Great Ships Initiative

Procedure No: GSI/SOP/G/A/RK/1
Issue Date: May 17, 2010
Number of Pages: 9

STANDARD OPERATING PROCEDURE:
Procedure for Record Keeping

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RECORD OF AMENDMENTS:

No.	Date	Type	No.	Date	Type
1	02/22/2011	Changed "Equipment List" to "Supplies". Added text to § "Error Corrections", "Maintenance", and "Standard Operating Procedures".	7		
2	05/23/2011	Moved "Introduction" before "Definitions", and added definitions. Added detail on computer records in "Document Management - Maintenance". Added "Test/Quality Assurance Plans" to "Specific Records and Documents"; and added text to "Field and Laboratory Notebooks", "SOPs", and "QAQC Records" in this section. Added references.	8		
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STANDARD OPERATING PROCEDURE
Procedure for Keeping Records

BACKGROUND

The Great Ships Initiative (GSI) is a regional effort devoted to ending the problem of ship-mediated invasive species in the Great Lakes-St. Lawrence Seaway System and globally. In support of that goal, the GSI has established superlative freshwater ballast treatment evaluation capabilities at three scales—bench, land-based, and on board ship. Each scale is dedicated to addressing specific evaluation objectives. These include:

GSI Bench-Scale Tests

- Range finding for effective treatment dose against diverse freshwater taxa and water quality conditions;
- Generation of freshwater relevant chemical degradation curves; and
- Estimation of residual toxicity given diverse freshwater taxa and water quality conditions.

GSI Land-Based Tests

- Pre-certification testing, i.e., operational and biological performance (including residual toxicity) status-testing given scale-up and a range of challenge conditions; and
- Certification/verification testing, i.e., formal assessment of performance against international and other discharge standards.

GSI Shipboard Tests

- Confirmation of biological and operational treatment performance as expected in the ship environment;
- U.S. Coast Guard Shipboard Technology Evaluation Program (STEP) testing;
- Shipboard type approval testing;
- Ship discharge monitoring; and
- Methods development.

GSI awards its independent status-testing services to candidate systems only if technical and programmatic criteria are met. Decisions are based on third party technical assessments as well as GSI Advisory Committee programmatic input. Testing services are currently offered at no cost to the developer with the exception of transportation and system installation/removal costs. Instead, tests are supported by general project funds which derive from federal and state agency grants, Great Lakes port contributions, and in-kind contributions by local governments and universities.

GSI has no involvement, intellectual or financial, in the mechanics, design or market success of the actual treatment systems it tests. To ensure GSI remains completely independent and is uncompromised by any real or perceived individual or project bias, GSI subjects itself to rigorous quality management policies and procedures. In addition, GSI test activities are subject to rigorous QAQC procedures and documentation. This attention to quality management and QAQC assures the high quality and credible evaluation of both GSI and its findings.

INTRODUCTION

This GSI standard operating procedure (SOP) describes the practices used for correct documentation, data collection, and record retention during GSI research activities. GSI documentation standards closely follow the United States Environmental Protection Agency's (USEPA) Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice Standards (40 CFR Part 160, 1989).

Specific GSI Documents and Records

Quality Management Plan (QMP)

This document details the structure of the GSI's quality system from an organizational perspective. It covers all aspects of GSI's commitment to quality including policies and procedures; criteria for and areas of application; roles, responsibilities, and authorities; and assessment and response. It is the framework for planning, implementing, documenting, and assessing the GSI's quality assurance and quality control (QAQC) activities.

The GSI Senior Quality Systems Officer is responsible for preparing the QMP, with the document based on the U.S. EPA's "*EPA Requirements for Quality Management Plans*" to the greatest extent possible. The QMP is distributed to the GSI PI for review in draft form. Once a draft is finalized, the document is approved and forwarded to GSI senior research personnel and QAQC officers. Draft and final copies of the document are posted to the GSI SharePoint intranet website; the final version may also be posted to the GSI public website. The GSI's QMP is valid for a maximum period of five years, with an annual review and revision (as needed) occurring at the end of each calendar year.

