

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH DAKOTA AGREEMENT STATE PROGRAM

April 13-16, 1999

DRAFT REPORT

U.S. Nuclear Regulatory Commission

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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 paragraph on the results of the MRB meeting will be included here in the final report.]

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. The State expects that these inspections will be completed by May 31, 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 early 1998; and (4) the extended absence of one of the program's inspector/license reviewers for several weeks during 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, 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 recommends that North Dakota's performance with respect to the indicator, Status of Materials Inspection Program, be found unsatisfactory.

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. 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. As evidenced during the team accompaniments, 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 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. Since the source was recovered four months later, it will not be reported to NMED.

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 Rules 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 Part 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 review team found North Dakota's performance to be satisfactory for five of the six performance indicators. The review team found North Dakota's performance to be unsatisfactory for the indicator, Status of Materials Inspection Program. Accordingly, the review team recommends that the Management Review Board find the North Dakota Agreement State Program to be adequate, but needs improvement and compatible with NRC's program.

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

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Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	North Dakota's Questionnaire Response

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

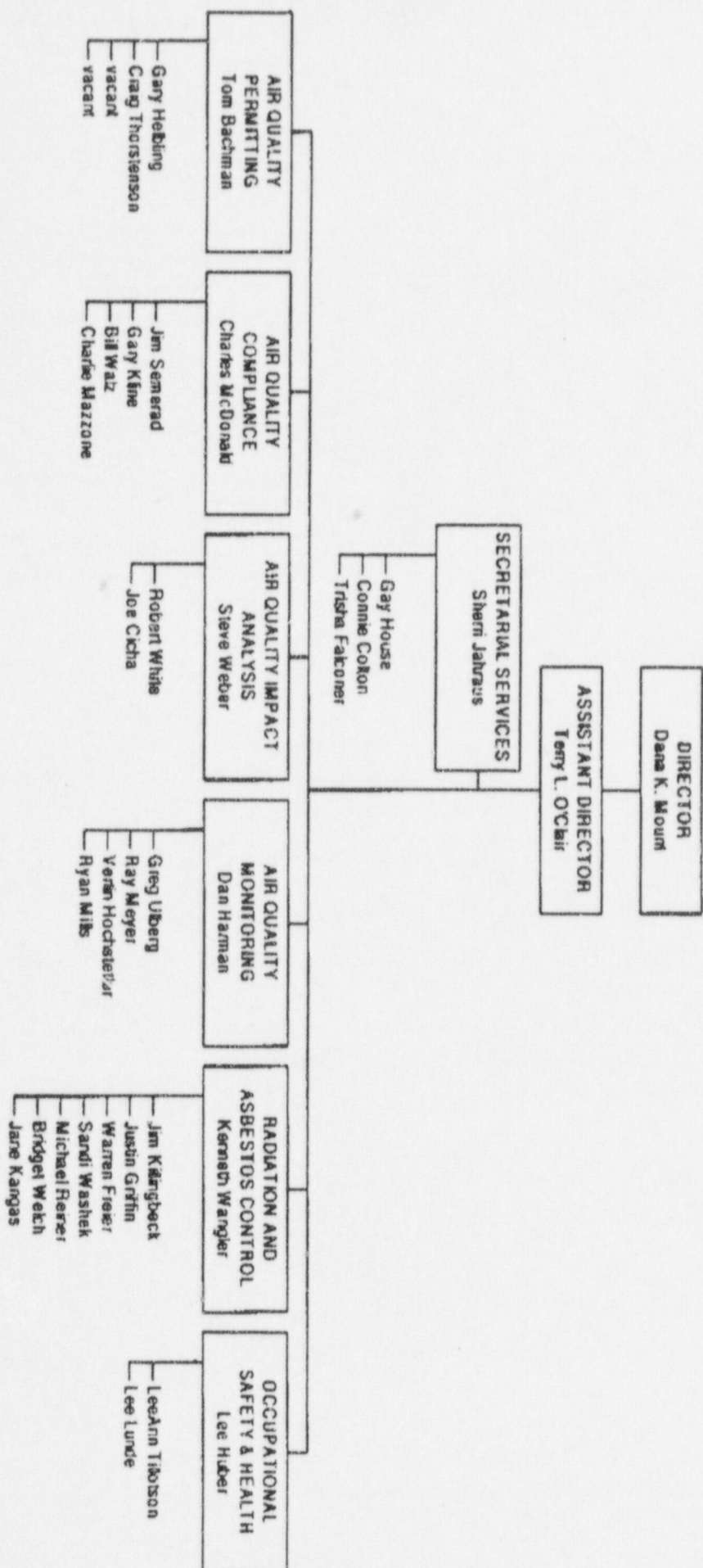
APPENDIX E

NORTH DAKOTA

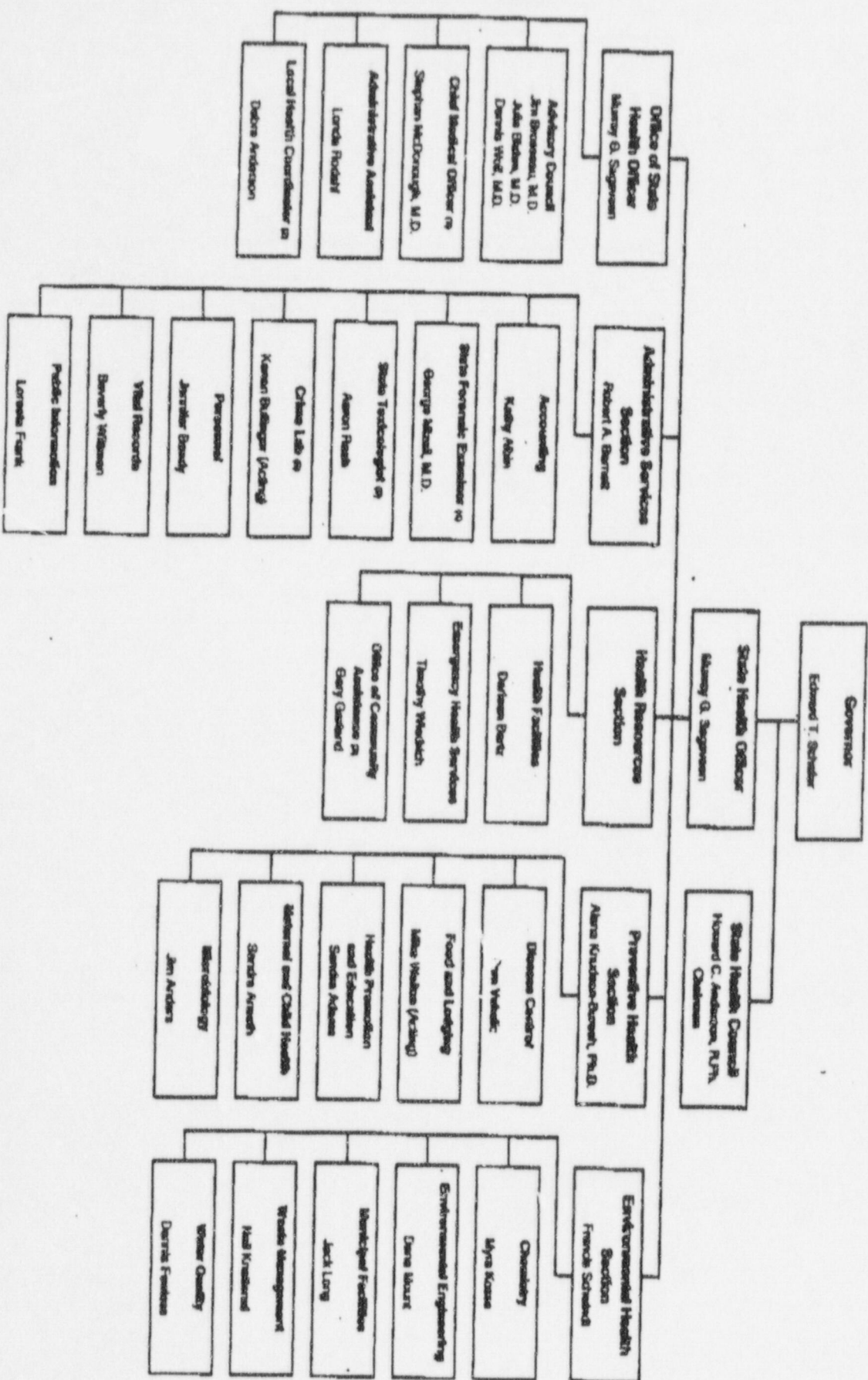
DEPARTMENT OF HEALTH
and
DIVISION OF ENVIRONMENTAL ENGINEERING

ORGANIZATION CHARTS

NORTH DAKOTA DEPARTMENT OF HEALTH
DIVISION OF ENVIRONMENTAL ENGINEERING



NORTH DAKOTA DEPARTMENT OF HEALTH October 6, 1998



- (a) Coordination with local public health officers
