Sandra Breitborde, Deputy Administrator Division of Public Health Wisconsin Department of Health Services P.O. Box 2659 Madison, WI 53701-2659

Dear Ms. Breitborde:

A periodic meeting with your program was held on August 10, 2011. The purpose of the meeting was to review and discuss the status of Wisconsin's Agreement State Program. The Nuclear Regulatory Commission was represented by Anne Boland, Stephen Poy and me.

I have completed and enclosed a general meeting summary, including any specific actions that will be taken as a result of the meeting.

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 (630) 829-9661 or email to <a href="mailto:james.lynch@nrc.gov">james.lynch@nrc.gov</a> to discuss your comments.

Sincerely,

Jim Lynch Regional State Agreements Officer Division of Nuclear Materials Safety

Enclosure: As stated

cc w/ encl: Charles Warzecha, Director, Bureau of Environmental & Occupational Health

Paul Schmidt, Manager, Radiation Protection Section

Distribution: Anne Boland, Pat Louden, Allan Barker, Lisa Dimmick, Michelle Beardsley, Stephen Poy

# AGREEMENT STATE PERIODIC MEETING SUMMARY FOR THE WISCONSIN DEPARTMENT OF HEALTH SERVICES

DATE OF MEETING: AUGUST 10, 2011

NRC Attendees	Wisconsin Attendees
Jim Lynch, RSAO	Sandy Breitborde, Deputy Administrator
Anne Boland, Director, DNMS	Chuck Warzecha, Bureau Director
Steve Poy, FSME	Paul Schmidt, Section Manager
	Cheryl Rogers, Unit Supervisor

#### **DISCUSSION:**

#### Agreement and Reviews

Wisconsin became the 33<sup>rd</sup> Agreement State on August 11, 2003. The Agreement discontinued NRC regulatory authority in the State for: a) Byproduct materials as defined in Section 11e.(1) of the Atomic Energy Act; b) Source materials; and c) Special nuclear materials in quantities not sufficient to form a critical mass. The Agreement does not cover land disposal of radioactive material, uranium recovery processes, or sealed source and device evaluation.

The last Integrated Materials Performance Evaluation Program (IMPEP) review of the radioactive materials program was conducted in 2009. All performance indicators were found to be satisfactory and no recommendations were made. The Wisconsin program was found to be adequate to protect public health and safety and compatible with NRC's program. The State's initial IMPEP review, in 2005, yielded similar results.

#### Organization

The Radiation Control Program is administered by the Radiation Protection Section, Division of Public Health, Department of Health Services. Paul Schmidt is the Manager of the Radiation Protection Section. Cheryl Rogers is the Supervisor of the Radioactive Materials Licensing and Inspection Unit, which is part of the Section. Wisconsin regulates approximately 322 specific licenses, including naturally occurring or accelerator-produced radioactive material (NARM). Management support for the program appears good and the program is well funded. A dedicated fee fund allows the program to be 100% fee recoverable.

Cheryl Rogers is Chair-Elect of the Organization of Agreement States (OAS). Paul Schmidt has previously chaired the OAS and the Conference of Radiation Control Program Directors, Inc. Mr. Schmidt is also the State Liaison Officer.

# Agreement State Program Staffing

Despite a general Department hiring freeze, program managers have been able to hire staff, through an exemption process, to address significant turnover in the program. Several senior Enclosure

staff members left the program for retirement or other job opportunities. The program is adequately staffed, with a total of 7.5 FTE dedicated to the inspection and licensing programs. One vacancy exists, but has not been posted. Paul Caleb, a recent retiree, was hired back on a temporary basis to provide continuity in the program.

One of the staff members, Megan Shober, is located in the Green Bay field office. All staff members are cross-trained in both inspection and licensing to provide maximum flexibility and backup.

### **Training**

A training matrix was developed for all employees to track their training history. Formalized training requirements were developed for inspectors and license reviewers. Ms. Rogers and senior health physics staff train and accompany each inspector before certifying them to conduct independent inspections.

With several new staff members in the program needing licensing training, in 2010, Mr. Schmidt requested that Region III provide training for license reviewers. Colleen Casey, of the Region III office, provided a week-long licensing training session in Madison. Mr. Schmidt stated that the training was extremely valuable and he appreciated the positive working relationship that Wisconsin has with Region III.

The Department has imposed an out-of-State travel restriction for all employees. Exemptions to the restriction have been received when the training need is essential to the program.

