

DATED: AUGUST 28, 1996

SIGNED BY: HUGH L. THOMPSON, JR.

Mr. Christopher Atchison, Director
Iowa Department of Public Health
Lucas State Office Building
Des Moines, IA 50319

Dear Mr. Atchison:

On August 7, 1996, 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 considered and concurred with the review team's recommendation that the Iowa program be found adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) regulatory program. The next IMPEP review will be scheduled in three years, unless program concerns develop that require an earlier evaluation. However, based on the continuing good performance of the State, the review schedule may be extended to four years.

NRC recognizes the efforts of Iowa and the other Agreement States to maintain an adequate and compatible program. During the MRB meeting, the potential impact of NRC's new policy on funding Agreement State travel and training was discussed. Although the Iowa staff is stable at the moment, the State should consider developing plans for staff training in light of NRC's policy, which will end funding by NRC for Agreement State travel and require tuition for attendance at certain NRC training courses.

Section 5 page 16 of the enclosed final report presents the IMPEP team's recommendations. We have received your letter dated August 1, 1996, and appreciate the positive actions that you and your staff have taken and are continuing to implement with regard to our comments. No response to this letter is necessary.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to working with you in the future.

Sincerely, */RA/*

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosure:
As stated

cc: Donald A. Flater, Bureau
of Radiological Health
S. Parveen Baig, State Liaison Officer

Mr. Christopher Atchison, Director
Iowa Department of Public Health
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cc: Donald A. Flater, Bureau
of Radiological Health
S. Parveen Baig, State Liaison Officer
bcc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

*See previous concurrence.

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF IOWA AGREEMENT STATE PROGRAM

April 1 - 4, 1996

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Iowa radiation control program. The review was conducted during the period April 1 - 4, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Washington. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period December 15, 1993, to March 31, 1996, were discussed with Iowa management on April 4, 1996.

A draft of this report was issued to Iowa for factual comment on May 8, 1996. The State of Iowa responded in a letter dated May 22, 1996 (Attachment 1), and the comments were incorporated into the proposed final report. The State of Iowa responded to the recommendations in the proposed final report in a letter dated August 1, 1996. The Management Review Board (MRB) met on August 7, 1996, to consider the proposed final report. The MRB concurred in the teams' overall recommendations and found that the Iowa radiation control program was adequate to protect public health and safety and was compatible with the NRC's regulatory program.

The Iowa Department of Public Health (IDPH) is the agency within Iowa State government that regulates, among other public health issues, radiation hazards. The Director, IDPH, is appointed by, and reports directly to, the Governor. Within IDPH, the Iowa radiation control program is administered by the Bureau of Radiological Health (BRH), Division of Health Protection. The Division of Health Protection organization chart is included as Appendix B. The Iowa program regulated 215 specific licenses at the time of the review. In addition to radioactive materials, the BRH is responsible for superfund risk assessment, control of machine-produced radiation, and radon control. 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 indicators was sent to the State on January 31, 1996. Iowa provided its response to the questionnaire on February 29, 1996. A copy of that response is included as Appendix C to this report.

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

Section 2 below discusses the State's actions in response to recommendations made following the previous review. 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 indicators, and Section 5 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on December 14, 1993, and the results were transmitted to Mr. Christopher G. Atchison, Director, Iowa Department of Public Health, on April 11, 1994. NRC visited the program again in December 1994 to evaluate the status of open issues identified in the 1993 review. The results of this visit were transmitted to Mr. Donald A. Flater, Chief, Bureau of Radiological Health, on February 13, 1995.

2.1 Status of Items Identified During the December 1993 Routine Review

A number of recommendations were identified as part of the December 1993 review. Some of the recommendations were closed at the time of the December 1994 visit. The review team looked at each remaining item to determine whether or not the Iowa program had taken additional actions to close open recommendations. The team's review of recommendations open after the December 1994 visit are summarized below:

- (1) The 1993 reviewer recommended the computer tracking system be updated to track licensee responses.

Current Status: The computer tracking system has been updated to track licensee responses to inspection letters. The program secretary gives the Program Coordinator a monthly printout. This previous recommendation is closed.

