State Health Services
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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR
TEXAS DEPARTMENT OF STATE HEALTH SERVICES
DATE OF MEETING: FEBRUARY 10, 2016

U.S. Nuclear Regulatory Commission (NRC) Attendees	Texas Department of State Health Services Attendees
Randy Erickson, State Agreements Officer, Region IV	Kathryn Perkins, RN, MBA, Assistant Commissioner, Division for Regulatory Services
Mark Shaffer, Director, Division of Nuclear Materials Safety, Region IV	Greg Wilburn, Inspection Unit Manager, Environmental and Consumer Safety Section
Duncan White, Senior Health Physicist, NMSS	Charlotte Sullivan, M.S.A., B.S.N., Manager, Regulatory Licensing Unit
	Helen D. Watkins, Radiation Branch Manager, Environmental and Consumer Safety Section
	Chuck Flynn, Radiation Group Manager, Policy, Standards & Quality Assurance Unit
	Eric Skotak, Manager, Radioactive Materials Group, Environmental and Consumer Safety Section
	Robert Free, Manager, Environmental Monitoring Group, Environmental and Consumer Safety Section
	Chris Myers, Policy, Standards and Quality Assurance Group
	Jason Kelly, Advanced Technology Licensing Program & SSD Coordinator

DISCUSSION:

The Texas Agreement State Program (the Program) is administered by two State agencies, the Texas Department of State Health Services (DSHS) and the Texas Commission on Environmental Quality (TCEQ).

During the 2014 Integrated Materials Performance Evaluation Program (IMPEP) review of the Texas Program, the review team found the Program's performance satisfactory for all indicators reviewed. The review team did make three recommendations specific to TCEQ's program. These included developing and implementing a strategy to address staffing in the Low-Level Radioactive Waste (LLRW) and Uranium Recovery inspection areas; developing detailed inspection procedures for LLRW inspections to provide feedback to the LLRW program and enhance the inspection program; and, developing detailed inspection procedures for uranium recovery inspections to provide feedback to the uranium recovery program and enhance the inspection program.

The review team also recommended, and the Management Review Board (MRB) agreed, that the Texas Agreement State Program was adequate to protect public health and safety, was compatible with the NRC's program; and, that the next IMPEP review should take place in approximately four years.

The following report is limited to a summary of the February 10, 2016, Periodic Meeting held with DSHS managers and staff. A separate report was generated for the February 11, 2016, Periodic Meeting held with TCEQ. That report will discuss the recommendations described above.

TOPICS COVERED DURING THE MEETING INCLUDED:

Program Challenges

The Division for Regulatory Services (DRS) has responsibility for five regulatory program strategies. These include Food and Drug Safety, Environmental Health, Radiation Control, Health Care Professionals, and Health Care Facilities. Within each of these strategies are a number of programs (i.e., Food and Drug, Environmental, Radiation and Health Care Professionals). DRS is made up of two Sections, the Health Care Quality Section and the Environmental and Consumer Safety Section. Within those two sections are eight Units. The Radiation Control Program is divided by organizational function and portions fall into more than one of these organizational Units. In general, regulatory programs must cover the costs of the program through fees. Due to budgetary shortfalls the Radiation Program reported that, at this time, vacancies require approval to be filled. Additionally, the Radiation Program reported that finding qualified applicants for posted positions can be challenging in certain geographic areas across the state. Factors considered when filling vacancies include budgetary constraints, necessity, federal or state mandates, complexity of position, length of time position has been vacant and vacancy rate of the impacted area

The Program also noted that the Inspections Unit recently replaced four inspectors in the Houston area and the training of their replacements has strained the capabilities of senior inspectors who do not live or work in the Houston area.

DSHS also reported that the implementation of Texas' equivalent to 10 CFR Part 37 has placed an additional workload on an already strained staffing situation.

Feedback on NRC's Program

DSHS staff noted a concern related to Texas' ability to host NRC sponsored courses. Previously the NRC allowed States to host courses which would allow the State to have up to 25 percent of the available seats. Because DSHS has experienced significant turnover in the last few years, they are concerned that continued staff losses could result in a large backlog for training, requiring additional slots and expanded access to seats in training classes. Being able to host classes could help alleviate that problem for them.

Program Reorganizations

There have been no reorganizations since the 2014 IMPEP review.

