

APPENDIX A
to the Consent Decree in
Maine People's Alliance v. HoltraChem Mfg. Co., LLC,
No. 1:00-cv-00069-JAW (D. Me)

Statement of Work

STATEMENT OF WORK
For Remediation Activities

in the Penobscot River Estuary, Maine
to Accompany the Consent Decree in

Maine People's Alliance v. HoltraChem Manufacturing Co., No. 1:00-cv-00069-JAW, D. Me.

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I. Introduction

1. **Purpose of the SOW.** This Statement of Work (“SOW”) sets forth the procedures and requirements for implementation of the Work by the Remediation Trust and Project Trust (although certain sections of this SOW may only be applicable to one of the Trusts) as defined in the Consent Decree entered in the matter of *Maine People’s Alliance and Natural Resources Defense Council, Inc. v. Mallinckrodt US LLC, et al.*, Case No. 1:00-cv-00069-JAW, in the United States District Court for the District of Maine.

2. **Definitions.** The terms used in this SOW that are defined in the Consent Decree or in a Trust Agreement have the meanings assigned to them in the Consent Decree or Trust Agreement, except that, unless otherwise stated:

- a. “Paragraph” means a paragraph of the SOW;
- b. “Beneficiaries” has the meaning assigned in the Consent Decree and includes Mallinckrodt US LLC, Maine People’s Alliance, and Natural Resources Defense Council; and
- c. “Section” means a section of the SOW.

3. Structure of the SOW

a. Section II (Work Design) sets forth requirements regarding the design, implementation, and completion of design plans to implement Work activities, including the submission of Work Plan documents.

b. Section III (Implementation of Work) sets forth requirements regarding the implementation and completion of Work activities, including the submission of Deliverables.

c. Section IV (Community Involvement) sets forth the responsibilities of the Trusts, the Trustees and the Beneficiaries for community involvement, including the submission of specified deliverables.

d. Section V (Recordkeeping and Reporting) sets forth the Trustees' recordkeeping and reporting obligations.

e. Section VI (Deliverables) describes the Deliverables, and procedures for submission of, review of, and comment on the Deliverables.

f. Section VII (Schedules) describes the Trustees' duties to establish and update schedules for the Work at the Site.

g. Section VIII (Permitting and Regulatory Cooperation) describes the Trustees' responsibilities to coordinate with, and obtain authorizations (regulatory approvals, permits, or other permissions required to undertake the Work at the Site) from, federal, state, and local regulatory and permitting entities, and to obtain access agreements or any other private, third-party permissions required for the Work.

h. Section IX (Contracting) sets forth requirements for any contracts that the Trustees enter into for Work at the Site.

i. Section X (Modifications) sets forth the procedures for modifications to this SOW.

j. Section XI (Appendices and References) lists references and appendices to this SOW.

4. The extent of Work is limited to the actions described in Section VI (Commitments by Mallinckrodt) of the Consent Decree. Work to be completed at the Site, including the remediation activities to be designed and implemented and the available funding for the remediation activities, is set forth in Paragraphs 10-15 of the Consent Decree. Notwithstanding the Trustees' obligations to comply with the requirements set forth in Paragraphs 5 through 11 hereafter, the Trustees are authorized to undertake alternative approaches to Work Design and Work Implementation that streamline the processes so long as the Trustees provide justification for such changes in Work Plans and other relevant Deliverables, including the opportunity for potential cost savings and schedule improvements, enhanced remediation outcomes, and other efficiencies, and demonstrate that a more streamlined approach satisfies all permit requirements and otherwise complies with all requirements of the Consent Decree and the Trust Agreements, including but not limited to the Beneficiaries' right to comment on and object to any such changes. Such alternative approaches to Work Design and Work Implementation may include, but are not limited to, awarding Engineer-Procure-Construct and/or modified design-build contracts which may be more cost effective, save time, or mitigate potential or perceived risks associated with the Work, while remaining protective of human health and environment. The Trustees' utilization of any such alternative approach shall not in any way change, alter, or otherwise modify the scope of the Work beyond those actions provided for in Section VI of the Consent Decree.

II. Work Design

5. **Design Work Plans.** The Trustees shall prepare and submit to the Beneficiaries for comment and opportunity for objection, a work plan for the design of the Work to be conducted for each Work Category (“Design Work Plan”). The Trustees must give notice to the Beneficiaries if the nature or scope of the Work as described in the applicable Design Work Plan materially changes after the opportunity for objection has occurred, and in such event the Trustees shall provide a brief written explanation of the material change(s) and either an errata to the Design Work Plan or an amended Design Work Plan that clearly marks the changes. Design Work Plans and any erratum or amendments thereof are Deliverables subject to the requirements of Paragraph 31 (Decisions Regarding Work and Deliverables) of the Consent Decree, including but not limited to the opportunity for comment and objection by the Beneficiaries. The purpose of the Design Work Plans is to document the technical scope, basis of design, design process, strategy for securing regulatory approvals, and Work schedule. The Design Work Plans shall include the following elements, as applicable to the Work:

- a. A summary of existing conditions and Work objectives;
- b. A Basis of Design that identifies the objectives, requirements, and performance criteria to be met by the Work;
- c. A description of the overall management strategy for performing the Work, including a proposal for phasing design and construction, if applicable;
- d. A schedule for design activities;

e. A description of the proposed approach to contracting, construction, operation, maintenance, and monitoring of the remediation activities as necessary and applicable to implement the Work;

f. A description of the roles, responsibilities, and authorities of all organizations/entities and key personnel responsible for development of the Work Design for a Work Category;

g. Descriptions of any areas requiring clarification and/or anticipated problems (e.g., data gaps, Site access issues, anticipated permitting issues, etc.);

h. Descriptions of any proposed investigations, pilot tests, or treatability studies required to complete the design;

i. Descriptions of any uncertainties or data gaps that are not anticipated to require clarification or further investigation;

j. Descriptions of applicable permitting and authorization requirements and other regulatory requirements, including the timeline for securing regulatory approvals and the Trustees' plans for meeting the applicable permitting and regulatory requirements during the Work Design process;

k. Descriptions of plans for obtaining any access rights or other public or private authorizations needed in connection with the Work, such as access agreements, property acquisition, property leases, and/or easements; and

l. Preparation of a Health and Safety Plan, Emergency Response Plan, Field Sampling Plan, and Quality Assurance Project Plan ("QAPP"), both for any proposed investigations, pilot tests, or treatability studies and for the Work itself.