- (2) The 1993 reviewer recommended that the Program Coordinator attend the licensing course and that the Environmental Specialist attend the industrial radiography course. It was recommended that new Environmental Specialists attend all of the NRC core training courses.

Current Status: The Environmental Specialist has attended the radiography course. The Bureau is committed to have all new Environmental Specialists attend all NRC core courses. The Program Coordinator was scheduled to attend the licensing course in 1995, but was rescheduled and attended the course in June 1996. The attendance of the Program Coordinator at the licensing course will be discussed in Section 3.2. This previous recommendation is closed.

2.2 Status of Items Identified During the December 1994 NRC Review Visit

Several recommendations were also identified as part of the December 1994 NRC visit to the State. The review team looked at each item to determine whether or not the Iowa program had taken actions to close the recommendation. The recommendations opened during the December 1994 visit are summarized below:

- (1) NRC recommended the expansion of audits of program areas such as the computer tracking system, which was recently compromised due to improper use, would benefit the program.

Current Status: The Program Coordinator had been identifying problems with the computer tracking system and coordinating with the computer

support staff within the State to rectify errors. The tracking system was examined in relationship to the common performance indicators, and a discussion on its performance is found in Section 3.1. This previous recommendation is closed.

- (2) NRC recommended that the State require from its two major broad scope academic licensees a statement of intent containing a cost estimate for decommissioning and an indication that funding will be obtained when necessary.

Current Status: The Program Coordinator recalled conversing with the appropriate individuals at the licensees in question and believed that the required documentation had already been received. However, no record could be found in the files. The Program Coordinator will be contacting the licensees and will obtain the required documentation. This previous recommendation is closed.

- (3) NRC recommended that the qualification journals be kept up to date.

Current Status: The supervisor sign off sheet for courses completed by the staff was not kept up to date for two environmental specialists. All other portions of the qualification journals were complete. However, these two environmental specialists had copies of the certification of completion for the NRC courses in the Journal. This previous recommendation is closed.

- (4) NRC recommended that the State continue to address the need to have additional qualified personnel capable of inspecting complex licensee programs. At the time of the review visit, only one inspector was qualified to evaluate health and safety issues at complex licensee programs such as nuclear pharmacies and broad scope universities.

Current Status: The inspection staff is qualified to perform complex inspections. Two additional inspectors are qualified to inspect nuclear pharmacies now. The Program Coordinator is qualified and has been the team leader for the broad scope universities, and one inspector has the qualifications and experience to team lead broad scope universities and other complex inspections as backup to the Program Coordinator. The remaining inspection staff is continuing to work towards their qualifications in this area. 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) Status of Materials Inspection Program, (2) Technical Staffing and Training, (3) Technical Quality of Licensing Actions, (4) Technical Quality of Inspections, and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees.

Review of the State's inspection priorities showed that the State's inspection frequencies for various types or groups of licenses are, with few exceptions, at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter (IMC) 2800. Although the State had not incorporated some of the April 1995 revisions to IMC 2800, with the exception of the three instances noted below, the State is conducting inspections at the same frequency or more frequent than NRC currently requires. Those categories for which NRC revisions to IMC 2800 were more conservative than the Iowa frequencies are: (1) medical private practice license inspections conducted as a Priority 4 in Iowa v. NRC's change to Priority 3; (2) nuclear laundry licenses, which Iowa considers as a Priority 3, but treated by NRC as a Priority 2; and (3) possession only/storage licenses, which Iowa codes as a Priority 7, and NRC considers as a Priority 3. In discussions with the Program Coordinator, these three categories were overlooked in the State's review of the changes to IMC 2800. It is the State's intention to have inspection frequencies at least as frequent as those of NRC. When these preliminary findings were raised with the Iowa staff, the State revised the inspection frequency on April 1, 1996, to reflect the April 1995 revisions to IMC 2800. The inspection frequencies of licenses selected for inspection file reviews were compared with the frequencies listed in the State's data system and were verified to be consistent with the State's system and as frequent as similar license types under the IMC 2800 system.

