

DATED: JULY 13, 1999

SIGNED BY: FRANK J. MIRAGLIA

Mr. Murray G. Sagsveen
State Health Officer
North Dakota Department of Health
Capitol Building
600 East Boulevard
Bismarck, ND 58505-0200

Dear Mr. Sagsveen:

On June 30, 1999, 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 MRB found the North Dakota program adequate to protect public health and safety and compatible with NRC's program.

Section 5.0, page 13, of the enclosed final report presents the IMPEP team's recommendations. We received your June 7, 1999 letter which described your actions taken in response to the recommendations in the draft report. We request no additional information.

Based on the results of the current IMPEP review, a follow-up IMPEP review focusing on the common performance indicator, Status of Materials Inspection Program, will be completed in one year and the next full review will be in approximately 4 years.

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 our agencies continuing to work cooperatively in the future.

Sincerely, */RA/*

Frank J. Miraglia, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Dana K. Mount, Director
Division of Environmental Engineering

Roland G. Fletcher, Organization of
Agreement States Liaison to the MRB

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bcc: Chairman Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH DAKOTA AGREEMENT STATE PROGRAM

April 13-16, 1999

FINAL REPORT

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 April 13-16, 1999, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of South Carolina. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 25, 1998, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period February 10, 1996 to April 16, 1999 were discussed with North Dakota management on April 16, 1999.

A draft of this report was issued to North Dakota for factual comment on May 10, 1999. The State responded in a letter dated June 7, 1999. The Management Review Board (MRB) met on June 30, 1999, to consider the proposed final report. The MRB found the North Dakota radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The North Dakota Agreement State program is administered by the Radiation and Asbestos Control Program (RCP), located in the Department of Health's Division of Environmental Engineering. Organization charts for the Department of Health and the Division of Environmental Engineering are included as Appendix B. The North Dakota program regulates approximately 68 specific licenses authorizing agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Dakota.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on January 28, 1999. The State provided a response to the questionnaire on March 16, 1999. A copy of the questionnaire response is included as Appendix F 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 RCP's licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of both North Dakota 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 applicable non-common performance indicator and made a preliminary assessment of the RCP's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP 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 performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 9, 1996, four recommendations and five suggestions were made and the results transmitted to Jon R. Rice, State Health Officer, on June 11, 1996. The review team's evaluation of the current status of the recommendations is as follows:

1. The review team recommends that the State adopt a written timeliness goal for issuance of inspection findings to the licensee.

Current Status: The State has adopted written timeliness goals for issuance of inspection findings that are consistent with NRC Inspection Manual Chapter (IMC) 0610. This is contained in the RCP's Administrative Procedures Manual. This recommendation is closed.

2. The review team recommends that State management and staff devote increased attention to issuing inspection results in a timely manner.

Current Status: Although State management and staff devoted increased attention to issuing inspection results in a timely manner, the State did not successfully meet the 30-day time frame over the course of the review period. Since October 1998, however all inspection results have been transmitted to licensees within 30 days. This recommendation is closed. However, a new recommendation is identified in Section 3.1, for the State to continue efforts to transmit inspection findings within 30 days and to promptly evaluate licensee responses to inspection findings.

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.

Current Status: The State did monitor the timeliness of issuing inspection findings and did systematically assess the tracking system. Based on this assessment, RCP management re-emphasized the importance of inspection report timeliness with the inspection staff in October 1998, and began to closely monitor the status of inspection findings following inspections. Each of the 10 inspections (core and non-core), performed between November 1998 and March 1999, resulted in letters of noncompliance being issued less than 30 days following the inspection. This recommendation is closed.

4. The review team recommends that, over the next year, the State should assess whether initial inspections have been performed within six months of licensee issuance or within the provisions of IMC 2800, and whether the State's method for scheduling initial inspections has worked adequately.

Current Status: The State has assessed whether initial inspections have been performed within six months of licensee issuance. The RCP did this not only over the year following the 1996 IMPEP review but on an ongoing basis. Assessment of the tracking system has indicated that the State's method for "documenting" the next scheduled initial inspection has worked adequately, however, deficiencies in conducting initial inspections in a timely

manner resulted from not following the inspection schedule. This recommendation is closed, as the evaluation was performed. A new recommendation regarding initial inspection timeliness is discussed in Section 3.1.

The five suggestions concerned: (1) licensing training for a staff member; (2) licensing and inspection training for the Program Manager; (3) impediments to training needs from curtailment of out-of-state travel; (4) inspection field notes not signed by inspectors; and (5) inspection field notes not signed by supervisors. The review team determined that the State considered the suggestions and took appropriate actions.

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 Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The review team focused on four factors in evaluating this indicator: inspection frequency, overdue inspections, initial inspection of new licensees, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on RCP's questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection computer printouts, the examination of completed inspection casework, and interviews with the staff.

The review team's evaluation of the State's inspection priorities revealed that inspection frequencies for each type of license were the same as those listed in IMC 2800, with only one exception. The State assigns a Priority 4 frequency for licensees authorized for portable nuclear gauging devices. This is more restrictive than the Priority 5 designation in IMC 2800. The review team also noted that the State established written procedures to extend or reduce the next inspection interval based upon licensee performance.

In their response to the questionnaire, the State indicated that during the review period, 22 inspections were overdue by more than 25% of the specified frequency at the time they were performed. During the review period, the RCP performed 60 inspections: 38 routine inspections, 9 initial inspections, 7 reciprocity inspections, and 6 special inspections. The review team identified that 31 of the 60 inspections performed were core licenses. Of the 31 core license inspections conducted during this review period, 20 were overdue on the date of the inspection. Delays ranged from 1 to 12 months late. The review team also verified that, as of the date of this review, two inspections remained overdue past the 25% window. These inspections were approximately four months and seven months overdue. These inspections were completed on May 5 and May 18, 1999. Further, the review team noted that 11 additional inspections (four core and seven non-core) were past the scheduled inspection due date, but not yet past the 25% overdue window.