6. **Investigations.** The purpose of any investigation (“Investigation”) is to address key data gaps identified in the Design Work Plan that require further investigation in order to complete the Work Design for a Work Category.

a. Investigation Work Plan. The Trustees shall submit to the Beneficiaries for comment a work plan for any proposed Investigation that includes, as applicable to the Work:

i. An evaluation and summary of existing data and a description of the data gaps that require further investigation in order to complete Work Design for a Work Category;

ii. A description of the required technical and/or regulatory decisions to be made or questions to be answered with the Investigation results, along with a summary of the type, quantity, and quality of data needed to reach those decisions (“Data Quality Objectives” or “DQOs”);

iii. A sampling plan including media to be sampled, contaminants or parameters for which sampling will be conducted, location (areal extent and depths), and number of samples;

iv. A schedule for the Investigation; and

v. Cross references to quality assurance/quality control (“QA/QC”) requirements set forth in the QAPP as described in Paragraph 31(d).

b. Investigation Report. Following any Investigation, the Trustees shall submit to the Beneficiaries an Investigation Report that includes, as applicable to the Investigation objectives:

- i. A summary of the investigations performed;
 - ii. A summary of the investigation results;
 - iii. Summaries of validated data (i.e., tables and graphics);
 - iv. Summaries of data validation reports and laboratory data reports;
 - v. Narrative interpretation of data and results, including how the Investigation objectives and DQOs were satisfied;
 - vi. Results of statistical and modeling analyses;
 - vii. Summary photographs documenting the work conducted;
- and
- viii. Conclusions and recommendations for Work Design, including any resulting modifications to design parameters and criteria provided for in the Basis of Design or other Deliverables.

7. Treatability Studies and Pilot Tests

a. The purpose of any treatability study or pilot test is to provide Site-specific data to address key data gaps and/or uncertainties related to treatment technologies, remediation techniques, or Site-specific conditions that may affect remediation methods. Treatability studies and pilot tests may be undertaken if needed, but are not required, and may be unnecessary for well-established or

proven remediation methods. If the need for a treatability study or pilot test is identified, the treatability study or pilot test shall be proposed by a Trustee in a Design Work Plan.

b. Treatability Study or Pilot Test Work Plans. For any treatability study or pilot test, the Trustees shall submit to the Beneficiaries for comment a Treatability Study or Pilot Test Work Plan that includes:

- i. An evaluation and summary of existing data and a description of the data gaps to be addressed by the treatability study or pilot test;
- ii. A description of the treatability study or pilot test objectives, including the criteria by which the resulting data will be evaluated;
- iii. A sampling, analysis, and/or testing plan including media to be evaluated, analyses to be conducted, contaminants or parameters to be analyzed, number of samples, and pilot test plans;
- iv. A schedule for the treatability study or pilot test; and
- v. Cross references to QA/QC requirements set forth in the QAPP as described in Paragraph 31(d).

c. Treatability Study or Pilot Test Evaluation Report. Following any treatability study or pilot test, the Trustees shall submit to the Beneficiaries a Treatability Study or Pilot Test Evaluation Report that includes, as appropriate:

- i. A summary of the treatability study or pilot test performed, referencing consistency with the Treatability Study or Pilot Test Work Plan and noting key deviations therefrom, if any;
 - ii. A summary of the treatability study or pilot test results, including a description of whether the design objectives were met;
 - iii. Summaries of validated data (i.e., tables and graphics);
 - iv. Summaries of data validation reports and laboratory data reports;
 - v. Narrative interpretation of data and results, including an evaluation of the results with respect to the performance criteria identified in the Treatability Study or Pilot Test Work Plan;
 - vi. Results of statistical and modeling analyses;
 - vii. Summary photographs documenting the work conducted;
- and
- viii. Conclusions and recommendations for Work Design, including design parameters and criteria.

8. **Work Design Process.** The Trustees shall ensure that their staff, consultants, and contractors use best professional judgment to complete all Work Designs in accordance with the Design Work Plan in an efficient, timely, rigorous, and scientifically justified manner. As part of the Work Design process, the Trustees shall prepare preliminary Work Designs needed to provide the information required to implement the Work and to secure the required regulatory approvals and permits.

However, the Trustees are encouraged to prepare only those Work Designs required to secure regulatory and permitting approvals and address Beneficiary comments. The Trustees and their consultants and contractors are expected to use their best professional judgment to prepare Work Designs that are efficient and cost-effective, address comments from regulatory agencies, and, in the Trustees' discretion, consider and address comments from the Beneficiaries.

9. **Work Designs.** The Trustees shall submit a draft of each Work Design, including any preliminary Work Designs needed for regulatory and permitting purposes, to the Beneficiaries for comment and opportunity for objection. The Beneficiaries shall have at least fourteen (14) days to review and provide comments on each draft Work Design, including any proposed final Work Design. If a Beneficiary wishes to object to any element of any Work Design, that Beneficiary shall initiate the Dispute Resolution process provided in the Consent Decree and, in doing so, the Beneficiary shall identify with specificity the element(s) of the Work Design to which it objects. When submitting a Work Design to the Beneficiaries, the Trustees shall include a brief summary of the material changes and alterations from the prior version of the Work Design. The Trustees' Work Designs for Work in each Work Category shall include the elements necessary to support the Work objectives and may include the following elements:

- a. A description of the Work to be implemented, including the Work Design objectives;

b. Drawings and specifications. Any preliminary Work Design may include preliminary drawings and specifications. The final Work Design shall include:

i. A complete set of construction drawings and specifications that are (A) certified by a registered professional engineer, and (B) suitable for procurement; and

ii. A survey and engineering drawings showing existing Site features, such as elements, property borders, easements, and Site conditions;

c. Descriptions of permit requirements and any other authorization requirements;

d. An Operation and Maintenance (O&M) Plan and O&M Manual, if necessary;

e. A description of how the Work will be implemented in a manner that minimizes environmental risks and adverse impacts;

f. A description of monitoring and control measures to protect human health and the environment, such as water and air monitoring and dust suppression, during the Work;

g. A proposed Work Schedule;

h. Any updates to the supporting Deliverables if required to accompany the Design Work Plan (Health and Safety Plan, Emergency Response Plan, Field Sampling Plan, and QAPP), and the following additional supporting

Deliverables described in Paragraph 31 (Supporting Deliverables), if applicable: Site Wide Monitoring Plan, Transportation and Off-Site Disposal Plan, O&M Plan, and Institutional Controls Implementation and Assurance Plan; and

i. Such other elements as the Trustees determine are necessary and appropriate in their best professional judgment.

j. The Trustees may recommend a more limited Work Design effort if a more streamlined, cost-effective approach to contracting for the Work does not require a detailed Work Design and complies with all regulatory requirements and permits.

10. **Feasibility of Work.** If at any time during the performance of the Work Design tasks the Trustees determine that the Work is not Feasible, as defined in the Consent Decree, the Trustees shall provide written notice to the Beneficiaries of the basis for such a determination as soon as reasonably possible, and provide the Beneficiaries with an opportunity to object to the Trustees' conclusions.

III. Implementation of Work

11. **Implementation Work Plans.** The Trustees shall prepare and submit to the Beneficiaries for comment and opportunity for objection plans to implement the Work Design(s) for each Work Category ("Implementation Work Plans"). The Trustees must give notice to the Beneficiaries if the nature, scope, or schedule of an Implementation Work Plan later changes in a material way by briefly explaining in writing the material change(s) and providing an errata or draft amended Implementation Work Plan that clearly marks the changes. Implementation Work Plans and any errata or amendments

thereof are Deliverables subject to the requirements of Paragraph 31 (Decisions Regarding Work and Deliverables) of the Consent Decree, including but not limited to the opportunity for comment and objection by the Beneficiaries. The Trustees' Implementation Work Plans shall include at least the following elements:

- a. A Work construction schedule in an appropriate format, such as a critical path or Gantt chart;
- b. An updated Health and Safety Plan that meets all applicable regulatory requirements and covers activities during the Work; and
- c. Plans for satisfying all permit, authorization, and access agreement requirements, including for obtaining all necessary permits, authorizations, and permissions for on- and off-Site activities, and for satisfying any requirements of such permits, authorizations, and permissions.

12. Meetings and Inspections

a. The Trustees will ensure appropriate oversight of all construction activities and enter into contracts that provide for contractor responsibility for addressing any deficiency in the performance of the Work and compliance with the Implementation Work Plan and final Work Design.

b. The Trustees shall report to the Beneficiaries as required by the Consent Decree. If requested by a Beneficiary, the Trustees shall make reasonable efforts to allow the Beneficiary's representatives to inspect or observe the Work, so long as the request does not unreasonably create health or safety risks or interfere with the timely implementation of any Work.

13. **Emergency Response and Reporting**

a. Emergency Response and Reporting. If any event occurs during performance of the Work that causes or threatens to cause a release of Waste Material on, at, or from the Site and that either constitutes an emergency situation or that may present an immediate threat to public health or welfare or the environment, the Trustees (or their contractors) shall: (1) immediately take or direct all appropriate action to prevent, abate, or minimize such release or threat of release; (2) immediately notify the appropriate state and federal regulatory agencies orally and notify the Trustees, who will notify the Beneficiaries orally or by electronic mail; and (3) take such actions in accordance with all applicable provisions of the Health and Safety Plan, the Emergency Response Plan, and any other relevant Deliverables. All oral notifications made to state and federal regulatory agencies pursuant to the Emergency Response and Reporting provisions herein must be followed up in writing within 48 hours of issuance to document the time, date, nature, and content of the oral notification that was provided.

b. Release Reporting. Upon the occurrence of any event during performance of the Work that a Trustee (or its contractor) is required to report pursuant to Section 103 of CERCLA, 42 U.S.C. § 9603, or Section 304 of the Emergency Planning and Community Right-to-know Act (EPCRA), 42 U.S.C. § 11004, the Trustee shall immediately notify the appropriate state and federal

regulatory agencies orally and notify the Beneficiaries and the Trustees orally or by electronic mail.

c. For any event covered by Paragraph 12(a) and/or (b), the Trustee shall: (i) within fourteen (14) days after the onset of such event, submit a report to the Beneficiaries describing the actions or events that occurred and the measures taken, and to be taken, in response thereto; and (2) within thirty (30) days after the conclusion of such event, submit a report to the Beneficiaries describing all actions taken in response to such event. This reporting requirement is in addition to any other reporting required by the Consent Decree. The Trustee shall also submit any required reporting under CERCLA § 103 or EPCRA § 304.

14. Off-Site Shipments and Waste Disposal

a. Beneficial reuse of any sediment, debris, and other materials removed from the Site is preferable to landfill disposal and is the appropriate method for management of materials removed from the Site if such reuse is permissible as determined by the granting of all necessary permits and approvals for such reuse. Material may be reused in other states. The Trustees shall make best efforts to beneficially reuse all sediment, debris, and other materials removed or excavated from the Site.

b. The Trustees may ship waste materials from the Site to an off-Site disposal facility only if beneficial reuse is not Feasible or if required regulatory approvals or permits cannot be secured in a timely manner, and, in such case, only if the off-Site facility is qualified to receive the waste materials under applicable

federal and state laws and the Trustees, or their contractors, obtain all applicable state and/or federal permits and authorizations for such waste transportation and disposal.

c. All plans to transport and dispose of waste materials off-Site must be described in a Transportation and Off-Site Disposal Plan that accompanies the applicable final Remedial Design Work Plan.

