

DATED: JUNE 11, 1996

SIGNED BY: HUGH L. THOMPSON, JR.

Jon R. Rice, M.D.
State Health Officer
State Department of Health
Capitol Building
600 East Blvd.
Bismark, North Dakota 58505-200

Dear Dr. Rice:

On May 14, 1996, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the North Dakota Agreement State Program. The review team found the State's performance with respect to four of the five common performance indicators to be fully satisfactory. On the Status of Materials Inspection Program indicator, the review team found the State's performance to be satisfactory with recommendations for improvement. The review team found the State's performance on the only applicable non-common performance indicator to be satisfactory. The MRB considered and concurred with the review team's recommendation that the North Dakota program be found adequate to protect public health and safety and compatible with NRC's regulatory program. Based on the results of the current IMPEP review, the next review will be scheduled in two to three years, unless program concerns develop that require an earlier evaluation.

Section 5 (page 18) of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review.

Sincerely, */RA/*

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

Enclosure:
As stated

cc: Dana Mount, Director
Division of Environmental Engineering
North Dakota Department of Health

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cc: Dana Mount, Director
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 North Dakota Department of Health

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH DAKOTA AGREEMENT STATE PROGRAM

February 6 - 9, 1996

FINAL REPORT

Office of State Programs

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the North Dakota radiation control program. The review was conducted during the period February 6 - 9, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Colorado. 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 July 1993 to January 1996, were discussed with North Dakota management on February 9, 1996.

A draft of this report was issued to North Dakota for factual comment on March 18, 1996. The State of North Dakota responded in a letter dated April 11, 1996 (Attachment 1) and the comments were incorporated into the proposed final report. The Management Review Board (MRB) met on May 14, 1996, to consider the proposed final report. The review team found the State's performance with respect to four of the five common performance indicators to be fully satisfactory. On the Status of Materials Inspection Program indicator, the review team found the State's performance to be satisfactory with recommendations for improvement. The review team found the State's performance on the only applicable non-common performance indicator to be satisfactory. The MRB concurred in the team's individual and overall recommendations and found that the North Dakota program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

The North Dakota Department of Health (NDDH) is the agency within North Dakota State government that regulates, among other public health issues, environmental health. The State Health Officer, who heads NDDH, is appointed by, and reports directly to, the Governor. Within NDDH, the North Dakota radiation control program is administered by the Environmental Health Section, Division of Environmental Engineering. The Department of Health and Division of Environmental Engineering organization charts are included as Appendix B. The North Dakota program regulated 69 specific licensees at the time of the review. In addition to radioactive materials, the Division of Environmental Engineering is responsible for regulating air quality permitting, compliance, impact, and monitoring; asbestos control; 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 North Dakota.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the State on December 5, 1995. North Dakota provided its response to the questionnaire on January 17, 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 North Dakota's response to the questionnaire; (2) review of applicable North Dakota 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 the two North Dakota inspectors in January 1996; 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 June 25, 1993, and the results were transmitted to John R. Rice, M.D., State Health Officer, North Dakota State Department of Health and Consolidated Laboratories, on October 29, 1993. NRC visited the program again in October 1994 to evaluate the status of open issues identified in the 1993 review. The results of this visit were transmitted to Dr. Rice on July 14, 1995.

2.1 Status of Items Identified During the June 1993 Routine Review

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

(1) The 1993 reviewer recommended that the State utilize technical assistance findings by NRC to reevaluate the tritium and carbon-14 disposal authorizations given to two broad-scope academic licensees. The 1994 status was that the North Dakota program had proposed amendments to the two licensees and was awaiting responses from the licensees. Also, the North Dakota program had sent a memorandum on the subject of waste disposal to all medical licensees.

Current Status: The North Dakota program had received NRC's response to the technical assistance requests. However, program personnel reported that the waste disposal authorizations in question for the two licensees had expired, and that the licensees were not pursuing renewing the authorizations. Because the authorizations had expired and the academic licensees were not continuing disposal in this manner, the recommendation is closed.