The staff uses a computer database program to track inspection due dates. This data is provided to inspection staff and management to monitor upcoming inspections. Interviews with the staff indicated that inspection schedules are not routinely scheduled based on their priority. All types of licenses (core and non-core) are tracked chronologically based on "inspection due

date” and are scheduled based on their percent overdue status and geographic location within the State.

With respect to initial inspections of new licenses, the review team evaluated those licenses issued since the last review and used this information to determine the appropriate initial inspection due date based on IMC 2800 guidance. Of the eight new licenses issued during the review period, six of the initial inspections were not conducted within the six-month or one-year time frame as appropriate. These overdue initial inspections are included in the total number of overdue core inspections noted above. Delays ranged from 3 to 12 months late. No new licenses have been issued since April 1997.

The review team discussed the significant number of overdue core inspections performed during this review period with the Program Manager. The Program Manager discussed several contributing causes including: (1) the departure of one of RCP’s two materials inspector/license reviewers in July 1997; (2) the Program Manager’s involvement with other significant issues during the review period, including his response to a natural disaster during 1997 (floods in Grand Forks, North Dakota), and his involvement during 1998 with the litigation of an asbestos case, another program area under his direct supervision; (3) the staff’s work on the formulation of regulations to ensure compatibility during 1997 and 1998; and (4) the extended absence of one of the program’s inspector/license reviewers for several weeks during early 1997 and in mid-1998 for personal reasons. In addition, the Program Manager noted that although the RCP was able to successfully hire a new inspector in November 1997, this individual is still in the training process and does not yet perform inspections independently. In summary, the Program Manager stated that RCP continues to make progress in eliminating the number of overdue inspections, and with his increased oversight of the program it is expected that the timeliness of inspection activities will be performed in accordance with State procedures. The review team recommends that RCP management devote additional attention to a “pro-active” review of the current inspection tracking systems, and adjust staff priorities accordingly to ensure core licensees are inspected at the required intervals.

The review team also evaluated the status of reciprocity inspections. During the previous IMPEP review in 1996, the review team noted that no reciprocity inspections had been conducted. During the current review period, 40 requests for reciprocity were filed with the program. The majority of the reciprocity requests were for Priority 3 and 4 licensees, which include portable gauge and service licensees. The review team noted a considerable improvement in the number of reciprocity inspections performed by the RCP in 1998. Five of the 15 licensees granted reciprocity were inspected. However, the State did not meet its goals for Priority 1 or 2 licensees during 1998. Three Priority 1 reciprocity licenses were granted with one licensee inspected. One Priority 2 reciprocity license was granted but the licensee was not inspected. While the State improved in the number of reciprocity inspections conducted over the review period, they are not meeting the inspection frequencies outlined in NRC’s IMC 1220. The State indicated that it is difficult to conduct inspections of reciprocity licensees due to the short lead time of when work will be performed in the State, and the strain on resources to support the travel to remote field site locations on short notice. The review team recommends that RCP continue their efforts to complete inspections of high priority reciprocity licensees in accordance with IMC 1220.

The RCP has a written policy that establishes inspection report timeliness goals consistent with IMC 0610. RCP’s goal is to dispatch written findings of inspections to licensees within 30 days of completing an inspection. Initial communication of inspection findings is provided at the conclusion of each inspection through an exit briefing with licensee management, however, as

indicated in the questionnaire, written inspection findings were not always communicated to licensees in a timely manner. Of the 10 core licensee inspection files evaluated by the team, six letters of noncompliance were issued greater than 30 days following the exit briefing with the licensee. Delays ranged from 36 to 102 days. Upon review of the State's questionnaire response, the review team determined that, of the 31 core inspections performed during the review period, 10 of the inspection letters were issued greater than 30 days following exit briefings with licensees.

The review team also noted that the State's review of licensee responses to letters of noncompliance were not always performed in a timely manner. The review team identified several instances when licensee responses were not evaluated and/or dispositioned by RCP for several months. The review team considered the issue of report timeliness and licensee response reviews to be of particular concern since it was also identified as an area of improvement during the State's previous IMPEP review. The review team discussed this issue with the Program Manager and was informed that increased management attention to this area was implemented in October 1998. The Program Manager stated that he had re-emphasized the importance of inspection report timeliness with the inspection staff and began to closely monitor the status of inspection findings following each inspection. Management stated that increased oversight and discussions with the inspection staff appear to have corrected the problem. Upon further review of the State's inspection tracking system data, the team did note that each of the 10 inspections performed between November 1998 and March 1999, resulted in letters of noncompliance being issued in less than 30 days following the inspection. The review team recommends that RCP management continue to provide additional oversight to ensure inspection findings (letters of noncompliance) are communicated to licensees in a timely manner, and that licensee responses are evaluated promptly upon their receipt by RCP.

Based on the IMPEP evaluation criteria, the review team initially recommended that North Dakota's performance with respect to the indicator, Status of Materials Inspection Program, be found unsatisfactory. Due to the State's actions involving the status of the materials inspections program (as detailed in their June 7, 1999 response to the draft IMPEP report), the team and the MRB agreed that North Dakota's performance with respect to this indicator be found satisfactory with recommendations for improvement.

3.2 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation and inspection field notes, and interviewed inspectors for 10 materials inspections conducted during the review period. The casework included both of the State's two materials license inspectors, and covered inspections of various types including medical institutions, industrial radiography, well logging, academic broad scope, mobile nuclear medicine, and reciprocity. Appendix C lists the inspection casework evaluated for completeness and adequacy, with case-specific comments.

North Dakota's inspection procedures are consistent with NRC procedures. Inspections were generally unannounced; however, RCP staff commented that inspectors may contact the licensee either the day before, or the morning of, an inspection to ensure that appropriate licensee personnel are available prior to dispatching an inspector to the facility. Inspection files were found to be complete and in good order. Field notes have been developed to cover all types of inspections that are conducted by the RCP. The information contained in the field notes was consistent with the applicable NRC inspection procedures. Based on casework evaluations,

the review team noted that routine inspections covered all aspects of licensees' radiation safety programs. Team inspections were performed when appropriate and for training purposes.