Program Budget/Funding

DSHS is fee funded with fee revenues sent to the general revenue account. DSHS then receives a legislatively directed appropriation. Fees collected by DSHS exceed \$12M per year but only \$9M have been appropriated. The DSHS Inspection Unit Manager reported that there could be additional revenue appropriated over their base budget; however, they do not know when or if that will occur.

Technical Staffing and Training (2014 IMPEP: Satisfactory)

At the time of the periodic meeting, DSHS had a total of 51 technical positions with 42 of those dedicated to the radioactive materials program. Thirty eight of those are fulltime positions with the remainder of the staff having split responsibilities.

Since the 2014 IMPEP review 14 staff (36 percent) have left DSHS for various reasons and they currently have five vacancies. Two of the vacancies are currently posted. Of the five current vacancies, three are in licensing, one is in inspection and one is a Pantex emergency response position. Two of the licensing positions are management/supervisory positions. Given their importance to the Agreement Program, DSHS senior management stated that a request will be made shortly to fill one of these positions and the second is undetermined. At the present time DSHS has four new inspectors completing the qualification process. Two of those are expected to receive qualification soon.

At the time of the 2014 IMPEP review, DSHS had a documented training plan consistent with NRC's Inspection Manual Chapter (IMC) 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs." A discussion was held to clarify the 24 hour continuing education requirement and the various ways that this requirement can be met.

Status of Materials Inspection Program (2014 IMPEP: Satisfactory)

Technical Quality of Inspections (2014 IMPEP: Satisfactory)

DSHS staff reported that they had conducted 354 Priority 1, 2, and 3 inspections since the 2014 IMPEP review. They also performed an additional 109 initial inspections. Of the 354 Priority 1, 2, and 3 inspections performed, 37 were conducted overdue (10.4 percent) and of the 109 initial inspections performed nine were conducted overdue (8 percent). Combined they performed a total 9.9 percent of all inspections overdue since the last IMPEP review. Two inspections are currently overdue and those have been assigned for inspection. A subsequent discussion was held with DSHS staff regarding Management Directive 5.6 and the threshold levels between the indicator outcomes for the Status of the Materials Inspection Program indicator used during IMPEP reviews.

DSHS staff reported that they performed 38 percent of all reciprocity notifications in 2014 and 31 percent in 2015 which exceeds the 20 percent target for performing reciprocity inspections.

DSHS has 14 inspector positions in regional offices placed across the State. In 2014 management accompanied 10 inspectors with four positions not accompanied due to vacancies or staff in the qualification process. In 2015 management accompanied 9 inspectors with five positions not accompanied due to vacancies or staff in the qualification process.

The incident investigation staff are often required to perform inspections as a part of the investigation process. Five incident investigators are currently going through the full inspector qualification process to document their ability to perform these inspections.

DSHS staff reported that they are meeting the 30 day goal of forwarding inspection findings to licensees following an inspection.

Technical Quality of Licensing Actions (2014 IMPEP: Satisfactory)

DSHS currently has 1528 specific licensees, 45 licensed waste shippers and transporters, and completed a total of 4158 licensing actions since the 2014 IMPEP review. License renewals occur at 10 year intervals. At the time of the 2014 IMPEP review DSHS had 68 licenses under timely renewal for a period of greater than one year. Currently they are down to five licensees under timely renewal for a period greater than one year.

Since the 2014 IMPEP review the radiography certification program has administered 6295 radiography exams either directly or through the States of Alabama, Georgia, Illinois, Iowa, Louisiana, Maine, Oklahoma and North Dakota. The manager of the certification program reported an approximate 70 percent pass rate and a 30 percent fail rate for those taking the test.

At the time of the 2014 IMPEP review, DSHS was following NRC's revised pre-licensing guidance. License reviewers performed pre-licensing checks of all new applicants and once they completed that process either performed a pre-licensing visit themselves or requested a site visit from the Radioactive Materials Inspection Group.

In 2015, the Government Accountability Office was able to, under false pretense, obtain a radioactive materials license from the Program. This was due in part to licensing staff not following the DSHS established pre-licensing program. In response to this, they performed a self-assessment and root cause analysis of the actions leading up to this event. They also made staffing changes, developed new procedures, established new protocols and provided additional staff training. DSHS management believes that these changes will strengthen and enhance their pre-licensing guidance program.