(2) The 1993 reviewer recommended that the State update the Administrative Procedures Manual so that it contains only current information and that it be made available for all staff members. The 1994 status was that the draft revised manual was under review by the North Dakota staff. The 1994 visit also recommended that the North Dakota program consider use of the procedures developed by the Conference of Radiation Control Program Directors (CRCPD) as guides to facilitate the manual development.

Current Status: The North Dakota program has updated the Administrative Procedures Manual and issued it in final form in June 1995. All North Dakota staff in the program were aware of the Administrative Procedures Manual and had access to the manual. The recommendation is closed.

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

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

- (1) The NRC reviewer recommended that the State continue to apply regulatory attention to a licensee that had repeatedly been cited for violations in 1990, 1991, and 1994, until it was demonstrated that the licensee's problems are resolved. NRC also recommended in the 1994 review visit that the State should consider that further escalated enforcement may be required for this licensee.

Current Status: The State has not inspected the licensee, Trinity Medical Center (ND 33-04608-01), since the October 1994 review. The last inspection was conducted in February 1994, before the review visit, and the State did not take escalated enforcement following that inspection. Inspection frequency for this licensee is every three years. The State should increase regulatory attention to this licensee, until the State determines that the licensee's problems are resolved. The State has scheduled this licensee's inspection for the Spring 1996. This recommendation is closed.

- (2) NRC recommended that the State should consistently use checklists and notes to document licensing decisions, and that supervisory reviewers should always sign-off on the checklists.

Current Status: Since this IMPEP review was performance-based and no significant licensing concerns were noted, no further follow-up of this issue is needed. The recommendation is closed.

- (3) NRC recommended that the State should follow its commitment for staff training. Specifically, the NRC reviewer noted that the State program manager and one staff member needed to complete the series of NRC core training courses.

Current Status: The program manager and staff member have not yet taken the NRC core training courses identified in the [now-suspended] May 28, 1992, Policy Statement (57 FR 22495). Although the Policy Statement is no longer in effect, the review team continues to recommend that both individuals complete the licensing course. The staff member performs license reviews for roughly half of the State's licensees. The program manager serves as the sole reviewer. In the longer term, the program manager should also attend the inspection procedures course, but that need is not as immediate. The review team examined this recommendation as part of the Technical Staffing and Training common performance indicator (see Section 3.2). This recommendation is considered closed and will be tracked as a new recommendation (see Section 5.0).

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 at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter 2800 (IMC 2800). Inspection frequencies under the State's system range from 1-year to 5-year intervals. The State requires more frequent inspections in some license categories as follows: moisture/density gauges and portable gauges are inspected on a 4-year frequency compared with an NRC 5-year frequency; self-shielded irradiators are inspected on a 3-year frequency compared with an NRC 5-year frequency; laboratory facilities are inspected on a 4-year frequency compared with an NRC 5-year frequency; and testing and calibration licensees are inspected on a 3-year frequency compared with an NRC 5-year frequency. 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, North Dakota indicated that as of January 17, 1996, only one licensee identified for a core inspection in IMC 2800 was overdue by more than 25 percent of the NRC frequency. This number is well within the 10 percent criterion for overdue inspections of Management Directive 5.6. By the time of the on-site review, on February 6-9, 1996, this well-logger licensee had received its initial inspection, about three and one-half months past the inspection overdue date.