- (b) Coordination with local public health administrators
- (c) Coordination with Center for Rural Health
- (d) Coordination with county coroners
- (e) Coordination with law enforcement

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: ALL INSPECTIONS LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Licensee: Midwest Industrial X-Ray

Location: Fargo, ND

License Type: Industrial Radiography

Inspection Date: 7/8/98

License No.: 33-14907-01

Inspection Type: Routine, Unannounced

Priority: 1

Inspectors: JG, KW

Comments:

- a) Inspection was performed four months late.
- b) The inspection resulted in no violations being identified. The previous inspection conducted in 1996, also did not identify any violations. However, consideration was not given to extend the next inspection interval based on good licensee performance.

File No.: 2

Licensee: DMS Imaging

Location: Devils Lake, ND

License Type: Mobile Nuclear Medicine

Inspection Date: 6/25/97

License No.: 33-11325-01

Inspection Type: Routine, Announced

Priority: 2

Inspector: JK

Comments:

- a) Inspection was performed 10 months late.
- b) Field notes were not signed by the inspector.

File No.: 3

Licensee: St. Joseph's Hospital & Health Center

Location: Dickinson, ND

License Type: Medical Institution

Inspection Date: 10/27-28/97

License No.: 33-01901-01

Inspection Type: Routine, Announced

Priority: 3

Inspectors: JK, KW

Comment:

- a) Inspection was performed eight months late.

North Dakota Draft Report
Inspection Casework Reviews

C.2

File No.: 4

Licensee: BNI Coal, Limited
Location: Center, ND
License Type: Well Logging
Inspection Date: 1/30/98

License No.: 33-24716-01
Inspection Type: Routine, Announced
Priority: 3
Inspectors: JK, JG

Comments:

- a) The State's acknowledgment letter, requesting additional information from the licensee, was transmitted seven months after receipt of the licensee's response.
- b) The State's acknowledgment letter does not clearly indicate whether a violation was withdrawn or upheld, following the licensee's response which appears to deny a violation.
- c) As of April 14, 1999, the State had not reviewed/acknowledged the licensee's response letter dated January 25, 1999.

File No.: 5

Licensee: Ewer Testing & Inspection, Inc.
Location: Bismarck, ND
License Type: Industrial Radiography
Inspection Date: 3/5/98

License No.: 33-32610-01
Inspection Type: Initial, Unannounced
Priority: 1
Inspectors: JK, JG

Comment:

- a) Inspection was performed seven months late.

