

March 21, 2002

Donald A. Flater, Chief
Bureau of Radiological Health
Iowa Department of Public Health
401 SW 7th St., Suite D
Des Moines, IA 50309

Dear Mr. Flater:

A periodic meeting with Iowa was held on March 13, 2002. The purpose of this meeting was to review and discuss the status of Iowa's Agreement State program. The NRC was represented by Lloyd Bolling from the NRC's Office of State and Tribal Programs, Cindy Pederson from the NRC Region III office, and me. Specific topics and issues of importance discussed at the meeting included: IDPH staffing, regulation development, and your recent program self assessment.

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 if you have any additional remarks about the meeting in general, please contact me at (630) 829-9661, or e-mail to JLL2@NRC.GOV to discuss your comments.

Sincerely,

/RA/

James L. Lynch
State Agreements Officer

Enclosure: As stated

cc w/encl.: S. Quirk, Director, Environmental Health
D. McGhee, Iowa State Liaison Officer
D. Cool, NMSS
L. Bolling, STP
K. Schneider, STP
C. Pederson, RIII

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OFFICE	RIII	RIII by email			
NAME	Lynch:jb	Lynch for Bolling			
DATE	03/19/02	03/19/02			

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AGREEMENT STATE ANNUAL MEETING SUMMARY FOR IOWA

DATE OF MEETING: MARCH 13, 2002

ATTENDEES:	<u>NRC</u>	<u>STATE</u>
	James Lynch Lloyd Bolling Cynthia Pederson	Stephen Quirk Donald Flater George Johns Daniel McGhee Nancy Farrington Charlene Craig Ramona Ubaldo-Mealey

DISCUSSION:

The following is a summary of the meeting held in Des Moines on March 13, 2002, between representatives of the NRC and the State of Iowa.

Previous IMPEP Review Findings

The previous Integrated Materials Performance Evaluation Program (IMPEP) review was conducted during the period August 17-20, 1999, with the findings discussed in a meeting between the State and the IMPEP Management Review Board (MRB) on November 9, 1999. The results were issued in a final report dated November 23, 1999. The MRB found that the Iowa radiation control program was adequate to protect public health and safety and compatible with NRC's program.

Radiation Control Program Staffing and Training

The Iowa Department of Public Health (IDPH) radiation control program experienced the loss of two health physics staff, recently. Mark Flickinger left State employment for a job in the private sector and, sadly, Joyce Spencer passed away.

The loss of two health physics staff in a small program such as Iowa's is a serious challenge to maintaining an adequate and compatible radiation control program. Nancy Farrington, an experienced nuclear medicine technologist was hired in September 2001, to fill Mr. Flickinger's position. Nancy is in the process of attending the required core training courses. To date, she completed the Licensing Practices and the Inspection Procedures courses. She is enrolled in the Inspecting For Performance (G-304), Industrial Radiography (H-305), and Transportation of Radioactive Materials (H-308) courses in March-April 2002.

The remaining position is currently being reviewed, at a Division level, to determine the possibility of funding the position during the current State monetary shortfall. Stephen Quirk asked what the acceptable level of staffing was for a program like Iowa's and whether the level is a function of the number of State licensees. The NRC no longer uses the 1 to 1.5 FTE per

100 licensees criteria as an adequate staffing level. Rather the IMPEP review criteria requires the State to assess its staffing level based on the routine work, possible emergencies, and the number and complexity of its license base.

With the staff shortage, inspection and licensing activities were affected as described below.

In 2001, the Radioactive Materials Coordinator participated as a team member on the Nevada IMPEP team. His support to the team was notable.

Inspection Program

The materials program staff completed 44 inspections in 2001. Included was an inspection of the University of Iowa. Since the program was short-staffed, two inspectors from the Wisconsin Department of Health were requested to participate in the inspection. The assistance from Wisconsin allowed the team inspection to be performed in a timely and thorough manner. It also provided Wisconsin valuable experience in support of their effort to become an Agreement State in 2003.

The Radioactive Materials Coordinator indicated that no specific license inspections are overdue, at this time.

Scoping surveys at the Iowa Army Ammunition Plant identified minor uranium-238 contamination, historical in nature, in some of the buildings. Historical records indicate that other radionuclides were also used at the site. Iowa requested that the Army perform a full site evaluation to determine the extent of contamination. The U. S. Congress, in the Energy and Water Appropriations Bill, directed the Army Corps of Engineers to report, in consultation with the State of Iowa, its recommendations for conducting a site-wide radiological survey of the Army Ammunition Plant. The State provided information to the Army Corps of Engineers and is awaiting further developments.

Fansteel/Wellman Dynamics Corporation, Creston, Iowa, researched its buried thorium waste legacy, and is evaluating monitoring data to determine the appropriate course of action. The waste is in an old 10 CFR 20.304 (before Iowa became an Agreement State) thorium slag burial site. A bankruptcy filing by the company in January 2002 apparently slowed progress in the area. The State is monitoring the licensee's actions.

Licensing Program

A total of 110 licensing actions were completed in 2001. The Radioactive Materials Coordinator stated that the program does not have a licensing backlog.

The loss of staff members resulted in a less extensive peer review process for licensing actions. In any case, all licensing actions are signed by the Bureau Chief before issuance.

IDPH identified what they call an anomaly in the NRC guidance regarding the Novoste Corporation Intravascular Brachytherapy device. NRC guidance allows for the licensee to deviate from the Food and Drug Administration (FDA) issued Pre-Market Approval while Iowa licensees are required to follow the Pre-Market Approval unless granted a waiver by the FDA. This issue will be forwarded to the NRC NMSS medical staff.

