#### November 7, 2003

Mary Mincer Hansen, RN, Ph.D. Director Iowa Department of Public Health Lucas State Office Building 321 East 12<sup>th</sup> Street Des Moines, IA 50319

Dear Dr. Hansen:

On September 30, 2003, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Iowa Agreement State Program. The MRB found the Iowa program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's program.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Radiation Control Program and the excellence in program administration demonstrated by your staff as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and State Programs

Enclosure: As stated

cc: Tom Newton, Director

Division of Health Protection and Environmental Health

Donald A. Flater, Chief Bureau of Radiological Health

Daniel K. McGhee, State Liaison Officer Bureau of Radiological Health

Pearce O'Kelley, SC OAS Liaison to the MRB Mary Mincer Hansen, RN, Ph.D. Director Iowa Department of Public Health Lucas State Office Building 321 East 12<sup>th</sup> Street Des Moines, IA 50319

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bcc: Chairman Diaz

Commissioner McGaffigan Commissioner Merrifield

<u>Distribution</u>: DCD (SP01) PDR (YES√)

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| DATE   | 10/23/03*  | 10/24/03*                      | 10/24/03*                  | 11/07/03*    |  |

# INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF IOWA AGREEMENT STATE PROGRAM

July 29 - August 1, 2003

#### **FINAL REPORT**

U.S. Nuclear Regulatory Commission

#### 1.0 INTRODUCTION

This report presents the results of the review of the Iowa Agreement State program. The review was conducted during the period of July 29 - August 1, 2003, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of New York. 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of August 21, 1999 to August 1, 2003, were discussed with Iowa management on August 1, 2003.

A draft of this report was issued to Iowa for factual comment on August 29, 2003. The State responded by letter dated September 9, 2004 (sic). The Management Review Board (MRB) met on September 30, 2003 to consider the proposed final report. The MRB found the Iowa radiation control program adequate to protect public health and safety and compatible with NRC's program. In addition, in a letter dated October 1, 2003, the State provided clarifying information to its September 9, 2004 (sic) letter involving Nuclear Materials Events Database (NMED) reporting.

The Iowa Agreement State program is administered by Iowa Department of Public Health (the Department). The Department Director is appointed by and reports directly to the Governor. Within the Department, the Iowa radiation control program is administered by the Bureau of Radiological Health (the Bureau), Division of Health Protection and Environmental Health. Organization charts for the Department are included as Appendix B. At the time of the review, the Iowa program regulated 182 specific licenses authorizing Agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Iowa.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Bureau on, April 16, 2003. The Bureau provided a response to the questionnaire on June 25, 2003. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML032380269.

The review team's general approach for conduct of this review consisted of: (1) examination of lowa's responses to the questionnaire; (2) review of applicable lowa statutes and regulations; (3) analysis of quantitative information from the Bureau licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two lowa inspectors; and (6) interviews with Bureau staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common indicator and made a preliminary assessment of the lowa Agreement State program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close-out of the recommendations. Results of the current review for the IMPEP common performance

indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings.

#### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 20, 1999, one recommendation was made and transmitted to Stephen C. Gleason, D.O., Director, Iowa Department of Public Health, on November 23, 1999. The team's review of the current status of the recommendation is as follows:

1. The review team recommends that staff who conduct independent inspections and/or license reviews of teletherapy and brachytherapy licenses complete a teletherapy and brachytherapy course. (Section 3.3)

Current Status: Staff performing independent inspections and/or license reviews of teletherapy and brachytherapy licenses have completed the NRC-sponsored Teletherapy and Brachytherapy course. This recommendation is closed.

#### 3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State 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) Response to Incidents and Allegations.

#### 3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Bureau'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 Bureau's questionnaire response relative to this indicator, interviewed Bureau management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

Prior to a reorganization that occurred in early July 2003, the Bureau was structured with a Bureau Chief, three Program Coordinators and ten staff members under the three programs. The radioactive materials program included one Program Coordinator, two health physicists, and one clerical staff member. One Program Coordinator devoted his time to training and emergency response, and the third Program Coordinator was responsible for radiation machines. The Bureau Chief spent about 30 percent of his time in administration of radioactive materials program activities. Note that Appendix B contains two Bureau's organization charts: one is prior to the reorganization and the other is current.

The Bureau completed the reorganization several weeks prior to the on-site review. As noted in Appendix B, the Bureau is currently structured with a Bureau Chief, two Program Coordinators, and 10 staff members under the two programs. The Radioactive Materials, Transportation and Environmental Program includes one Program Coordinator, three health physicists, and one clerical staff member. Consistent with the State's past practices, all of the technical staff members perform duties in licensing, inspection, and incident response. The second Program Coordinator is responsible for radiation machine certification.

During 2001, the two health physicists left the radioactive materials program. The Bureau had significant staffing challenges that year. In spite of the staff shortages at that time, the Bureau took actions to alleviate the losses and remained viable. The actions taken included hiring two new health physicists; one began work in September 2001 and the other in October 2002. One other action taken noted by the review team is that since the Bureau was short-staffed at that time, two inspectors from the Wisconsin Department of Health were requested to participate in a team inspection of a broad scope licensee. 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. In addition, in April 2003, the Program Coordinator of the radioactive materials program left the lowa program.