In its response to the questionnaire and additional correspondence with staff, Iowa indicated that as of March 1996 no licensee identified as a core inspection in IMC 2800 was overdue by more than 25 percent of the NRC frequency. The IMPEP review team also looked at the State's experience with overdue inspections during the entire review period. As a result, two licenses were identified by the State during the IMPEP review as exceeding the inspection frequency (These were inspected the week of April 22, 1996). In discussions with the Program Coordinator, BRH employed a secretary in 1995 who did not enter all data in the computer tracking system on the licensees inspections. During 1995, the Program Coordinator and staff reviewed the information in each file against the data in the tracking system in an attempt to identify and correct all instances of missing information to the tracking system used by BRH. However, during the review of the data and the files, BRH staff have found that copies of correspondence had been lost also. The two licenses had been overlooked in the State's audit.

With respect to initial inspections of new licensees, the team reviewed the computer tracking data system and license files. The State identified 21 new licenses that were issued during the review period, 15 agreement material licenses and 6 non-agreement material licenses. At the time of the review, two new licenses issued since November 1995 were not due for inspection, two licenses were overdue and two licenses had been inspected at intervals of 13 months and 14 months in 1994. All other new licenses had been inspected within six months of license issuance. The team found that the two licenses that were inspected late occurred following the last review, when the State was training staff and management had approved the delay. The two new licenses that had not been inspected, an in-vitro testing lab and a portable gauge, are overdue by nine months and seven months, respectively, beyond the six month due date. These two licenses had not been entered into the computer tracking system and had not been identified in the audit conducted by BRH. The review team recommends that the two new licenses that have not been inspected, be scheduled for inspection and that the State continue to follow the IMC 2800 provisions for new licenses.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Out of 23 compliance files examined both in detail for quality of the inspection program and for issuance of inspection findings, 11 had inspection correspondence sent to the licensee within 30 days after completion of the inspection. On closer examination, 16 out of 23 were issued within five weeks of the inspection. Six inspection findings were issued within the time range of 8 to 16 weeks. The remaining case had taken six months, however, it was a team inspection of Iowa State University's licenses with significant findings. Management was aware of this delay due to the complexity of the Iowa State University's report. Delays in issuing inspection reports impairs the effectiveness of getting prompt corrective action by the licensee to any violations. Late reports make it difficult for the program to require a prompt response from the licensee. Finally, late reports open the program to criticism by licensees. The review team suggested that State management and staff continue to devote increased attention to issuing inspection results in a timely manner (30 days).

On examination of the root case for both the timeliness of new license inspections and the timely issuance of inspection findings, it was noted that the computer tracking system contributed to some problems experienced by BRH. The computer tracking system generates reports based on the date of the cover letter to the notice of violation. There is a time lag as much as three weeks between the cover letter and the date the notice of violation is signed. The reports used by management to track the 30-day response are in some cases based on artificially generated information, such as the 30 days from the inspection and not the actual date the notices of violation are signed. The review team recommends that management information systems, e.g., the computer tracking system, be reviewed with the appropriate management and support staff to ensure that the BRH is receiving the information to manage the program. The review team suggests that the data in the computer tracking system be reviewed to ensure the information is complete and correct.

The State reported in its response to the questionnaire that 70 requests for reciprocity were received during the review period; 18 from industrial radiographers, 1 well-logger, and 51 portable gauge users and other licensees with an inspection frequency of more than three years. The State conducted 13 inspections of reciprocity licensees during the review period. The State requires radiographers to be certified and conducts an aggressive program on verifying radiographers conduct their licensed activities in accordance with Iowa regulations. In its response to the questionnaire, the State reported conducting three field inspections on a non-reciprocity industrial radiography licensee.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.2 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed IDPH management and staff, and considered any possible workload backlogs.

IDPH organization chart shows that BRH was staffed with 1 program supervisor and 14 staff at the time of the review. The staff positions cover radioactive material, radon, machine-produced radiation, and superfund risk assessment.

