Great Ships Initiative

# GREAT SHIPS INITIATIVE (GSI)

## TECHNICAL SYSTEMS AUDIT CHECKLIST FOR SAMPLES COLLECTED DURING INTAKE

| | |
|---|---|
| **Purpose/Scope of Audit:** | **GSI Research, Development, Testing, and Evaluation (RDTE) Facility Technical Systems Audit** |
| Brief Description of Audit: | Audit of sample labeling, collection, transport, and analysis at the GSI RDTE Facility during performance evaluation of the Siemens SiCURE Ballast Water Management System (~~Trial #4~~ ① Trial #7). Quality system documentation will be reviewed. A procedural audit will be conducted to verify that the technical aspects of this project are being performed according to GSI standard operating procedures. |
| Auditee: | GSI scientists |
| Audit Location: | RDTE Facility (Superior, WI) |
| Auditors: | Kelsey R. Prihoda, GSI Assistant Quality Assurance Manager |
| Audit Dates: | Monday, September 21, 2009 |

### SAMPLE BOTTLE LABELING, SAMPLE COLLECTION, AND SAMPLE TRANSPORT TO UWS

**SAMPLE TEST ID: 09-SI-7F** KRP Labeled bottles 9-18-09.

Relevant GSI SOPs:

- *GSI/SOP/G/RA/SC/3 – Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility (DRAFT)*
- *GSI/SOP/LB/G/O/5 – Procedure for Injecting Organisms and Solids into the GSI Land-Based RDTE Facility*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Algae/Small Protozoa Sample Collection*
- *GSI/SOP/LB/RA/SC/4 – Procedure for Microbial Sample Collection*
- *GSI/SOP/LB/RA/SC/6 – Procedure for Zooplankton Sample Collection*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Collecting Physical/Chemical Data and Samples at the GSI Land-Based RDTE Facility (DRAFT)*

➢ **Time Fill Started:** 9:38 am (Line samples @ 9:48 am, 10:08 am, 10:28 am) Filled tanks C1 and T1.

➢ **Time Fill Completed:** 10:36 am

| Sample Collection Type (Code) | Sample Port/Point | Tub Number | Sample Type (Collected By) | Labeled Correctly & In Crate? | | Collected Following SOPs? | | Transported Back to UWS? | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Y | N | Y | N | Y | N |
| Before Fill (BF) | Pond | | • Phytoplankton (Euan) | ✓ | | ✓ | | | |
| Before Fill (BF) | SP2 | 3 | • Harbor Phytoplankton (Don/AMI) | ✓ | | ✓ | | | |
| | | | Harbor Zooplankton (Don/AMI) | ✓ | | ✓ | | | |
| Control Tub | SP2 | 1 | TRC and TRO (Lana) | ✓ | | ✓ 10:39 am | | | |