15. Determinations Regarding Contingent Funding for Work Categories

a. Consistent with Paragraphs 10(b), 11(b), 14(b), and 15(a) of the Consent Decree, and as further specified herein, the Trustees shall determine if any of Mallinckrodt's Contingent Funding obligations are triggered. In making this determination, the Trustees shall be guided by sound professional environmental engineering and scientific principles and advice. All best efforts shall be made to design and complete the Work without the Contingent Funding but the Trustees shall not sacrifice sound engineering and scientific principles to do so.

b. In the Orrington Reach, the Trustee of the Remediation Trust may require the Contingent Funding of up to \$10 million if it determines that the Work in this Reach, including remedy design, implementation, monitoring, and maintenance, cannot feasibly be completed within the Committed Funding of \$50 million. This determination shall be based on the professional judgement and advice of the Trustee and its experts, taking into account feedback from regulatory agencies and the Beneficiaries, bids from potential Implementation Work

contractors, the need for O&M in this Reach, and any other factors that professionals, including environmental engineers and/or scientists would consider. The Trustee may make this determination at any time until it certifies that the Implementation Work in the Orrington Reach, including O&M, is complete.

c. For the Mobile Sediments and Surface Deposits, the Trustee of the Remediation Trust may require the Contingent Funding of up to \$50 million for landfill (off-Site) disposal of sediment, debris, and other materials for which beneficial reuse is not permitted by the relevant regulatory agency or agencies or otherwise is not Feasible, consistent with Paragraph 14 above.

d. For Long-Term Monitoring, the Trustee of the Remediation Trust may require the Contingent Funding of up to \$10 million in additional funds if it determines that a scientifically justified Long-Term Monitoring program cannot feasibly be completed within the Committed Funding of \$10 million. This determination shall be based on the Trustee's best professional judgment, taking into account the advice of its technical experts, feedback from regulatory agencies and the Beneficiaries, existing monitoring data from the Site, bids from potential monitoring contractors, and any other factors consistent with the Trustee's fiduciary obligations to its Beneficiaries. The Trustee may make this determination at any time until it certifies that the Long-Term Monitoring is complete, which shall be determined consistent with the procedures in Paragraph 14(c) of the Consent Decree.

16. **Certification of Implementation Work Completion**

a. Work Completion Inspection. Upon the completion of any Implementation Work for a Work Category or a discrete part of a Work Category, the Trustees shall inspect the construction and, if applicable, implementation of the remedial Work to ensure that it was constructed in accordance with the Design Plan and consistent with all contract specifications and requirements.

i. If, based on the Implementation Work Completion Inspection and review of all accompanying documentation, any aspect of the Implementation Work is deficient, the Trustees will ensure that its contractors correct any deficiencies and thereafter confirm proper completion of Implementation Work. The Trustees shall report any such deficiency to the Beneficiaries not later than in the next Quarterly Progress Report after the deficiency is discovered, along with a description of corrective actions taken.

ii. If any Implementation Work includes construction of a treatment system or any other mechanical system that is required to meet a specific performance standard, the Trustees' inspections shall occur during and after startup and once operations are stabilized as set forth in the Work Design documents and O&M Plan, to ensure that the system is functioning properly and as designed.

b. Final Implementation Work Report. Following a successful inspection of completed Implementation Work in a Work Category, the Trustees

shall submit to the Beneficiaries an Implementation Work (Construction Completion) Report, which may be submitted concurrently with, or as a separate section of, a Quarterly Progress Report required by Paragraph 37 of the Consent Decree and Paragraph 25 of this SOW. The Implementation Work (Construction Completion) Report will include the following as applicable: (i) statements by a registered professional engineer and by the Trustees that construction of the Implementation Work is complete and is consistent with the Work Design(s) and Work Implementation Plan(s) and all contract documents and specifications; (ii) supporting documentation that construction of the Implementation Work is complete and that the Implementation Work was constructed consistent with the Work Design(s) and Work Implementation Plan(s) (and all contract documents and specifications); (iii) record drawings signed and stamped by a registered professional engineer; (iv) a description of any deviations from the Work Design(s) and Work Implementation Plan(s) and how they were corrected; and (v) a certification in accordance with Paragraph 28 (Certification). The Trustees shall also prepare and submit any completion report(s) required by a regulatory agency or other permitting authority as a condition of any permit or other authorization, and the Trustees shall provide a copy of any such report(s) to the Beneficiaries.

c. A Beneficiary may dispute a final Implementation Work Report by initiating the Dispute Resolution provisions of the Consent Decree.

17. **Determinations Regarding Reallocation of Funds.** Upon completion of all Work in a Work Category, the Trustees shall determine if there is any Remaining Funding

for that Work Category. Within sixty (60) days after a determination that there is Remaining Funding for a Work Category, the Trustees shall propose to the Beneficiaries a reallocation of any Remaining Funding to Work in other Work Categories or to Beneficial Environmental Projects, consistent with Paragraph 17 of the Consent Decree.

18. Long-Term Monitoring

a. As part of the development of the Site Wide Monitoring Plan required by Paragraph 31(e), the Trustees shall develop a Long-Term Monitoring Plan for the Site. The Long-Term Monitoring Plan shall be consistent with Paragraph 14 of the Consent Decree and shall provide for monitoring biota, sediment, and water at the Site and at appropriate reference locations at three-year intervals for at least 30 years. The Long-Term Monitoring Plan shall include:

- i. The objectives and scope of the Long-Term Monitoring Plan;
- ii. A sampling plan including media to be sampled, contaminants or parameters for which sampling will be conducted, location (areal extent and depths), and number of samples;
- iii. A projected budget and schedule for the next cycle of Long-Term Monitoring;
- iv. A description of the roles of all organizations/entities and key personnel involved, and proposed to be involved, in the development and implementation of the Long-Term Monitoring Plan; and
- v. Cross references to QA/QC requirements set forth in the QAPP as described in Paragraph 31(d).

b. The Long-Term Monitoring Plan may be part of the Site Wide Monitoring Plan or a standalone document, at the discretion of the Trustees.

c. The Long-Term Monitoring Plan shall be informed by all existing Site data and Reports, including the Long-Term Monitoring Recommendations in Section 8.7 of Amec's Phase III Engineering Study Report. The Trustees shall review and, if needed, update the Long-Term Monitoring Plan prior to each cycle of Long-Term Monitoring sampling.

d. In each year that precedes the next scheduled cycle of Long-Term Monitoring, the Trustees shall submit draft, proposed final, and final updated versions of the Long-Term Monitoring Plan to the Beneficiaries on the same schedule as the annual budget and work plan required by Paragraph 34 of the Consent Decree (e.g., the updated Long-Term Monitoring Plan for 2023-24 shall be submitted in Fall 2022 and so on).

