

Included in this response to the *Integrated Materials Performance Evaluation Program, Review of the North Dakota Agreement State Program* (ML111220487) are three technical corrections to the draft report and actions taken to address each of the recommendations.

The first technical correction is in Section 2.1, paragraph 4, third line from the bottom. Please change "... inspection of a radionuclide production (cyclotron) facility." to read "... inspection of an Academic Type A Broad Scope with an associated medical facility."

The second technical correction is in Section 3.1, subsection 3.1.1, second paragraph which should read as follows:

One rulemaking action affecting the Radiation Control Program was approved during the review period. Prior to the review period, the Radiation Control Program was funded through license fees as well as obtaining approximately 30-40% of its funding from the State's General Fund. During the past year, the proposed rules were adopted that puts in place a 6-year implementation period for the Radiation Control Program to become fully fee funded. This matter went through the State's rulemaking process including a public comment period. During the implementation period, licensees will receive a fee increase every year for six years. At the end of six years, the Radiation Control Program will be fully fee funded.

The third technical correction is in Section 3.1, subsection 3.1.3, third paragraph which should read as follows:

The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The rulemaking process begins with the Branch drafting the proposed rules, which are submitted to NRC for a compatibility review. Concurrently, a public notice is then submitted for publication and public comment in the official newspaper of each of the 53 counties in the State. After a public hearing wherein additional comments can be submitted, any received comments will be evaluated and any necessary changes are made. The proposed rules are then submitted to the State Attorney General for a legal opinion. After the Attorney General's legal opinion is received, the legal opinion and rulemaking package are submitted to the State Health Council for adoption. The package is then submitted to the State's Legislative Council. The Legislative Council submits the package to the Legislative Rules Committee for final approval. After final approval is received, the Legislative Council publishes the rules. The rules become effective on the date they are published. The Branch Manager indicated that this rulemaking process typically takes 9-12 months.

Below are review team's recommendations, as mentioned in the report, for evaluation and implementation. Following each recommendation are the actions implemented with training or actions planned.

1. The review team recommends that the State update its existing procedures and develop new procedures, as necessary, to memorialize the policies and practices of the Agreement State program and to serve as a knowledge management tool. (Section 2.1)
 - a. After considering several options, the *Radiation Control Program Administrative Procedures Manual* (Manual) was selected as the repository for memorializing all policies and procedures. In the instance of, for example, inspection procedures, the Manual will simply contain a reference to the Radiation Control Program's *Materials Inspection Manual*. In other instances, the policy or procedure will be incorporated into the Manual.
2. The review team recommends that the State take measures to ensure that initial inspections are performed at the interval prescribed in IMC 2800. (Section 2.2)
 - a. This recommendation was addressed by adding to the pre-licensing inspection form a step that sets the initial inspection due date to nine months after the license is issued. The immediate fix for handling this in the database is as follows: The "Inspection Priority" will be set to "1" and the "Inspection Date" will be set to the license "Effective Date" plus nine (9) months. After the initial inspection, the "Inspection Priority" will be reset to the appropriate priority for the NRC Program Code. A permanent fix will be made with the next database update.
3. The review team recommends that the State take measures to ensure that inspection findings are communicated to licensees within 30 days of the date of the inspection. (Section 2.2)
 - a. Bi-weekly Radioactive Materials staff meetings are held on Monday morning to review the status of active inspection reports. These meetings are scheduled using MS Outlook Calendar. If a Monday is a holiday, then the meeting is held on Tuesday. If the Manager is unavailable, the lead HP convenes the meeting. This will be documented in the Manual with the next update.
4. The review team recommends that the State take measures to ensure that sufficient information pertaining to inspection observations and identified non-compliances is documented in inspection records and in letters to licensees and that these documents be appropriately reviewed by management, prior to issuance, for thoroughness and consistency. (Section 2.3)
 - a. Arrangements have been made with NRC Region IV to accompany and observe Region IV inspectors when they are in South Dakota, Wyoming and Montana. Learning from NRC inspectors and applying what is learned as well as passing that training on to the other two staff inspectors is expected to improve our inspections to a "Satisfactory" level within two years.
5. The review team recommends that the State obtain additional training (formal and on- the-job, as appropriate) for the Branch manager and members of the technical staff to enhance inspection skills, particularly with regards to: (1) radiation safety issues associated with cyclotron operations, and (2) proper operation and use of radiation survey and measurement instrumentation. (Section 2.3)