① KE KRP 9-21-09



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| Sample Collection Type (Code) | Sample Port/Point | Tub Number | Sample Type (Collected By) | Labeled Correctly & In Crate? Y | Labeled Correctly & In Crate? N | Collected Following SOPs? Y | Collected Following SOPs? N | Transported Back to UWS? Y | Transported Back to UWS? N | |
|---|---|---|---|---|---|---|---|---|---|---|
| (C) | | | Chem. Bucket (Don) | ✓ | | ✓ | | | | |
| | | | Phytoplankton (Euan) | ✓ | | ✓ 10:39am | | | | |
| | | | Zooplankton (Don) | ✓ | | ✓ recieved at 11:33am | | | | |
| Pre-Treatment Tub (PT) | SP3 | #4 5 | TRC and TRO (Lana) | ✓ | | ✓ 10:41am | | | | |
| | | | Chem. Bucket (Don) | ✓ | | ✓ | | | | |
| | | | Phytoplankton (Euan) | ✓ | | ✓ 10:40am | | | | |
| | | | Zooplankton (Don) | ✓ | | ✓ Rec'd at 11:12am | | | | |
| | | | Microbe Rep. 1 (Lana) | ✓ | | ✓ 10:41am | | ✓ | | H. Saillard to transport. |
| | | | Microbe Rep. 2 (Lana) | ✓ | | ✓ 10:42am | | ✓ | | |
| | | | Microbe Rep. 3 (Lana) | ✓ | | ✓ 10:42am | | ✓ | | |
| Pre-Treatment In-Line (PT) | SP3 | | TSS, POC, DOC Rep. 1 – 10 min. ~~(Heidi Schaeffer)~~ KMP | ✓ | | ✓ 9:48 | | ✓ | | |
| | | | TSS, POC, DOC Rep. 2 – 30 min. ~~(Heidi Schaeffer)~~ KMP | ✓ | | ✓ 10:08 | | ✓ | | |
| | | | TSS, POC, DOC Rep. 3 – 50 min. ~~(Heidi Schaeffer)~~ KMP | ✓ | | ✓ 10:28 | | ✓ | | |
| Filter Backwash (BW) | Line to Backwash Storage Tank | | TRC and TRO Rep. 1 – Beginning (Lana) | ✓ | | ✓ 9:53am | | | | |
| | | | TRC and TRO Rep. 2 – Middle (Lana) | ✓ | | ✓ 10:12am | | | | |
| | | | TRC and TRO Rep. 3- End (Lana) | ✓ | | ✓ 10:34am | | | | |
| | | | Disinfection Byproducts Rep. 1 | ✓ | | ✓ 10:31am | | ✓ | | Tom Markee to transport |
| | | | Disinfection Byproducts Rep. 2 | ✓ | | ✓ 10:31am | | ✓ | | |
| Post-Treatment Tub | SP15 | 6 | Phytoplankton | ✓ | | ✓ 10:43am | | | | |
| | | | Zooplankton | ✓ | | ✓ Rec'd at 12:15pm | | | | |



Initial/Date KMP/9-21-09

| Sample Collection Type (Code) | Sample Port/Point | Tub Number | Sample Type (Collected By) | Labeled Correctly & In Crate? Y | Labeled Correctly & In Crate? N | Collected Following SOPs? Y | Collected Following SOPs? N | Transported Back to UWS? Y | Transported Back to UWS? N | |
|---|---|---|---|---|---|---|---|---|---|---|
| (T) | | | Cold Water Bioassay | ✓ | | ✓ 10:46 | | ✓ | | H. Saillard to transport. |
| | | | Chem. Bucket | ✓ | | ✓ | | | | |
| | | | Microbe Rep. 1 | ✓ | | ✓ 10:43 | | ✓ | | |
| | | | Microbe Rep. 2 | ✓ | | ✓ 10:44 | | ✓ | | |
| | | | Microbe Rep. 3 | ✓ | | ✓ 10:44 | | ✓ | | |
| | | | Disinfection Byproducts Rep. 1 | ✓ | | ✓ 10:44 | | ✓ | | Tom Markee to transport. |
| | | | Disinfection Byproducts Rep. 2 | ✓ | | ✓ 10:45 | | ✓ | | |
| | | | TRC and TRO | ✓ | | ✓ 10:44 | | | | |
| Post-Treatment In-Line (T) | SP16 | | TSS, POC, DOC Rep. 1 – ~10 min. (Tom) | ✓ | | ✓ 9:52am | | ✓ | | H. Saillard to transport |
| | | | TSS, POC, DOC Rep. 1 – ~10 min. Duplicate (Tom) | ✓ | | ✓ 9:52am | | ✓ | | |
| | | | TSS, POC, DOC Rep. 2 – ~30 min. (Tom) | ✓ | | ✓ ~10:10am | | ✓ | | |
| | | | TSS, POC, DOC Rep. 3 - ~50 min. (Tom) | ✓ | | ✓ 10:32am | | ✓ | | |
| | | | TRC and TRO Rep. 1 – ~10 min. (Tom) | ✓ | | ✓ 9:52am | | | | |
| | | | TRC and TRO Rep. 2 – ~30 min. (Tom) | ✓ | | ✓ ~10:10am | | | | |
| | | | TRC and TRO Rep. 3 – ~50 min. (Tom) | ✓ | | ✓ 10:32 am | | | | |
| Post-Treatment In-Line (T) | Siemens TAP (S TAP) | | TRC and TRO Rep. 1 – ~10 min. (Tom) | ✓ | | ✓ 9:49am | | | | |
| | | | TRC and TRO Rep. 2 – ~30 min. (Tom) | ✓ | | ✓ ~10:08am | | | | |
| | | | TRC and TRO DUP Rep. 3 – ~50 min. (Tom) | ✓ | | ✓ 10:28am | | | | |
| | | | TRC and TRO ~~DUP~~ Rep. 3 – ~50 min. (Tom) | ✓ | | ✓ 10:29am | | | | |