As noted in the questionnaire, the State has a variety of portable instruments available for routine confirmatory surveys and for use in incident response. All instruments used for inspections and those which are considered essential for incident response are calibrated semi-annually. RCP staff perform calibrations using a Gammatron calibrator containing a nominal 30 millicurie cesium-137 sealed source and employing appropriate calibration methods for each type of instrument.

RCP's administrative procedures state that approximately 10 percent of all field inspections include the Program Manager, Assistant Division Director, or Division Director accompanying the inspector. Management accompanied inspectors on 5 of the 60 inspections performed during the review period, including each of the materials inspectors at least once each year. Interviews of RCP's inspectors disclosed that following each accompaniment, supervisors provided feedback to inspectors regarding their performance.

During the weeks of January 19-22 and February 22-25, 1999, a review team member performed accompaniments of both RCP's inspectors at licensed facilities (See Appendix C). The five accompaniments included one medical license, one portable gauge license, one self-shielded irradiator license, one industrial radiography license, and one well logging license. Both RCP's inspectors were involved in all of the inspections. The more senior inspector was the lead inspector for four of the five inspections. For the portable gauge license, the other inspector lead the inspection.

During the accompaniments, both inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were well prepared and thorough in their review of licensee programs but could benefit from additional training in brachytherapy technology. Although the brachytherapy inspection was adequate, the reviewer observed that the inspectors were not well acquainted with brachytherapy treatment planning and the differences in dose delivery systems for temporary versus permanent implant procedures. Familiarity with this technology is important when reviewing written directives so that the inspector can compare the final treatment planning data and dose delivered to the patient to the authorized user's prescription. Overall, the reviewer observed that both inspectors utilized good health physics practices and their interviews with licensee personnel were performed in an effective manner. The inspections were adequate to assess radiological health and safety at the licensed facilities.

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.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator and interviewed the Program Manager and staff. The RCP is staffed with one Program Manager and two staff. An environmental scientist and an environmental engineer, both full-time positions, comprise the RCP technical staff. Both of the technical staff members perform duties in licensing, inspection, and event response. In response to the questionnaire, the State reported that the Program Manager spends about 57 percent of his effort on the

program. Division managers spend between 5 and 10 percent of their time on supervision of the program.

There was one vacancy during the review period. The environmental engineer position was vacant for about three months in 1997 before it was filled by the current staff member. There were no other vacancies within the program during the review period. The State budgets in two-year cycles. The current staffing level will remain in effect through June 30, 1999. The same level of staffing is expected for the next budget cycle.

The Program Manager explained that technical staff positions require a Bachelor's degree in a science or engineering field. The Program Manager and both technical staff members have a Bachelor's degree in science or engineering.

Based on the areas of improvement and contributing factors noted in Section 3.1, and discussions with State management regarding the small size of the RCP, and its vulnerability to disruptions during staff losses and/or outside events, the review team recommends that management perform an in-depth review of the RCP's current and future anticipated activities and obligations to ensure budgeted staffing levels are adequate to fulfill the responsibilities of the program.

The review team evaluated the training of the three personnel involved with the RCP. None have attended the Teletherapy and Brachytherapy Course (H-313), which is a core course for license reviewers and inspectors, but one staff member is scheduled to attend, and is confirmed for, the course offering in August 1999. North Dakota currently has five conventional brachytherapy facilities licensed and a high dose-rate afterloader (HDR) application in house. During a brachytherapy inspection where State staff was accompanied by a team member (as discussed in Section 3.2), State inspectors performed adequately, however, the staff could benefit from training in this area. The review team recommends that the State provide training to technical personnel, either by formal course work or equivalent, in the area of brachytherapy.

The newest staff member has completed the following courses since his employment in November 1997: (1) Selected Topics in Radiological Engineering (a general overview of health physics through the nuclear engineering program at Louisiana State University); (2) NRC courses on Transportation of Radioactive Materials, Licensing, Inspection Procedures, and Diagnostic and Therapeutic Nuclear Medicine; (3) Hazardous Waste Operations and Emergency Response Refresher Course; (4) Troxler Moisture Density Gauge Course; and (5) Laboratory Use of Radioactive Material, a State-sponsored short course. He is scheduled to attend the Well-Logging and Industrial Radiography Courses in 1999, the Five-Week Health Physics Course in the year 2000, and the Two-Week Health Physics Technology Course in 2001.

In addition to the courses recommended by NRC, the Program Manager and staff have completed numerous other training courses and have attended job-specific technical conferences and meetings, such as Become a Better Communicator, Hazardous Waste Operations and Emergency Response Training Refresher, Safety Training (through the Health Department), Texas Industrial Radiographer Exam Proctor Training, All Agreement States Meeting, and the Conference of Radiation Control Program Directors (CRCPD) Annual Meeting.

The Program Manager is supportive of staff training and demonstrated a commitment to staff training during the review. The review team did not find any evidence of out-of-state travel being

an impediment to staff receiving necessary training. As discussed above, the newest staff member attended five courses since his employment, with two additional core courses scheduled for 1999, and the five-week course scheduled for the year 2000.

In summary, the review team found that although the program has an adequate level of staffing it is particularly vulnerable due to its size. The staff is qualified and knowledgeable of the regulations and the licensing and inspection guidance but could use additional training in brachytherapy technology. The RCP provides for staff training, both for core and specialized courses, and out-of-state travel has not been an impediment to receiving necessary training as it was in the past.

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.

3.4 Technical Quality of Licensing Actions

The review team examined the completed licenses and casework for 17 licensing actions, representing the work of three license reviewers and the Program Manager. The staff was interviewed to supply additional information regarding licensing decisions or file contents.