Technical Quality of Incidents and Allegations (2014 IMPEP: Satisfactory)

Due to the large number of events and allegations received by DSHS annually, they are one of the only Agreement State programs who have a multi-person staff specializing in incident and allegation reviews. Texas' incident investigation group includes a manager and four specially trained incident investigators.

At the time of the periodic meeting the incident staff had reported 115 events to the NMED database since the 2014 IMPEP review. All HOO reportable events were conveyed to the NRC in accordance with the guidance in SA-300, "Reporting Materials Events". At the time of the meeting, only seven events were currently open.

DSHS staff also directly receive approximately 70 allegations each year. The complaints were divided about equally between Radioactive Materials and X-Ray. They also reported that since the 2014 IMPEP review, they received a total of nine allegations from NRC as well as two incidents. Each of those has investigated and closed.

Regulations and Legislative Changes (2014 IMPEP: Satisfactory)

The Department is granted the legal authority to establish regulations through the Texas Radiation Control Act, Chapter 401 of the Texas Health and Safety Code. Chapter 401 outlines that the Department is the Texas Radiation Control Agency. It further outlines the jurisdictional authorities between the Texas Department of State Health Services and the Texas Commission

on Environmental Quality. No significant legislative changes affecting the Program have occurred since the last IMPEP review.

At the time of the 2014 IMPEP review the review team found that DSHS had submitted four amendments overdue. They also found that at the time of the review that no other amendments were currently overdue. At the time of the 2016 Periodic Meeting, they were current on rule development. Texas' equivalent to Part 37 has also been developed and reviewed by the NRC. They anticipate implementation on March 1, 2016.

Sealed Source and Device (SS&D) Evaluation Program (2014 IMPEP: Satisfactory)

At the time of the 2014 IMPEP review, DSHS did not have any staff dedicated specifically to the SSD Registration Program. At that time work was distributed based on type and complexity, to one of six licensing staff who were qualified to perform safety evaluations of SS&D applications. Today, they have one staff specifically dedicated to the SS&D Registration Program and one who is designated as back-up. They have identified three staff who need to take the next NRC sponsored SS&D training course when it becomes available.

DSHS staff reported that they have issued 320 SS&D registrations with 180 of those currently active. Since the 2014 IMPEP review, staff have completed 47 SS&D actions which included 4 new actions, 15 amendments and 28 inactivations. They also reported there are 120 registrations that need to be inactivated or authority transferred in the next few years. Most of these inactivations are because the manufacturer, distributor or custom user is no longer in business.

Information Exchange

Current State Initiatives

- The DSHS inspections unit is preparing for the use of electronic tablets for use during inspections. Tablet security is a large focus of the project related to physical protection issues.
- DSHS management has been aggressive in staying current with NRC core training courses. DSHS employees worked with NRC staff to present a Texas based version of the Inspection Procedures course to more than 20 members of DSHS staff.
- DSHS also contracted with NRC's medical training contractor in April and June of 2013 to provide the nuclear medicine and brachytherapy classes to their inspection staff. They would like to continue to find other ways to facilitate the training needs of their program.

Current NRC Initiatives

NRC managers presented several current initiatives ongoing at NRC. These included:

- Project AIM 2020
- Rebaselining
- Management Changes
- Agreement State training
- New methods of training offered by NRC
- Part 35 Rulemaking

- Agreement State participation on working groups
- Status of the combined policy statements on adequacy and compatibility
- Greater than Class C waste
- The status of the Government Accountability Office license audit
- Web Based Licensing
- Wyoming and Vermont pursuing agreements

Emerging Technologies

Areva Medical based out of France wants to start manufacturing and distributing Pb-212/Ra-224 generators in Texas so they can begin clinical trials using Pb-212 in cancer treatment. They will use Th-228 as the parent isotope to produce Ra-224 for their generators. The facility is currently under construction in Dallas, Texas.

CONCLUSIONS:

The Texas Department of State Health Services continues to be an effective and vital part of the overall Texas Agreement State program. There are presently five staff level vacancies. The Program is effectively managing its licensing and inspection activities. The Program is responding to incidents and allegations as appropriate and has no overdue regulation amendments.

NRC staff recommends that the next IMPEP review be conducted as scheduled in February 2018.