File No.: 6

Licensee: Trinity Medical Center
Location: Minot, ND
License Type: Medical Institution
Inspection Date: 7/27-29/98

License No.: 33-04608-01
Inspection Type: Routine, Announced
Priority: 3
Inspectors: JK, JG

Comment:

- a) Inspection was performed eight months late.

File No.: 7

Licensee: MQS Inspection, Inc.
Location: Temporary Jobsite in Beulah, ND
License Type: Industrial Radiography - Reciprocity
Inspection Date: 4/22/98

License No.: N/A
Inspection Type: Routine, Unannounced
Priority: 1
Inspectors: JK, JG

North Dakota Draft Report
Inspection Casework Reviews

C.3

File No.: 8

Licensee: North Dakota State University

License No.: 33-06769-06

Location: Fargo, ND

Inspection Type: Routine, Unannounced

License Type: Research and Development (Type A Broad)

Priority: 2

Inspection Date: 4/13-15/98

Inspectors: JK, JG, KW

Comments:

- a) Inspection was performed three months late.
- b) Letter of apparent noncompliance (8 violations and 4 recommendations) transmitted 55 days following on-site exit briefing.
- c) Licensee response to noncompliance received by State on August 19, 1998; however, as of April 16, 1999, no review of the licensee's response had been performed.

File No.: 9

Licensee: University of North Dakota

License No.: 33-12827-01

Location: Grand Forks, ND

Inspection Type: Routine, Announced

License Type: Research and Development (Type A Broad)

Priority: 2

Inspection Date: 9/29 - 10/2/98

Inspectors: JK, JG, KW

File No.: 10

Licensee: Wedge Dia-Log, Inc.

License No.: 33-32319-01

Location: Williston, ND

Inspection Type: Initial, Announced

License Type: Well Logging

Priority: 3

Inspection Date: 3/19/98

Inspectors: JK, JG

Comments:

- a) Initial inspection was performed nine months late.
- b) Inspection letter sent to licensee 102 days following on-site exit briefing.

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the on-site IMPEP review.

Accompaniment No.: 1

Licensee: Dakota Clinic, Ltd.

License No.: 33-02604-01

Location: Fargo, ND

Inspection Type: Routine, Unannounced

License Type: Medical Institution

Priority: 3

Inspection Date: 1/19-21/99

Inspectors: JK, JG

Comment:

- a) The review of brachytherapy treatment planning, dose delivery system and written directives for permanent and temporary implants could be stronger.

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Inspection Casework Reviews

C.4

Accompaniment No.: 2
Licensee: Midwest Testing Laboratory, Inc.
Location: Fargo, ND
License Type: Portable Gauge
Inspection Date: 1/21/99

License No.: 33-07712-01
Inspection Type: Routine, Unannounced
Priority: 4
Inspectors: JG, JK

Accompaniment No.: 3
Licensee: United Blood Services
Location: Fargo, ND
License Type: Self-Shielded Irradiator
Inspection Date: 1/21/99

License No.: 33-05427-02
Inspection Type: Routine, Unannounced
Priority: 5
Inspectors: JK, JG

Accompaniment No.: 4
Licensee: Ewer Testing & Inspection, Inc.
Location: Bismarck, ND
License Type: Industrial Radiography
Inspection Date: 2/23/99

License No.: 33-32610-01
Inspection Type: Routine, Unannounced
Priority: 1
Inspectors: JK, JG

Accompaniment No.: 5
Licensee: Dakota Geophysics
Location: Dickinson, ND
License Type: Well Logging
Inspection Date: 2/24/99

License No.: 33-28628-01
Inspection Type: Routine, Announced
Priority: 3
Inspectors: JK, JG

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: ALL LICENSES LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Licensee: UniMed Medical Center

Location: Minot, ND

License Type: Medical Institution

Date Issued: 11/25/97

License No.: 33-09805-01

Amendment No.: 52

Type of Action: Amendment

Reviewer: JK

File No.: 2

Licensee: Endorex Corporation

Location: Fargo, ND

License Type: Laboratory Use

Date Issued: 6/2/98

License No.: 33-21122-01

Amendment No.: 8

Type of Action: Termination

Reviewer: KW

File No.: 3

Licensee: Ewer Testing & Inspection

Location: Bismarck, ND

License Type: Industrial Radiography

Date Issued: 2/19/97

License No.: 33-32610-01

Amendment Nos.: 0 and 2

Type of Action: New and Amendment

Reviewer: GK

File No.: 4

Licensee: Northern Improvement Company

Location: Bismarck, ND

License Type: Portable Gauge

Date Issued: 3/19/97

License No.: 33-32706-01

Amendment No.: 0

Type of Action: New

Reviewer: GK

File No.: 5

Licensee: Nuclear Imaging, Ltd.

Location: Carrington, ND

License Type: Mobile Nuclear Medicine

Date Issued: 11/18/98

License No.: 33-28601-01

Amendment No.: 6

Type of Action: Renewal

Reviewer: JG

Comment:

- a) The license allows only for medical diagnostic use of radioactive material, yet several conditions in the license are specific only to therapeutic uses of radioactive material, including patient release criteria.

North Dakota Draft Report
License Casework Reviews

D.2

File No.: 6

Licensee: T & K Inspection

Location: Williston, ND

License Type: Industrial Radiography

Date Issued: 9/18/98

License No.: 33-22313-01

Amendment No.: 13

Type of Action: Renewal

Reviewer: JG

Comment:

- a) The approved license application allows for a dose limit of three rem per calendar quarter for occupationally exposed individuals. The licensee's procedures do not reflect the current dose limits specified in the State's equivalent to 10 CFR Part 20.