Licensing actions were evaluated for completeness, consistency, proper radionuclides and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. Casework was evaluated for adherence to good health physics practices, reference to appropriate regulations, supporting documents, peer or supervisory review, and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

The licensing actions evaluated included the following types of licenses: academic broad scope; well logging; industrial radiography; mobile nuclear medicine; medical; laboratory use; and portable gauges. Licensing actions included two new licenses, seven amendments, six renewals, and two terminations. A list of these licenses with case-specific comments may be found in Appendix D. There were no licensee bankruptcy cases during this review period.

The review team noted that licensing actions are reviewed by the Program Manager. Each license is signed by the Division Director or his designee.

The review team found that the licensing actions were thorough, complete, consistent, and of high technical quality, with health and safety problems properly addressed. Tie-down conditions are backed by information contained in the file, and are inspectable. Deficiency letters clearly state regulatory positions, and identify deficiencies in licensees' documents. License files are complete and organized. Licensing checklists are used and maintained on file. Applicable guidance documents are complete, well organized, available to reviewers, and appear to be followed.

The review team noted that the license reviewers also work as inspectors. This allows the reviewers to utilize inspection findings to improve a license through either a licensing amendment or renewal.

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.

3.5 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, evaluated selected incidents reported for North Dakota in the "Nuclear Material Events Database (NMED)" against those contained in the North Dakota files, and evaluated the casework and supporting documentation for four material incidents. The team also evaluated the State's response to five allegations. No allegations were referred to the State by NRC during the review period. A list of the incident casework with comments is included in Appendix E.

The review team interviewed RCP management and staff to discuss the State's incident and allegation process, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center.

When notification of an incident or allegation is received, the Program Manager and staff meet to discuss the initial response and the need for an on-site investigation. The safety significance of the incident/allegation is evaluated to determine the type of response that North Dakota will take. The State's incident procedures include a section entitled "Activation of Radiation Control Program Staff." This section, modeled after another Agreement State's procedure, discusses the potential hazards and indicates safety considerations and response actions for various license categories.

Four incidents were selected for evaluation of the 15 incidents suitable for review by the team. Not evaluated were 11 alarms at a medical waste incinerator. The incidents evaluated were: (1) loss of control of iodine-125 seeds; (2) a radiography vehicle accident; (3) an unknown source found on roadside; and (4) a lost static eliminator.

The review team found that the State's responses to incidents and allegations were complete and comprehensive. Initial responses were prompt and well-coordinated. The level of effort was commensurate with the health and safety significance of the event. Inspectors were dispatched for on-site investigations when appropriate and the State took suitable enforcement action, when indicated. The review team found the documentation of the incidents and allegations to be consistent. The staff was familiar with the guidance contained in the "Handbook on Nuclear Event Reporting in the Agreement States."

North Dakota submits incident information electronically to NMED. Only three incidents met the criteria for reporting to the NMED system, of which two were reported. The third, a lost static eliminator, was not reported. RCP staff indicated that it was an oversight that the incident was not reported. The RCP manager did not, however, agree that the failure to enter the event in the NMED system was an oversight, but rather intentional since the RCP expected the licensee to eventually locate the source. Since the source was recovered four months later, it will not be reported to NMED. As detailed in their June 7, 1999 response to the draft IMPEP report, the RCP stated that in the future, they will immediately report all such occurrences and then update the NMED system, as appropriate, if and when the source is found.

During the review period, no allegations were reported to the State by the NRC. Five allegations were reported directly to the program. The review of the State's allegation files indicates that the State took prompt and appropriate action in response to the concerns raised. The review team noted that all documentation related to the investigation of allegations is withheld from public records. The State's allegation procedures declare that incoming allegations are to be handled on a case-by-case basis. Protection of an alleged's identity is provided for in Rule 509, North Dakota Rules of Evidence.

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 Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. North Dakota's Agreement does not cover a sealed source and device evaluation program or uranium recovery program, so only the first and third non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

North Dakota became an Agreement State in 1969. Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in the North Dakota Century Code Chapter 23-20. The Department of Health is designated as the State's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed since being found adequate during the previous review, and found that the State legislation is adequate.

4.1.2 Program Elements Required for Compatibility

The North Dakota Revised Radiological Health Rules, found in North Dakota Administrative Code Chapters 33-10-01 through 33-10-14, apply to all ionizing radiation, whether emitted from radionuclides or devices. North Dakota requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the State's rulemaking process and found that the process takes approximately nine months after preparation of a draft rule. Proposed rules are submitted to the State Health Council for consideration and approval to proceed with public comment. Public notice of proposed rule revisions is made and a 60-day public comment period, including a public hearing is conducted. Proposed rules are sent to NRC for a compatibility ruling. After resolution of comments and the Attorney General's approval, final draft rules are sent to the State Health Council for adoption. Final rules are sent to the NRC and to licensees. The State has the

authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated North Dakota's responses to the questionnaire and reviewed the status of regulations under the Commission's adequacy and compatibility policy. All regulations required to be adopted are currently in effect. Discussions with program staff indicated a good awareness of recently adopted rules.

The following regulations will become due in the future and are included here to assist the State in including them in future rulemakings or by adopting alternate generic legally binding requirements:

- "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.
- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective June 27, 1997.
- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.
- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.
- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.
- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendments (63 FR 37059) that became effective July 9, 1998.
- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32 and 39 amendments (63 FR 39477 and 45393) that became effective October 26, 1998.
- "Transfer for Disposal and Manifests; Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(c)(iii), provides that regulations required for compatibility issued prior to September 3, 1997, should be adopted by the State as expeditiously as possible, but no later than three years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on the IMPEP evaluation criteria, the review team recommends that North Dakota's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

Effective June 1, 1996, NRC reassumed regulatory authority for sealed source and device evaluations in North Dakota, in response to a request from the State to relinquish that authority. No sealed source or device evaluations were performed in North Dakota in the early part of the review period, prior to relinquishment. Accordingly, the review team did not evaluate this indicator.

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 LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although North Dakota has such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in North Dakota. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the MRB found North Dakota's performance to be satisfactory for five of the six performance indicators. The MRB found North Dakota's performance to be satisfactory with recommendations for improvement for the indicator, Status of Materials Inspection Program. Accordingly, the review team recommended and the MRB agreed that the North Dakota Agreement State Program be found adequate and compatible with NRC's program. A follow-up review focusing on the common performance indicator, Status of Materials Inspection Program, will take place in approximately one year.