19. Certification of Final Work Completion

a. Inspection. Upon the completion of all Work Site-wide, but while Long-Term Monitoring and any other long-term O&M is still underway, the Trustees shall inspect the completed Work to ensure that it was constructed and is functioning as designed.

b. Final Work Completion Report. Following a successful inspection of the completed Work, the appropriate Trustee shall submit a Final Work Completion Report to the Beneficiaries that includes:

i. Statements by a registered professional engineer and/or by the Trustee that all Implementation Work-related construction (other than Long-Term Monitoring and any other ongoing O&M) is complete;

ii. Supporting documentation that all applicable permit conditions have been satisfied (except for ongoing Long-Term Monitoring or O&M obligations);

iii. A description of the ongoing Long-Term Monitoring (which may be accomplished by incorporating the Long-Term Monitoring Plan by reference) and any ongoing O&M activities; and

iv. A certification in accordance with Paragraph 28 (Certification).

c. The Final Work Completion Report may be combined with the final Implementation Work Report for the last Work completed at the Site.

d. A Beneficiary may dispute the Final Work Completion Report by initiating the Dispute Resolution provisions of the Consent Decree.

20. Certification of Site Closure

a. Site Closure Report. Following the completion of all Work at the Site, including Long-Term Monitoring and O&M activities, the Trustees shall submit a joint Site Closure Report to the Beneficiaries that includes the following:

i. Statements by a registered professional engineer and by the Trustees that all Work, including Long-Term Monitoring and O&M, is complete;

ii. A statement by the Trustees that any remaining Committed Funding is insufficient to support any additional Work, including Beneficial Environmental Projects, at the Site;

iii. A description of any remaining Trust Assets;

iv. Access to, or a complete copy of, the entire project database described in Paragraph 26 (Project Database); and

v. A certification in accordance with Paragraph 28 (Certification).

b. The Site Closure Report may be combined with a Quarterly Progress Report required by Paragraph 37 of the Consent Decree and Paragraph 25 of this SOW.

c. A Beneficiary may dispute the Site Closure Report by initiating the Dispute Resolution provisions of the Consent Decree.

IV. Community Involvement

21. The Trustees are responsible for developing and implementing community involvement activities to notify the public of planned Work activities and create opportunities for the public to provide comments regarding Work activities.

22. The Trustees must develop a Community Involvement Plan (“CIP”) and submit the CIP to the Beneficiaries for comment. The CIP must describe the public involvement activities and other methods that the Trustees will use to disseminate information to the public regarding the Work activities and opportunities for public

comment and must describe how the Trustees will provide public access to final copies of work plans, reports, schedules, and other Deliverables.

a. At a minimum, the Trustees must maintain a publicly available website that makes available, at no cost to the public, electronic copies of (i) final work plans, reports, schedules, and other Deliverables developed by the Trustees, and (ii) all final reports from the Phase I, II, and III Studies at the Site.

b. In developing the CIP, the Trustees shall consider, but are not bound by, the Communication and Community Involvement recommendations in Sections 7.0 and 8.8 of Amec's Phase III Engineering Study Report (ECF No. 972) and in Amec's Communication and Community Involvement Plan (ECF No. 981).

23. The Beneficiaries shall receive at least fourteen (14) days' prior notice of proposed materials for public dissemination, the plans for dissemination of information to the public, and public meetings or other events held to receive public comment or explain planned Work activities. The Beneficiaries may participate in the preparation of materials for public dissemination with the mutual consent of all Beneficiaries and the Trustees. However, any participation by the Beneficiaries shall not unreasonably delay the Trustees' public engagement activities.

24. The Trustees shall designate a Community Involvement Coordinator. The Trustees must notify the Beneficiaries of the designation of the Coordinator and provide the name, title, contact information, and qualifications of the Coordinator. The Coordinator shall be responsible for developing and implementing the CIP.

V. Recordkeeping and Reporting

25. Quarterly Progress Reports

a. As provided in Paragraph 37 of the Consent Decree, within ninety (90) days after the end of each calendar quarter (which shall end on March 31, June 30, September 30, and December 31), beginning with the quarter ended after assets are first received by the Trusts and ending as soon as practicable upon termination of the Trusts, the Trustees shall submit to the Beneficiaries and the Court a written Quarterly Progress Report.

b. Each Quarterly Progress Report shall include a summary of the following for the reporting period:

i. The actions that have been taken toward achieving compliance with the Consent Decree;

ii. A summary of key results of sampling, tests, and all other data received or generated by the Trustees and its contractors;

iii. A list and brief description of all Deliverables that the Trustees submitted to the Beneficiaries;

iv. A description of all activities relating to the Work that are scheduled for the next four months;

v. An updated Milestone Work Schedule, together with information regarding percentage of completion, delays encountered or anticipated that may affect the future schedule for implementation of the

Work, and a description of efforts made to mitigate those delays or anticipated delays;

vi. A description of any material modifications to the work plans or other schedules that have been proposed to the Beneficiaries;

vii. A description of all activities undertaken in support of the CIP during the reporting period and those planned to be undertaken in the next four months;

viii. A summary of any updates made to the form, location, or management of the project database; and

ix. Financial statements of the Trusts and Trust Accounts at the end of such calendar quarter and the receipts and disbursements of the Trusts for such quarter, provided by the Trustees.

c. Each Quarterly Progress Report should be a standalone document that succinctly summarizes the current status of the Work without a need to refer to other documents or prior reports. To minimize administrative burdens, each Quarterly Progress Report may be structured as an iterative revision of the prior Quarterly Progress Report, however, any substantial changes or additions must be marked or itemized in a way to make it easy for readers to see what has changed.

d. If the schedule for any activity described in a Quarterly Progress Report, including activities scheduled to be performed in the following four

months, changes in a material way, the Trustees shall notify the Beneficiaries of such change at least fourteen (14) days before performance of the activity.