File No.: 7

Licensee: BJ Services Company

Location: Dickinson, ND

License Type: Portable Gauge

Date Issued: 3/18/99

License No.: 33-16822-01

Amendment No.: 6

Type of Action: Termination

Reviewer: JG

Comment:

- a) Licensing documentation does not confirm that gauges were transferred to a specifically licensed recipient. Also, there was no confirmation or documentation that the recipient actually received the radioactive material.

File No.: 8

Licensee: University of North Dakota

Location: Grand Forks, ND

License Type: Academic Broad Scope

Date Issued: 9/25/98

License No.: 33-12827-01

Amendment No.: 21

Type of Action: Amendment

Reviewer: JG

Comment:

- a) The license allows for use of sealed sources up to 200 mCi for purposes of research and development, with source and holder models unspecified. There is no language in the license indicating that sources and devices will be used in accordance with the specifications contained in the Sealed Source and Device Registry.

File No.: 9

Licensee: St. Alexius Medical Center

Location: Bismarck, ND

License Type: Medical Institution

Date Issued: 3/13/97

License No.: 33-11320-01

Amendment Nos.: 27 and 28

Type of Actions: Renewal and Amendment

Reviewer: GK

North Dakota Draft Report
License Casework Reviews

D.3

File No.: 10

Licensee: Schlumberger Technology Corporation

Location: Williston, ND

License Type: Well Logging

Date Issued: 1/21/97

License No.: 33-00090-01

Amendment No.: 35

Type of Action: Renewal

Reviewer: GK

Comment:

- a) Condition 11 of this license does not require the licensee to comply with Chapter 33-10-12 of North Dakota's radiation protection regulations. This chapter is applicable to well logging.

File No.: 11

Licensee: Technology Plus, Inc.

Location: Grand Forks, ND

License Type: Industrial Radiography

Date Issued: 6/1/98

License No.: 33-31901-01

Amendment No.: 4

Type of Action: Amendment

Reviewer: JK

File No.: 12

Licensee: Jamestown Hospital

Location: Jamestown, ND

License Type: Medical Institution

Date Issued: 7/23/97

License No.: 33-05026-01

Amendment No.: 29

Type of Action: Amendment

Reviewer: JK

File No.: 13

Licensee: West River Regional Medical Center

Location: Hattinger, ND

License Type: Medical Institution

Date Issued: 7/3/97

License No.: 33-08310-01

Amendment Nos.: 39 and 40

Type of Actions: Renewal and Amendment

Reviewer: JK

File No.: 14

Licensee: North Dakota State University

Location: Fargo, ND

License Type: Academic Broad Scope

Date Issued: 6/10/97

License No.: 33-06769-06

Amendment No.: 36

Type of Action: Renewal

Reviewer: JK

Comment:

- a) The license allows for the use of sealed sources up to 200 mCi for purposes of research and development, with source and holder models unspecified. There is no language in the license indicating that sources and devices will be used in accordance with the specifications contained in the Sealed Source and Device Registry.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: ALL INCIDENTS LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Licensee: Altru Health System
Site of Incident: Grand Forks, ND
Date of Incident: 3/10/99
Investigation Date: 3/10/99

Licensee No.: 33-01599-03
Incident Log No.: ND 990001
Type of Incident: Lost Iodine-125 Seeds
Type of Investigation: Telephone

Summary of Incident and Final Disposition: Five iodine-125 seeds were not appropriately accounted for after an implant therapy on 3/9/99. The seeds set off alarms at a medical waste incinerator. A DOT E-11406 shipment exemption was issued by the RCP for the licensee to return the seeds back to Altru Health System.

File No.: 2

Licensee: Twin Ports Testing, Inc.
Site of Incident: Bismarck, ND
Date of Incident: 10/18/96
Investigation Date: 10/18/96

Licensee No.: 48-23476-01(NRC)
Incident Log No.: ND 960001
Type of Incident: Transportation
Type of Investigation: Telephone

Summary of Incident and Final Disposition: This NRC licensee's radiography truck was involved in a traffic accident. The truck was carrying three radiography cameras, each with approximately 100 curies of iridium-192. The driver was arrested for driving under the influence of alcohol and was jailed. The licensee sent another truck to remove the radiography cameras before the State learned of the incident. The State made appropriate notifications to NRC and other organizations.

File No.: 3

Licensee: Northrop Grumman
Site of Incident: New Town, ND
Date of Incident: 6/19/97
Investigation Date: 6/20/97

Licensee No.: General License
Incident Log No.: N/A
Type of Incident: Lost Source
Type of Investigation: Telephone

Summary of Incident and Final Disposition: Lost generally-licensed polonium-210 static eliminator. The device was found by the licensee in October 1997.

Comment:

a) Lost source not reported to NMED.

North Dakota Draft Report
Incident Casework Reviews

E.2

File No.: 4

Licensee: Non-licensee

Site of Incident: Jamestown, ND

Date of Incident: 10/96

Investigation Date: 10/96

Licensee No.: N/A

Incident Log No.: N/A

Type of Incident: Unknown Source Found

Type of Investigation: On-site

Summary of Incident and Final Disposition: An unknown source which appeared to be a civil defense water standard was found along a highway. The RCP performed an on-site investigation, recovered the source, and determined it to have a small quantity of uranium-238. The source is in storage at the Department of Health.

APPENDIX F

STATE OF NORTH DAKOTA
QUESTIONNAIRE RESPONSE

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE

North Dakota

Reporting Period: February 10, 1996 to April 12, 1999

A. COMMON PERFORMANCE INDICATORS

I. Status of Materials Inspection Program

1. Please prepare a table identifying the licenses with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800. The list should include initial inspections that are overdue.

