United States Government

Department of Energy

memorandum

Carlsbad Field Office
Carlsbad, New Mexico   88221

DATE: March 24, 2003

REPLY TO
ATTN OF: CBFO:QA:DSM:GS:03-0024:UFC 2300.00

SUBJECT: Surveillance Report S-03-12, Rocky Flats Environmental Technology Site

TO: John Schneider, Assistant Manager for Projects, RFFO

The Carlsbad Field Office (CBFO) conducted a surveillance of the Rocky Flats Technology Site (RFETS) on February 11, 2003 of software quality assurance activities related to headspace gas analytical equipment. The surveillance team concluded that software quality assurance for the headspace gas analytical software is acceptable. The CBFO surveillance report is attached.

There were no deficiencies identified that were corrected during the surveillance and there were no CBFO Corrective Action Reports issued. There were two observations and five recommendations issued as a result of the surveillance.

If you have any questions or comments concerning this report, please contact me at (505) 234-7311.

Dennis S. Miehls
Quality Assurance Specialist

Attachment

cc: w/attachment
A. Holland, CBFO   *ED
K. Watson, CBFO   *ED
L. Xuan, RFFO   *ED
J. Jeffries, RFFO   *ED
G. O'Leary, RFETS   *ED
E. Feltcorn, EPA   *ED
R. Joglekar, EPA   *ED
M. Eagle, EPA   *ED
S. Zappe, NMED   *ED
B. Walker, EEG   *ED
C. Riggs, CTAC   *ED
T. Bowden, CTAC*   *ED
P. Roush, WTS
CBFO QA File
CBFO M&RC

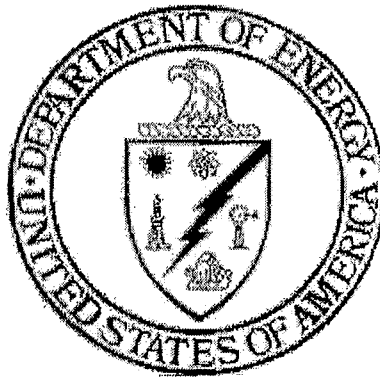030336

U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE

SURVEILLANCE REPORT
OF THE
ROCKY FLATS ENVIRONMENTAL
TECHNOLOGY SITE
(RFETS)

Denver, Colorado

SURVEILLANCE NUMBER S-03-12

January 11, 2003

TRANSURANIC WASTE CHARACTERIZATION PROGRAM

Prepared by: _James R. Schuetz_   Date: 3/20/3
James R. Schuetz, CTAC
Surveillance Team Leader

Approved by: _Ava L. Holland_   Date: 3/24/03
Ava L. Holland, CBFO
Quality Assurance Manager

1.0   EXECUTIVE SUMMARY

CBFO Surveillance S-03-12 was conducted to evaluate the life-cycle documentation, configuration management, and change control for software related to Rocky Flats Environmental Technology Site (RFETS) headspace gas (HGAS) analysis systems provided by the Los Alamos National Laboratory (LANL). The surveillance was conducted at RFETS on January 11, 2003. The surveillance team determined that software for the HGAS systems is classified in accordance with procedures and that the life-cycle documentation and software control are acceptable.

The surveillance team identified no conditions adverse to quality that required the issuance of a Corrective Action Report (CAR) and there were no issues identified and corrected during the surveillance (CDS). The surveillance team identified two Observations and offered five Recommendations for management review as a result of this surveillance. The Observations and Recommendations are described in Section 6.0.

2.0   SCOPE

CBFO Surveillance S-03-12 was conducted to evaluate the life-cycle documentation, configuration management, and change control for software related to Rocky Flats Environmental Technology Site (RFETS) Headspace Gas (HGAS) analysis systems provided by the Los Alamos National Laboratory (LANL).

3.0   SURVEILLANCE TEAM, INSPECTORS AND OBSERVERS

James R. Schuetz   Surveillance Team Leader, CTAC
No Inspectors and/or Observers participated in the surveillance.

4.0   SURVEILLANCE PARTICIPANTS

A list of personnel contacted during the course of the surveillance is provided as Attachment 1.

5.0   SUMMARY OF SURVEILLANCE RESULTS

5.1   Surveillance Activities

Details of surveillance activities, along with the specific objective evidence reviewed and the results of the reviews are contained within the surveillance checklists. The checklists are maintained as QA records. No conditions adverse to quality requiring the issuance of a CAR were identified. Also, there were no issues identified and corrected during the surveillance. Two Observations and five Recommendations were issued as a result of this surveillance.

5.1.1   Data Analysis for Headspace Gas Samples

The surveillance team evaluated the processes and software used for collection of headspace gas samples, data analysis, and analysis reporting of HGAS assay. The

surveillance team evaluated documentation of the draft software baseline, software error/problem reporting, software change control, configuration management, software testing, software verification and validation, and computer access controls for analysis of transuranic (TRU) waste HGAS samples using LANL enhanced software (G1701HG). This software is part of LANL's HGASII sampling and analysis system that is an advanced extension of the Agilent Technologies, Inc., G1701CA MSD Chemstation software (G1701HG). The LANL software is written to control the automated collection of samples and LANL has integrated this package with the Agilent software for data analysis and reporting. The systems were originally intended to gather samples and perform batch method analyses. RFETS has submitted change requests to LANL and the software has been modified to allow data/sample collection on one hardware platform and analysis/reporting on a separate platform in a continuous method. The surveillance team identified that this revised continuous operation method is the method that is currently in use and that the revised continuous method is addressed in the baseline documentation.