- a. Arrangements have been made with the Minnesota program to inspect the UND cyclotron while we observe their inspection technique and procedure. Also, we have arranged to visit a same-brand, similar configuration, cyclotron in Minnesota at their convenience.
 - b. Arrangements have been made with NRC Region IV to accompany their inspectors when they are in South Dakota, Wyoming and Montana. To date NRC has provided opportunities to accompany inspections in both Wyoming and South Dakota. We have had to pass on both opportunities because we were unable make the arrangements due to flood related activities in the Bismarck-Mandan area. We hope to still make arrangements to accompany NRC inspectors.
 - c. For training in proper operation and use of radiation survey and measurement instrumentation, the applicable sections in ORAU's Applied Health Physics training course, Books 1 and 2 will be used for classroom instruction. Laboratory type exercises will be drawn from the Lab Workbook exercises. The training will be documented in the individual Radiation Control Program - Training Regimen Checklist.
6. The review team recommends that the State take measures to ensure that the Branch's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance. (Section 2.4)
 - a. A request has been made to Region IV through our State Agreement Officer, Rachael Browder, to have an NRC licensing person come to North Dakota to review our process, practices, and license templates for improvements. We will select two or three of the more challenging licenses to review for accuracy and completeness. The final process and procedures will be documented in the Manual.
7. The review team recommends that the State provide additional training to the Branch manager and technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with: (1) the regulations under North Dakota's equivalent to 10 CFR Parts 30 through 39, and (2) applicable licensing guidance documents for use authorization and license conditions. (Section 2.4)
 - a. On January 1, 2011, the applicable NRC rules were adopted by reference. Therefore, the format is new, the location of some rules are new, and some rule content has changed since the last rule update of the 2002 NRC rules. With time and experience, knowledge of the new rules will be gained.
 - b. We have obtained copies of applicable license templates and standard conditions from Region IV Licensing Branch. We plan to have someone from the Licensing Branch come here to help us work through the licensing process using the process NRC uses.
8. The review team recommends that the Branch take measures to determine and document the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the

application or amendment request, prior to authorizing the material on the license. (Section 2.4)

- a. The Pre-licensing Checklist and Implementing Guidance check list issues by NRC on September 22, 2008 has been fully implemented. The check lists, along with the instructions, have been provided to the staff and reviewed during a biweekly program staff meeting. This change to the licensing process will be incorporated in the Manual with the next update.
9. Regarding financial assurance, the review team recommends that the State: (1) develop a procedure or policy to assess finance assurance requirements as part of significant licensing actions and during licensing renewals; (2) review all North Dakota licenses to determine whether licensees require financial assurance, and either request financial assurance for licenses that are authorized to possess the applicable quantities or revise the license conditions to ensure clear quantity limits that will not require provision of financial assurance; and (3) take measures to ensure that any financial assurance instruments received by the Branch are maintained and stored in accordance with State requirements. (Section 2.4)
- a. The review for financial assurance has been added to initial license application and any licensing action that adds an isotope or increases the licensed activity. If the license already requires financial assurance, then any isotope change will be reviewed to determine if the action changes the required financial assurance. If any licensing action changes the licensee's financial assurance status, a specific letter will be sent to the licensee addressing the status change. This will be documented in the Manual with the next update.
 - b. Beginning June 1, we will perform the financial assurance calculations during updating the licenses to include maximum activity per source and maximum possession activity per isotope. Performing the calculations on licenses already updated will be completed no later than December 2011.
 - c. A tracking spreadsheet has been created using templates provided by NRC. The existing financial assurance documents have been logged in and stored in a lock fireproof file cabinet.
10. The review team recommends that the State strengthen its incident response program and take measures to ensure that: (1) reported incidents are consistently evaluated to determine the appropriate type and level of Branch response; (2) licensee event reports are reviewed by the Branch for completeness and appropriate corrective actions; and (3) the Branch's evaluation of licensee events, whether based on a review of licensee reports, on-site reviews, or inspection follow-up, is properly documented to facilitate future follow-up. (Section 2.5)
- a. The Program has acquired the NRC's *Handling of Materials Licensee Event Reports (LERs) by DNMS Staff* (PG9007B.1) to use as a template for handling reported events.
 - b. A full review of how to best use and incorporate this document into our program has not been completed. Once a resolution is reached, training will be provided and documented in the Manual.
11. The review team recommends that the State strengthen its allegation program and take measures to ensure that: (1) allegations are promptly evaluated to determine the appropriate type and level of Branch response; (2) the Branch's evaluation of

allegations and any actions taken in response to allegations is properly documented to facilitate future follow-up; and (3) processes are in place to provide a response to allegers as appropriate. (Section 2.5)

- a. The plan is to use NRC's DH 8.8 (Management of Allegations) along with NRC's *Allegation Receipt Form* and *Branch Evaluation, Plan & Recommendation* form as the foundation for handling allegations. Once the process and procedure is completed, training will be provided and the process and procedure documented in the Manual.