26. Project Database.

a. The Trustees, or their designated contractors, shall maintain a project database containing all data generated by the Trustees and their contractors necessary to complete the required Work and all Site data provided by the Beneficiaries. The Trusts shall retain ownership over, and intellectual property rights to, the database, which must comply with any data requirements imposed by permits or other regulatory authorizations for the Work.

b. Upon reasonable notice, and at least triennially after each cycle of Long-Term Monitoring data are added to the database, the Trustees shall provide access to the updated project database to the Beneficiaries.

c. Upon request, the Trustees may share data from the project database with any federal, state, or local regulatory agency or permitting authority, after giving at least fourteen (14) days' prior notice to the Beneficiaries. In its discretion, the Trustees may share data with any university or researcher; however, it may deny duplicative or unreasonably frequent data-sharing requests, or place other conditions on data sharing if data-sharing requests would unreasonably interfere with the Trustees' management of the database, increase administrative costs of managing the database, or unreasonably interfere with the Trustees' other Work at the Site.

d. Consistent with Paragraph 20, the Trustees shall provide the Beneficiaries with access to the entire project database at-will upon submittal of the Site Closure Report. Alternatively, the Beneficiaries may request complete copies of the project database, provided all costs associated with the Trustees providing copies of the project database shall be borne by the requesting Beneficiary or Beneficiaries. Concurrently, the Trustees shall affirmatively offer to provide access to the project database to the Maine Department of Environmental Protection, Maine Department of Inland Fisheries and Wildlife, Maine Department of Marine Resources, and the U.S. Environmental Protection Agency, or their successors, and shall provide such access upon request. To the extent that any regulatory authority requires the project database to be maintained or preserved after the termination of the Trusts, Mallinckrodt shall be responsible for such maintenance and preservation of the project database. Mallinckrodt shall retain sole discretion with respect to selecting the method and manner for maintaining and preserving the project database in the event it is required to do so.

VI. Deliverables

27. **General Requirements.** The Trustees shall submit draft and final copies of Deliverables to the Beneficiaries as required by the Consent Decree and this SOW. Deliverables must be in writing unless otherwise specified. The Trustees shall submit all copies of Deliverables to the Beneficiaries in electronic form and by a method mutually agreed upon with the respective Beneficiary.

28. **Certification.** All Deliverables that require compliance with this Paragraph must be signed by the appropriately responsible Trustee, and must contain the following statement:

I certify that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I have no personal knowledge that the information submitted is other than true, accurate, and complete.

29. **The Beneficiaries' Review of Deliverables**

a. Consistent with Paragraph 31 of the Consent Decree, the Beneficiaries may provide comments on the draft versions of any Deliverables to the appropriate Trustee, within a timeframe specified by the Trustee that is appropriate for the particular Deliverable and not less than ten (10) business days. If a Beneficiary wishes to object to any element of any Deliverable submitted by a Trustee, the Beneficiary shall initiate the Dispute Resolution process provided by the Consent Decree and, in doing so, the Beneficiary shall identify with specificity the element of the Deliverable to which it objects.

b. Except as otherwise provided in Section XIV of the Consent Decree (Dispute Resolution) or Paragraph 31 of the Consent Decree (Decisions Regarding

Work and Deliverables), a Beneficiary's objection or the pendency of Dispute Resolution procedures shall not delay or stay any severable Work.

c. In the event of a dispute for which a stay or delay of a specific element of a Deliverable is ordered, a dispute regarding a severable element of a Deliverable shall not delay or prevent implementation of other elements of the Deliverable during the pendency of the dispute, if cost-effective and advisable. The Trustees shall determine whether elements of a Deliverable are severable based on whether the elements can be completed separately without substantial inefficiencies and/or significant impacts to the cost or schedule of Work.

d. All Deliverables submitted in accordance with this SOW are presumptively approved in the absence of timely objection by a Beneficiary. Unless a Beneficiary initiates Dispute Resolution, no additional action or approval by the Court, any Beneficiary, or the Trustees is required for any Deliverable. However, any Deliverable that requires approval by a regulatory agency or other permitting authority as a condition of a permit or other authorization (e.g., a completion report) shall not be considered complete and approved until such regulatory agency or permitting authority approval is obtained.

30. **Primary Deliverables.** Consistent with the Consent Decree and this SOW, the Trustees shall submit all primary Deliverables to the Beneficiaries for review and comment. Primary Deliverables for the Site include:

a. Design Work Plans required by Paragraph 5;

- b. Investigation Work Plans and Investigation Reports required by Paragraph 6;
- c. Treatability Study and Pilot Test Work Plans and Treatability Study and Pilot Test Evaluation Reports required by Paragraph 7;
- d. Work Designs required by Paragraph 9;
- e. Implementation Work Plans required by Paragraph 11;
- f. Permit applications to regulatory agencies or other permitting authorities and/or access agreements for obtaining private permissions required to undertake the Work at the Site, as required by Paragraph 35;
- g. Final Implementation Work Reports required by Paragraph 16(b);
- h. The Final Work Completion Report required by Paragraph 19(b);
- i. The Site Closure Report required by Paragraph 20(a); and
- j. The Community Involvement Plan required by Paragraph 22.