The IMPEP review team also looked at the State's experience with overdue inspections during the entire review period. In practice during IMPEP reviews, the 10 percent criterion for overdue inspections is applied at the time of the review, but North Dakota had a recommendation in the June 1993 review regarding overdue inspections that were closed during the October 1994 review visit, and a cursory review of the inspection dates led the review team to examine this issue more closely. The review team identified 8 inspections of core licensees out of approximately 27 routine (non-initial) core inspections conducted during the review period that were overdue by more than 25 percent of the NRC frequency. These core inspections ranged from a few weeks to over seven months beyond the 25 percent window. In discussions with the program manager and staff, the State personnel had been aware of these cases during the review period. The program manager had, during the review period, developed and implemented a plan to complete overdue inspections, and by December 1995 the program had completed all of its overdue core inspections. Because the State recognized the problem with overdue inspections, developed a management plan to address overdues, and implemented effective measures to eliminate overdues, the review team concluded that the State has successfully addressed its earlier problem with overdue core inspections.

With respect to initial inspections of new licensees, the team reviewed the inspection tracking data system and verified that the initial inspections had been entered into the tracking system. The State identified six new licenses that were issued during the review period. At the time of the review, five of the new licensees had been inspected and the sixth was still within the 6-month time frame for inspection. The review team looked further to determine whether the State inspected the new licensees within six months of license issuance, or within the provisions of IMC 2800. The team found that

during the review period four of the initial inspections had been conducted late. The program manager was aware that during the review period the State had a problem in conducting initial inspections within the established criteria, but that the problem had since been resolved. Of the four initial inspections that were late, they ranged from about seven weeks past the due date (for a moisture/density gauge licensee) to over a year past the due date (for a mobile nuclear medicine licensee). Three of the four overdue initial inspections were inspected in January 1996, the month before the IMPEP review.

In discussions with the program manager and staff, it was evident that the State was aware of their overdue initial inspections and had successfully addressed the problem by completing the overdue initial inspections. In addition, the program manager showed the IMPEP reviewer a management database system that he had recently implemented to track assignments of the two staff members. Although the review team concluded that the State had trouble conducting initial inspections within the prescribed time frame in IMC 2800, at the time of the review the State had conducted all overdue initial inspections. It is too early to determine whether the new management tracking system will be effective in preventing future initial inspections from becoming overdue, because the system has not been in use long and because most of the overdues were inspected in the final month before the IMPEP review.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Out of eight inspection files examined in depth, five had inspection correspondence sent to the licensee within 30 days after completion of the inspection. Of the remaining 3 inspections, 2 took 10 months to issue the reports. The third was inspected two months before the IMPEP review and findings had not yet been sent at the time of the review. In addition, State personnel informed the review team of two other inspections where inspection findings were not yet communicated to the licensee. One of these two cases was a level gauge licensee that had been inspected in January 1995. In this particular case, it took so long to issue the inspection findings that Division managers decided to re-inspect, rather than to issue inspection findings almost a year old. This caused the review team to look further into the timeliness of issuance of inspection findings.

The IMPEP reviewers selected another 13 files for inspections conducted during 1994 and 1995, by both program staff members. These 13 were not selected at random; the review team had indications that some were issued late. Of those 13, seven had inspection findings communicated to the licensee in excess of 30 days after completion of the inspection. The times ranged from one week to 14 months beyond the 30-day criteria, but six of the seven were over six months late. The IMPEP reviewer discussed this issue with the program manager and staff. They attributed the cause of the late inspection reports to a lack of punctuality by an inspector coupled with, until recently, the lack of close management oversight. The program manager told the reviewer that the recently-instituted management tracking system will address the timeliness issue and give the manager information to track when reports are due. The IMPEP reviewer observed that several factors caused the reports to be issued late: (1) until recently, no formal tracking system, (2) lack of availability of staff and management (staff effort on promulgation of regulations during Summer 1996 and significant leave during early Fall 1996), (3) lack of staff and management attention to the problem, and (4) no formal policy on timeliness of issuing inspection results.

The State's difficulty in issuing inspection findings to the licensee in a timely manner is significant. Delays in issuing inspection reports impairs the effectiveness of getting prompt corrective action by the licensee to any violations. Some of the findings on the overdue reports had safety

significance, both individually and as a group. 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, as was seen in one licensee's response to the inspection findings.