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

RECOMMENDATIONS:

1. The review team recommends that RCP management devote additional attention to a "pro-active" review of the current inspection tracking systems, and adjust staff priorities accordingly to ensure core licensees are inspected at the required intervals. (Section 3.1)
2. The review team recommends that RCP continue their efforts to complete inspections of high priority reciprocity licensees in accordance with IMC 1220. (Section 3.1)
3. The review team recommends that RCP management continue to provide additional oversight to ensure inspection findings (letters of apparent noncompliance) are communicated to licensees in a timely manner, and that licensee responses are evaluated promptly upon their receipt by RCP. (Section 3.1)

4. The review team recommends that management perform an in-depth review of the RCP's current and future anticipated activities and obligations to ensure budgeted staffing levels are adequate to fulfill the responsibilities of the program. (Section 3.3)
5. The review team recommends that the State provide training to technical personnel, either by formal course work or equivalent, in the area of brachytherapy. (Section 3.3)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	North Dakota Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Attachment	North Dakota's Response to Draft IMPEP Report Dated June 7, 1999

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Response to Incidents and Allegations Legislation and Program Elements Required for Compatibility
Mark Shaffer, Region IV	Status of Materials Inspection Program Technical Quality of Inspections
James Peterson, South Carolina	Technical Quality of Licensing Actions
Torre Taylor, NMSS	Technical Staffing and Training Status of Materials Inspection Program