Within that group, five technical staff comprise the radioactive materials control program. Mr. Dan McGhee is the Program Coordinator for the radioactive materials control program. The three environmental specialist/engineers (including the Program Coordinator) in the radioactive materials control program are full-time positions, with few outside (non-program) duties. One environmental specialist spends 40 percent of her time in licensing and the other environmental specialist has begun her training in the inspection program at a 10 percent effort at this time. In response to the questionnaire, the State reported that the Bureau Chief spends about 33 percent of his effort on the radioactive material program. In response to the questionnaire, the State reported that 3.8 FTEs were assigned to the radioactive materials control program. In addition, BRH retains the services of a consultant (former NRC employee) at .33 FTE level per year. One position was filled during the review period. No vacancies were forecast in any of the radioactive materials positions in the near future. If the funding for the radon program is reduced, any radon program excess FTE will be placed in the radioactive material inspection program. The Bureau Chief also told the review team that he does not know of any plans to reduce the staffing level for the radioactive materials control program.

The licensing and inspection functions of the program are integrated, and therefore, both full time environmental specialists and Program Coordinator perform duties in licensing, inspection, and event response. Balance between the licensing and inspection functions is achieved by basing staff assignments on program needs.

The Bureau Chief explained that, when vacancies occur, the positions require bachelor's degrees in a science/engineering field or a technologist degree with at least three years experience. The review team reviewed the qualifications of the technical staff and concluded that the State has been able to retain well-qualified individuals. The Program Coordinator and both environmental specialists have at least a bachelor's degree in science or engineering or technologist degree with at least three years experience.

The review team reviewed the training of all personnel involved with the radioactive materials control program. The Program Coordinator provided the review team Iowa's "Inspector Qualification Journal" and the "Supervisor's Manual" as developed for the program by their consultant. The inspector qualification involves completing a series of written examinations and participating in accompanied inspections, until the Program Coordinator evaluates their performance as acceptable to perform independent inspections. Each inspector had their journal up to date except for the sign off sheet for completed course work. However, two of the staff had copies of the certification of completion for the NRC courses in the Journal.

The documentation of licensing qualifications is not as structured as the inspection journals. License reviewer candidates are assigned case work in a given program area after an orientation with a qualified license reviewer. The Program Coordinator evaluates these reviews and makes the decision as to whether the candidate is able to conduct independent reviews. Although courses are not considered as an actual part of the qualification process, BRH attempts to schedule new staff for the licensing and inspection courses within the first nine months of employment. The Program Coordinator had not completed the licensing course at the time of the review. However, he received on the job training from Region III staff and the Regional State Agreements Officer and no licensing performance weakness was identified because of the lack of this training course. The Program Coordinator was scheduled for the 1995 course, but was rescheduled and attended the June 1996 course.

The IMPEP reviewer discussed training with the Bureau Chief and Program Coordinator. Based on the training that program personnel have taken during the review period, the State appears supportive of continued staff training, and management demonstrated a commitment to staff training during the review. However, the State has concerns as to the impact of NRC's change in policy for funding State training will have on their program. It was also noted that the Bureau Chief had requested specialized training for BRH staff on investigation techniques from the State Highway Patrol for this summer.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the four reviewers for 14 licenses. Licensing actions were reviewed for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation and consideration of safety evaluation reports, product certification or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review, and proper signature authorities. Licenses were reviewed for accuracy, appropriateness of the license and its conditions and tie-down conditions, and overall technical quality. The files were checked for retention of necessary documents and supporting data.

The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all license reviewers. The cross-section sampling included 14 licenses and included the following types: medical-institution and medical-mobile, industrial radiography, research and development, fixed and portable gauges, an in vitro laboratory, and a nuclear laundry. Licensing actions included two new licenses, five renewals, four amendments and three terminations. A list of these licenses with case-specific comments is included in Appendix D.

The review team found that the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Special license tie-down conditions were stated clearly, backed by information contained in the file, and were inspectable. The licensees' compliance histories were taken into account when reviewing renewal applications. The State's licensing guides were based upon NRC Regulatory Guides and several were in the process of being revised and updated for use by Iowa licensees. Reviewers were observed to be skilled with the use of these and other licensing documents. Reviewers used licensing guides appropriately and generally used check lists in reviewing applications, although these were not retained for the files. There was no apparent procedure for terminating licenses which may have contributed to some inconsistencies in closing files, particularly with respect to unsealed materials. The Bureau Chief, unless absent for a prolonged period, reviews and signs all licenses following both a peer review and a supervisory review by the Program Coordinator. No potentially-significant health and safety issues were identified.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes for 17 materials inspections conducted during the review period. The casework included all three of the State's materials inspectors and covered a sampling of different license types as follows: industrial radiography, broad scope university, broad scope research and development, broad scope medical, teletherapy, nuclear medicine, large hospital, nuclear pharmacy, laboratory use, portable gauge, and fixed gauge licensees. Appendix E provides a list of the inspection cases reviewed in depth with case-specific comments.