5.1.2   Software Classification

The surveillance team determined that the software was properly classified by RFETS as being developed under another program. RFETS has reviewed the software quality assurance requirements of Revision 4 of the CBFO QAPD and has elected to apply both basic requirements and NQA-2 Part 2,7 requirements for the HGAS systems software. Per interviews with RFETS chemistry department personnel, the surveillance team determined that this additional level of software quality assurance was included because of the development undertaken by RFETS and LANL to accommodate the change from the batch operation method to data/sample – data analysis continuous operation method. The additional requirements were necessary to provide communication and review/approval cycles between RFETS and LANL for the software development process.

5.1.3   Software Life-Cycle Documentation

The surveillance team reviewed documentation of RFETS' evaluation and acceptance of LANL life-cycle documents and LANL testing reports for both the manifold and Agilent components of the software. RFETS has installed the software and has completed installation testing on both the RFETS data/sampling and analysis operating hardware platforms. After an inspection of the RFETS and LANL software testing documentation, it was determined that verification methods were comprehensive and valid for results covering the range of the intended use. RFETS personnel also indicated that the baseline life-cycle documentation books were presented to the surveillance team in draft form and will be submitted as QA records pending resolution of any concerns generated during the surveillance.

5.1.4   Software Change Control and Configuration Management

The surveillance team reviewed the software inventory list and directory listing of components installed on data/sampling and analysis hardware platforms and determined that configuration management was adequate for the suite of software

components and the classification of the software package. After a review of software management practices, error reporting forms, and software change request forms, the surveillance team determined that change control, computer security, verification and validation, installation and checkout, and access control practices were adequate and properly implemented for the analysis and data reporting software packages.

5.1.5 Review / Validation of HGAS Results

After an interview with the RFETS chemists and a review of RFETS operating procedures, the surveillance team determined that RFETS has elected to perform 100% review and validation of results reported using the HGAS software. This validation has been elected by RFETS due to the high number of error/problem reports for the pre-baseline software and will be continued at the discretion of RFETS chemists until the volume of error/problem reports decreases.

6.0 CORRECTIVE ACTIONS, OBSERVATIONS, AND RECOMMENDATIONS

The surveillance team identified no deficiencies during the surveillance that required the issuance of Corrective Action Reports (CARs). There were no deficiencies identified and corrected during the surveillance. Two Observations and five Recommendations were issued as a result of this surveillance. Observations were made to address concerns related to the draft life-cycle document books. Since the books have not been issued, the surveillance team determined that there was no deficiency; however, if the observation is not addressed, there is a possibility for a deficiency in the issued documentation.

6.1 Observations

6.1.1 Observation Number 1

Review of software validation and verification (V&V) indicates that RFETS has evaluated software to function up to a third level dilution. RFETS has determined that a fourth level dilution would be a rare occurrence. A note should be placed in the appropriate analysis procedure to flag the analyst to hold reports pending additional software V&V when the software performs a fourth dilution.

6.1.2 Observation Number 2

RFETS has evaluated life-cycle documents in files on the LANL-supplied CD *HGAS Test Plans, User's Guides and Procedures*. A paragraph should be placed in the *Headspace Gas Sampling and Analysis Integrated System – System Evaluation* (tab 4, book 1) reporting this evaluation and identifying items not included in either book 1 or book 2 of the draft evaluation documentation. Also, an evaluation should be performed of the Agilent software users manual to determine if this document is valid for the installed version and if it should be included in the evaluation book set.

6.2 Recommendations

6.2.1 Recommendation Number 1

There is an invalid hardware platform reference in the draft document *Headspace Gas Sampling and Analysis Integrated System – System Evaluation* dated January 16, 2003 (tab 4, book 1). Recommend that the document be scanned for hardware references and corrected prior to issue.

6.2.2 Recommendation Number 2

Installation and Check-out forms for hardware platforms GB-01 through GB-08 have not yet been completed and are not attached to tabs 6 through 10 in book 2 of the draft *Headspace Gas Sampling and Analysis Integrated System – System Evaluation* document. Recommend completing RFETS Installation and Check-out forms for the hardware platforms and attaching the forms to the tabs prior to issuing the document. Documentation of testing for the installation should reference V&V performed by LANL for validation of the software version, and the 100% V&V of an actual run of the specific machine, for verification of the installation on the specific hardware platform. Also recommend adding tabs in book 2 for Installation and Check-out forms and directory listings for machines GB-02 and GB-08.

6.2.3 Recommendation Number 3

Recommend adding page numbers and number of pages to directory listings in tabs 6 through 10 of book 2 of the *Headspace Gas Sampling and Analysis Integrated System – System Evaluation*.

6.2.4 Recommendation Number 4

Draft procedure PRO-1676-HGAS-S&A includes a step in Appendix 9 directing the user to transfer data files between GB machines on-line or via Zip Disc to perform data analysis. Recommend that a note be added in the draft procedure to alert the user to take care in data transfer due to the fact that data file names are similar between machines and could be easily confused.

6.2.5 Recommendation Number 5

Recommend placing HGAS Operations Anomaly Reports in software change request records packages. There is no upper level requirement for this record, but the report would provide better traceability between errors/corrections for items identified by RFETS and communicated to the vendor of a software package developed under the outside QA program.

7.0 ATTACHMENTS

Attachment 1: Personnel Contacted During the Surveillance

PERSONNEL CONTACTED DURING THE SURVEILLANCE

PERSONNEL CONTACTED			
NAME	**TITLE/ORG**	**CONTACTED DURING SURVEILLANCE**	**EVALUATION AREA**
Charlie Turner	RFETS HGAS / Chemistry Lab	Chief Chemist	HGAS Equip. (LANL GB-01 thru GB-08) Software QA
Tom Nolan	RFETS HGAS / Chemistry Lab	Chemist / SQA	HGAS Equip. (LANL GB-01 thru GB-08) Software QA

JRS 03/17/2003