The State reported in its response to the questionnaire that 30 requests for reciprocity were received during the review period, of which 14 were from industrial radiographers, well-loggers, and mobile nuclear medicine licensees, and 16 were from portable gauge users and other licensees with an inspection frequency of more than 3 years. The State did not conduct any inspections of reciprocity licensees during the review period. The staff and program manager said that the short lead time on reciprocity requests and the distance involved in travel to the site usually prohibit inspections of reciprocity licensees.

In its response to the questionnaire, the State reported conducting one field inspection on a non-reciprocity industrial radiography licensee, and State staff told the IMPEP reviewer that they may have also conducted another radiography field inspection not identified in the questionnaire. The staff also reported efforts to conduct another field inspection of a radiographer that was cancelled because of poor weather. For comparison, the State listed four industrial radiography companies in its list of licensees, one of which is a new licensee. When possible, the State attempts to conduct field inspections of radiographers, but has had limited success in doing so.

In summary on this indicator, the State program had inspection frequencies at, or more frequent than, NRC's inspection frequencies. During the review period, the North Dakota program experienced a problem with overdue core inspections, but the program had corrected that problem by the time of the review. Similarly, the program had conducted a number of initial inspections late during the review period, but the overdue initial inspections had been completed by the time of the review. Finally, the State experienced serious delays in issuing inspection findings to licensees.

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

Recommendations:

- The review team recommends that the State adopt a written timeliness goal for issuance of inspection findings to the licensee.
- The review team recommends that State management and staff devote increased attention to issuing inspection results or notice in a timely manner (30 days).
- The review team recommends that the State monitor the timeliness of issuing inspection findings to licensees, as experience is gained with the new management tracking system. Within the next year, the State should perform a systematic assessment of use of the tracking system, and decide whether it is effective in tracking assignments and prompting staff and management to issue inspection findings.
- The review team recommends that, over the next year, the State assess whether initial inspections have been performed within 6-months of license issuance or within the provisions of IMC 2800, and whether the State's method for scheduling initial inspections has worked adequately.

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 regarding this indicator, interviewed NDDH management and staff, and considered any possible workload backlogs.

The Division of Environmental Engineering organization chart shows that the Radiation and Asbestos Control program was staffed with one program manager and seven staff at the time of the review. Within that group, an environmental scientist and an environmental engineer comprise the radioactive materials control program staff. The other staff positions cover radon, machine-produced radiation, and asbestos control. The two radiation control program staff members are full-time positions, with few outside (non-program) duties. In response to the questionnaire, the State reported that the radiation control program manager spends about 57 percent of his effort on radiation-specific tasks, including machine-produced radiation tasks (the other 43 percent of his effort being spent on special projects and asbestos). Upper division management spends between 5 and 10 percent of their time on supervision of the program. In response to the questionnaire, the State reported that 2.6 FTEs were assigned to the radioactive materials control program. None of the three positions (one manager and two staff) directly involved with the radiation control program was vacant at any time during the review period, nor were vacancies forecasted in any of the three positions in the near future. The State budgets in 2-year cycles. The current staffing level will remain in effect through July 1, 1997, according to the program manager. The program manager also told the review team that he does not know of any plans to reduce the staffing level for the radioactive materials control program in the next budget cycle, after July 1997.

The licensing and inspection functions of the program are integrated, and therefore, both radiation control program staff members 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 69 specific licensees are assigned, by licensee, to one of the two radioactive material staff. In discussions with the staff during inspection accompaniments, the IMPEP reviewer was told that the State does not have specific plans, at this time, to switch licenses between the two radioactive materials control program staff. While not a formal review team recommendation, the State should consider switching licensees between the two staff members, at some point in the future. Benefits of assigning particular licensees to a particular staff member, especially for inspections, may be outweighed by the benefits that result from inspection by a person who has no pre-conceived views about licensees' programs based on prior inspections. At this time, over-familiarity is not a problem.