The review team noted several strengths in the Iowa program on this indicator. For instance, the IMPEP reviewer noted that the routine inspections covered all aspects of the licensee's radiation program and often included a written summary of the root cause if a deficiency or violation was noted. The IMPEP reviewer also noted that the inspectors observed licensed operations whenever possible. The observation of licensed activities provides the inspectors with an indication of the effectiveness of the licensee's radiation protection program. Another strength noted was the numerous inspection accompaniments conducted during the review period by the Program Coordinator or the Bureau Chief, more than the minimum annual standard in the IMPEP evaluation criteria. This gives program management a better understanding of both inspectors' abilities and on-site conditions. Finally, the State conducted team inspections of larger licensees, where the Program Coordinator was joined by one or both of the environmental specialists along with one or both individuals who supported the radioactive materials program part time. Having multiple inspectors review a particular licensee's operations may lead to more thorough inspections and provide the opportunity for less experienced inspectors to observe experienced inspectors as an effective training technique.

The review team reviewed the inspection reports and found them to be comparable with the types of information and data collected under NRC Inspection Procedure (IP) 87100. The inspection field notes provided documentation of inspection findings in a consistent manner. The State uses separate inspection field notes for various classes of licensees, such as nuclear medicine, portable gauges, radiography, and industrial/academic. The inspection field notes provide documentation of the scope of the licensee's program including: unusual occurrences; postings; storage and use of radioactive material; receipt, transfer, and disposal of radioactive material; inventory; leak tests; radiation protection program; personnel monitoring; training; independent measurements; and inspection findings. The IMPEP reviewer noted that the State had specific field notes for radiography field sites that include documentation for security of radioactive material, security and posting of radiation areas, personnel monitoring, radiation surveys and instruments, training, operating and emergency procedures, records and confirmatory measurements. The reviewer concluded that separate field notes specific for field radiography were a good addition to the State program to provide inspectors with an effective means to document the use of large activity sources in the public domain.

During the review of the inspection files, the IMPEP reviewer noted that one of the medical licensees possesses and uses a high dose rate afterloader (HDR). Although the inspection documentation for this licensee was in the form of a written report, the State does not have field notes specific for the inspection of a HDR. The review team suggests that the State have field notes specific to HDRs in order to document the proper use and compliance with the regulations and license conditions for this medical device.

The IMPEP reviewer noted that the field notes did not include documentation for the evaluation of dose to members of the public or instruction on dose limits to embryo/fetus and declared pregnant women. Although the dose to members of public was evaluated for nuclear pharmacy and one of the large broad scope inspection reports reviewed by the team, there are other facilities where such an evaluation is appropriate. The reviewer also noted that the State had Quality Management Program (QMP) requirements in the State Code, but the State's field notes or inspection reports did not address this area of a medical licensee's program. In discussions with one of the inspectors, the reviewer was informed that the inspector did look at the licensee's QMP activities and compared their implementation to the regulations, but the observations were not documented. In addition, the reviewer noted that level of documentation for a particular section of one class of field notes was different from another. For example, the radiation protection section in the academic/industrial field notes has an additional item for review compared to the State's medical and teletherapy field notes.

The review team suggests that the State revise their field notes to incorporate dose to members of the public and instruction on dose limits to embryo/fetus and declared pregnant women for all field notes and to revise the medical and teletherapy field notes to incorporate the State's QMP requirements. In addition, the review team suggests that the State review their field notes to incorporate consistent content of sections in all classes of field notes.