Quality System Annual Report

The GSI Quality System Annual Report documents the GSI's quality system activities over the previous calendar year, including a summary of the year's projects and activities; a summary of the year's project-specific audits, assessments and responses; a list of quality system documentation and SOPs developed during the year; a list of quality management training GSI personnel received during the year; a discussion on the status of the GSI quality system including strengths, weaknesses, successes and problems, and recommendations for improvements; and an assessment of the adequacy of the GSI QMP and recommended changes. The GSI Senior Quality Systems Officer is responsible for preparing the report in conjunction with the GSI Senior QAQC Officer. Once a draft is finalized, the document is then passed on to the GSI PI for approval. The final report is distributed to relevant GSI research team personnel. Final copies are also posted to the GSI SharePoint intranet website.

Quality Assurance Project Plans (QAPPs)

GSI's Quality Assurance Project Plans (QAPP) describes the activities undertaken by GSI to assure the quality and credibility of its project-specific research findings, i.e., at the land-based

facility or bench-scale of testing. Each QAPP covers all aspects of quality assurance/quality control (QAQC) relative to the specific project area, including data quality indicators, evaluation processes, performance measures and acceptance criteria; instrument certification and calibration; personnel training requirements; documents and records; data management; and QAQC assessments and response actions.

The GSI Senior Quality Systems Officer, in conjunction with the GSI Senior QAQC Officer, is responsible for developing the QAPPs. The plans follow the format of the U.S. Environmental Protection Agency's (EPA's) "*EPA Guidance for Quality Assurance Plans*" to the greatest extent possible. Draft QAPPs are distributed to relevant GSI senior research personnel for review and comment. Once a draft is finalized, the documents are then passed on to the GSI PI for review and approval. Draft and final copies of QAPPs are posted to the GSI SharePoint intranet website; the final versions may also be posted to the GSI public website. All QAPPs, once approved, are valid for a period of five years, though they are reviewed annually and revised as needed.

Test/Quality Assurance Project Plans (TQAPs)

A Test/Quality Assurance Project Plan (TQAP) is a written, planning document that describes the procedures used by GSI for conducting a verification test, according to the US EPA ETV Program's *Generic Protocol for the Verification of Ballast Water Treatment Technology* (ETV Protocol; NSF International, 2010), on a specific ballast water treatment system at the GSI Land-Based RDTE Facility. A separate TQAP is written for each ETV verification test conducted on a ballast water treatment system. The GSI Land-Based QAPP is included as an appendix to each TQAP to provide detailed information for implementing GSI's quality assurance/quality control activities at the GSI Land-Based RDTE Facility. According to the ETV Protocol, the TQAP must include specific procedures to be followed by GSI personnel at the GSI Land-Based RDTE Facility for sample and data collection, sample handling and preservation, precision, accuracy, goals, and quality assurance and quality control requirements (NSF International, 2010).

Standard Operating Procedures (SOPs)

Standard operating procedures are used to implement all routine GSI test activities. This facilitates consistent conformance to technical and quality system requirements and increases data quality. The SOPs include both programmatic and technical processes and procedures such as organism culturing; operation of the GSI Land-Based RDTE facility; sample collection, labeling, analysis and custody; and health and safety.

GSI SOPs are developed by the relevant GSI senior research personnel in conjunction with the GSI Senior Quality Systems Officer and GSI Senior QAQC Officer. The GSI Senior Quality Systems Officer is responsible for distributing finalized SOPs to the GSI PI for approval. Draft and final copies of all SOPs are posted to the GSI SharePoint website; the final versions are also posted to the GSI public website. All GSI SOPs are reviewed and/or revised at least every 12 months.

To date approximately 50 SOPs have been finalized, with many more in draft form or planned. The SOPs follow a common format and include specific QAQC procedures and metrics. GSI SOPs are grounded in published standard methods. They are also consistent with international and domestic guidelines where they exist. All GSI SOPs are subject to periodic review and revision to assure that the most up to date approaches are employed.

Field and Laboratory Notebooks

Bound field and laboratory notebooks, each having a unique identification code, are used to record observations, sampling details, and laboratory and field measurements. Notebooks are also used to record instrument and equipment calibration and maintenance information. GSI personnel are responsible for maintaining the notebooks on site, creating electronic copies (required for land-based verification testing), and posting to the GSI SharePoint website for storage and archiving. The requirement for a backup, electronic copy of field and laboratory notebooks is implemented during ballast water treatment system verification testing at the GSI Land-Based RDTE Facility only. The GSI Senior QAQC Officer will ensure that all required field and laboratory notebooks are electronically scanned during the data verification process.