① RE KMP 9-18-09
② RE KMP 9-21-09

Potable Water Tank

Zooplankton ✓ ✓ 2:13pm



Initial/Date
KMP / 9-21-09

**COMMENTS OR OBSERVATIONS DURING FILL AND SAMPLE COLLECTION:**

**SAMPLE ANALYSIS**

**SAMPLE TEST ID: 09-SI-7F**

**QUALITY SYSTEM DOCUMENTATION**

| AUDIT QUESTIONS | RESPONSE | | | COMMENTS |
|---|---|---|---|---|
| | Y | N | NA | |
| 1. Is there an approved Quality Assurance Project Plan for the overall project and has it been reviewed by all appropriate personnel? | | ✓ | | There is a DRAFT GSI QAPP. It has not been finalized because it has not been reviewed by all appropriate staff. |
| 2. Is a copy of the current approved QA Project Plan maintained near laboratory work station areas? | | | ✓ | |
| 3. Is the implementation of the project in accordance with the QA Project Plan? | | | ✓ | |
| 4. Are there deviations from the QA Project Plan? Explain. | | | ✓ | |
| 5. Do any deviations from the QA Project Plan affect data quality? | | | ✓ | |
| 6. Are sample handling and storage procedures in accordance with the QA Project Plan? | | | ✓ | Sample handling and storage procedures are in accordance with GSI documents listed in this doc. |
| 7. Are written and approved current standard operating procedures (SOPs) used in the project? If so, list them and note whether they are maintained near laboratory work station areas? | ✓ | | | Approved and draft SOPs are listed throughout this doc, and are maintained in mobile lab and with Assistant QAM. |
| 8. Are data/observations appropriately recorded in laboratory notebooks/forms according to the QA Project Plan (i.e., entries in ink, dated, initialed, corrections done properly)? Are data contained in bound, well-labeled notebooks or three-ring binders? | | | | |
| 9. Do supervisory and/or QA personnel inspect laboratory notebooks/forms on a regular basis and initial notebook after review? | | ✓ | | QA personnel will inspect notebooks and forms after trial 7 discharge. There is not enough QA staff to inspect during trials. |
| 10. Are paper records written in indelible ink? | ✓ | | | All observed recording done in indelible ink. |

**Additional Questions or Comments:**

It is recommended that following the Siemens SiCUKE performance evaluation, the Draft GSI QAPP be reviewed by all appropriate staff, approved, and finalized. In addition, it is recommended that all Draft SOPs be reviewed, revised, and finalized following performance evaluation.

- It is recommended that datasheets be stored in three-ring binders (with appropriate codes assigned) immediately after they are filled out to avoid potential loss of raw data. There should be a separate three-ring binder for each BWTS performance evaluation.



**Initial/Date** KMP/9-21-09

**CHEMISTRY**

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Determining Total Residual Oxidants (TRO) in Water*
- *GSI/SOP/BS/RA/C/3 – Procedures for Measuring Organic Carbon in Aqueous Samples*
- *GSI/SOP/BS/RA/C/6 – Procedure for Analyzing Total Residual Chlorine (TRC) Concentrations in Water*
- *GSI/SOP/BS/RA/C/8 – Procedure for Analyzing Total Suspended Solids (TSS)*