The Bureau currently has one health physicist position vacant under the Radioactive Materials, Transportation and Environmental Program. The new Program Coordinator for that program was the Program Coordinator of the Training, Emergency Response and Environmental Issues Program which existed prior to the reorganization.

The review team noted that the Bureau had stable funding during the review period from a general fund. In addition to the general fund, the Department implemented a fee for transportation of radioactive waste shipments in 2002. The fee was established to fund training for personnel who might respond to transportation accidents involving radioactive materials.

Training and qualification requirements for Bureau staff are established in a procedure which sets forth essentially the same recommendations detailed in NRC Inspection Manual Chapter (IMC) 1246. The review team noted that a qualification journal is used for each technical staff member. Technical staff members have at least a Bachelor's degree or equivalent training and experience. Overall, the staff is well trained and qualified from an education and experience standpoint.

All technical staff members have taken the NRC courses deemed appropriate for their tasks. The training records demonstrate that Bureau management is committed to a high degree of training for the staff. The review team noted that one new staff member attended 11 NRC courses within 18 months, and the other new staff member is scheduled to complete nine NRC courses within a year. Bureau management indicated that upper level management has been very supportive of training opportunities. Based on the lack of backlogs and the quality of the licensing actions and inspections, the review team concluded that the Bureau has a well-balanced staff, and a sufficient number of trained personnel to carry out regulatory duties.

Before performing an inspection independently, inspectors accompany qualified inspectors to licensee sites to observe inspections. Next they assist in an inspection with a qualified inspector, and finally perform as a lead inspector with an accompanying qualified inspector.

During the review period, two self-assessments were conducted. One reviewed radioactive materials program activities in 2001 and the other one reviewed all the Bureau's programs in 2002. The self-assessments covered a variety of areas including training and staffing levels, licensing and inspection status and discussion of incidents. The review team noted that one of the strengths of the lowa program is the annual self-assessment program.

The review team noted the apparent benefits to the Bureau from staff participation on IMPEP reviews. The Program Coordinator who left the Bureau in April 2003 participated on two IMPEP review teams during the review period. The review team noted that the knowledge and experience gained from participation of IMPEP activities have been reflected back to the Bureau.

During the on-site review, Bureau management expressed concerns about the effect of an aging workforce and the Bureau's ability to maintain continuity of experience. The review team noted that one of the Department's challenges is to effectively deal with the potential loss of an experienced workforce because of the possible retirement of senior Bureau staff and managers in the near future.

The State Board of Health is the policy making body for the Department. Their duties include the adoption and promulgation of rules. The Board is composed of five members experienced in health-related disciplines and four members representing the general public. The Department Director serves as secretary of the Board. As stated in the Iowa Code, Chapter 68B, Government Ethics and Lobbying, any person who serves or is employed by the State or a political subdivision of the State shall not engage in any outside employment or activity which is in conflict with the person's official duties and responsibilities.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that lowa's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

#### 3.2 Status of Materials Inspection Program

The review team focused on five factors in reviewing the status of the material inspection program: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the Bureau's questionnaire response relative to this indicator, data gathered independently from the Bureau's licensing and inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with Bureau staff and management.

Evaluation of Iowa's inspection priorities for the materials program indicated that the maximum period for an inspection interval is seven years. The Bureau has adopted inspection categories and inspection frequencies consistent with those in NRC IMC 2800.

The Bureau conducted a total of 113 core and 69 non-core routine inspections during the review period. There were no overdue core inspections and no overdue inspections of non-core licenses.

With respect to initial inspections, the Bureau assigns the inspection due date six months from the issuance of a new license. This information is entered into the Bureau's database. In practice, the Bureau conducts initial inspections six months from receipt of radioactive materials or commencement of licensed activities. The review team noted that all new licenses are inspected within one year of license issuance regardless of licensed activities.

With respect to reciprocity, the Bureau recognizes licensees for 180 days from the date of their initial request to enter the State. The review team found that the Bureau's reciprocity program was similar to NRC IMC 1220. The Bureau's database indicated that 13 core reciprocity inspections were conducted during the review period. Overall it appears that 25 percent of the core reciprocity licensees entering the State on an annual basis during the review period were inspected.

The review team noted that the information regarding reciprocity inspections provided in the Bureau's response to the questionnaire was not accurate due to a database error. Bureau management indicated that they have been trying to upgrade their database system for years. Due to fiscal constraints beyond the Bureau's control, the system has not been upgraded. Bureau management indicated that they will continue their effort to resolve this issue and have the database system upgraded. As a result, the review team's statistical analysis was based on the reciprocity inspection information obtained during the on-site review.

The timeliness of the issuance of inspection findings was also evaluated. The Bureau has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. The Bureau's goal is to complete each inspection report and deliver the notice of violation, as appropriate, to the licensee within 30 days. Of the 12 core licensee files reviewed, no inspection reports exceeded the 30 day goal. A review of the Bureau's database also supported this finding and did not reveal any inspections issued over 30 days past the inspection date.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that lowa's performance with respect to the indicator, Status of the Materials Inspection Program, was satisfactory.

#### 3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 12 materials inspections conducted during the review period. The casework included all of the Bureau's materials inspectors, and covered inspections of various types including both fixed facilities and temporary job sites of industrial radiography; medical institutions including group and private practices; academic broad scope; nuclear pharmacy; and nuclear medical vans. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensees' radiation safety programs. The review team found that inspection reports were thorough, complete, and consistently of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

The review team found that routine inspections include a written summary of the scope of the licensed activities and categorize violations into severity levels which can later be used for escalated enforcement, if necessary. Iowa Administrative Code 641, Chapter 38 provides for

the initiation of enforcement actions and civil penalties. The review team noted that enforcement actions have been taken for facilities when appropriate.