Forms and Records

Specific forms are used to record sample collection and analysis data. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out in dark, waterproof, and permanent ink. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage and archiving. In general, hard copies of all forms are stored in three-ring binders, each with a unique identification code.

Specific forms are also used to record sample custody, handling and storage information. Chain of custody forms are employed only when an outside laboratory is contracted to conduct sample analyses. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out at the time of changes to sample custody, and sample handling and storage. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage.

In addition, specific forms are used to record operation, maintenance and safety information. The GSI Land-Based RDTE Facility Operations Manager is responsible for ensuring that all forms associated with safety (i.e., confined space entry permit forms, daily safety checklist) and operation and maintenance of the land-based test facility are correctly filled out. It is the responsibility of the GSI Land-Based RDTE Facility Operations Manager to ensure that equipment maintenance and instrument calibration is properly documented, and that forms are maintained on file, and also posted to the GSI SharePoint website for storage.

Personnel Records

GSI quality management personnel are responsible for maintaining on the GSI SharePoint site copies of all GSI personnel resumes, and training and certification documents. The documents are updated on an as-needed basis by the relevant personnel.

Test Findings and Other GSI Products

NEMWI personnel are responsible for maintaining on file and posting to the GSI SharePoint website all test findings and other GSI products. These include applicant and public reports of test findings, public summaries of test findings, peer-reviewed scientific papers and reports, outreach documents, and conference presentations. NEMWI personnel are also responsible for distributing copies of these documents to relevant parties, and posting to the GSI public website, if required.

Quality Assurance/Quality Control Records

GSI assesses its quality system on a project by project (i.e., test by test) basis using a variety of tools. In this situation, one project/test is defined as a series of trials of a specific ballast treatment system. For example, one test may constitute a set of five trials of a ballast treatment system at the GSI land-based facility. The purpose, procedural details, and implementation frequency of each of these assessment tools are outlined below.

GSI QAQC Officers assess the implementation of project-specific QAPPs, ballast water treatment specific TQAPs, and SOPs during each verification test of a ballast treatment system through the use of technical systems audits and data verification. In addition, GSI QAQC Officers also verify data recording and archiving procedures by randomly evaluating data recording forms and field notebooks for completion, compliance and correct storage procedures. A GSI Deviation Form will be completed in response to any deviations to the planning documentation (e.g., land-based QAPP, TQAP, test plans, or bench-scale QAPP) or the GSI SOPs that are discovered during a technical systems audit or during data verification. The GSI Deviation Form will detail any corrective action (e.g., retraining, repeat sampling event, etc.) that is needed as a result of the deviation.

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers determine if the data quality objectives outlined in the relevant GSI QAPP have been successfully met. GSI QAQC Officers also determine if the performance criteria outlined in the relevant GSI QAPP have been successfully met.

Following completion of verification testing and data verification and validation, the results from these activities are summarized in a Quality Assurance/Quality Control Report specific to the ballast water treatment system. Each report is submitted to the GSI Senior Quality Systems Officer and GSI PI for review and approval. The reports include a table listing deviations to the specific QAPP (land-based or bench-scale) and TQAP/test plan associated with the testing and a table listing deviations to the specific SOPs that were used during the testing. Any corrective

action that is taken as a result of deviations will be discussed in the Quality Assurance/Quality Control Report, and all GSI Deviations Forms completed during testing will be attached to the report as an appendix. In addition, results from the data quality objectives analysis will be detailed in this report. Final copies of each Quality Assurance/Quality Control Report are stored on GSI SharePoint.

DEFINITIONS

Data Validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs (USEPA, 2010).

Data Verification: Evaluating the completeness, correctness, and conformance/compliance of a specific data set against method, procedural, or contractual requirements (USEPA, 2010).

Raw Data: Any laboratory datasheets, records, memoranda, notes, or exact copies that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, computer printouts, and recorded data from automated instruments (USEPA, 1989).

Reconstruction: Authenticating the conduct of an activity using documentation.

SUPPLIES

- Data and count sheets
- Field notebooks
- Laboratory notebooks
- Forms

PROCEDURE

General GSI Good Documentation Standards

Note: Documentation and raw data must stand alone and require no verbal explanation. Testing/research activities must be able to be **reconstructed from the raw data only** by someone other than the scientist performing the activity.