| AUDIT QUESTIONS | RESPONSE Y | RESPONSE N | RESPONSE NA | COMMENTS |
|---|---|---|---|---|
| 1. Describe the analytical instrumentation. List the brand and model number for each instrument. | ✓ | | | Spectronic 20D+ #4157 Orion 290A #290-2 |
| 2. Are calibration and maintenance logs kept for the instrumentation (e.g., balances and other equipment)? | ✓ | | | No maintenance log devoted to each individual piece of equipment. |
| 3. Review the maintenance and operational records for the equipment. Based on your findings, do all instruments/equipment appear to be in good operating condition? | ✓ | | | Calibration written on pre-printed data sheets. |
| 4. Are the manufacturer's operating manuals readily available to the instrumentation operators? | | ✓ | | Operating manuals at UWS campus, not RDTE Facility. |
| 5. Describe the routine calibration procedure. | ✓ | | | See GSI/SOP/BS/RA/C/2 + GSI/SOP/BS/RA/C/6. |
| 6. Does the calibration documentation show that the calibration procedures are being followed? | | | | |
| 7. Do the calibration standards have the appropriate levels (i.e., bracket the samples to be measured)? | ✓ | | | |
| 8. What is the instrumentation calibration error according to the calibration documentation? | ✓ | | | |
| 9. Are duplicate samples collected and analyses conducted on at least 10% of the physical/chemical samples? | ✓ | | | 1 post-treatment TRO/TRC and 1 post-treatment TSS, DOC, POC. |
| 10. Are reagent blank samples analyzed with each set of samples? | ✓ | | | Deionized water for TRC and TRO. |
| 11. Are a minimum of three and preferably more standards required for standard curves? | ✓ | | | 5-point std. curve for TRO and TRC. |
| 12. When applicable, do routine procedures that require standard curves bracket concentrations? | ✓ | | | |
| 13. When applicable, have analytical method detection limits been established and clearly documented? | ✓ | | | |

**Additional Questions or Comments:**

-TRO background correction procedure: An aliquot of water sample plus reagent pillow is used to correct background turbidity.

-A QC standard is analyzed for TRC and TRO after standard curve is generated and $r^2$ value calculated. Samples are not run unless QC standard is within acceptance limits.

- TRC SOP #2 - use deaerated, deionized water to create standards and dilute samples. Deionized water was brought to RDTE ∴ could not be deaerated. Will this have an affect on results?



**Initial/Date** MMP/9-21-09

**MICROBIOLOGY** Reviewed datasheets 23 October 2009. UMR.

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/MA/1 – Procedure for Quantifying Heterotrophic Plate Counts (HPCs) using IDEXX's SimPlate® for HPC Method*
- *GSI/SOP/BS/RA/MA/3 - Procedure for the Detection and Enumeration of Enterococcus using Enterolert™*
- *GSI/SOP/BS/RA/MA/4 – Procedure for the Detection and Enumeration of Total Coliforms and E. coli using IDEXX's Colilert®*

| AUDIT QUESTIONS | RESPONSE Y | RESPONSE N | RESPONSE NA | COMMENTS |
|---|---|---|---|---|
| 1. Are duplicate sample analyses conducted on at least 10% of the microbiology samples? | ✓ | | | 6 duplicate analyses. |
| 2. Are at least 10% of the samples counted by a second qualified individual (i.e., QA count)? | | ✓ | | QA count for TC. No QA counts for EC, ENT, HPC, or NC-DNA + RNA. |
| 3. Are ~~reagent~~ blank samples analyzed with each set of samples? (RL) UMR 10-23-09 | ✓ | | | |
| 4. When applicable, have analytical method detection limits been established and clearly documented? | ✓ | | | |

**Additional Questions or Comments:** Samples collected 10:41-10:44 am. Time of reciept in laboratory was not recorded. Samples were centralized and media added/analyzed by 1:50 pm.
The QA counts should be done by a senior staff member not a student.
-29 min. between RNA membrane at 36°C and exposure to UV light; this should only be 10 min.
Data entry proofed by TJJ 05 Oct. 09. Calculations verified for ~10% of samples.
UMR 10-23-09.