The review team noted that a practice, which allowed two broad scope licensees to evaluate the inspection report prior to issuance, had been implemented. This resulted in revisions to the final inspection report, including items that had indicated a violation involving testing of a high dose rate afterloader (HDR). The review team discussed this issue with Bureau management since the practice of sharing draft inspection reports with broad scope licensees and revising inspection findings based on the licensees' comments is not a common practice. The Bureau Chief noted the issue raised by the review team and indicated that he will consider changing the practice. In the State's response to the draft IMPEP report dated September 9, 2004 (sic), it was indicated that the Bureau has modified the practice and will no longer send draft inspection reports to the broad scope licensees for review and comment.

The Program Coordinator conducts supervisory accompaniments of material inspectors at least once a year. In addition, the Bureau Chief periodically accompanies inspectors on inspections. The results of the annual supervisory accompaniments were reviewed and signed by the inspector and supervisor, and were documented as part of the inspector's qualification journal.

During the week of June 16, 2003, a review team member performed accompaniments of two of the Bureau inspectors. The inspections included a HDR and an institutional nuclear medicine facility. These accompaniments are identified in Appendix C. During the accompaniments, the Iowa inspectors conducted performance-based inspections and demonstrated thorough knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was good, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

The Bureau has adequate numbers and types of survey meters to support the current inspection program, as well as for responding to incidents and emergency conditions. The Bureau uses the State Calibration Shop operated by the Homeland Security and Emergency Management Division of the Iowa Department of Public Defense for calibration of their survey instruments on a biannual basis. Appropriate documentation of calibrated survey instruments such as Geiger Mueller meters, scintillation detectors, and ion chambers was provided. Air monitoring equipment as well as prepared emergency field kits are also available for emergency use. Contamination wipes are primarily evaluated at the State Hygienic Laboratory which is located in Iowa City and is designated as the State Public Health Laboratory by Iowa Code.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that lowa's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

#### 3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 15 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance,

operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period. The cross-section sampling focused on the new licenses, amendments, renewals, and licenses terminated during the review period. The sampling included the following types: broad scope research and development, medical institution - written directive required, private practice, research and development, nuclear pharmacy, industrial radiography, and portable gauge. Licensing actions reviewed included two new, three renewals, three amendments and seven termination files. A listing of the casework licenses evaluated with case specific comments can be found in Appendix D.

The review team found that licensing actions were thorough, complete, consistent, and of high quality, with health and safety issues properly addressed. Tie-down conditions were backed by information contained in the file, and inspectable. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified deficiencies in the licensees' documents. License files were complete and well organized. The Bureau used a combination of NRC and State regulatory guides, and State regulations. In addition, licensing checklists were used and designed for each category of license. These documents were complete, well organized, available to reviewers, and were followed by reviewers. Based on the files reviewed, actions were completed in a timely manner.

Terminated licensing actions were well-documented, showing appropriate transfer and survey records with one exception. During review of terminated portable gauge licenses, it was noted that records of final radiological status of portable gauges were not included in the file. After discussing the issue with Bureau staff, the review team noted that information concerning the final radiological status of portable gauges was not required by the Bureau staff for license termination.

Bureau staff indicated that due to the integrity of sealed sources used in portable gauges and the good track record of portable gauges in general, verification that there is no source leakage from these gauges is not conducted in all cases during the license termination process. The review team believes that the radiological hazard of typical portable gauge sources pose external and internal hazards to the general public if leakage occurs. The review team discussed this issue with Bureau management and staff, and initially made a recommendation that the Bureau take appropriate action to verify that there is no source leakage for each portable gauge possessed under a license prior to termination of the license.

In the State's response to the draft IMPEP report dated September 9, 2004 (sic), it was indicated that the Bureau took action to address this issue. Specifically, Bureau staff has been advised that in order to terminate a gauge license, verification that a leak test of the source was performed and no leakage of radioactive material was present must be received. During the September 30, 2003 MRB meeting, this issue was discussed and the recommendation was removed from the report.

The review team noted that the Bureau identified a potential problem associated with model number designations involving Troxler 3400 Series and other Troxler Model 34XX portable gauges. Specifically, the Bureau recognized that the Troxler 3400 Series listing in the Sealed Source and Device (SS&D) Registry Sheet consists of only four model numbers, i.e., 3430, 3430B, 3440 and 3440B, and that other Troxler model numbers such as 3450 and 3451 do not fall within the Troxler 3400 Series. The review team further noted that other model numbers such as 3401 and 3411 can be considered as part of the Troxler 3400 Series based on additional information contained in the Troxler 3400 Series SS&D Registry Sheet. This can be misleading and confusing for both the licensee and the license reviewer. To avoid the potential problem, the Bureau revised all portable gauge licenses that authorized Troxler 3400 Series by removing the 3400 Series authorization and specifying each portable gauge in the Series by its own model number. It should be further noted that the Bureau shared this problem and remedy with other Agreement States, as other programs may face similar situations. The review team recommended that the Bureau's revision of all Troxler portable gauge licenses to specifically list each gauge model number be found a good licensing practice, and the MRB agreed.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that lowa's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

#### 3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Bureau's actions in responding to incidents, the review team examined the Bureau's response to the questionnaire regarding this indicator, evaluated selected incidents reported for Iowa in NMED against those contained in the Iowa files, and evaluated the casework and supporting documentation for ten material incidents. A list of incident files examined along with case specific comments is contained in Appendix E. The review team also reviewed the Bureau's response to three allegations, including one allegation referred to the State by NRC, during the review period.