1. Ensure that the following information is documented in a laboratory/field notebook or on pre-printed datasheets using indelible ink during all GSI testing/research activities:
    a. Where and when the activity was performed.
    b. The procedures, events, and the results.
    c. Any observations, data, etc., needed for reconstruction.

2. Ensure that all titles and headers needed to identify the document is recorded.

3. Ensure that signatures/initials and dates of those collecting and analyzing the data are recorded. Note: Data cannot be pre- or post-dated.

Document and Records Management

Delegation of Authority

1. Ensure that the GSI PI delegates authority, i.e., delegates a "Document Manager", for the development of GSI documents and records to the appropriate person, as well as provides a timeframe for which to start and complete the document. The "Document Manager" is responsible for the document's management. The Document Manager works in conjunction with the GSI PI to determine document format, scope, audience, length, etc. The Document Manager also works with GSI quality management officers to coordinate assignment of a specific and unique GSI document code.

2. Ensure that the Document Manager distributes the document to the GSI PI, and other GSI senior research personnel (if required) for review once complete. She/he is also responsible for maintaining a master version of the document on file, and also on GSI SharePoint. Once complete, the final version of the document is also saved in the appropriate subfolder on GSI SharePoint.

Format

1. Ensure that all GSI documents and records include the following specifications, at a minimum:
    a. A unique document code placed in the top right hand corner of the document header as well as the date and number of pages. Codes are provided by the GSI Senior Quality Systems Officer.
    b. A cover page including the GSI logo in the top left hand corner, as well as the title and authors.

Error Corrections

1. Ensure that errors made when recording data are not obscured. Instead, a single line must be drawn through the error and the correct entry should be clearly recorded.
2. Initial and date the correction.
3. Ensure that errors in recording observations or data that have been lined through have an explanation for the change.
4. Designate reording error as "R.E.", as described in the error code table below:

Examples of Error Codes that may be Used:	
WE:	Wrong Entry
RE:	Recording Error
CE:	Calculation Error
WD:	Wrong Date
FN:	See Footnote
LE:	Late Entry
NU:	Data not Used

Revision

1. Ensure that all changes to documents are recorded on a record of amendments table that is attached to the original document. The record must describe the revision as well as the date. GSI quality management personnel are responsible for updating the record of amendments for all quality documents (i.e., QMP, QAPPs, SOPs, etc).

Maintenance

GSI quality management personnel are responsible for maintaining on file and on GSI SharePoint a matrix of all GSI documents and records. The matrix includes the following headings: document type (i.e., SOP, QAQC, findings report, form, etc), document code, title, manager, status and date.

GSI quality management personnel are also responsible for maintaining all documents and records for a period of at least seven years. Computer data and records must be ***retrievable*** (i.e., software must be available to access the data), not just stored, for at least seven years. Electronic versions of GSI documents and records, including all method SOPs, Test/Quality Assurance Plans or Test Plans, Quality Management Plans, and Quality Assurance Project Plans, are saved to the GSI SharePoint website (www.greatshipsinitiative.info). Hard copies of GSI documents and records, including raw data, are scanned and also saved to the GSI SharePoint website. Due care and diligence is taken to properly dispose of documents and records that are no longer required after the seven year period has lapsed. Disposal procedures involve electronic deletion of documents and records from the GSI SharePoint website and the personal computers of GSI personnel, as well as manual shredding of hard copies.

REFERENCES AND RELATED DOCUMENTS

GSI/QAQC/QMP/1 – Great Ships Initiative Quality Management Plan, Revision 2 (2011).

GSI/QAQC/QAPP/LB/1 - Quality Assurance Project Plan for Great Ships Initiative (GSI) Land-Based Tests (2011).

Great Ships Initiative website: www.greatshipsinitiative.org.

Great Ships Initiative Standard Operating Protocols: http://www.nemw.org/GSI/protocols.htm.

NSF International (2010). Generic Protocol for the Verification of Ballast Water Treatment Technology. Version 5.1. EPA/600/R-10/146. Produced for the USEPA, Environmental Technology Verification Program in Conjunction with U.S. Coast Guard, Environmental Standards Division and U.S. Naval Research Laboratory, Center for Corrosion Science and Engineering. NSF International, Ann Arbor, Michigan.

United States Environmental Protection Agency Office of Water (2010). Glossary of Data Review and Related Terms.