APPENDIX B

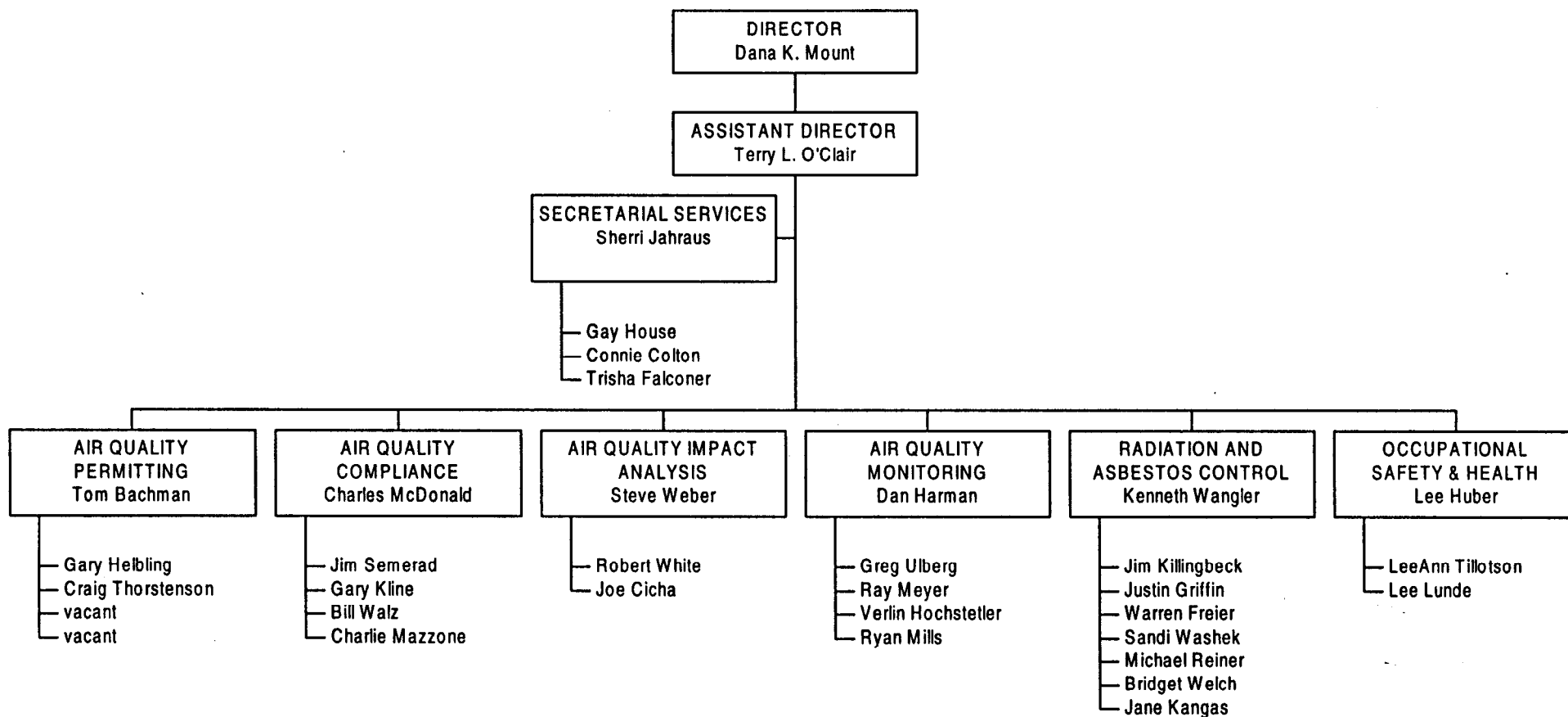
NORTH DAKOTA

DEPARTMENT OF HEALTH
and

DIVISION OF ENVIRONMENTAL ENGINEERING

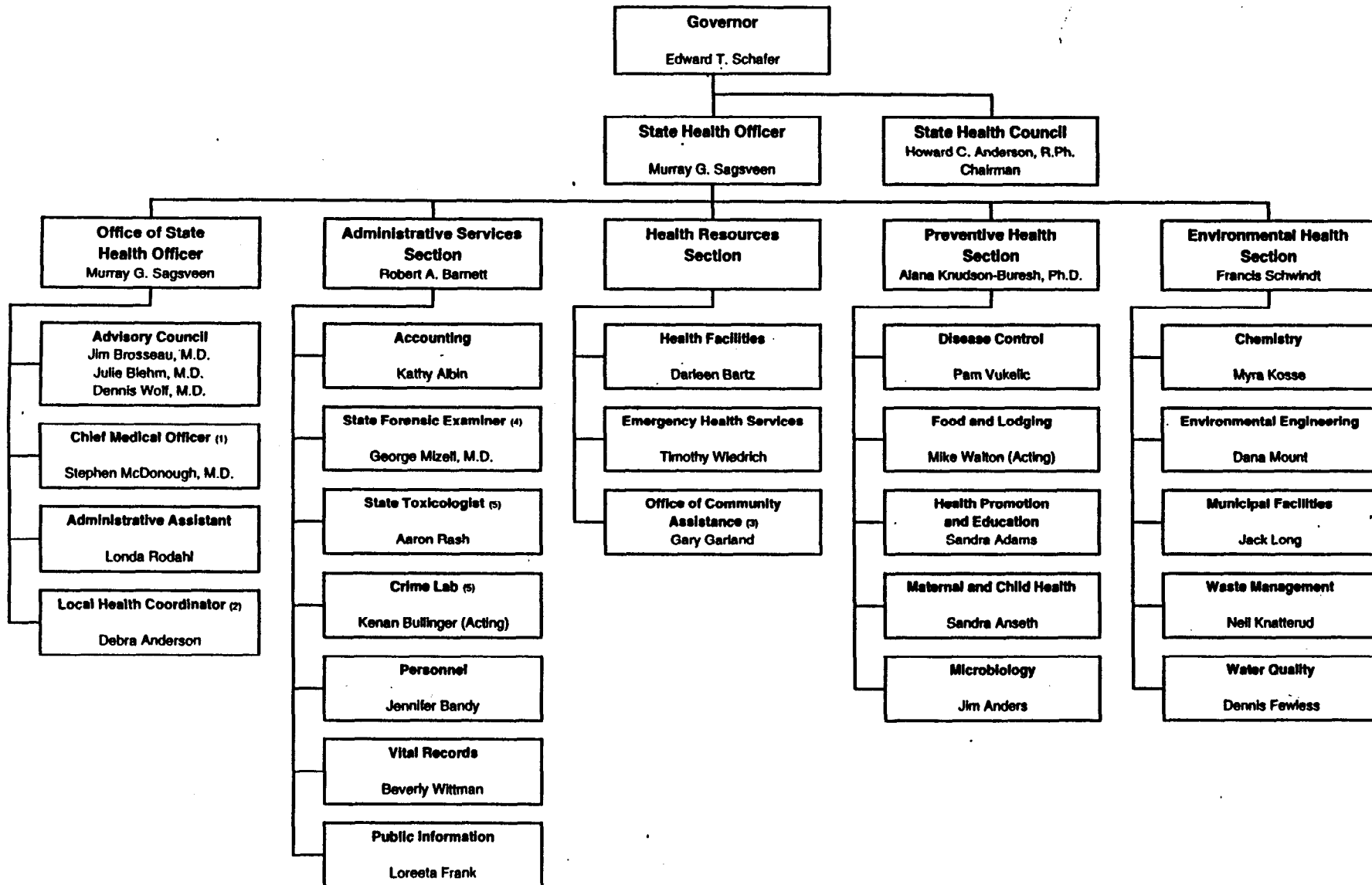
ORGANIZATION CHARTS

NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF ENVIRONMENTAL ENGINEERING



NORTH DAKOTA DEPARTMENT OF HEALTH

October 6, 1998



- (1) Coordination with local public health officers
- (2) Coordination with local public health administrators
- (3) Coordination with Center for Rural Health
- (4) Coordination with county coroners
- (5) Coordination with law enforcement



**NORTH DAKOTA
DEPARTMENT OF HEALTH**

600 E. Boulevard Avenue
Bismarck, ND 58505-0200

OFFICE OF
STATE HEALTH OFFICER
701-328-2372
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June 7, 1999

Paul H. Lohaus, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

99 JUN 11 PM 3:22

OSP

Dear Mr. Lohaus:

The North Dakota Department of Health (Department) has reviewed the U.S. Nuclear Regulatory Commission's (NRC) May 10, 1999 draft Integrated Materials Performance Evaluation Program (IMPEP) report of the Department's Radiation Control Program (RCP).

The following comments address the technical and clerical accuracy of the draft report:

- On page 4, third paragraph, line 8 reads in part, "of regulations to ensure compatibility during early 1998;..." The RCP staff actually began work on the regulation revisions in early 1997 and continued through August 1997. Work on the rule revision was then delayed until February 1998, at which time, work resumed and the rules were promulgated May 1, 1998. An appropriate correction may be to replace the word, "early" with "1997 and".
- On page 4, third paragraph, line 9 reads in part, "the program's inspector/license reviewers for several weeks during 1998 for personal reasons." The extended absences occurred in two separate periods, one in early 1997 and one in mid-1998. During both these periods, the staff member consumed large amounts of leave in relatively short periods of time. The specific correction could include adding the words, "early 1997 and again in mid" in front of "1998".
- On page 5, first paragraph, line 5, we suggest that the word, "written" be added between the words, "questionnaire," and "inspection" since verbal inspection findings were communicated to the licensees during the exit briefing.
- On page 5, first paragraph, beginning on line 6 states, "Of the 10 core licensee inspection files evaluated by the team, six letters of noncompliance were issued greater than 30 days following the exit briefing of the licensee." This would seem to indicate that 60% of the core licensee inspections were not responded to within 30 days. However, during the review, IMPEP inspectors indicated that these ten core licensee

inspection files were not selected randomly. Rather they were selected based on their delayed inspection status as indicated in the state's response to the questionnaire. A sentence should be added indicating that these ten core licensee inspection files were not randomly selected, but rather were selected based on an indication of other timeliness problem issues.

