13.0 QUALITY ASSURANCE PROGRAM

Under the "no action" alternative, the decommissioning activities yet to be performed involve only sampling and survey activities, the removal of non-radioactive structures and systems, and the removal of a container of sample-derived waste previously generated at the site. These activities are not expected to produce significant radiological hazards, to result in substantial challenges to regulatory compliance, or to require skills that are technically difficult to master. Nonetheless, the MDNR plans to perform several types of activities that rightfully fall under the purview of a quality assurance (QA) program; the necessary program elements are described below.

13.1 ORGANIZATION

Due to the extremely limited and straightforward nature of the activities that are proposed, QA of those activities by an organization with multiple units and disciplines is unwarranted. Thus, the decommissioning project's QA organization is commensurate with the scope of the planned activities and is far less complex and detailed than that described in NUREG-1727. There is no separate or discrete organizational chart for the QA organization. MDNR retains the ultimate responsibility for the overall quality of the decommissioning project. However, the project QA function is to be performed by a contractor with extensive experience in remediation of radioactively contaminated sites, performance of statistically based final-status radiological surveys, and waste management. The project organizational chart and a detailed description of QA supervisory personnel are found in Section 9.0.

Mr. Michael O'Hearn will be the project QA Specialist. The contractor is committed to giving Mr. O'Hearn full authority for QA issues, and he will be involved in all decommissioning activities that have a quality implication. Mr. O'Hearn will identify quality issues or problems, work through the contractor's Project Manager, as necessary, to provide solutions, and will ensure that solutions are implemented. Mr. O'Hearn will verify that the quality requirements for all activities are attained and appropriately documented. The contractor's Field Superintendent will be in charge of site operations. He (or his appointed designee) will be on site during active work periods and will be the line manager directly responsible for activities performed at the site. By reporting to the contractor's Project Manager, the project QA Specialist is at an organizational level equal to that of the Field Superintendent.

The project QA Specialist will be independent of the cost and schedule responsibilities of the MDNR and will have the authority and responsibility to stop any work that does not meet specifications or does not conform with accepted and approved procedures affecting quality. If an issue affecting quality arises and cannot be resolved by the contractor, the contractor's PM and QA Specialist will confer with the MDNR Project Manager. The MDNR Project Manager will be the arbiter of the issue.

13.2 QUALITY ASSURANCE PROGRAM

13.2.1 Summary of QA Policy

The contractor will perform work in accordance with their company QA policy, general company QA program, and specific QA program elements that will be developed for the decommissioning project. All activities to be performed in support of the site decommissioning effort will be subject to the applicable controls of the QA Program. The purpose of the QA Program will be to provide sufficient controls so that activities performed during decommissioning meet the commitments of the MDNR and meet NRC requirements and expectations. The QA Program will provide management, control and verification of quality so that decommissioning activities meet established requirements, are performed in accordance with applicable federal and local laws and regulations, and are performed in an ethical and professional manner. Adherence to established requirements will be the responsibility of all who perform the work. The function of verifying quality achievement will be accomplished by an individual who does not have direct responsibility for performing the work, and who has sufficient authority, direct access to management, organizational freedom, and access to the work to perform the QA function.

Quality-related activities will be conducted and controlled using documented procedures appropriate to the complexity of the work; the use of the term "procedures" includes instructions, drawings, material specifications, data collection, and other appropriate documents. The procedures will specify quality-related activities and the controls used to ensure that quality is achieved; the training and special skills required; the equipment or tools needed; and the means of verifying that quality requirements have been met.

The contractor will perform activities under a work control process that ensures work is performed according to plan. The contractor will confirm that all appropriate procedures are in place, personnel are trained as needed, hazards are assessed, appropriate controls are in place, quality controls are understood, quality-compliant materials will be available in a timely manner, and support personnel are available before work begins.

13.2.2 Development and Modification of QA Procedures and Controls

During detailed work planning, the contractor will identify the discrete activities necessary to accomplish the decommissioning. As part of the planning, the contractor will identify the requirements applicable to those discrete activities (whether the requirements are related to training, safety, waste management, compliance with the license and final status survey plan or other) and will ensure that the requirements are integrated into all appropriate work documents. The requirements will be assessed by the trained and experienced professionals who are listed in Section 9, and will be approved by the MDNR Program Manager.