<u>Licensee Name</u>	<u>Insp. Frequency (Years)</u>	<u>Due Date</u>	<u>Months O/D</u>
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Response: See Attachment A. Attachment A lists each inspection conducted since 2/10/96, the percent overdue at the time the licensee was inspected and how long it took to establish the first contact with the licensee after the inspection. The RCP tries to deliver written findings of the inspection to the licensee within 30 days of completing an inspection. Initial communication regarding inspection findings are done at the conclusion of an inspection during a close out meeting with licensee management.

Attachment B lists the new licenses issued and initial inspections conducted during this review period. Attachment B identifies the date the license was issued and the date the initial inspection was completed. The RCP attempts to inspect each licensee within 6 months of a licensee receiving a radioactive material (RAM) license. This time may be extended to one year if operations involving RAM have not begun.

2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.

Response:: Yes. Attachment C is the scheduled inspections through August 1999. The RCP tries to complete inspections within 25% of the scheduled due date. As can be seen in Attachment C, two licensees are in excess of 25% overdue. These should be completed by May 31, 1999. After that time no licensees will be in excess of 25% overdue.

3. Please identify individual licensees or groups of licensees the State is inspecting more or less frequently than called for in NRC Inspection Manual Chapter 2800 and state the reason for the change.

Response: North Dakota requires more frequent inspections on Moisture/density gauges and portable gauges which are inspected on a four year frequency compared with the NRC five year frequency;

North Dakota does not inspect any other licensees more or less frequently than NRC Inspection Manual Chapter 2800

4. Please complete the following table for licensees granted reciprocity during the reporting period.

Response:

Priority	Year	Number of Licensees Granted Reciprocity Permits Each Year	Number of Licensees Inspected Each Year
Service Licensees performing teletherapy and irradiator source installations or changes	YR 96	0	0
	YR 97	0	0
	YR 98	0	0
	YR 99	0	0
1	YR 96	0	0
	YR 97	2	0
	YR 98	3	1
	YR 99	0	0
2	YR 96	1	0
	YR 97	1	0
	YR 98	1	0
	YR 99	0	0
3	YR 96	6	1
	YR 97	4	0
	YR 98	5	2
	YR 99	0	0
4	YR 96	6	0
	YR 97	4	2
	YR 98	6	2
	YR 99	1	0
All Other	YR 96	0	0
	YR 97	0	0
	YR 98	0	0
	YR 99	0	0

5. Other than reciprocity licensees, how many field inspections of radiographers were performed?

Response:: North Dakota conducted one field inspection of an industrial radiographer. The RCP conducted a field inspection of TECHNOLOGY PLUS, INC. license # ND 33-31901-01 on 8/7/98.

6. For NRC Regions, did you establish numerical goals for the number of inspections to be performed during this review period? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

Response: Not Applicable

II. Technical Quality of Inspections

7. What, if any, changes were made to your written inspection procedures during the reporting period?

Response:: North Dakota updated its inspection procedures since February 1996. The changes were not significant. Amendments were made to make the procedures more complete, to more accurately reflect the procedures followed by the RCP and to make the RCP inspection procedures more closely align with those of the NRC. Prior to the 1996 IMPEP review, North Dakota had developed inspection report forms for each type of inspection. Minor amendments were made to these forms as necessary to make them conform to the new requirements contained in the North Dakota Radiological Health Rules. Copies of the forms are enclosed in Attachment D.

8. Prepare a table showing the number and types of supervisory accompaniments made during the review period.

Response:

<u>Supervisor</u>	<u>Inspector</u>	<u>Licensee (License Type)</u>	<u>Date</u>
Ken Wangler	Jim Killingbeck & Greg Krause	UND (broad scope A academic)	5/20- 22/96
Ken Wangler	Jim Killingbeck	Dakota Gasification (gage)	1/23/97
Ken Wangler	Jim Killingbeck / Justin Griffin	NDSU (broad scope A academic)	4/14-16/98
Ken Wangler	Justin Griffin	Amoco Refinery (gage)	8/25-26/98
Ken Wangler	Jim Killingbeck and Justin Griffin	UND (broad scope A academic)	9/29-10/2/98

9. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.

Response: North Dakota's RCP Administrative Procedures Manual section III. E. states, Approximately 10% of all field inspections include the Radiation Control Program Manager or Assistant Division Director or Division Director accompaniment of the inspector. 60 inspections have been conducted during this review period. Management has accompanied on 5 of the inspections. There is no specific documentation of the accompaniment other than the appropriate notation made on the final inspection report. Copies of the inspection reports are not enclosed with this questionnaire.

10. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?

Response: All program instrumentation is calibrated every six months. See attachment E. Attachment E lists all the RAM measurement equipment, however not all instruments listed in attachment E are kept in calibration. Column one of attachment E identifies those meters which are in calibration. All meters used for inspections and those which are considered essential for emergency response are calibrated semi annually. This is in line with the RCP Administrative Policy Manual section XIV.

The calibrations are conducted by Department staff using a Gammatron calibrator equipped with a 30 millicurie cesium-137 source. The calibrations are done at the

Department's east laboratory in the upper floor penthouse. The meters are calibrated at two points located approximately 1/3 and 2/3 of full scale on each meter for linear scale instruments; and at midrange at each decade and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments.

III. Technical Staffing and Training

11. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts.

Response:

NORTH DAKOTA RCP PERSONNEL EFFORT

NAME	POSITION	AREA OF EFFORT	FTE%
D. Mount	Division Director	RAM Admin./ Supervision of Program	10%
T. O'Clair	Assistant Division Director	RAM Admin./Supervision	5%
K. Wangler	RCP Manager	Supervision/Admin. RAM Licensing/Inspection Radon Asbestos Indoor Air Quality X-Ray Emergency Response Special Projects	40% 15% 10% 10% 10% 10% 2% 3%
J. Killingbeck	Env. Sci. III	Licensing Inspection Correspondence Emergency Response Special Projects	35% 40% 20% 2% 3%
J. Griffin	Env. Eng. II	Licensing Inspection	35% 40%

Correspondence	20%
Emergency Response	2%
Special Projects	3%

Secretarial*

0.21 FTE

Total RAM FTE 2.87

68 specific licensees = 4.13 persons per 100 licenses

Person years = $0.10 + 0.05 + 0.57 + 0.97 + 0.97 + 0.21 = 2.87$ person years.