- On page 8, paragraph 1, line 5, the words, "Industrial Radiographer" should be added between the words, "Texas" and "Exam" for clarification purposes.
- On page 10, second paragraph, beginning on line 3, a statement is made that, "RCP staff indicated that it was an oversight that the incident was not reported." While this statement may be factually correct and that the RCP staff considered it an oversight, the RCP manager does not agree. The RCP manager indicated that at the time the source was lost, the licensee was instructed to continue searching his facility with continued follow-up by the RCP. The RCP manager indicated that, as he recalls, the event was purposely not entered into NMED until such time as the RCP was convinced the source was indeed lost rather than misplaced. A suggested correction would be to follow the above sentence in paragraph 2 with an additional sentence stating, "The RCP manager did not, however, agree that the failure to enter the event in the NMED system was an oversight, but rather intentional since the RCP expected the licensee to eventually locate the source."

This practice will no longer be followed by the RCP. The incident above occurred on June 19, 1997. Agreement States Letter SP-98-018 dated March 19, 1998 discusses using NMED reporting as a national method for the purpose of tracking and locating lost or stolen sources. In the future, the RCP will immediately report all such occurrences. The RCP will then update the NMED as appropriate if and when the source is found.

- On page 11, first paragraph, the first sentence contains the word, "Rules" twice. The second word, "Rules" should be replaced with the words, "North Dakota Administrative Code Chapters". The sentence would then read as follows, "The North Dakota Revised Radiological Health Rules, found in North Dakota Administrative Code Chapters 33-10-01..."
- On page D.3, in Appendix 3, File No. 13, under the "Location" field, the word "Hettinger" is misspelled as "Hattinger".

This concludes our comments to the technical and clerical accuracy of the report. The above comments represent only minor suggested changes. In the last sentence of page 1, the NRC states, "A response is requested from the State to all recommendations in the final report." Since it is not anticipated that significant changes will be made to the draft report recommendations in the final report, and in the interest of expediting the review process, we would also like to respond to the recommendations contained on page 13 of the draft report at this time. This would eliminate the need for the IMPEP review team to send a corrected report to the RCP for our response to recommendations. We request that

a corrected report and the following comments be concurrently submitted to the Management Review Board for their consideration.

The recommendations will be addressed in the order in which they appear. The recommendation will be repeated followed by the our comment.

1. **RECOMMENDATION:** The review team recommends that RCP management devote additional attention to a "pro-active" review of the current inspection tracking systems, and adjust staff priorities accordingly to ensure core licensees are inspected at the required intervals. (Section 3.1)

RESPONSE: The RCP management has already begun this process and will continue to do so. As was indicated by members of the IMPEP team during the review, the RCP's current tracking system is an excellent tool for this purpose. While attention had been paid to the tracking system during the current review period, RCP management will seek new ways to improve the timeliness of inspections. RCP management was aware of the 25% overdue criteria; however, was not aware that this was only applied to core inspections.

During this review period, RCP did not impose a superficial inspection priority over the existing inspection priority system for the purpose of focusing on core inspections. Core inspections represent licensees with inspection priorities of 1, 2, and 3. The interval between inspections for these licensees is 1 year, 2 years, and 3 years respectively.

As indicated in the IMPEP report, the RCP inspected licensees based on their scheduled time of inspection, percent of time overdue, and geographic location in the State relative to other inspections being conducted. This means that priority 4 and 5 inspections were scheduled along with priority 1, 2, and 3.

Higher inspection priority licensees, i.e.; priority 1, 2, and 3 exceed the 25% overdue value more quickly than do priority 4 and 5. In an inspection program that has fallen behind, and one where all licensees due for inspection are in excess of 25%, the program will likely have a higher percentage of core licensees in excess of 25% overdue.

In the future the RCP will prioritize core inspections to help ensure they do not go over 25% of their inspection frequency. The RCP has found it advantageous from an IMPEP accounting perspective to focus on the core inspections since they are the only ones evaluated for timeliness. Since implementing this strategy following the IMPEP review, the RCP has been able to inspect all core licensees such that none are currently outside the 25% overdue window. Additionally, all of the inspections conducted since the IMPEP review have had inspection findings submitted to the licensee in less than 30 days following the inspection. It should be noted that

continuing to focus such high priority on the core licensees could result in extended inspection intervals for priority 4 and 5 licensees.

2. **RECOMMENDATION:** The review team recommends that RCP continue their efforts to complete inspections of high priority reciprocity licensees in accordance with IMC 1220. (Section 3.1)

RESPONSE: The RCP will continue its efforts to complete inspections of high priority reciprocity licensees in accordance with IMC 1220. The RCP staff has found the inspection frequency for reciprocity licensees to be very difficult to comply with. These difficulties are due to short advanced notice, limited amount of time spent in the State and unusual hours. An example is a recent industrial radiography reciprocity licensee who began work in the State on Friday, May 7, at 6:00 p.m. and completed his project by Saturday morning, May 8 at 5:00 a.m. The job site was 80 miles northwest of Bismarck.

It is not unusual for industrial radiographers and other reciprocal licensees, such as well loggers, to conduct work in the State after normal working hours and on weekends to avoid interrupting normal processes at their location of work or to fit the schedule of their clients. It is our understanding that many states have trouble meeting this requirement. Perhaps the IMPEP criteria dealing with this issue should be revisited.

Licensees who work in other states under reciprocity must be regularly inspected by their licensing agency. These inspections may include home office as well as field inspections. While there is merit in promoting compliance through reciprocity inspections, its importance may be overestimated. If a licensee is responsible enough to establish and maintain compliance in their area of jurisdiction, one could expect that to carry over to all areas of operation as well.

Also, in addition to being extremely burdensome on the agency granting reciprocal privileges, these mandatory inspections impose a mandatory increased inspection frequency on the licensee. We support inspection of reciprocity licensees particularly if poor performance could be expected. However, we do not support the mandatory inspection of reciprocal licensees for the reasons mentioned above. States should be given more discretionary authority over inspections of reciprocal licensees.