The inspection reports and field notes demonstrated that the State inspectors were examining appropriate radiation health and safety issues at licensees' facilities. Two environmental specialists told the reviewer that they are required to review all aspects of the licensee's radiation safety program and document that review in the field notes. Inspectors routinely performed independent measurements at the licensee facility. The performance of such measurements by the State inspectors in one case resulted in the identification of a significant safety problem, inadequate survey of a patient room after a therapeutic treatment. Inspectors' written comments in the field notes indicate that they discussed safety issues with licensee personnel. The field notes or reports indicate that licensee operations were observed when licensed operations were being conducted by the licensee, and interviews with the State inspectors support that they routinely tour licensee areas such as laboratories, other locations of use, and storage areas. Both environmental specialists told the IMPEP reviewer that they emphasize the observation of licensed activities to determine the effectiveness of the licensee's radiation safety program and compliance to the requirements, a critically important inspection technique. The field notes indicate that the inspectors consistently examined and, when appropriate, closed-out previous violations. Also, because the environmental specialists serve as both inspectors and license reviewers for the same licensees, there was evidence that licensing issues were considered in the inspection process.

While reviewing the 17 inspection cases, the IMPEP reviewer found a number of minor issues, that were discussed directly with the State staff. However, none of the issues indicated a systemic problem in the technical quality of inspections.

Three inspector accompaniments were performed by a review team member during the period of March 4-7, 1996. All three of the Iowa inspectors were accompanied during the period. One of the environmental specialists was accompanied during the inspections of a mobile nuclear medicine program and a fixed gauge program. The second environmental specialist and the Program Coordinator were accompanied during the inspection of a nuclear pharmacy. On

April 3, 1996, the environmental specialist who participated at the nuclear pharmacy inspection was accompanied by a review team member during the inspection of a diagnostic nuclear medicine licensee. During the accompaniments, the Iowa inspectors demonstrated appropriate inspection techniques and knowledge of the regulations and licenses. The reviewer particularly noted that all three inspectors emphasized observation of licensed activities and interview of personnel to assess the effectiveness of licensee's radiation safety program. The inspectors were well-prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was satisfactory, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

In response to the questionnaire, the State reported that the two staff members were accompanied by the Program Coordinator during the review period. In addition, two individuals who did not inspect independently during the review period were also accompanied by the Program Coordinator. The questionnaire indicates that the Program Coordinator conducted accompaniments with each staff inspector twice during 1995. Based on interviews with the State staff, the number of accompaniments was actually higher than the number in the questionnaire. The questionnaire did not include the accompaniments by the Bureau Chief or the Program Coordinator. The Program Coordinator also observed staff during team inspections that were conducted. The inspectors reported receiving feedback from the supervisor on their performance during the accompaniments. In response to the questionnaire, the State reported that supervisory accompaniment procedures were not fully developed since only one inspector (Program Coordinator) could independently inspect all areas. The State noted, however, by the end of 1996, the goal was to accompany each inspector twice a year. The review team found that the State was exceeding the IMPEP criteria in NRC Management Directive 5.6 for annual accompaniments.

It was noted that the State has a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments were a mix of low and high range Geiger-Mueller (GM) detectors and pancake probes, micro R meters, higher-range instruments, instrumentation for alpha detection, pocket dosimeters, and audible dosimeters. The portable instruments used during the inspector accompaniments were observed to be operational and calibrated. The portable instruments maintained in the office were also observed to be calibrated. The reviewer noted that instruments are calibrated at least on a quarterly basis.

The IMPEP reviewer noted that all of the beta/gamma detection instrumentation was calibrated in units of exposure rate without a detector efficiency. Without an efficiency, the State inspectors would not be able to evaluate a licensee's compliance with contamination release limits. The State's instruments are calibrated by another State agency: Iowa Department of Public Defense, Disaster Services Division located at Camp Dodge in Johnson, Iowa. The IMPEP reviewer toured the facility and spoke to the individual responsible for the calibration of the State's radiological survey instrumentation. The calibration facility had National Institute of Science and Technology traceable sealed sources to determine the efficiency of beta/gamma instrumentation. The determination of the instrument efficiency will enable the inspector to convert counts per minute (cpm) to disintegration per minute (dpm) in order to determine the licensee's compliance with surface contamination release criteria. The review team suggests that some of the State's instrumentation be calibrated with the efficiency to convert cpm to dpm.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire relative to this indicator, reviewed the incidents reported for Iowa in the "Nuclear Material Events Database" (NMED) against those identified by Iowa, and reviewed the casework and license files, as appropriate, of six incidents. There were no allegations during the time period covered by the review. In addition, the review team interviewed the staff assigned to each response.