The review team interviewed program management and staff to discuss the Bureau's incident and allegation process, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC. The ten incidents selected for review included the following event categories: medical event, radiation overexposure, contamination event, leaking sealed sources, damaged radiography equipment and lost sources.

Radiological incidents can be reported 24 hours a day through the State's Radiological Response Team emergency telephone line. When notification of an incident or an allegation is received, the Bureau Chief and staff meet to discuss the safety significance, initial response, and need for an on-site investigation. The small size of the lowa program allows for the prompt dissemination of information regarding the event to all personnel in the program.

The review team found that the Bureau's responses to incidents and allegations were complete and comprehensive. Initial responses were prompt and well coordinated. The level of effort was commensurate with the health and safety significance. Inspectors were dispatched for onsite investigations when appropriate and the Bureau took suitable enforcement action.

The review team found the documentation of the incidents to be consistently of high quality, with one exception. One incident was not discussed with a licensee during the next inspection

of the license after the incident, as required by Bureau procedures. Corrective actions promised by the licensee in response to the incident were therefore not confirmed by the inspector. The Program Coordinator stated that the incident follow-up would be reviewed during a planned inspection of the licensee later this year. Staff will be reminded by the Program Coordinator of the need to review any incidents and/or corrective actions which occurred since the previous inspection.

Reportable incidents are promptly communicated to the NRC Operations Center and are reported to NMED. One incident, which occurred in 2000, was not reported to NMED. This was apparently an oversight and the Program Coordinator stated that he would update NMED to include the incident. The staff was familiar with the guidance contained in the Office of State and Tribal Programs Procedure SA-300, Reporting Material Events.

During the review period, one allegation was referred to the State by the NRC and two allegations were reported directly to the Bureau. The evaluation of the Bureau's allegation files indicated that the Bureau took prompt and appropriate action in response to the concerns raised. The review team noted that all documentation related to the investigation of allegations was maintained in the allegation file. Allegers were properly notified of investigation results. There were no performance issues identified from the review of the casework documentation.

The Bureau has complete written guidance for handling incidents and allegations in their inspection procedures. The review team noted that Iowa's Freedom of Access law requires that all public documents be made available for inspection and copying. The State makes every effort to protect an alleger's identity, but it cannot be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Iowa's performance with respect to the indicator, Response to Incidents and Allegations, was satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Iowa's Agreement does not authorize low-level radioactive waste disposal or uranium recovery activities, and the SS&D Evaluation Program was returned to NRC on June 1, 1996. Accordingly, only the first non-common performance indicator was applicable to this review.

#### 4.1 <u>Legislation and Program Elements Required for Compatibility</u>

#### 4.1.1 Legislation

Iowa became an Agreement State in 1986. Along with their response to the questionnaire, the Bureau provided the review team with the opportunity to review copies of legislation that affects the radiation control program. The current effective statutory authority for the radiation control program is contained in the Iowa Code, Chapter 136C. The Department is designated as the State's radiation control agency. The review team noted that one legislation change affecting the program was passed during the review period. As a result of the change, persons

convicted of violation of the Iowa Code, Chapter 136C are guilty of a serious misdemeanor instead of a simple misdemeanor. For a serious misdemeanor, a convicted person may be fined up to one thousand five hundred dollars. In addition, the person may be imprisoned for up to one year.

#### 4.1.2 <u>Program Elements Required for Compatibility</u>

The Iowa Regulations for Control of Radiation, found in the Iowa Administrative Code, Section 641, Chapters 38-45, apply to all ionizing radiation, whether emitted from radionuclides or devices. Iowa requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State's administrative rulemaking process and found that the process takes approximately five months after filing the draft administrative rule with the State Rules Coordinator. Draft rules are published in the State Administrative Bulletin and a public hearing is scheduled. Rules are presented to the Board of Health prior to being adopted. The State has Emergency Rule capability, if public health and safety is at risk. It was noted that the State's rules and regulations are not subject to "sunset" laws.

Proposed rules are sent to all potentially impacted licensees for comment. The Bureau also sends proposed rules to NRC for review. Comments are considered and incorporated, as appropriate, before rules are finalized. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of rule adoption until equivalent State rules become effective.

The review team 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 Office of State and Tribal Programs' State Regulation Status Data Sheet. Since the previous IMPEP review, the Department has adopted 26 regulation amendments. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. The review team found that the State currently has no overdue NRC amendments. The State has adopted all the regulation amendments that are due up to the year of 2005.

The review team noted that NRC reviewed the lowa proposed rules and requested that the State provide a copy of the final published rules for review. It was noted that some final rules have not been submitted to NRC for review as requested. The review team discussed this issue with the Bureau Chief and staff. During the on-site review, the Bureau contacted NRC on submitting the final rules. Subsequently, the Bureau submitted the final rules for NRC review shortly after the on-site review.