The specifications for quality-related aspects will be incorporated into appropriate instructions, procedures, and drawings. These aspects will include acceptance criteria that will be used to ensure decommissioning activities are performed with sufficient quality.

Documented procedures used to accomplish the decommissioning activities (where "procedures" include instructions, drawings, material specifications, data collection activities, and the like) will be developed by a multi-disciplined team that includes the QA Specialist, work managers such as the Project Manager and Field Superintendent, the RSO, and the members of the engineering support group. Each procedure will include at least the relevant quantitative and qualitative quality acceptance criteria for performing the work; description of personnel responsibilities; description of any quality "hold points" beyond which work shall not proceed without verification that it meets the quality criteria; description of the expected environmental and safety hazards and their control; a list of required training or skills; and a list of the applicable requirements.

At a minimum, each procedure having quality implications will be reviewed and accepted by the QA Specialist and contractor Project Manager; other people will review procedures as appropriate. Their review and acceptance will be documented. Every project procedure will be reviewed and concurred on before work begins. Although the expected short duration of activities makes program, procedure, and personnel changes unlikely, if changes are made, the NRC will be notified within 30 days through the MDNR.

Quality-affecting procedural controls will be incorporated directly into procedures. General controls are expected for activities that will not have qualitative or quantitative quality requirements. Detailed controls are expected for activities such as soil sampling, laboratory quality assurance, equipment calibration, activities related to making repairs of the engineered clay cover, radiological surveys, waste characterization and transportation, and record keeping. The controls will be accepted during the procedure development and review process.

13.2.3 Training Program

Due to the limited scope of the proposed decommissioning activities, QA functions will be accomplished by the contractor QA Specialist. However, the MDNR retains ultimate responsibility for ensuring QA requirements are met, and all personnel will be responsible for ensuring that the work they perform meets the requirements of the applicable procedures.

The proposed QA Specialist, Mr. O'Hearn, has 22 years of experience in environmental site remediation project management, with 14 years of experience in oversight and responsibility for quality assurance and quality control. The other key members of the

contractor staff have extensive experience in their areas of expertise and each has a proven record of managing work to meet quality requirements.[1]

All management personnel selected are trained and qualified to perform their functions, and only workers previously trained in their overall job functions will be selected for the project. Both management and workers will receive site-specific radiological protection training through the existing RP Training Program (Section 10.0). If a worker needs additional task-specific training, it will be provided through a trade union or at the site by a qualified person. In all cases, training provided as part of the decommissioning project will be documented and will indicate the objective(s) and content of the training, the instructor's name, the attendees, and the date.

Quality-affecting procedural controls will be incorporated directly into procedures. Quality training for the decommissioning project procedures will be provided as part of the training. That training will include the principles and techniques to be used, the requirements of the activity, as well as other key and relevant aspects of the procedure. Depending on the scope of the activity, training may be accomplished as part of a documented tailgate session or in a more formal setting. No formal training related only to quality is planned for the decommissioning work.

The QA Specialist will be responsible for ensuring that personnel performing quality-related activities are adequately trained in the requirements and procedures associated with their work assignments. The QA Specialist will verify that training needs have been assessed, training has been provided, and training is documented before work begins.

13.2.4 Assessments of the QA Program

The procedure creation and review process discussed in Section 13.2.2 will ensure that the QA program is assessed initially by a range of people. Due to the short time period during which decommissioning activities will be performed, there will likely not be a need to perform regular assessments of the QA program. However, the QA program will be assessed by management should the QA Specialist determine that a procedure is inadequate, that work is not meeting quality standards, or that conditions have changed in a way that affects or could affect work quality.

The scope of proposed activities will require few personnel and a minimal project organization. Combined with the short duration of work, no self-assessments are planned. The QA Specialist (or appropriately qualified and autonomous designee) will perform all assessments of work, and thus assessments will be performed by an independent person who will not have direct responsibility for the work. Although the QA Specialist will perform assessments, all project personnel will be held responsible for meeting the quality requirements applicable to their tasks.

1 For details about the training and qualification of personnel presently filling key organizational positions, refer to Section 9.0.