*Total available Division Secretarial resource is 3.5 FTE. Secretarial support for the Branch is 40% of Division. Radioactive Materials is 15% of Branch effort. Total Secretarial effort for Branch is $3.5 \times 0.40 \times 0.15 = 0.21$ FTE.

(Special projects include noise response and nonionizing radiation)

12. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

Response: Justin Griffin was hired on November 3, 1997 to replace Greg Krause who left July 31, 1997. A copy of Justin's resume is enclosed as Attachment F.

13. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.

Response: See Attachment G. Jim Killingbeck had completed all the core training requirements that were identified as such prior to October 1998. In October 1998 the RCP received a license amendment request from Altru Hospital in Grand Forks to use high dose rate after-loading brachytherapy (HDR). Prior to this time there were no HDRs in North Dakota. Following that request the RCP added the Teletherapy & Brachytherapy (H-313) course as a core training course for North Dakota's Radiation Control Program. Current plans are to send Jim to the H-313 course in August 1999. As indicated in attachment G, Justin Griffin has not completed the core training requirements for RAM licensing and inspection. Attachment H is a memorandum to Health Department Management describing Justin's training history and the plan for Justin to accomplish the full training suite with the exception of the H-313 course. Plans for Justin to complete the H-313 course have not yet been made. Justin will likely attend the course sometime in 2001 or later. Planned training for Ken Wangler includes the transportation course (H-308) although a date for attending the course has not been determined. No other training for Ken is planned at this time.

14. Please identify the technical staff who left the RCP/Regional DNMS program during this period.

Response: Greg Krause, one of the two licensing and inspection staff, left the Health Department on July 31, 1997. No other personnel have left the RCP since the last NRC review.

15. List the vacant positions in each program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

Response: The RCP does not have any vacant positions at the present time.

IV. Technical Quality of Licensing Actions

16. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period. Also identify any new or amended licenses that now require emergency plans.

Response: Endorex Corporation was a 'laboratory use' licensee who used unsealed RAM. Endorex Corporation terminated their license on June 2, 1998. The University of North Dakota, a broad scope type A licensee, received a significant penalty for violations discovered during a May 1996 inspection.

Both Universities who possess Broad Scope Type A RAM licenses renewed their license during this review period. A Number of medical licensees such as UniMed and DMS Imaging also renewed their license during this review period. A full listing of all licensing actions performed during this review period can be made available for the review.

17. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

Response: There were no variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

18. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

Response: There were no changes made in the RCP written licensing procedures during the reporting period?

19. N/A

V. Responses to Incidents and Allegations

20. Please provide a list of the reportable incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc. See Handbook on Nuclear Material Event Reporting in Agreement States for additional guidance.) that occurred in the Region/State during the review period. For Agreement States, information included in previous submittals to NRC need not be repeated (i.e., those submitted under OMB clearance number 3150-0178, Nuclear Material Events Database). The list should be in the following format:

Response: The RCP continues to utilize the Nuclear Material Events Database (NMED) system for reporting and tracking unusual events. All of the reportable incidents were reported to NRC using the NMED system. They are as follows:

<u>Licensee Name</u>	<u>License No.</u>	<u>Date of Incident</u>	<u>Date of Report</u>	<u>Type of Incident</u>
Twin Ports Testing, Inc.	48-23476-01	10/18/96	10/21/96	Industrial radiography truck with 3 Amersham 660B cameras crashed into a highway barrier on Interstate 94 near Bismarck. Driver was arrested and incarcerated for driving under the influence of alcohol.
Porter Brothers	N/A	3/3/98	3/3/98	Naturally occurring radioactive material (NORM) in rail car of scrap metal (not reportable)
Porter Brothers	N-A	2/13/98	2/13/98	NORM in rail car of scrap metal (not reportable)
MeritCare Health Systems	33-10227-02	1998	12/15/98 & 3/8/99	Cory Teigen, MD, an interventional radiologist received 7.61 rem whole body in 1998 (Machine generated x-ray dose; not reportable)
Altru Health System	33-01599-03	3/10/99	3/10/99	Loss of control of four I-25 brachytherapy sources

Attachment I is a printout of the tracking system information used to track incidents and misadministrations since January 21, 1995.

21. During this review period, did any incidents occur that involved equipment or source failure or approved operating procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified? For States, was timely notification made to NRC? For Regions, was an appropriate and timely PN generated?

Response: No

22. For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.

Response: N/A

23. In the period covered by this review, were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case.

Response: The Department is considering seeking a voluntary restraining order against the past University of North Dakota Radiation Safety Officer to prevent him from participating on a North Dakota Radioactive Material License for five years for his culpability in the University of North Dakota violation. There were no other cases involving possible wrongdoing during this review period

24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

Response: There have been no changes to the RCP procedures for handling allegations during this review period. The allegations that have been handled by the RCP this reporting period are listed in Attachment J.

- a. For Agreement States, please identify any allegations referred to your program by the NRC that have not been closed.

Response: There have been no allegations referred to the State program by the NRC during this review period.

VI. General

25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.