Based on IMPEP evaluation criteria, the review team recommended and the MRB agreed that lowa's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, was satisfactory.

#### 5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team and the MRB found lowa's performance to be satisfactory for all performance indicators. Accordingly, the review team recommended and

the MRB concurred in finding the Iowa Agreement State program adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, it was agreed that the next full review should be in approximately four years. No recommendations were made for the State. The good practice recommended by the review team and approved by the MRB is also given.

#### **GOOD PRACTICE**

The Bureau identified a potential problem associated with model number designations involving Troxler 3400 Series and other Troxler Model 34XX portable gauges. To avoid the potential problem, the Bureau revised all portable gauge licenses that authorized Troxler 3400 Series by removing the 3400 series authorization and specifying each portable gauge in the Series by its own model number. Other programs may face similar situations and may be able to apply this practice. The Bureau's revision of all Troxler portable gauge licenses to specifically list each gauge model number was found a good practice. (Section 3.4)

#### LIST OF APPENDICES AND ATTACHMENTS

Appendix A IMPEP Review Team Members

Appendix B Iowa Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

Attachment September 9, 2004 (sic), Letter from Donald A. Flater, Chief,

Bureau of Radiological Health

#### APPENDIX A

#### IMPEP REVIEW TEAM MEMBERS

Name Area of Responsibility

Kevin Hsueh, STP Team Leader

**Technical Staffing and Training** 

Legislation and Program Elements Required for

Compatibility

James Lynch, Region III Response to Incidents and Allegations

Inspector Accompaniments

James Mullauer, Region III Technical Quality of Licensing Actions

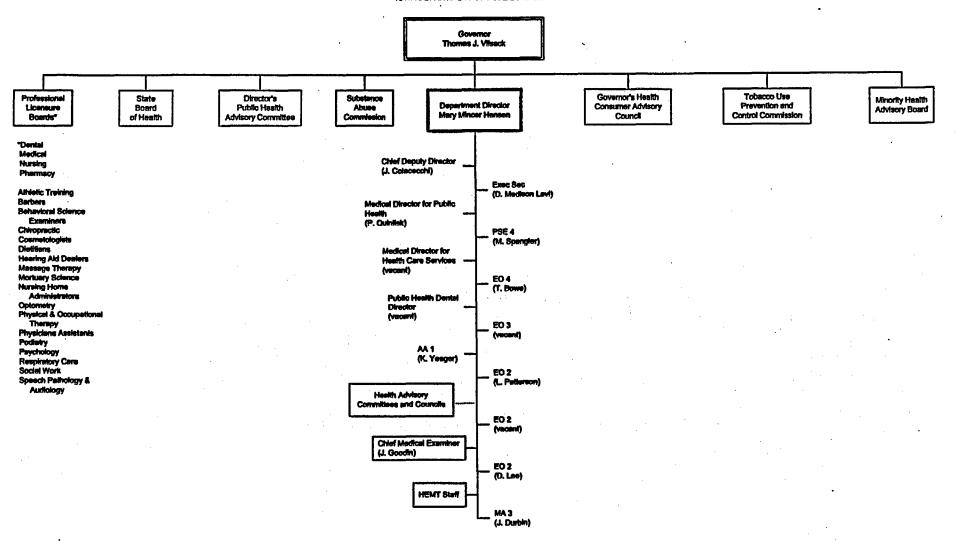
Gary Baker, New York Status of Materials Inspection Program

Technical Quality of Inspections

## APPENDIX B IOWA ORGANIZATION CHARTS

ML032390179

#### IOWA DEPARTMENT OF PUBLIC HEALTH



| Director's Office   |
|---------------------|
| Mary Mincer Hanson, |
| Department Director |

#### Division of Administration Jane Colececthi, Chief **Deputy Director**

Division of Communications. Plenning, and Personnel Tom Carney, Division Director **Division of Community Health** Julie McMahon, Division Director Medical Director (vecent) PH Dental Director (vecent)

Division of Epidemiology, **EMS and Observe** Operations Mary Jones, Division Director Division of Health Promotion, Prevention and Addictive **Behaviors** Janet Zwick, Deputy Director

- Cardiovescular Rick Reduction - Comprehensive Cancer Control

- Gambling Treatment/Prevention

- Dishetes

- Disability Prevention

- Health Promotion

- Physical Fitness

- Governor Meth, Initiative

Lab Approval

Regulatory

- WISEWOMAN

Making Board

- Private Sector Drug Teeting/

- State Incentive Program (SIG)

- Substance Abuse Prevention

- Substance Abuse Treatment/

Substitute Medical Decision-

- Syner Compliance Checks

- Substance Abuse Training

Division of Health Protection and **Environmental Health Torn Newton, Division Director** Chuck Barton, Toxicologist Ed Bottel, Medical Textcolonisti **Poison Center Medical Director** 

Division of Tobacco Use Prevention and Control Janet Zwick, Interim Division Director Threase Harms-Hassoun. Tobacco Administration Director

- Legislative/Congressional Relations
- Scope of Practice Review Committee
- Center for Health Statistics
- Chronic Renet Disease - Financial Services
- Information Management
- Office Services
- Professional Licensure
- Rape Prevention Education
- Vital Records