The program manager explained that, when vacancies occur, the positions require Bachelor's degrees in a science or engineering field. 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 manager and both radioactive materials control program staff have at least a Bachelor's degree in science or engineering.

The review team reviewed the training of all three personnel involved with the radioactive materials control program. According to information provided in the questionnaire, one staff member has attended all of the core training courses outlined in the [now-suspended] May 28, 1992, Policy Statement

(57 FR 22495). That is, he has attended the licensing, inspection procedures, industrial radiography, and medical courses. He has also attended the 5-week Health Physics and Radiation Protection course. The other staff member has attended all of the core training courses except for the licensing course. The program manager has attended the radiography and medical courses, but has not attended the inspection procedures or licensing courses. The program manager has also attended the 5-week Health Physics and Radiation Protection course. In addition to these courses, the program manager and staff have completed numerous other training courses and have attended job-specific technical conferences and meetings. Examples of training the program manager or staff attended during the review period include: Radionuclide NESHAPS, OSHA refresher, All Agreement States Meeting, CRCPD Annual Meeting, Health Physics Engineering, Nuclear Materials Events Database Event Reporting, and Health Physics Technology.

The program manager provided the review team an internal memorandum dated February 1, 1996, that he had written to the Division Director regarding the training schedule for program personnel. The State plans for one radioactive materials staff member to attend the licensing course in September, which will complete his core courses. In addition, the State plans for both staff members to complete an additional technical training course during the upcoming year involving teletherapy and brachytherapy. The plan also notes that the program manager's "long range training plans" include eventual attendance at the licensing class and inspection class, among others. Because of the program manager's plans to attend technical meetings in the coming year and because of his plans to prioritize more technical health physics training for himself, the review team concludes that it is unlikely that he will be able to attend the licensing and inspection courses this year. The review team suggests that the State follow-through on its plan to have the radioactive materials control program staff member complete the licensing course. The review team also suggests that the program manager attend the licensing course as soon as practical, because the program manager serves as the secondary reviewer for all licensing actions. The program manager should eventually complete the inspection procedures course, and the State plans include this. These training issues were also identified on the October 1994 visit (see Section 2.2).

The IMPEP reviewer discussed training with the program manager and both staff members. The program manager was knowledgeable and had good documentation of the training that each individual has completed. 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 review team learned that approval for out-of-State travel can be an impediment to training, and limits the amount of training that can be taken. The February 1, 1996, training memorandum also implies that out-of-State travel should be minimized. The review team notes that because of the highly-specialized nature of training involving health physics and regulation of radioactive materials, out-of-State travel is unavoidable. The review team suggests that out-of-State travel considerations should not curtail necessary training for program personnel.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota'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 for 11 licenses and interviewed the two radioactive materials control program staff. 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 of safety evaluation reports, product certification or other supporting documents, 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 both license reviewers. The cross-section sampling included 11 licenses and included the following types: academic broad scope, medical-institution and medical-mobile, industrial radiography, well-logging sources and well-logging tracers, research and development, and portable gauges. Licensing actions included two new licenses, two terminations, and 16 amendments. 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 able to be inspected. The licensees' compliance histories were taken into account when reviewing renewal applications. The State's licensing guides were based upon NRC Regulatory Guides, but had been revised and updated for use by North Dakota licensees. The administrative policies had been rewritten during the review period. 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. The Division Director, or alternatively the Assistant Division Director, reviews and signs all licenses. No potentially-significant health and safety issues were identified.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota'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 the data base information for 8 materials inspections conducted during the review period. The casework included both of the State's materials inspectors and covered a sampling of different license types as follows: industrial radiography, broad scope university, nuclear medicine, laboratory use, well logging, portable gauge, and level 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 North Dakota program on this indicator. For instance, the IMPEP reviewer saw examples where inspectors included photographs of licensee operations in the inspection files. This

practice is not widely used by NRC Regions and other Agreement States. The photographs help supervisors and future inspectors have a visual indication of licensee facilities, equipment, and operations. This novel inspection practice is to be commended. Likewise, the State has inspection field notes available on computer, which helps with inspection documentation. Another strength is that the program manager conducted numerous inspection accompaniments during the review period, 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 licensee conditions. Finally, the State was able to conduct a number of joint inspections, where the two staff members (sometimes joined by the program manager) conducted inspections together. Having two different inspectors review a particular licensee's operations may lead to more thorough inspections.

