CONFIDENTIAL REPORTING OF DATA INTEGRITY ISSUES

CONTENTS

1.0 OBJECTIVE

The purpose of this standard operating procedure (SOP) is to provide a local mechanism for Lockheed Martin Scientific, Engineering, Response and Analytical Services (SERAS) Contract employees to confidentially report data integrity issues. It is the policy of Lockheed Martin to conduct business in accordance with our ethical principles. These ethical principles include:

- **Honesty** - To have the courage to speak out the truth and to be absolutely forthright in all cases with our customers, co-workers, suppliers, communities, and shareholders.

- **Integrity** - To say precisely what we mean, and to deliver what and when we promise. To be willing to raise and address difficult issues that may affect safety, performance, or legal responsibility. To forthrightly admit error and make amends where appropriate.

- **Responsibility** - To speak out without fear of reprisal to call attention to any workplace violation of law, safe design and engineering standards, ethical codes, community standards, sexual harassment, equality, diversity, health, safety, and related issues.

- **Trust** - To recognize our position as stewards of our customers' businesses. To place the best of our thinking, energies and abilities into supporting customer enterprises. To be willing to raise issues if customer practices are not in alignment with our ethics policies.

- **Respect** - To value the differences as well as similarities in all of our customers, co-workers, suppliers, communities, and shareholders. To support and assist minority candidates in their endeavors, so that the Corporation reflects national diversity.

- **Citizenship** - To obey all the laws of any country in which we do business, to respect environmental concerns, and to give back to the communities by improving and enriching community life.

2.0 APPLICABILITY

This SOP is applicable to all data generated, reviewed or validated by Lockheed Martin SERAS personnel. Laboratories are under increasing scrutiny for improper practices. In 2001, an open letter to the environmental community drew attention to lab misconduct and unethical practices. This letter stated the need for the effective implementation of a strong Quality System and ethical practices. Decision-making requires reliable data of known and documented quality. Poor data affects regulatory programs, public health, industry, individuals and other laboratories.

3.0 DESCRIPTION

3.1 Improper Practices

Improper practice is defined as a scientifically unsound or technically unjustified omission, manipulation or alteration of procedures or data that bypasses the required quality control (QC) parameters, making the results appear acceptable. Some examples of improper practices are:

- Deletion of noncompliant data
- Adding surrogates or matrix spikes after sample extraction or digestion
- Using a previous initial calibration
- Improper peak integrations (e.g., peak shaving)
- Fabrication or falsification of records
- Improper alteration of instrument conditions
- Spiking more than required to improve recoveries
- Forging another person's name or initials
- Disabling audit trails
- Time traveling
- Performing multiple calibration runs and picking the best one
- Discarding points in a method detection limit (MDL) study without statistical justification or evidence of a known error
- Improper Gas Chromatography/Mass Spectrometry (GC/MS) tuning
- Over-dilution of samples or misrepresentation of reporting limits
- Unwarranted manipulation of computer software
- Overwriting files

3.2 Ethics and Data Integrity/Manual Peak Integration Training

All laboratory and field analytical personnel are required to participate in Ethics and Data Integrity training upon employment and annually thereafter. This training will cover Lockheed Martin's organizational mission, how and when to report data integrity issues, recordkeeping practices and data integrity procedure documentation. All Lockheed Martin/SERAS personnel involved with the direct measurement of or acquisition of GC or GC/MS data are also required to participate in a separate module dealing with manual peak integration procedures upon employment and annually thereafter. Training will be documented and all participating employees are required to sign an Ethics and Data Integrity Agreement (Figure 1, Appendix A). Both of these training modules are given in addition to the Lockheed Martin corporate annual Live Ethics training provided to all SERAS employees.

3.3 Confidential Reporting of Data Integrity Issues

A Data Integrity Reporting Form located on the Pub files under the Forms folder on the SERAS Local Area Network (LAN) is available for use by all SERAS employees for reporting improper laboratory practices. This form is to be printed out and may be submitted anonymously. A description of the situation that involved an improper practice or practices including the dates and the employee involved is required.

This form is to be submitted to the Quality Assurance Officer (QAO), assigned a unique identifier by the QAO and recorded into a logbook. Based on the nature of the improper practice, the QAO and the Program Manager will enlist the help of an experienced chemist, not part of management, for the evaluation of the improper practice. If it is determined that further investigation is warranted, the QAO and the PM will conduct a confidential investigation using qualified technical and management personnel. The investigation may be conducted in the form of an electronic data audit, a method audit, and interviews with personnel regarding laboratory practices or a surveillance to determine inappropriate practices.

If it is determined that the improper practice had an impact on the quality of the data reported to the client, the QAO and/or the PM will contact the client and recall/revise the data, if required.

No employee shall be discriminated against for making an allegation based on good faith or for providing evidence of an improper practice. All persons involved in any investigation will remain confidential.