13.3 DOCUMENT CONTROL

The QA requirements will be incorporated directly into procedures and other project documents, and therefore QA program documents will effectively be issued and approved for release through the creation and review process discussed in Section 13.2.2. The process will ensure that the QA Specialist concurs with all procedures before they are finalized. The contractor will keep a complete set of approved procedures in a single location at the site during the decommissioning activities, and these procedures will be available to all personnel. Due to the short duration of the project, revisions to the various documents are not expected. Workers and overseers will have access to the latest approved versions of each document.

All project documents, including technical reports, will be filed at the end of the project by verifying that the MDNR has a copy of each. The documents will be retained as part of the MDNR's record retention program.

13.4 CONTROL OF MEASURING AND TEST EQUIPMENT

There are two schools of thought concerning what is included in the category of measurement and test equipment (M&TE). Some broadly apply the term to mean any device that is used to make a measurement (e.g., an ion chamber used to make a field measurement), while others (taking into account ANSI and ISO standards describing the controls associated with such) apply the terms to the category of instruments and test equipment used to establish or transfer a calibration (i.e., calibration standards). The NRC's stated objective in reviewing the licensee's test and measurement equipment calibration program is "…to ensure that equipment used to support decommissioning activities is properly controlled, calibrated, and maintained" (NRC 2000a). It is understood, then, for the purposes of this DP, that the term "measurement and test equipment" applies in the broader sense and that there is no intention to invoke standards or requirements for M&TE (e.g., ANSI or ISO) that are clearly intended to address calibration standards as opposed to end-use, field-measurement equipment.

The project QA Specialist will oversee the M&TE QA program element for the decommissioning project and ensure that M&TE used in support of decommissioning is calibrated, stored, and maintained according to written procedures, instructions, or other guidance documents reviewed and approved by the RSO, or by a commercial calibration service vendor. M&TE will be calibrated at least annually, as appropriate, or following maintenance, repair, or adjustment likely to affect the primary calibration. M&TE will be calibrated using traceable standards and sources (e.g., NIST). Standards used to calibrate radiation measurement instruments shall be appropriate for the types and energies of radiation emitted by the radionuclides present at the site. In some cases (e.g., ISOCS gamma spectrometry systems), it may be possible to establish a calibration factor for a radiation measurement system without the use of a radioactive calibration source (a sourceless efficiency calibration). Standards for calibration are determined with appropriate reference to nationally accepted standards, manufacturers' instructions,

intended uses, and other factors. If national standards do not exist, the basis for calibration will be documented. Calibrations will be performed prior to use when such action is necessary to maintain or ensure accurate measurements and tests.

Section 10.1.6 of the DP describes the instrument calibration and controls proposed for radiation measurement equipment and provides a summary list of the M&TE expected to be used in the decommissioning project.

When not in use, M&TE used in decommissioning activities will be stored in a clean, dry environment. It will be stored in a manner that provides a reasonable expectation that it will not become physically damaged and where unauthorized access is prevented. For example, M&TE may be stored in the LCTS building on the site or in a vehicle that is locked outside of working hours.

Each piece of M&TE used onsite in support of decommissioning activities will be labeled or tagged with the following information, as applicable:

- Unique identification (e.g. serial number),
- Initials or specific identifying mark of individual completing the calibration,
- Energy correction factors,
- Instrument response to an identified check source,
- Unusual or special use conditions or limitations, and
- Date by which calibration is again required.

Before measuring and test equipment is used, it will be checked by the user to have a current calibration, to be operable, and to be in good physical condition. In addition, response checks of portable field radiation detection instruments will be performed against a known standard, to verify the operational status of the equipment prior to daily use. Response check results will be documented in accordance with written procedures. M&TE will be removed from service if it has suffered damage that might impair its ability to return accurate and reliable measurements. Portable radiation instruments will be removed from service if periodic response checks are not within ±20 percent of the initial post-calibration value.

Documented calibration and response check records will be maintained as Quality Assurance records, in accordance with applicable procedures. When M&TE is used to make a measurement associated with decommissioning activities, the measurement will be documented. Documentation will include the unique identification number of the M&TE used, the calibration due date, the date and time of the measurement(s), and the name and signature of the person making the measurement.