Responsibility for initial response and follow-up actions to materials incidents and allegations rests with BRH. Written procedures require the prompt response by BRH to each incident or allegation, with no specific instruction. In the response to the questionnaire, Iowa noted that their policy was to inform the Region III Regional State Agreements Officer within 24 hours of any unusual occurrence or incident. The review team suggested that the procedures for notifying NRC of incidents be revised to reflect the current guidance to Agreement States to notify the NRC headquarters operations office of events requiring immediate or 24-hour reporting by the licensee.

Because of the size of the program, each incoming notification is discussed with staff and management, as appropriate. If the response included an on-site inspection, this was completed by the assigned staff. The review team examined the State's response to all the events including three events that were identified by the State (two contamination events and a lost gauge) as most significant in the IMPEP questionnaire, the State's incident and allegation process, and the appropriate license files. The information in NMED agreed with the information in the Iowa files. The incident files reviewed included a lost generally-licensed gauge, fire at a nuclear laundry, damage to a specific gauge, and three contamination incidents. A list of the incident casework with comments is included in Appendix F.

In the cases reviewed in depth, the review team found that the State's responses were well within the performance criteria. Responses were prompt and well-coordinated, and the level of effort was commensurate with health and safety significance. The IMPEP reviewer noted that most incident reports included a written summary of the root cause if a deficiency or violation was noted. BRH staff were dispatched to the sites when appropriate. The State took suitable enforcement actions, required the licensee to implement corrective actions, and completed all steps of the investigation through close-out.

Although there were no allegations received by the State during the time period covered by the review, the State told the review team that they do protect alleged identities, and notify alleged of the results of the State's investigation.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Response to Incidents and Allegations, be found 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 Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery. Iowa's Agreement does not cover low-level radioactive waste disposal and uranium recovery operations, so only the first two non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Along with their response to the questionnaire, the State provided the review team with copies of legislation that affects the radiation control program. The Department of Public Health is designated as the State radiation protection agency in the Iowa Code, Chapter 136C. With response to the questionnaire that there had been no change to the State legislation, the review team did not review the legislation but relied on previous reviews where State legislation was determined to be adequate. Although the State indicated there were no changes to Iowa Code in the questionnaire that affects the radiation control program, the review team discussed both the radiation control act and the administrative act with the staff. The Iowa Code grants the Department of Public Health the authority to promulgate rules and regulations in accordance with the administrative act to be followed in the administration of a radiation protection program.

4.1.2 Status and Compatibility of Regulations

Iowa's final equivalent rules and amendments to the following NRC rules became effective September 7, 1994: "Quality Management Program and Misadministrations" 10 CFR Part 35; "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72; "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70; and "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70. These regulations were promulgated within the three year period. NRC staff has reviewed the amended regulations and has found these regulations are compatible with equivalent NRC regulations.

According to information provided in the questionnaire, the State does not regulate uranium recovery operations or a low-level radioactive waste disposal facility; it does not have a rule equivalent to NRC's 10 CFR Part 61 and NRC's regulations applicable to uranium recovery contained in 10 CFR Part 40. Therefore, it will not adopt the regulations equivalent to the following NRC rules:

- "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 amendments (58 FR 33886) that became effective on July 22, 1993.
- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendments (59 FR 28220) that became effective on July 1, 1994, and will need to be adopted by July 1, 1997.

Given the absence of any interest in the use of irradiators in Iowa, the State is postponing development and adoption of the "Licensing and Radiation Safety Requirement for Irradiators," 10 CFR Part 36 equivalent rulemaking as stated in their March 24, 1994, letter to NRC. In the August 31, 1994 response from NRC, this action was deemed acceptable and would not affect the compatibility

determination for the Iowa program. However, Iowa committed in the March 24, 1994 letter, to take action to adopt the provisions of Part 36, if an application for a large irradiator were to be received, and until such a rule becomes effective, to incorporate the provisions of Part 36 through license conditions.