All records will remain confidential and will be kept for a minimum period of five years. All records of improper practices and the results of the investigation will be included in the quarterly quality assurance report submitted to the Environmental Response Team (ERT) Project Officer and Quality Assurance (QA) Manager.

3.4 Disciplinary Action

Any employee who participates in improper practices is subject to disciplinary action up to and including termination of employment in accordance with Lockheed Martin Human Resources policies.

When the law is violated, the improper practice becomes a fraudulent act. When presented to the government, the offense is attempting to defraud the US government.

4.0 RESPONSIBILITIES

4.1 Laboratory and Field Analytical Personnel

- Every employee shall perform all of their assigned duties in accordance with established QA and QC procedures, which have been developed to conform to contractual requirements. This includes but is not limited to SOPs, the SERAS Quality Management Plan (QMP) and the SERAS Program Quality Assurance Project Plan (QAPP).

- Every employee is expected to use professional judgment and to document all

situations thoroughly.

- Every employee is expected to disclose any instance of noncompliance and report these instances in the case narrative and final analytical reports.

- Every employee is required to initial and date all manual integrations in accordance with SERAS SOP #1001, *Chromatographic Peak Integration*.

4.2 Quality Assurance Officer

- The QAO will conduct a confidential investigation using qualified technical and management personnel. This may be in the form of a data audit, electronic audit, interviews or surveillances. In conjunction with technical and management personnel, the QAO will determine if the inappropriate practice had an impact on data integrity.

- The QAO will provide data integrity training on an annual basis to all field analytical and laboratory personnel.

- The QAO is responsible for maintaining records for the five-year contractual period including but not limited to confidential investigation records, signed ethics statements

4.3 Analytical Section Leader

- The Analytical Section Leader is responsible for ensuring data integrity and good laboratory practices in the SERAS fixed laboratory facility.

4.4 Advanced Analytics Group Leader/EEU Task Leader

- The Advanced Analytics Group Leader is responsible for ensuring data integrity and good laboratory practices in the Trace Atmospheric Gas Analyzer (TAGA) Mobile Laboratory.

- The Engineering Evaluation Unit (EEU) Task Leader is responsible for ensuring data integrity and good laboratory practices for the preparation of Toxicity Characteristic Leaching Procedure (TCLP), Synthetic Precipitation Leaching procedure (SPLP) and Multiple Extraction Procedure (MEP) extracts.

REFERENCES

National Environmental Laboratory Accreditation Committee. 2004. Quality Systems.

APPENDICES
SOP #1003
January 2006

Appendix A
Figure 1
Ethics and Data Integrity Agreement
SOP #1003
January 2006

FIGURE 1.

Ethics and Data Integrity Agreement

I. I, _____, understand the high standards of integrity required of me with regards to the duties that I perform and the data that I generate and report in connection with my employment with Lockheed Martin on the Scientific, Engineering, Response and Analytical Services (SERAS) Contract.

II. I agree that in the performance of my duties at SERAS:

a. I shall not intentionally report data values that are not the actual values generated;

b. I shall not intentionally report the dates and times of analyses that are not the actual dates and times of analyses; and

c. I shall not intentionally represent another's individual's work as my own.

III. I agree to inform Lockheed Martin/SERAS of any accidental reporting of non-authentic data by myself in a timely manner.

IV. I agree to inform Lockheed Martin/SERAS of any accidental or intentional reporting of non-authentic data by other employees in a timely manner.

V. I agree that all work performed and the information gathered by Lockheed Martin/SERAS will be kept confidential (NELAC 5.4.2.3).

VI. I understand the options that are available for the reporting of ethical and data integrity issues.

VII. I understand that disciplinary action and possible criminal penalties can result from unethical behavior. I understand that adherence to data integrity and ethics policies are imperative for continued employment.

_____ _____

Signature Date

APPENDIX B
Figure 2
Improper Practice Reporting Form
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FIGURE 2 Improper Practice Reporting Form

Section 1. Origination

Date Initiated _____ Involved Personnel: _____

_____

Nature of the Improper Practice

Section 2 - Investigation/Action

Action Taken (Check all that apply)

Date Reviewed [ ] Reanalyzed [ ] Client Contacted [ ]
Training [ ] SOP Reviewed/Revised [ ] Equipment Service [ ]
Other [ ] (specify)

Comments:

NOTE: Attach appropriate documentation of investigation such as instrument printouts, copies of logbooks, results of meetings, etc.

Investigator(s): _____ _____ _____
(Signature) (Title) (Date)

_____ _____ _____
(Signature) (Title) (Date)

Section 3 – Followup

Comments:

QA Officer _____ _____Date
(Signature)(Date)

Section 4 – Closure

Corrective Action Taken:

Corrective Action Verified _____ _____
(QA Officer - Signature) (Date)

_____ _____
(Analytical Group Leader/ (Date)
Advanced Analytics Group Leader/
EEU Task Leader - Signature)