31. **Supporting Deliverables.** The Trustees shall submit each of the following Supporting Deliverables to the Beneficiaries for review and comment. The Trustees shall update each of these supporting Deliverables as necessary or appropriate during the course of the Work and as specified in this SOW.

- a. Health and Safety Plan(s). The Health and Safety Plan(s) (“HASP(s)”) describes all activities to be performed to protect on-site personnel and area residents from physical, chemical, and all other hazards posed by the Work. A HASP shall be prepared to meet all applicable laws and regulations

associated with applicable activities conducted in the performance of Work, and individual HASPs may be developed for different Work Categories.

b. Emergency Response Plan. The Emergency Response Plan (“ERP”) shall be developed to meet all applicable laws and regulations and describe procedures to be used in the event of an accident or emergency at the Site (for example, power outages, on-water vessel failure, treatment plant failure, slope failure, etc.). The ERP must include:

i. Name of the person or entity responsible for responding in the event of an emergency incident;

ii. Plan and date(s) for meeting(s) with the local community, including local, State, and federal agencies involved in the cleanup, as well as local emergency squads and hospitals;

iii. Spill Prevention, Control, and Countermeasures (“SPCC”) Plan (if applicable) describing measures to prevent, and contingency plans for, spills and discharges;

iv. Notification activities in accordance with Paragraphs 13(a) (Emergency Response and Reporting) and 13(b) (Release Reporting) in the event of a release of hazardous substances requiring reporting under federal or State law; and

v. A description of all necessary actions to ensure compliance with Paragraph 13 (Emergency Response and Reporting) in the event of an occurrence during the performance of the Work that causes or threatens a

release of Waste Material from the Site that constitutes an emergency or may present an immediate threat to public health or welfare or the environment.

c. Field Sampling Plan. The Field Sampling Plan (“FSP”) addresses all sample collection activities. The FSP must be written to ensure that all data collected meets the applicable Data Quality Objectives and in a format such that a field sampling team unfamiliar with the project would be able to gather the samples and field information required. As appropriate, the FSP may be adapted from Amec’s FSP for the Phase III Engineering Study.

d. Quality Assurance Project Plan. The Quality Assurance Project Plan (“QAPP”) augments the FSP and addresses sample analysis and data handling regarding the Work. The QAPP must include a detailed explanation of the Trustees’ quality assurance, quality control, and chain of custody procedures for all treatability, design, compliance, and monitoring samples. As appropriate, the QAPP may be adapted from Amec’s QAPP for the Phase III Engineering Study. The QAPP must include provisions:

i. To show that the selection of laboratory methods has considered the results of Amec’s Analytical Methods Comparison (Sept. 15, 2017), ECF No. 974;

ii. To ensure that the Trustees’ contracted laboratories perform all analyses using EPA-accepted methods (i.e., the methods documented in *USEPA Contract Laboratory Program Statement of Work for Inorganic Analysis*,

ILM05.4 (Dec. 2006); *USEPA Contract Laboratory Program Statement of Work for Organic Analysis*, SOM01.2 (amended Apr. 2007); and *USEPA Contract Laboratory Program Statement of Work for Inorganic Superfund Methods (Multi-Media, Multi-Concentration)*, ISM01.2 (Jan. 2010)) or other generally accepted scientific methods; and

iii. To ensure that the Trustees' contracted laboratories participate in an EPA-accepted QA/QC program or other generally accepted QA/QC program.

e. Site Wide Monitoring Plan. The purpose of the Site Wide Monitoring Plan ("SWMP") is to supplement existing baseline information regarding the extent of contamination in affected media at the Site; to obtain information, through short- and long-term monitoring, about the movement of and changes in contamination throughout the Site, before, during, and after performance of the Implementation Work; to obtain information regarding contamination levels to determine whether Performance Standards, if any, are achieved; and to obtain information to determine whether to perform additional actions, including further Site monitoring. The SWMP may incorporate the Long-Term Monitoring Plan by reference if the Trustees decide to create a standalone Long-Term Monitoring Plan. The SWMP must include:

i. Description of the environmental media to be monitored Site-wide and for monitoring during performance of Implementation Work;

ii. Identification of Performance Standards and DQOs, including a description of the data collection parameters, including existing and proposed monitoring devices and locations, schedule and frequency of monitoring, analytical parameters to be monitored, and analytical methods employed;

iii. Description of how performance data will be analyzed, interpreted, and reported, and/or other Site-related requirements;

iv. Description of verification sampling procedures;

v. Description of deliverables that will be generated in connection with monitoring, including sampling schedules, laboratory records, and reports to the Beneficiaries; and

vi. Description of triggers for and proposed changes and/or additions to monitoring and data collection actions (such as increases in frequency of monitoring, and/or installation of additional monitoring devices in the affected areas) in the event that results from monitoring devices indicate changed conditions (such as higher than expected concentrations of the contaminants of concern).

f. Transportation and Off-Site Disposal Plan. The Transportation and Off-Site Disposal Plan (“TODP”) describes plans to ensure compliance with Paragraph 14 (Off-Site Shipments and Waste Disposal). The TODP must include:

i. Proposed routes for off-site shipment of Waste Material;

ii. Identification of communities affected by transportation and disposal of Waste Material; and

iii. Description of plans to minimize impacts on affected communities.

g. O&M Plan. To the extent that any Implementation Work requires ongoing O&M after the Implementation Work is complete (such as periodic inspection and maintenance of a cap), the Trustees shall prepare an O&M Plan for such O&M activities. The O&M Plan describes the requirements for inspecting, operating, and maintaining the Implementation Work that includes O&M. The O&M Plan must include at least the following elements:

i. Description of the O&M activities to be performed;

ii. Description of records and reports that will be generated during O&M, such as daily operating logs, laboratory records, records of operating costs, reports regarding emergencies, personnel and maintenance records, monitoring reports, and reports to the Beneficiaries; and

iii. Description of corrective action, if any, to be implemented if O&M activities identify a failure or substantial deficiency in the Work element that would compromise the performance (e.g., if erosional damage to a cap cannot feasibly be repaired or a cap cannot feasibly be maintained for its intended lifespan).