#### Materials Inspection Program

Wisconsin inspection frequencies are at least as frequent as found in NRC's Inspection Manual Chapter (IMC) 2800. Ms. Rogers said that a few inspections are currently overdue. She was well aware of the due dates but made informed decisions based on program priorities. New licensees are inspected within 12 months of license issuance, regardless of whether the licensee has received radioactive material. Reciprocity inspections are performed in accordance with the frequencies identified in NRC Manual Chapter 1220.

Ms. Rogers stated that they plan to have inspectors provide handouts to licensees emphasizing the need for a positive safety culture in licensee programs.

#### Materials Licensing Program

Ms. Rogers stated that no significant licensing backlogs exist; however, with the ongoing training of newer staff, some actions have exceeded their timeliness goals. She stated that prelicensing visits are performed for all new license applicants. A pre-licensing checklist is used for all licensing actions.

As a direct result of the afore-mentioned licensing training by Region III, Ms. Rogers indicated that the licensing backlog was significantly decreased.

Mr. Schmidt discussed the need for a close working relationship between NRC and Wisconsin on a potential license for SHINE Medical Technologies which is proposing an accelerator-based system to produce medical isotopes, including molybdenum-99.

#### Regulations

To date, the State's regulations are mostly up-to-date and compatible. A regulation review letter was sent to the State in July 2010 identifying seven corrections to the regulations which need to be implemented. Ms. Rogers stated that those items would be addressed in the next rulemaking. The rulemaking process in Wisconsin typically takes 1.5 years to complete.

State managers are aware of the significant changes to medical and security regulations which will need to be promulgated in the near future.

#### Security

According to Wisconsin managers, Increased Controls inspections are being performed on schedule, in conjunction with routine inspections.

The State has accurately updated the National Source Tracking System interim inventory with information for Wisconsin licensees.

#### **Incidents**

Wisconsin staff members responded to approximately 19 reportable incidents since the last IMPEP review. On-site inspections were performed, when appropriate, and staff communicated reportable incidents promptly to the NRC Operations Center and to Region III.

Wisconsin has done extensive evaluations of all of the prostate seed therapy programs licensed in the State. They have been active in the National development of radiation therapy regulations and guidelines.

Two Abnormal Occurrences were identified at Wisconsin medical licensee facilities in the current fiscal year. Summaries of those events will be submitted to the Regional State Agreements Officer for inclusion in the annual report to Congress.

Wisconsin's investigation of an incident at a medical facility involving a high-dose rate remote afterloader identified a potential generic problem with an applicator. The incident data was provided to Steve Poy to pass to the NRC medical group in FSME for evaluation.

Inspectors input incident information directly into the Nuclear Material Events Database (NMED) as incidents occur. A review of NMED identified timely and quality input of incidents.

# **Allegations**

One allegation, involving a State industrial facility, was transferred to Wisconsin from NRC since the last IMPEP review. The allegation involved potential excessive radiation levels and improperly stored radioactive waste. Wisconsin staff investigated the allegation and took prompt, appropriate action, including feedback to the alleger. Investigation results were provided to the Regional State Agreements Officer.

# **General Licenses**

Wisconsin has an active program for registering generally licensed devices. General licensees are required to update inventories on an annual basis. Inspections of these licensees are

performed as time permits.

# **Current NRC Initiatives:**

NRC staff discussed ongoing initiatives with the Wisconsin representatives. These included: medical rulemaking and workshops; brachytherapy guidance; control of sensitive information; NRC's enforcement guidance for portable gauges; and the recently published Inspection Manual Chapter 1248 which regards staff training and qualification.

#### **CONCLUSIONS:**

The Wisconsin Radiation Control Program remains a very active, strong Agreement State program. Although staffing has been challenging over the past several years, program managers have been able to hire and train qualified personnel.

Management support for the program is very good. The managers liked the IMPEP process and saw great benefit in Wisconsin's participation in the program. The NRC representatives urged the managers to consider allowing senior staff members to participate on future IMPEP teams.

#### Schedule for the Next IMPEP Review:

NRC staff recommends that the next IMPEP review, currently scheduled for 2013, be extended to 2014, in accordance with the IMPEP Self-Assessment Working Group report from August 2010. Recommendation 3 of the Working Group's report recommends that consistently high performing organizations that have two consecutive IMPEP reviews with findings of satisfactory on all performance indicators be recognized for its achievements.