#### Office of State Medical Exeminer Julia Goodin

- Domestic Death Review

- Abuse Education Review Panel
- Administrative Rules - Certificate of Need
- Healthy lowers 2010 - IDPH Annual Reports
- Internetipe
- Iowa Health FOCUS
- Media Contacts/Advocacy
- Organized Delivery Systems
- Publications - Personnel
- Strategic and Performance Plenning

- Abetinence Education
- Access to Health Care for **Special Populations**
- AIDS/HIV Care - AIDS/HIV Prevention
- AIDS/HIV Survellance
- Breastfeading Promotion
- Center for Rural Health and Primary Care
- Center for Healthcare **Workforce Shortege**
- Child Death Review Team - Children with Special Health
- Care Needs Community Health **Development**
- Community Health Needs Accessment/Health Improvement Planning
- Covering Kids Initiative
- Critical Access Hospital/ Flex Progress
- Dental/Oral Health · Early ACCESS (IDEA Part C)
- Early Hearing Detection &
- Family Planning
- Food Stamp Nutrition Education
- Genetics/Eirth Defects Institute
- Heelth Start heelth
- Houlth & Safety in Child Care
- Healthy Families Phone Line
- Home Care Alde
- HOPESARI
- Immunization Vaccine Preventable Disease Vaccines for Children
- Lieleon with Community Francisco
- Local Boards of Health Lisieon
- Maternal and Child Health
- Office of Minority Health
- Newtorn Screening
- **Mutrition Services**
- OB Indigent
- Perinatel Core Pregnency Prevention
- PRIMECARRE
- Public Health Nursing - Refuses Health
- School and Adolescent Health
- Sexually Transmitted Diseases
- Sudden Infant Deeth Syndrome
- Teen Line
- Tuberculosia
- Viral Hepatitis
- Volunteer Health Care Provider Program
- Women, Infents, and Children (WIC)
- Women's Health

- CADE
- Infectious Disease Surveillance, investiga-
- tion, and Control - Pandemic Influenza Plenning and
- Preparedness - Smellpox Plerming and Preneradoses
- State and National Disease Reporting Program - Vector Borne Disease
- **Program** - West Alle and Other
- Mosquito Borne Viruees Plenning and Preparedness

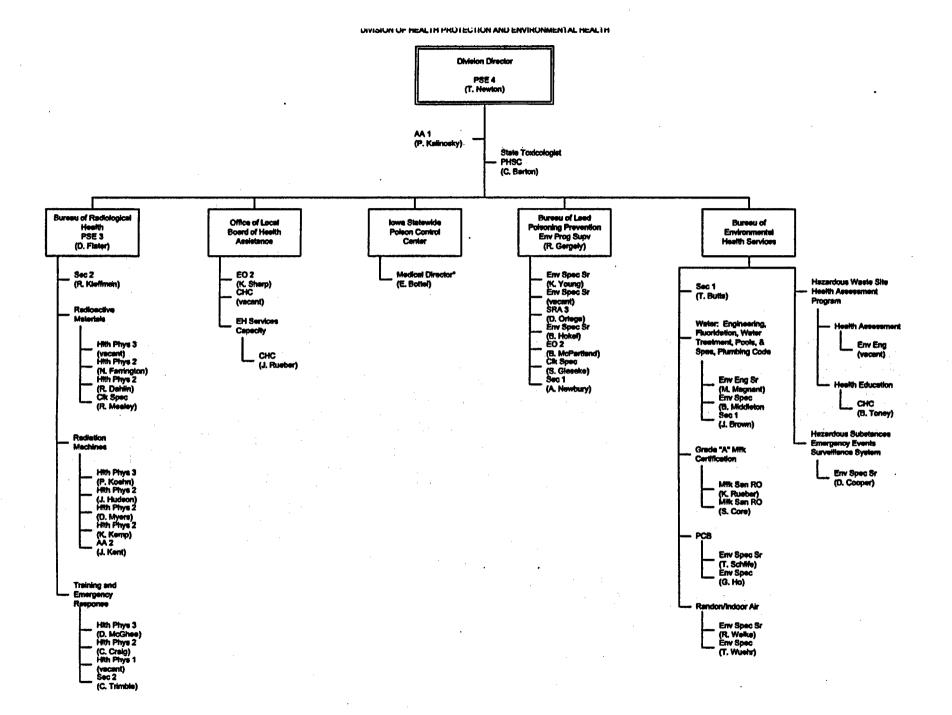
#### CDOR

- Bio Security Council Program
- DPH Emergency Operating Procedures and Home-
- land Security Program - Health Alart Naturals (HAN) Program
- Iowa Disaster Medical Assistance Teams (IA-DMAT)
- Public Health and Healthcare Diseate Preparedness Program
- Strategic National Stockpile (SNS) Program