The 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, and broad scope academic. The inspection field notes provide documentation of scope of the licensee's program; 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.

In general, the inspection reports demonstrated that the State inspectors were examining appropriate radiation health and safety issues at licensees' facilities. Inspectors performed independent measurements on seven of the eight cases reviewed. Inspectors' written comments in the field notes indicate that they discussed safety issues with licensee personnel. Some of the field notes 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. One inspector said that he sometimes asks the licensee to demonstrate licensed activities, which is a good inspection technique. The inspectors consistently examined and, when appropriate, closed-out previous violations. Also, because the radioactive materials control program staff 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 eight inspection cases, the IMPEP reviewer found a number of minor issues, that were discussed directly with the State staff. Examples included: no independent measurements in one case, frequent absence of interviews with licensee ancillary personnel, in one case not conducting the exit meeting with high-level licensee managers, lack of closure documented in the field notes on safety-significant inspection issues, and general documentation concerns. Most of these issues were resolved by asking the State inspectors to explain their comments on the inspection field notes, or to provide more details. On items that were not resolved, individual recommendations were made to the inspectors by the review team. 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 January 10-11, 1996. Both of the North Dakota inspectors were accompanied during the inspection of a hospital nuclear medicine/therapy program. One of the inspectors was also accompanied on a portable moisture

density gauge inspection and the other inspector was accompanied to an industrial radiography facility. During the accompaniments, the North Dakota inspectors demonstrated appropriate inspection techniques and knowledge of the regulations and licenses. 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 both staff members (i.e., inspectors/license reviewers) were accompanied by the program manager during the review period. The questionnaire and interviews with the staff indicate that the program manager conducted accompaniments with staff to 13 separate licensees between September 1993 and December 1995. The program manager had accompanied one particular inspector individually on four inspections, and he had accompanied both inspectors together on nine inspections. The inspectors reported receiving feedback from the supervisor on their performance during the accompaniments. In response to the questionnaire, the State reported that "supervisory accompaniments take place approximately every six months." The review team saw evidence 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 range GM tubes and pancake probes, micro R meters, higher-range instruments, instrumentation for alpha detection, pocket dosimeters, an audible dosimeter, and a multichannel analyzer. 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. Program staff explained that instruments are calibrated at least on an annual basis.

The review team found that the State is performing both announced and unannounced routine inspections of materials licensees. Of the eight inspection cases reviewed by the review team, five were announced to the licensee before the inspection. Several of the announced inspections had notes indicating that they were announced either one or two days in advance of the inspection. State staff reported that they announce about half of the inspections in advance to the licensees, sometimes on the day of, or the afternoon before, the inspections. The staff indicated that this is done for efficiency, to make sure that licensee personnel are present. One of the eight cases reviewed was a special inspection, to examine a medical licensee's problem involving no permanent Radiation Safety Officer or authorized user. That special inspection was not announced.

The review team examined whether inspection field notes were being signed by the inspectors, and reviewed and signed by the program manager. Of 20 inspection reports selected for detailed review or spot-check by the review team, 3 had not been signed by the inspector. In those cases, either the inspector signature line was blank, or the computer-generated field notes did not include a line for the inspector's signature. This is not indicative of a serious problem, but the review team suggests that inspectors sign all final versions of the inspection field notes or that management adopt a policy that inspectors need not sign the field notes.