3. **RECOMMENDATION:** The review team recommends that RCP management continue to provide additional oversight to ensure inspection findings (letters of apparent noncompliance) are communicated to licensees in a timely manner, and that licensee responses are evaluated promptly upon their receipt by RCP. (Section 3.1)

RESPONSE: The RCP management will continue to provide additional oversight to ensure inspection findings are communicated to licensees in a timely manner. The RCP staff recognizes the importance of timely response to inspections and appreciates the IMPEP recommendation.

4. **RECOMMENDATION:** The review team recommends that management perform an in-depth review of the RCP's current and future anticipated activities and obligations to ensure budgeted staffing levels are adequate to fulfill the responsibility of the program. (Section 3.3)

RESPONSE: RCP management has and will continue to consider this issue. According to models of a State RCP, North Dakota should have adequate staff for its number of licensees. The most recent guidance, which is in CRCPD Publication 99-2 dated April 1999 suggests 1.0 to 1.5 FTE per 50 uncomplicated licenses. North Dakota meets this staffing level. This, however, is misleading; in states with a small number of staff, a disproportionate percentage of total FTE is required for such things as rule revisions, responses to surveys, responses to incidents, employee illness or termination, or other matters which require staff time, and are outside the scope of licensing and inspection. In the case of North Dakota, if one staff member is diverted from their regular duties, this represents a 50% disruption in the inspection and licensing staff effort. Therefore, model numbers, as contained in the CRCPD's document, are not necessarily applicable to small programs such as North Dakota.

We believe North Dakota's program can function adequately, under normal circumstances, with existing staffing levels.

This assessment is based on the history of the program. During those times where two full-time, trained RCP staff were available, and ancillary responsibilities were minimal, the program was able not only to keep up with the inspection and licensing workload, but to make up overdue projects that accrued during periods of disruption. This is evident in the past year. In April 1998, after the newly hired RCP staff had attained some of the necessary training, a focused effort was made to begin to catch up on overdue inspections. Since that time there has been a steady decline in the number and severity of overdue inspections. Due to other complications, the findings of the inspections were still not being relayed to licensees in a timely manner. This, however, was corrected in October 1998 and since that time no problems of this nature have been observed.

However, RCP management recognizes that staff and scheduling disruptions are inevitable. The RCP management will, therefore, continue to provide close oversight of its staffing level needs. Management will consider whether additional radiation safety duties, outside of the IMPEP criteria responsibilities, could justify the addition of an RCP staff. This individual's duties could be shifted when needed to complete IMPEP criteria requirements during times of RCP staff and scheduling disruptions.

5. **RECOMMENDATION:** The review team recommends that the State provide training to technical personnel, either by formal course work or equivalent, in the area of brachytherapy. (Section 3.3)

RESPONSE: We agree with this comment. The senior licensing and inspection staff member is currently scheduled to attend the brachytherapy course in August 1999. The junior licensing and inspection staff will have the brachytherapy course added to his curriculum of core courses and will attend the course at the appropriate time.

Finally, we would like to comment on the criteria to which the IMPEP review team recommended a finding of unsatisfactory.

The RCP staff recognizes and agrees with the importance of this evaluation criteria. They also recognize that the degree of seriousness of this finding is elevated since, as the inspection team indicated on page 5 of the IMPEP report, this problem was identified during the 1996 IMPEP review as well.

The RCP staff realized these problems were occurring during the IMPEP review period; however, because of the circumstances, they were unable to maintain a timely inspection schedule and inspection response situation. This, however, is quite different than RCP management being unaware of the situation. The RCP management closely tracked this issue, and, as soon as possible took steps to remediate the problem. Recent history shows improvement. The RCP staff is committed to preventing the occurrence of a similar situation in the future.

A consideration in any IMPEP review in which the RCP has an improved situation from that which existed during the review period, such as less overdue inspections, has to be whether the RCP made a concerted effort to improve its statistics simply for the IMPEP. This is clearly not the case with North Dakota's program. North Dakota began correcting the overdue inspection deficiencies in early 1998. In June 1998 the NRC conducted a one-day interim review of North Dakota's program. After that review, it was our understanding, based on NRC correspondence, that it would not receive another IMPEP review until the year 2000. Had an IMPEP not occurred until the year 2000, and given the recent history of the RCP, we believe it would have been in full compliance with the timeliness of inspections and reporting of inspection findings in a timely manner well before the IMPEP review.

From a performance perspective, we feel that in spite of extenuating circumstances which occurred during the review period, it was able to maintain public health and safety concerning the use of radioactive materials and was able to recover from the loss of a well trained and experienced staff member which represented 50% of its licensing and inspection staff. This loss occurred in the middle of a rule revision process. The program's recovery demonstrates that the RCP was and is committed to performing above a level of unsatisfactory.

In addition to the above comments describing the situations leading to North Dakota's RCP deficiencies, we would ask the MRB to also consider the following:

1. The RCP's response to Recommendations 1 and 4.

2. The current status of North Dakota's RCP; i.e., no core inspections are currently in excess of 25% overdue and the length of time and number of overdue inspections has been steadily declining since April 1998.
3. No inspection findings have been reported to licensees in excess of thirty days from the inspection date, since October 1998.

Based on the above, we respectively request that the performance of this evaluation criteria be found by the Management Review Board to be satisfactory with recommendations rather than unsatisfactory.

We appreciate the efforts and professionalism of the IMPEP review team. The team conducted themselves in an exemplary manner throughout the IMPEP process. We also respect the findings of the team and appreciate that they did not compromise on applying the prescriptive review criteria of the IMPEP guidelines in making their recommendations. We, however, agree with the performance based concept of the IMPEP and respectively request MRB consideration of the program from a performance perspective.

If you have any questions concerning these comments or requests, you may contact me directly at 701-328-2372 or you may contact Mr. Dana Mount or Mr. Ken Wangler at 701-328-5188.

Sincerely,



Murray G. Sagsveen
State Health Officer

MGS:lrr

cc: Francis J. Schwindt, Chief, EHS
Jim Lynch, U.S. NRC Region III
Dana K. Mount, Director, RCP