h. Institutional Controls Implementation and Assurance Plan. The Institutional Controls Implementation and Assurance Plan (“ICIAP”) describes

activities and plans, if any, to implement, maintain, and enforce Institutional Controls at the Site. The ICIAP must include the following elements:

- i. Description of any Institutional Controls at the Site, including both Institutional Controls enacted and enforced by regulatory entities (such as consumption advisories or fishery closures), and Institutional Controls that are part of the Implementation Work (such as conservation easements), if any;
- ii. Locations of recorded real property interests (e.g., easements, liens) and resource interests in the property that may affect Institutional Controls (e.g., surface, mineral, and water rights) including accurate mapping and geographic information system (“GIS”) coordinates of such interests; and
- iii. Legal descriptions and survey maps that are prepared according to current American Land Title Association (“ALTA”) Survey guidelines and certified by a licensed surveyor.

VII. Schedules

32. **Work Schedule.** The Trustees shall prepare and update a Milestone Work Schedule for Work and deliverables that identifies key activities and covers at least the next five years. The Work Schedule shall be updated at least annually to reflect progress on the Work and any adjustments to the schedule. The Trustees shall include the current version of the Work Schedule in the Quarterly Progress Reports required by Paragraph 25 (Quarterly Progress Reports).

33. The Trustees shall include schedules for all activities contemplated under the Consent Decree at the level of detail necessary to manage the Work, ensure timely progress, and keep the Beneficiaries and Court informed of Work status, as required by this SOW.

34. It is the intention of the Beneficiaries that the Work will be completed as expeditiously as possible, consistent with sound scientific and engineering practices and in compliance with all applicable regulatory and permitting requirements. In contracts to carry out the Work, the Trustees are authorized, but not required, to provide for financial incentives of a magnitude consistent with typical environmental remediation practices to incentivize contractors to stay on schedule.

VIII. Permitting and Regulatory Cooperation

35. **Permits, Access Agreements, and Other Permissions.** The Trustees shall endeavor to obtain all necessary regulatory approvals, permits, access agreements, or other governmental or private permissions required to undertake the Work at the Site. The Trustees may contract with other entities to fulfill this function.

a. The applicable Trust shall be the permit applicant for any necessary permits or regulatory approvals and shall be the contracting entity for any access agreements or other private contracts.

b. The Trustees shall obtain all necessary regulatory approvals, permits, access agreements, or other permissions required to undertake the Work at the Site at the earliest possible time and prior to initiating any sampling,

construction, or other Work that requires such regulatory approvals, permits, access agreements, or other permissions.

c. The Trustees shall provide the Beneficiaries with a copy of any permit application or other authorization application submitted to a regulatory agency or other permitting authority for Work at the Site.

36. The Trustees shall engage in consultation and coordination with regulatory agencies and other permitting authorities (e.g., local municipalities with jurisdiction over portions of the Site) as early as possible to understand the applicable regulatory requirements for the Work, to determine what approvals are required to perform Work elements, the associated review process and timeframes needed by the agencies and/or authorities to provide their approvals, and to build trust and cooperation with regulatory agencies and permitting authorities. The Trustees shall cooperate fully with all regulatory agencies and permitting authorities that have jurisdiction over any aspect of the Site.

IX. Contracting and Insurance

37. The Trusts and Trustees are authorized to retain technical consultants and contractors to carry out the Work set forth in the Consent Decree and rely on the advice and recommendations of such consultants and contractors, provided such advice and recommendations are grounded in sound professional environmental engineering and scientific principles consistent with the Standard of Care in the Consent Decree. Prior to contracting with such technical consultants and contractors, the Beneficiaries shall have a reasonable opportunity to comment on or object to the Trustees' recommendations, in accordance with Paragraph 31 (Decisions Regarding Work and Deliverables) of the

Consent Decree, and the terms of the applicable Trust Agreement and this SOW, prior to finalizing any such contracts. The Trustees and Trusts may contract with an individual or entity that has a prior relationship with a Beneficiary, subject to the right of any other Beneficiary to object and initiate Dispute Resolution. Other than in the Trust Agreement, this SOW, and any other contracts necessary to effectuate the Consent Decree, the Trustees and Trusts may not contract with any Beneficiary or its corporate parents, subsidiaries, or affiliates to perform Work at the Site.

38. **Selection of Contractors.** After the formation of the Trusts, and prior to entering into contracts to implement the Work required by the Consent Decree, the Trustees shall consult with the Beneficiaries regarding the standard contracting terms and conditions to be used with contractors. The Trustees shall give at least ten (10) business days' notice to the Beneficiaries prior to entering into contract negotiations with any potential contractor. The Beneficiaries may object to a proposed contractor by initiating the Dispute Resolution process provided for in the Consent Decree prior to finalization of a contract between a Trust, Trustee, and the contractor. The Trustees shall give notice to the Beneficiaries upon executing a contract with any contractor, which shall be provided not later than in the next Quarterly Progress Report following the date the contract is executed.

39. **Insurance Requirements for the Trustees.**

a. The Trustees shall maintain insurance policies as required by Paragraph 45 of the Consent Decree and by Section 4.13 of the operative Trust Agreement.

b. On all such insurance policies, MPA, NRDC, and Mallinckrodt shall receive insured protection with an obligation by the insurer to defend them.

40. **Insurance Requirements for Contractors.** In any contracts to perform Work at the Site, the applicable Trustee shall require that consultants, contractors, and third-party professionals obtain insurance as required by Section 4.1.3 of the operative Trust Agreement.

X. Modifications

41. Modifications to the Statement of Work shall be in writing, signed by authorized representatives of Plaintiffs, Mallinckrodt, and the Trustees, and shall be effective immediately upon the Beneficiaries' and Trustees' written agreement. The Trustees shall provide notice to the Court of any modification to the Statement of Work.

42. Any dispute regarding modifications to the Statement of Work shall be resolved through the Dispute Resolution provisions set forth in Section XIV of the Consent Decree.