Of the same 20 inspection reports, 9 had not been signed by the program manager as being reviewed. In response to the questionnaire, the State said, "All inspection reports are reviewed and signed by the manager of the

Radiation Control Program." In discussions with the program manager, he was not aware of the cases where there was no supervisory signature on the field notes. In discussions with the inspectors, they were also not aware that the field notes had not been signed by the supervisor. In many cases, the inspectors could recall discussing specifics of the field notes with the program manager, indicating that they had been reviewed. Also, all enforcement letters (including letters with minor violations) are signed-out to the licensee at the Division Director level, so they pass through two more levels of management review. The Division Director was a past manager of the radiation control program, so he performs a detailed review, according to the current program manager. The multiple levels of management review mitigate the issue of supervisory signatures on the field notes, but the review team suggests that this is an area needing more attention by the State. The review team suggests that the State devote more attention to supervisory sign-off on inspection field notes, to indicate supervisory review. The program manager should sign all final field notes or the State should adopt a policy that the Division Director's signature on the letter to the licensee constitutes supervisory approval.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota'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 regarding this indicator and reviewed the casework, and license files as appropriate, of five incidents and two allegations. In addition, the review team interviewed the radioactive materials supervisor and the health physicists assigned to each response.

Responsibility for initial response and follow-up actions to materials incidents and allegations rests with the radioactive materials section. Written procedures require the prompt response by the section staff to each incident or allegation, with no additional specific guidance provided by the procedures. Because of the size of the program, each incoming notification is discussed with both health physicists and the supervisor. If the response included an on-site inspection, this was usually completed by two, or sometimes all three, staff. When a follow-up was completed via telephone or correspondence, it was assigned to the individual staff member responsible for that institution's routine licensing and compliance. Review of the files indicated that this approach provided effective response actions and an appropriate response time.

The review team examined the State's response to the four events that were identified as most significant in the IMPEP questionnaire, the State's incident and allegation file, and the appropriate license files. Events reviewed included two lost well-logging sources and a lost generally-licensed static meter. The incident file included three annual overexposures at two institutions which were determined to have been caused primarily by medical fluoroscopy. 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. Radioactive materials control program staff were dispatched to the sites when appropriate. The State took suitable corrective

and enforcement actions and followed the progress of the investigation through close-out.

Allegations were responded to promptly with appropriate investigations and follow-up actions. In one allegation the identity of the allegeder was inadvertently released to the licensee. Although the individual expressed concern, the individual did not wish to proceed with additional action regarding this issue. The State told the review team that they do not have written procedures regarding protecting allegeders' identities, except for cases that go the State's Attorney General.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota'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. North Dakota has no agreement to regulate uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Given the State's 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 in the response to the questionnaire that there were no changes to legislation that affect the radiation control program, the review team discussed both the radiation control act and the administrative act with the staff. The Department of Health is designated as the State radiation protection agency in the North Dakota Century Code, Chapter 23-20. The Code grants the Department of Health the authority to promulgate rules and regulations to be followed in the administration of a radiation protection program.

4.1.2 Status and Compatibility of Regulations

North Dakota's final equivalent rules and amendments to the following rules became effective in July 1995: "Licensing and Radiation Safety Requirement for Irradiators," 10 CFR Part 36; "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.

The State has not 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. North Dakota and other Agreement States are expected to have that equivalent rule effective on the same date.
- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective June 30, 1995.
- "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 Part 20 and 35 amendments (60 FR 50248) 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 two different 30-day comment periods and in a public hearing. According to program management, the 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, program management explained that they would begin the process of preparing draft revisions to the regulations in late 1996 for new regulations due in 1998. The State's formal regulation promulgation process takes approximately