**PHYTOPLANKTON**

Relevant GSI SOPs: Reviewed datasheets 19 October 2009 UMR.

- *GSI/SOP/LB/RA/SA/1 – Procedure for Algae/Small Protozoan Sample Analysis*

| AUDIT QUESTIONS | RESPONSE Y | RESPONSE N | RESPONSE NA | COMMENTS |
|---|---|---|---|---|
| 1. Were all data, observations, and comments appropriately recorded on the "Ballast Water Plankton Count Sheet"? | ✓ exceptions → | | | No error corrections. Data often covered when corrections made. Data difficult to read. |
| 2. Was sample assessment conducted within ~1-1.5 hours after sample collection? | ✓ | | | Began all analyses at 10:43 am. Done by 17:15 pm |
| 3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)? | | ✓ | | There was no QA count done during Trial 7. |

**Additional Questions or Comments:** 1386 live cells/mL in harbor → adding enough algae to make at least 1500 live cells/mL on intake. Pre-treatment fill sample + datasheet mislabeled. SP3-5 was PT sample, not SP3-4.
Pre-treat = 1505 cells/mL
Post-treat = 13 cells/mL (Paradinium → dinoflagette)


**Initial/Date**
UMR/ 10-23-09

**ZOOPLANKTON**

Relevant GSI SOPs: Reviewed datasheets 20 Oct. 2009 VMP.

- *GSI/SOP/BS/RA/C/2 – Procedure for Zooplankton Sample Analysis (DRAFT)*

| AUDIT QUESTIONS | RESPONSE Y | RESPONSE N | RESPONSE NA | COMMENTS |
|---|---|---|---|---|
| 1. Were all data, observations, and comments appropriately recorded on the "Zooplankton Identification Worksheet"? | ✓ | | ✓ | *SOP deviation |
| 2. Was sample assessment conducted within ~2 hours after sample collection? | ✓ | | ✓ | Tub 5 = 11:12 am-12:27 pm<br>Tub 6 = 12:27 pm-2:01 pm |
| 3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)? | A QA count was not done on the fill for Trial 7 ∴ it will have to be done on the drain. | | | |

**Additional Questions or Comments:**

Harbor rough estimate ≈ $6.7 \times 10^5$ orgs / $m^3$; Actual = $8.3 \times 10^5$ live orgs/$m^3$

* Harbor sample - rotifer counts had 241 and 239 total organisms per slide. This exceeds the limit of 200 organisms per slide directed in the SOP
* Pre-treatment sample - rotifer counts had 245 and 243 total organisms per slide, plus crustacean counts had 252 and 275 per wheel. Organisms need to be more dilute to avoid die-off while counting.

**Additional Questions and Comments on Technical Systems Audit:**

* At the start of the fill (@ 9:38 am) Tub 4 began to fill at a much higher rate than Tubs 5 and 6. Tyler S. was ~~altered~~ (SP) VMP 9-21-09 alerted of the situation and corrected the rate of flow to ~9.5 gallons per minute. All samples that were to be taken from Tub 4 (pre-treatment) will be taken from the backup Tub 5 in order to insure that there is consistency between the pre- and post-treatment.

- 9:52 am and 10:00 am Siemens personnel (Vadim and staff) observed a slight spike in ORP values measured by one of their probes. Siemens personnel were interested in whether this was caused by a change in flow rate or a change in water quality.

- Last time samples had more bubbles in them during collection than previously observed in collections 1 and 2.



Initial/Date

VMP/9-21-09

20 Sept. 2009

Trial 5 WET Test - algae appears to be not growing.

Initial algae counts - Trial ? $10 \times 10^4$.

CWB does not appear to be mixed well during first couple of days of testing - TRO background increases after day 3 because water is easier to mix. We should put FHW and CWB and WE on stir plate to ensure even mixing of sediment.

- check what age algae are harvested for use in WET test!

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21 September 09

- Can we blow air through pipes to ensure all water is removed? Vacuum for pipes to remove water?
- Should we ~~ex~~examine control (archived) samples to determine if bcanes or bdelloids present in sample?