Response: The State's last Integrated Materials Performance Evaluation Program (IMPEP) review was held February 6-9, 1996. The Management Review Board (MRB) met May 14, 1996 to consider the proposed final IMPEP report. The MRB concurred with the report's findings that four of the five common performance indicators were found to be fully satisfactory. The status of the fifth indicator, the Materials Inspection Program indicator, was found to be satisfactory with recommendations for improvement. The only applicable non-common performance indicator was found to be fully satisfactory. Overall North Dakota's program was found to be adequate to protect public health and safety and compatible with NRC's regulatory program.

The deficiencies in the Materials Inspection Program indicator were:

Failure to dispatch inspection findings to licensees in a timely manner.

Failure to conduct core inspections within 25% of their inspection frequency time interval.

Failure to conduct initial inspections within 6 months.

Four of the nine recommendations from the 1996 IMPEP relate directly to the deficiencies in the inspection program. The entire list of recommendations followed by the State's response and current status on the issue is listed below:

Recommendation No. 1: The review team recommends that the state adopt a written timeliness goal for issuance of inspection findings to the licensee.

Response: The state has adopted written timeliness goals for issuance of inspection findings. This is contained in the Radiation Control Program's Administrative Procedures Manual.

Recommendation No. 2: The review team recommends that state management and staff devote increased attention to issuing inspection results in a timely manner.

Response: State management and staff have devoted increased attention to issuing inspection results in a timely manner; however, have not successfully met the thirty day (30) time frame in all cases. As can be seen in Attachment A, the average number of days between the inspection and the first contact with the licensee is 29.2 days. Attachment A identifies how each inspection was conducted relative to its inspection frequency and how long it took to respond to a licensee after an inspection was completed.

Recommendation No. 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.

Response: The State did monitor the timeliness of issuing inspection findings and did systematically assess the tracking system. The tracking system was and is effective in tracking assignments and in prompting staff and management to issue inspection findings.

Recommendation No. 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 issuances or

within the provisions of IMC 2800, and whether the states method for scheduling initial inspections has worked adequately.

Response: The state has assessed whether initial inspections have been performed within six months of licensee issuance. The State did this not only over the year following the 1996 IMPEP review but on an ongoing basis. See attachment B which identifies the date all new licenses were issued and the date the initial inspection of that licensee was completed. Assessment of the tracking system has indicated that the State's method for scheduling initial inspection has worked adequately. The deficiency in conducting initial inspections in a timely manner has resulted from not following the inspection schedule.

Recommendation No. 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.

Response: The program staff member in question left the Radiation Control Program July 31, 1997. A replacement for that position was hired on November 3, 1997. Training of the newly hired individual, Justin Griffin, is ongoing. Attachments F, G and H identify Justin's prior training and experience, as well as, the core radiation courses he has attended and his proposed schedule for completing the remainder of the core training courses.

Recommendation No. 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.

Response: The program manager attended the licensing course in June 1996. The qualifications and training needs of the program manager concerning the inspection procedures course have been evaluated. Based on that evaluation, The RCP does not intend to send the present program manager to the inspection procedures course. The program manager has been with the Health Department ten

years and has extensive inspection and incident investigation experience, not only in radiation safety but in other program areas as well. Because of this experience, the RCP does not feel sufficient benefit would be gained to justify the cost of him attending the inspection course. There are considerations underway for him to attend the transportation course but a final decision has not been made regarding that matter.

Recommendation No. 7: The review team suggests that out-of-state travel consideration should not curtail necessary training for program personnel.

Response: All out-of-state travel is carefully evaluated and its costs considered against the benefit expected to be realized from the travel. In cases where there is a sufficient cost benefit ratio, out-of-state travel has been promptly approved by Health Department management and has not curtailed the necessary training for program personnel.

Recommendation No. 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.

Response: It is RCP procedure to have both the inspector and program manager sign final version of inspection field notes. Added emphasis has been placed on this issue since the last IMPEP review. The RCP has attempted to insure that all final versions of inspection field notes on inspections conducted since the 1996 IMPEP have been signed by both the inspector and the program manager.

Recommendation No. 9: The review team suggests that the state devote more attention to supervisory sign-off on management 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 signature on the letter to the licensee constitute supervisor approval.

Response: It is RCP procedure to have both the inspector and program manager sign final version of inspection field notes. Added emphasis has been placed on this issue since the last IMPEP review.

The RCP has attempted to insure that all final versions of inspection field notes on inspections conducted since the 1996 IMPEP have been signed by both the inspector and the program manager

The above responses appear to be in line with the commitments the RCP made in a July 10, 1996 letter to Mr. Hugh Thompson with the NRC at the conclusion of the 1996 IMPEP review. A copy of the July 10, 1996 letter is enclosed as Attachment K.

On July 22, 1998, representatives from the NRC including Mr. James Myers from NRC's Office of State Programs, Mr. Jack Horner, Regional State Agreement's Officer, and Ms. M. Linda McLean, NRC Region IV State Agreement's Officer met with the North Dakota Department of Health Radiation Control Program in the Bismarck, North Dakota office. The purpose of the meeting was to review and discuss the status of North Dakota's agreement state program. During that meeting, the NRC's staff discussed with the state each of the nine recommendations from the 1996 IMPEP review. The NRC staff recommended all except recommendation no. 4 be closed. The review teams response to recommendation no. 4 states, "the state said that its working towards accomplishing the IMC 2800 goal of performing initial inspections within six months of licensee issuance but have not been entirely successful. For example, during 1998, two new licenses were issued, one was inspected nine months after issuance." A copy of the correspondence related to the July 22, 1998 meeting is enclosed as attachment L.

26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties which occurred during this review period.

Response: The State's Radiation Control Program (RCP) answered a very similar question during the July 22, 1998 visit from the NRC. The RCP's responses to that question begins on page 3 of

Attachment L. The RCP has good intra program communication on issues affecting licensees. This is enhanced by the small number of program staff whose offices are located in close proximity to each other. Also because of the small staff size, every member is involved in all aspects of the RCP. Each staff is involved in licensing, inspection, rule revision, rule interpretation and correspondence with various types of licensees.