9-10 months. The State is aware of the importance of maintaining compatible regulations and the State plans to make every effort to maintain compatibility.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota'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 North Dakota Governor Edward T. Schafer to Richard L. Bangart, Director, Office of State Programs, on September 25, 1995, to relinquish its SS&D authority. The State did not perform SS&D evaluations in the past, except for two customized evaluations in 1983, and believes it is not likely that any devices containing radioactive material will be manufactured in the near future. In addition, such evaluations require large personnel resource requirements that are not within the scope of the North Dakota program. Based on the Governor's request, NRC assumed SS&D authority on June 1, 1996. The State has not performed any evaluations during the period covered by this review.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of low-level radioactive waste as a separate category. Those States with existing agreements prior to 1981 were determined to have continued low-level radioactive waste disposal authority without the need of an amendment. Although North Dakota has low-level radioactive waste disposal authority, NRC has not required the State to have a program for licensing a low-level radioactive waste disposal facility until such time as the State has been designated as a host State for a low-level radioactive waste disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a low-level radioactive waste disposal facility, it is expected to put in place a regulatory program which will meet the criteria for an adequate and compatible low-level radioactive waste disposal program. There are no plans for a low-level radioactive waste disposal facility in North Dakota. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Section 3 above, the review team found the State's performance with respect to four of the five common performance indicators to be fully satisfactory. On the Status of Materials Inspection Program indicator, the review team found the State's performance to be satisfactory with recommendations for improvement. As noted in Section 4 above, the review team found the State's performance on the only applicable non-common performance indicator to be satisfactory. The MRB concurred in the team's individual and overall recommendations and found that the North Dakota program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

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

1. The review team recommends that the State adopt a written timeliness goal for issuance of inspection findings to the licensee. (Section 3.1)
2. The review team recommends that State management and staff devote increased attention to issuing inspection results in a timely manner (30 days). (Section 3.1)
3. The review team recommends that the State monitor the timeliness of issuing inspection findings to licensees, as experience is gained with the new management tracking system. Within the next year, the State should perform a systematic assessment of the tracking system, and decide whether it is effective in tracking assignments and prompting staff and management to issue inspection findings. (Section 3.1)
4. The review team recommends that, over the next year, the State should assess whether initial inspections have been performed within 6 months of license issuance or within the provisions of IMC 2800, and whether the State's method for scheduling initial inspections has worked adequately. (Section 3.1)
5. The review team suggests that the State follow-through on its plan to have the radioactive material control program staff member complete the licensing course. (Section 3.2)
6. The review team suggests that the program manager attend the licensing course as soon as practical. The program manager should also eventually complete the inspection procedures course. (Section 3.2)
7. The review team suggests that out-of-State travel considerations should not curtail necessary training for program personnel. (Section 3.2)
8. The review team suggests that inspectors sign all final versions of the inspection field notes or that management adopt a policy that inspectors need not sign the field notes. (Section 3.4)
9. The review team suggests that the State devote more attention to supervisory sign-off on inspection field notes, to indicate supervisory review. The program manager should sign all final field notes or the State should adopt a policy that the Division Director's signature on the letter to the licensee constitutes supervisory approval. (Section 3.4)

LIST OF APPENDICES AND ATTACHMENTS

- Appendix A IMPEP Review Team Members
- Appendix B North Dakota Department of Health, Division of Environmental
Engineering Organization Charts
- Appendix C North Dakota's Questionnaire Response
- Appendix D License File Reviews
- Appendix E Inspection File Reviews
- Appendix F Incident File Reviews
- Attachment 1 North Dakota's Response to Review Findings

APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Scott Moore, NMSS/IMNS	On-Site Team Leader Status of Materials Inspection Program Technical Staffing and Training Technical Quality of Inspections
Charles Mattson, Colorado	Technical Quality of Licensing Actions Response to Incidents and Allegations
James Lynch, RIII	Advance Team Leader Inspection Accompaniments
Kathleen Schneider, OSP	Legislation and Regulations (from NRC Headquarters)

APPENDIX B
NORTH DAKOTA DEPARTMENT OF HEALTH
AND
DIVISION OF ENVIRONMENTAL ENGINEERING
ORGANIZATION CHARTS

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM QUESTIONNAIRE

ATTACHMENT 1

NORTH DAKOTA'S RESPONSE TO REVIEW FINDINGS