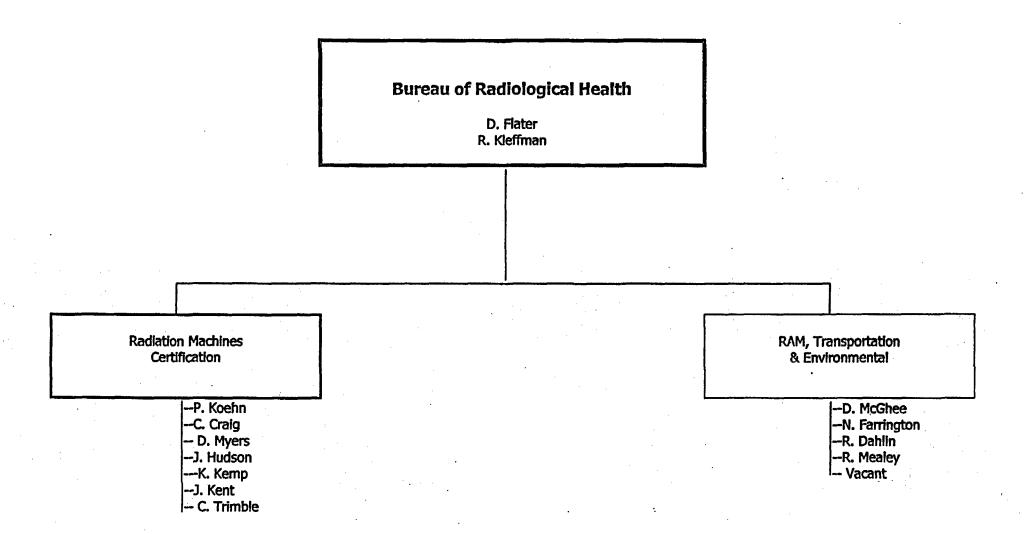
- Child Passenger/Bloyde Safety Program
- EMS & Priovider Authorization/Certification Program
- EMS Diseaser Plenning and Preparedness
- EMS Education and Training Program
- EMS for Children Program
- EMS System Deta Management Program
  - EMS System Development
- Program
- Injury Prevention Program - Iowa's Statewide Trauma
- System - SPRAINS

- ADAM - Anatomical Gifts
- Artivitis - Anthron
- Environmental Health - Brein Intury - Environmental Health Services - Breest and Cervical Cancer
  - Capacity - Grade "A" Milk Certification
  - Grants to Counties Well Program
  - Ground Water Data Collection
  - Hazardouis Substances **Emergency Events** Surveillance System
  - Lead Poisoning Prevention
  - Local Boards of Health Assistance
  - PCB
  - Pesticide Exposure Surveillance
  - Plumbing Code
  - Pools and Spes
  - Redicionical Health
  - Radon/Indoor Air - Statewide Poison Control
  - Carrie - Superfund Rick Assessment
  - Swimming Pools/Spee
  - Certification
  - Terming - Water Engineering and
  - Fluoridation - Water Treatment Devices
  - Local Contract Menegement
  - Burlel Site Preparation Inexections
  - Morent Housing
  - Tattoo Permits

- Consumer Product Safety
  - Tobacco Cessation
  - Tobacco Prevention



<sup>\*</sup> Iowa Statewide Poison Control Center Employee



#### **ATTACHMENT**

Letter from Donald A. Flater, dated September 9, 2004 (sic) lowa's Response to Draft IMPEP Report

ML032541016



### STATE OF IOWA

THOMAS J. VILSACK GOVERNOR

SALLY J. PEDERSON LT. GOVERNOR DEPARTMENT OF PUBLIC HEALTH
MARY MINCER HANSEN, RN, PhD
DIRECTOR

September 9, 2004

Kevin Hsueh, Ph.D.

State & Tribal Programs
U.S. Nuclear Regulatory Commission
One White Flint North – 3<sup>rd</sup> Floor
11555 Rockville Pike
Rockville, MD 20852

RE:

Iowa's IMPEP DRAFT Report 2003

Dear Dr. Hsueh:

Your letter to Tom Newton, Director, Division of Health Protection and Environmental Health dated August 29, 2003 and received in this office on September 3, 2003 has been referred to me for response. The draft document entitled "Integrated Materials Performance Evaluation Program – Review of Iowa Agreement State Program" was attached. The comments provided are directed toward that document.

In your letter you indicated that the preliminary schedule is that Iowa's Management Review Board (MRB) meeting should occur during the week of October 6, 2003. Because of our promptness in reviewing and submitting comments on your DRAFT Report, it is hoped that schedules would allow an MRB meeting prior to the current tentative schedule date. Please accept this letter as our formal request that our presence at the meeting is through the telecommunications process rather than a personal appearance.

#### DRAFT REPORT COMMENTS

#### 1. 1.0 INTRODUCTION

a. Page #1, paragraph #2. The second sentence of this paragraph states that the Iowa Department of Public Health is the agency within state government which among other things regulates "radiation hazards". Our reading of this sentence is that the only items we address are those that deal with "radiation hazards". We believe that this terminology is too restrictive regarding what is accomplished by the Radioactive Materials Program in Iowa. Our duties include licensing, inspections, education, investigation, etc. and addressing radiation hazards. Please reword the sentence so that what we do is truly reflected.

LUCAS STATE OFFICE BUILDING / 321 E. 12TH ST. / DES MOINES, IOWA 50319-0075
DEAF RELAY (HEARING OR SPEECH IMPAIRED) 1-800-735-2942 / INTERNET: http://www.idph.state.ia.us/

STP-OOL Template RIPS: SPOT Kevin Hsueh, Ph.D. September 9, 2003 Page 2

F. .... 44

- b. The first sentence on page 2 requests a response to recommendations being made. There is only one recommendation in the report and it will be addressed in our last comment.
- 2. 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS In the first sentence you refer to our previous Department Director as Dr. Gleason. I would suggest, for posterity purposes, that you use his full name and professional credentials, which is Stephen C. Gleason, DO.