The North Dakota Department of Health, in general, has good interdepartmental communication. The program manager has easy and ready access to managers all the way to the Office of the State Health Officer and ready access to the Assistant Attorney General assigned to the Environmental Section.

The technical capabilities of the program are good. All staff have recently upgraded computers and software. Management support for computer training, easy access to the Internet, strong clerical support, ready access to the Department's Chief Medical Officer, as well as, technical support on radiation safety issues from the machine generated radiation program help the program in carrying out its responsibilities.

Because of staff familiarity with licensees, good working relationships have been established with the regulated community such that the program is often able to obtain compliance without elevated enforcement action. The relationship also puts the program at ease with making recommendations in addition to required corrective actions, a licensee is requested to implement following an inspection.

There is of course a down side to small size. Because of the small program size, staff are not able to participate in national working groups and policy making activities because of the large percentage of time, represented when one staff member is taken from the program for activities outside of the scope of radioactive material licensing and inspection. Because of small staff size, the program has also been unable to move into radiation safety areas which are in need of attention such as the control of natural

occurring radioactive material enhanced during oilfield exploration and production activities. The rule revision process also requires a significant percentage of staff commitment which detracts from the timely completion of licensing and inspection activity. Finally, as experienced during the current review cycle, departure of one licensing and inspection staff represents a personnel deficiency in that area of 50%. This severely compromises the program's ability to conduct licensing and inspection actions in a timely manner.

B. NON-COMMON PERFORMANCE INDICATORS

I. Legislation and Program Elements Required for Compatibility

27. Please list all currently effective legislation that affects the radiation control program (RCP).

Response: North Dakota Century Code (NDCC) 23-20, 23-20.1 and 23-20.2

28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

Response: No, neither North Dakota Century Code nor North Dakota Administrative Code is subject to a "Sunset" or equivalent law.

29. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State, explain why they were not adopted, and discuss any actions being taken to adopt them. Identify the regulations that the State has adopted through legally binding requirements other than regulations.

Response: TABLE FOR QUESTION 29.

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Any amendment due prior to 1991. Identify each regulation (refer to the Chronology of Amendments)			All rules required prior to this time have been adopted by the State	
Decommissioning; Parts 30, 40, 70	7/27/91	3/1/94		
Emergency Planning; Parts 30, 40, 70	4/7/93	3/1/94		
Standards for Protection Against Radiation; Part 20	1/1/94	3/1/94		
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	3/1/94		
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	3/1/94		
Quality Management Program and Misadministrations; Part 35	1/27/95	3/1/94		
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96	7/1/95		
Definition of Land Disposal and Waste Site QA Program; Part 61	7/22/96	N/A		
Decommissioning Recordkeeping: Docu- mentation Additions; Parts 30, 40, 70	10/25/96	7/1/95		
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97	N/A		

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97	7/1/95		
Preparation, Transfer for Commercial Dis- tribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98	5/1/98		
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98	5/1/98		
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98	5/1/98		
Performance Requirements for Radiography Equipment	6/30/98	5/1/98		
Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98	5/1/98		
Clarification of Decommissioning Funding Requirements	11/24/98	5/1/98		
10 CFR Part 71: Compatibility with the International Atomic Energy Agency	4/1/99	5/1/98		
Medical Administration of Radiation and Radioactive Materials.	10/20/98	5/1/98		
Termination or Transfer of Licensed Activities: Recordkeeping Requirements.	6/17/99	5/1/98		
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act	1/9/00	5/1/98		
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State	2/27/00	N/A		
Criteria for the Release of Individuals Administered Radioactive Material	5/29/00	5/1/98		

10 CFR RULE	DATE DUE	DATE ADOPTED	OR	
			CURRENT STATUS	EXPECTED ADOPTION
Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations; Final Rule	6/27/00		Not yet adopted by the State. North Dakota has had an Industrial Radiography certification and two-man requirement in place since 1992. An initial evaluation reveals that North Dakota's rule is quite similar to NRC's rule. During the next rule revision, a detailed comparison will be conducted and the necessary changes made to make the State's rule fully compatible	
Radiological Criteria for License Termination	8/20/00		On May 1, 1998 North Dakota adopted a "Final Rule" as published on the internet. This needs to be evaluated against the rule as published in the Federal Register.	
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea	1/2/01		Not yet adopted by the State. Through Administrative Procedures, North Dakota does allow the exempt distribution of this drug.	
Deliberate Misconduct by Unlicensed Persons	2/12/01		Not yet adopted by the State	
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections	7/9/01		Not yet adopted by the State	
Minor Corrections, Clarifying Changes, and a Minor Policy Change	10/26/01		Not yet adopted by the State	

Attachment M is a copy of a December 29, 1998 from Mr. Paul Lohaus, Deputy Director of NRC's Office of State Programs indicating that the State's May 1, 1998 rules are compatible with applicable sections of 10 CFR.

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

Response: North Dakota does not intend to adopt the requirements for Land Disposal and Waste Site QA programs, nor the Uranium Mill Tailings: Conforming to EPA Standards since neither of these requirements are applicable to operations in North Dakota. Therefore North Dakota's regulations are compatible with adoption of all applicable NRC regulations through June 27, 2000. With regard to regulations which we are required to adopt on or before June 27, 2000, the program will begin the next rule revision process on or about October, 1999. From the time new or revised rules are proposed it takes approximately 9 to 10 months before they are promulgated. By beginning in October, 1999 this should allow the program sufficient time to adopt the necessary rules within the allowable NRC time frame.