The State has begun the process of promulgation of the following rules necessary for a compatible program:

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Iowa and other Agreement States are expected to have that equivalent rule effective on the same date.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48628) that became effective October 20, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that will become effective April 1, 1996.

The review team examined the procedures used in the State's regulation promulgation process and found that the public is offered the opportunity to comment on proposed regulations during a 20-day comment period and in a public hearing that follows the comment period. According to the Bureau Chief, NRC is provided with drafts for comment on the proposed regulations early in the promulgation process. A copy of the final regulation is submitted to NRC.

The State's regulations were compatible with those of the NRC at the time of the review, including all regulations necessary for a compatible program that are due by December 1997. During discussions with the review team, the Bureau Chief explained that they had begun the process of preparing draft revisions to the regulations which they expect to promulgate in October 1996 for new regulations due in 1998. The State's formal regulation promulgation process takes approximately five months. The State is aware of the importance of maintaining compatible regulations and the State plans to yearly update regulations to maintain compatibility.

Based on the IMPEP evaluation criteria, the review team recommends that Iowa's performance with respect to the indicator, Legislation and Regulations, be found satisfactory.

4.2 Sealed Source and Device Evaluation Program

The review team did not review the State's sealed source and device (SS&D) evaluation program because of the request from Iowa Governor Terry E. Branstead to Richard L. Bangart, Director, Office of State Programs, on January 22, 1996, to relinquish its SS&D authority. The State did not perform SS&D evaluations in the past and believes it is not likely that any devices containing radioactive material will be manufactured in the near future. In addition, such evaluations require personnel resource commitments that the Iowa program cannot justify. The Commission has agreed to these requests and NRC reasserted authority in this area on June 1, 1996.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the performance indicators to be satisfactory. The MRB concurred in the team's individual and overall recommendations and found that the Iowa program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for consideration by the State.

1. The review team recommends that the two new licenses that have not been inspected, be scheduled for inspection and that the State continue to follow the IMC 2800 provisions for new licenses. (Section 3.1)
2. The review team suggested that State management and staff continue to devote increased attention to issuing inspection results in a timely manner (30 days). (Section 3.1)
3. The review team recommends that management information systems, e.g., the computer tracking system be reviewed, with the appropriate management and support staff to ensure that the BRH is receiving the information to manage the program. (Section 3.1)
4. The review team suggests that the data in the computer tracking system be reviewed to ensure the information is complete and correct. (Section 3.1)
5. The review team suggests that the State have field notes specific to HDRs in order to document the proper use and compliance with the regulations and license conditions for this medical device. (Section 3.4)
6. The review team suggests that the State revise their field notes to incorporate dose to members of the public and instruction on dose limits to embryo/fetus and declared pregnant women for all field notes and to revise the medical and teletherapy field notes to incorporate the State's QMP requirements. (Section 3.4)
7. The review team suggests that the State review their field notes to incorporate consistent content of sections in all classes of field notes. (Section 3.4)

8. The review team suggests that some of the State's instrumentation be calibrated with the efficiency to convert cpm to dpm. (Section 3.4)
9. The review team suggests that the procedures for notifying NRC of incidents be revised to reflect the current guidance to Agreement States to notify the NRC Headquarter Operations Center. (Section 3.5)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Iowa Department of Public Health, Division of Health Protection Organization Chart
Appendix C	Iowa's Questionnaire Response
Appendix D	License File Reviews
Appendix E	Inspection File Reviews
Appendix F	Incident File Reviews
Attachment 1	Iowa's Response to Review Findings

APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Kathleen Schneider, OSP	On-Site Team Leader Status of Materials Inspection Program Technical Staffing and Training Response to Incidents and Allegations Legislation and Regulations
Terry Frazee, Washington	Technical Quality of Licensing Actions
Duncan White, RI	Technical Quality of Inspections

APPENDIX B

Iowa Department of Public Health
Division of Health Protection

ORGANIZATION CHART

APPENDIX C

Iowa's Questionnaire Response