#### 3. 3.1 Technical Staffing and Training

a. Page #4, the second full paragraph. We are uncomfortable with the wording of this paragraph. We suggest the following paragraph.

"During the on-site review, Bureau management expressed concerns about the effect of any aging workforce and the Bureau's ability to maintain continuity of experience. The review team noted that one of the department's challenges is to effectively deal with potential loss of an experienced workforce because of the possible retirement of senior bureau staff and managers in the near future."

b. Page #4, third full paragraph, second sentence. At the end of this sentence reference is made to "promulgation of rules and regulations". Please be advised that Iowa only promulgates rules. Please put a period after "rules" and delete "and regulations".

#### 4. 3.2 Status of Materials Inspection Program

- a. Page #4, the last paragraph on the page. The inspection this paragraph refers to was a special nuclear material license, which was one of two licenses, that NRC last inspected in 1998 (previous to transferring the license to Iowa in 2000)-a fact noted in the file. However, in preparing to conduct the inspection of both licenses, we found that the NRC had documented both inspections on one form. This form was not in the special nuclear materials license. This form indicated that the inspection interval had been increased by two years. This made the due date 2003. The inspection is not significantly overdue and we erred in reporting this to the review team.
- b. Page #5, the fourth full paragraph addressing the Bureau's long term efforts to establish an accurate data system. In the past we have had difficulty providing information in the format requested for tracking licensing actions and inspections. This issue has been discussed with Mr. Newton and he has indicated that the Iowa Department of Public Health Executive Team has identified the need for a

Kevin Hsueh, Ph.D. September 9, 2003 Page 3

consolidated database for tracking programs in the Bureau. He further indicates that the Team has placed our needs for a system on the Bureau of Information Management's priority list and the Team is in the process of identifying funding for the project. It is estimated that system development should be in full swing in fiscal year 2004.

#### 5. 3.3 <u>Technical Quality of Inspection</u>

- a. Page #6, third paragraph. We have discussed our practice and have modified it. We will no longer send "draft" inspection reports to the broad-scope licensees for review and comment.
- b. Page #6, sixth paragraph. The reference to Iowa Government is not correct. We suggest that paragraph read as follows:

"The Bureau has adequate numbers and types of survey meters to support the current inspection program, as well as for responding to incidents and emergency conditions. The Bureau uses the State Calibration Shop operated by the Homeland Security and Emergency Management Division of the Iowa Department of Public Defense for calibration of their survey instruments on a biannual basis. Appropriate documentation of calibrated survey instruments such as Geiger Mueller meters, scintillation detectors, and ion chambers was provided. Air monitoring equipment as well as prepared emergency field kits are also available for emergency use. Contamination wipes are primarily evaluated at the State Hygienic Laboratory which is located in Iowa City and is designated as the State Public Health Laboratory by Iowa Code."

- 6. 3.5 Response to Incidents and Allegations Page #9, second paragraph, first sentence. The fourth word in the sentence indicates that we "usually" promptly report incidents and allegations to NRC Operation Center and NMED. Our policy is to "always" report. We have reviewed our records and the results of the review indicate that we have met our policy. The one incident on NMED was reported but it appears to us that the NRC contractor or did not correctly enter the data. We would suggest that the word "usually" be removed.
- 7. 4.0 NON-COMMON PERFORMANCE INDICATORS First paragraph, last sentence indicates that Iowa's Agreement does not authorize SS&D evaluations. In fact in early years, former staff member Bruce Hokel worked with Lloyd Bolling to get a Radium device in the SS&D system. It was never accomplished because Iowa never held the status of a CRCPD: Licensing State". We do not have SS&D authority by virtue of the fact that in the 1990's I sent a letter to the NRC turning back our authority to perform SS&D evaluation. I would suggest that the paragraph be reworded to reflect what actually occurred.

Kevin Hsueh, Ph.D. September 9, 2003 Page 4

Sec. 14. 55

- 8. 4.1 <u>Program Elements Required for Compatibility</u> Page #10, paragraph's 3,4,&5 contain numerous references to "regulation". The Iowa Administrative Code is rules not regulations. Please replace all reference to regulation in these paragraphs with rule or rules, whichever is appropriate.
- 9. RECOMMENDATION Page 10. As a result of the recommendation being made by the IMPEP team, the following action was taken prior to the team completing their exit interviews.

We determined that in some cases we had paper work verifying the performance of a source leakage test prior to license termination. It was further determined that this type of over-sight was easily corrected by an educational process. Therefore, the Program Coordinator spoke with all RAM program staff and advised them that in order to terminate a gauge license the record must contain verification that a leak test of the source was performed and no leakage of RAM was present. Also, as part of the desk performance record for the individual who does the final overview of the termination of a license, words have been added to assure the above.

Reference is made to page #2 first sentence of the DRAFT Report which indicates that a response to nay recommendation is provided. Please accept the above as the requested response.

Thank you for the opportunity to review the Team's Draft Report. We hope that the information provided above will be of assistance to you. We look forward to the date of our conference call meeting with the MRB. If you have questions regarding the above, please do not hesitate to contact me. Again, thanks to everyone for all the help why in making the Iowa Radioactive Materials Program a success.

Sincerely,

Donald A. Flater, Chief

Bureau of Radiological Health

515-281-3478

515-725-0318 - FAX

dflater@idph.state.ia.us

DAF/rk

cc: Tom Newton