13.5 CORRECTIVE ACTION

The QA Specialist will assess aspects identified as quality-related in procedures. This will ensure that conditions adverse to quality are identified promptly. If a condition is determined to have a significant adverse affect on quality, the QA Specialist will stop work immediately. If a condition will not have a significant adverse affect on quality, work may continue while corrective actions are implemented. In either case, corrective actions will be determined and implemented as soon as possible.

Working with the contractor's Project Manager and workers as appropriate, the QA Specialist will identify the cause of out-of-specification conditions and violations of quality-related requirements and determine the appropriate corrective action(s). These will be documented, and the QA Specialist and contractor's Project Manager will be jointly responsible for ensuring that corrective actions are promptly implemented before work resumes.

A corrective action request (CAR) will be used by the QA Specialist to document deficiencies or nonconformances and the appropriate corrective action(s). The CAR will be issued to the responsible contractor organization and tracked to ensure that the appropriate corrective action is taken in a timely manner. A CAR will not be closed until the corrective actions have been accomplished and verified by the QA Specialist, as documented through the QA Specialist's signature on the CAR. After a CAR is closed, the associated documentation will be kept on file with the contractor; all CARs will be turned over to the MDNR at the completion of the project and will be retained as part of the MDNR's record retention program.

13.6 QUALITY ASSURANCE RECORDS

Quality assurance records are defined as those records that contain documentary evidence of activities or data relevant to the quality of an item or activity and testify directly or indirectly that the item or completed activity can perform in compliance with requirements. The QA program will ensure that quality assurance records are created and identified, protected against loss or damage, stored efficiently, and transferred to the MDNR when the project is complete. The MDNR will provide permanent storage and retention of all project quality assurance records in accordance with their existing record retention program.

Contractor management employees will create quality records during the course of their work. The QA Specialist will identify records, ensure needed records are created, and store the records during the project. Records generated during the conduct of the decommissioning project will be collected and stored in the local offices of MACTEC labeled "Tobico Marsh Project."

Records expected to be created relate to all quality assurance activities. They will include procedures; analytical results; survey results; material specifications; waste

characterization, storage, and disposal information; equipment calibration records; as-built drawings; results of QA assessments and corrective actions.

13.7 AUDITS AND SURVEILLANCES

The QA Specialist will assess aspects identified as quality-related in procedures, using checklists developed for each activity or item. Assessment will be accomplished through observation of work vs. procedures; review of material specifications vs. materials received; checking to ensure project documents are reviewed by appropriate management; verification of training records; verification of project conditions at QA "hold points"; review of project records; and assessment of other quality-related activities. These actions will ensure that conditions adverse to quality are identified promptly. If a condition is determined to have a significant adverse affect on quality, the QA Specialist will stop work immediately. If a condition will not have a significant adverse affect on quality, work may continue while corrective actions are implemented. In either case, corrective actions will be determined and implemented as soon as possible.

Working with the contractor's Project Manager and workers as appropriate, the QA Specialist will identify the cause and determine the appropriate corrective action(s). These will be documented, and the QA Specialist and contractor's Project Manager will be jointly responsible for ensuring that corrective actions are promptly implemented. The QA Specialist and Project Manager will review all assessments to determine if trends are occurring. If a trend is discovered, the QA Specialist will be responsible for working with management to develop corrective actions and ensuring that all affected aspects of the project are modified as needed (with notification to the NRC of any changes as specified in Section 13.2.2).

A corrective action request (CAR) will be used by the QA Specialist to document deficiencies, nonconformances, or trends and the appropriate corrective action(s). The CAR will be issued to the responsible contractor organization and tracked to ensure that the appropriate corrective action is taken in a timely manner. A CAR will not be closed until the corrective actions have been accomplished and verified by the QA Specialist, as documented through the QA Specialist's signature on the CAR. After a CAR is closed, the associated documentation will be kept on file with the contractor; all CARs will be turned over to the MDNR at the completion of the project and will be retained as part of the MDNR's record retention program.

The QA Specialist will review the results of assessments or trends with the affected managers and staff. Lessons learned will be communicated to all employees during the daily tailgate briefings.