Some uncomplicated licensing actions are performed by the Radioactive Materials Section secretary, under close supervision of the Radioactive Materials Coordinator.

General Licenses

Iowa's General License device registration and inspection program actively tracks 123 General Licenses. Annual inventory forms are sent to general licensees with an annual fee of \$150 per type of device. Inspections are scheduled to be performed at three-year intervals, but due to the staffing shortage, inspections of General Licenses have been severely curtailed. As generally-licensed devices have safer designs, inspection of the devices is a lower priority. The new employee will be assigned these inspections upon completion of appropriate training.

As discussed during the last Periodic Meeting in 2000, IDPH identified a generally-licensed device distributed from the State of New York, which did not have a valid Sealed Source and Device (SS&D) registry certificate. Discrepancies were noted with the manufacturer's name and the activity of the radioactive source (900 vs. 50 microcuries) in the generally-licensed device. Iowa requested that New York resolve the issue, but has not received cooperation in the matter. NRC also requested that New York issue an updated registry certificate, but was similarly unsuccessful.

New York State contended that generally-licensed devices are not required to have SS&D certificates since the product evaluation is covered under the license to manufacture or distribute. NRC will again raise the issue to New York during the upcoming IMPEP review since the SS&D certificate documents the evaluation and provides valuable product information to other licensing agencies and is the "industry standard." Iowa management indicated that they may submit, to the NRC, a "petition for rulemaking" to require that all generally-licensed devices have SS&D certificates in the national registry.

Future Periodic Meetings

Don Flater again expressed that two single-day Periodic Meetings between IMPEP reviews are not particularly useful either to the NRC or Iowa. Rather, a two - three day mini-review, with some file evaluation and inspector accompaniments, midway between IMPEP reviews, would be more informative and cost effective.

Jim Lynch commented that the IMPEP program working group studied the effectiveness of Periodic Meetings and is making recommendations to NRC management to improve the process. One of these recommendations will be that States perform self-assessments of their radiation control programs prior to Periodic Meetings. Changes to the program are expected in 2002.

Self-Assessments

In early 2002, the Radioactive Materials Coordinator performed a self-assessment of the radioactive materials program. The audit covered training and staffing levels, licensing and inspection status (including accelerator and industrial x-ray unit inspection programs), policies and procedures, the general licensing program, and the industrial radiography certification testing program. The audit was shared with the NRC prior to this Periodic Meeting and proved very useful in providing points of discussion. Lloyd Bolling was given permission by IDPH to

share the audit with other Agreement States wishing to perform self-assessments of their programs.

Regulations

IDPH updates its regulations on an annual basis. Late in the calendar year, a package of proposed regulation changes is sent to the NRC and the public for comment. The NRC provided two comments on the proposed rule package submitted in December 2001. Comments were requested by February 26, 2002.

Preliminary comments were discussed with the Radioactive Materials Coordinator on January 28, 2002. Formal comments had not yet been received at the time of this Periodic Meeting. The regulations were adopted, with the preliminary comments incorporated, on March 13, 2002, without formal NRC comment. Mr. Flater stated that NRC comments must be received in the specified comment period to be considered. Jim Lynch said that NRC is evaluating the regulation review process and the inherent delays in the process.

The regulation review program, described in the Office of State and Tribal Programs (STP) procedure SA-201, "Review of State Regulatory Requirements," was discussed in detail. Agreement States were recently reminded to submit both draft and final regulations as specified in the procedure to provide uniformity and help expedite the process. The "State Regulation Status" form, found in this procedure, is maintained by NRC to track Agreement State regulations.

George Johns asked whether a letter or an email message was acceptable to inform STP when final regulations become effective. Lloyd Bolling will discuss the question with STP management and inform IDPH if an email or a formal letter is acceptable provided that the required information as detailed in STP Procedure SA-201 is included. This requires, among other things, that the final amended rule be clearly identified and that any changes from the proposed rule be highlighted.

It was noted that two regulations will be required for adoption prior to the next IMPEP review. The first is "Respiratory Protection and Controls to Restrict Internal Exposure," due in February 2003 and the other is "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," due in May 2003. If these two regulations are not adopted by their due dates, legally binding requirements, such as license conditions or orders, may be used until compatible rules are adopted.

Incidents and Allegations

No allegations were transferred to Iowa from the NRC since the last review.

Similarly, there were no reportable events involving radioactive materials in the State during the same time period. IDPH did investigate several minor incidents and provided excellent support to NRC on two investigations: an Internet auction of radioactive materials; and a temporary loss of nuclear gauges in the transportation system.

Waste Disposal

Iowa regulations were modified on March 13, 2002, incorporating a provision for charging fees for radioactive waste shipments, both high and low-level, within the State. The regulations become effective in May 2002 and fee collection will begin in July 2002. Fees received pursuant to the rule are to be used for purposes related to transporting hazardous material, including an emergency response program.

CONCLUSIONS:

The Iowa Radiation Control Program has had significant staffing challenges over the past year. In spite of the staff shortage, the program has remained viable and is taking actions to alleviate the losses. The inspection and licensing programs appear to be meeting program goals, with the exception of the lower-priority General License inspection program.

The new hire, Nancy Farrington, is in an aggressive training program, scheduled for five core training courses in the first eight months of her employment.

The intravascular brachytherapy device Pre-market Approval issue will be forwarded to NRC NMSS medical staff.

NRC will again raise the generally-licensed device SS&D issue to the State of New York.

NRC will continue to review means for improving the timeliness of regulation reviews.

At the 1999 Management Review Board meeting, It was recommended that the next Iowa IMPEP review be scheduled in four years. Those present at this meeting agreed to schedule the review as planned, approximately August 2003.