ExxonMobil Biomedical Sciences, Inc.
Clinton Township
1545 US Highway 22 East
Annandale, NJ 08801-3059

ExxonMobil

August 24, 2016

H&P Labs, Carlsbad, CA (1266) Tier III - Low Risk Laboratory Quality Systems Self-Assessment Questionnaire Review

2016SRA 490

Janis Villarreal
2470 Impala Drive
Carlsbad, CA 92010

Dear Ms. Villarreal:

The purpose of this letter is to inform you of the result of our review of the Tier III - Low Risk Laboratory Quality Systems Self-Assessment Questionnaire submitted. This questionnaire was based on ExxonMobil's data integrity (DIAF) policy and laboratory quality assurance (QP&G) standard.

After our review of the information submitted, we have determined that you have met all requirements. Therefore, we are pleased to advise you that the overall status is Preferred.

As a general reminder, assessments have limitations because they are based on observations of selected areas at a single point in time. Like any sample, they are subject to error. Assessments cannot insure that all areas of nonconformance are identified and they cannot predict future performance.

If you have any questions regarding this assessment report, or if you need additional information or support in the future, I can be reached at (908) 335-1119 or via email at cindy.f.smelser@exxonmobil.com.

Sincerely,

Cindy Smelser

Cindy Smelser
EMBSI Approved Auditor

Attachments:
1 - Completed Tier III - Low Risk Laboratory Quality Systems Self-Assessment Questionnaire with auditor comments

cc:
Kearney, Christine
Drake, Ken
Partington, Susan
Minsavage, Gary
eMemory

ExxonMobil Environmental Lab Low Risk Audit Process (Tier III Checklist) (Rev. 5, 7/19/13)

Instructions

1. **Please answer the following questions with a (X) in the "Yes" or "No" box.**
2. **For clarity purposes, briefly comment in the spaces provided.**
3. **Please number all attachments to their corresponding Section (i.e. Attachment 4 – Change Management System / Program)**
4. **Return information via e-mail to the relevant ExxonMobil contact (if necessary alternative methods of response can be arranged). This form should be returned as an editable word document.**

Laboratory Name: H and P Mobile Geochemistry, Inc.

Address: 2470 Impala Drive, Carlsbad, CA 92010

Lab Contact : Louise Adams and Janis Villarreal

Phone #(s) : (760) 804-9678

Email Address: Janis.Villarreal@handpmg.com

Types of Samples Tested for ExxonMobil (check all that apply):
Water ☐ Soil ☐ Air ☒ Mostly Soil Vapor Other (specify):

Testing of Samples for ExxonMobil is ordered by (check all that apply):
ExxonMobil affiliate ☐ A third party subcontractor for ExxonMobil ☒ Both ☐

Approximate # Tests / year for ExxonMobil: Approximately <100 per year with some on-site services

Approximate annual revenue from ExxonMobil sample analyses: < $20,000.

1. Quality Assurance System & Management Commitment

	Yes	No
• Do you have a quality assurance system or program in place and supported by Management? *Evidence for such a system or program would include an authorized QA manual or other equivalent document(s) to address the QA/QC procedures, practices and operations that are followed by the lab.* **If yes, please provide the following documents**: ➢ Copies of the QA manual title page, contents pages, and relevant pages where the owner/approver is documented and approval signature is clearly visible and dated. Auditor Comment: The Quality Systems Manual is signed by the Laboratory Director and Field Operations Manager. The copy supplied is dated January 2016 and is Revision No. 15. One of the quality objectives is to be compliant with ISO/IEC 17025 and the manual appears to address all the elements of the Standard. It is reviewed annually.	☒	☐
• Is the laboratory certified or accredited by a laboratory specific international standard (e.g. ISO 17025) or regulatory authority (e.g. NELAC, CAEAL)? **If yes, please provide the following information/documents**: ➢ Name of accrediting/certifying agency, CA ELAP and DOD ➢ Tests that are included in your certification?): Various air (TO-15) and 8260 soil gas method ➢ Copy of current certificate(s)	☒	☐

Auditor Comment: CA ELAP for fixed lab and 6 mobile units - all accreditations current. DOD ELAP for all fixed lab and 6 mobile units - all accreditations current. AZ DHS current accreditation. WA accreditation for TO-15 current. LA DEQ accreditation for TO-15 current. All certificates submitted electronically for review and verification.		
2. Data Integrity and Improper Influence		
• Do you have a Data Integrity or Ethics Policy that covers improper influence and data misrepresentation? **<u>If yes, please provide the following documents</u>**: ➢ Copy of data integrity or ethics policy Auditor Comment: Complete policy that includes GC data issues such as peak shaving. Signature line with date for reading. The Quality Manual states there is annual training, confirmed via conversation with Lab Director.	**Yes** ☒	**No** ☐
3. Quality Assurance Assessments		
• Do you have an internal audit system in place and does it cover all aspects of your quality assurance system? **<u>If yes, please provide the following documents</u>**: ➢ Copy of recent internal audit conducted by lab staff, management or third party consultant which details the assessment of the lab quality system. Auditor Comment: Audit records provided include full internal audit, various data audits, and several laboratory/facility audits, all from 2015. All of these are very detailed, show findings and corrective actions, with dates and signatures.	**Yes** ☒	**No** ☐
4. Training and Qualifications		
• Do you have a documented training program that ensures that only qualified laboratory personnel conduct testing? **<u>If yes, please provide the following documents</u>**: ➢ Two examples of how staff training/qualification is documented for typical lab tests (e.g., volatile organics, metals) Auditor Comment: Lab submitted an initial and on-going training record for S. Parsons. Training requirements and competency requirements are listed in the QA Manual section 2.4. Laboratory also has a formal training program for field sampling staff.	**Yes** ☒	**No** ☐
5. Field Sampling		
• Does the laboratory collect field samples as well as analyze them? **<u>If yes, please provide the following documents</u>**: ➢ References for sampling methods used (please note if in-house procedure) Auditor Comment: Field sampling staff are certified and typically work in one of the mobile lab units as sampler and analyst. Laboratory records show ExxonMobil use of the mobile units in 2015 via ETIC, AECOM and CARDNO.	**Yes** ☒	**No** ☐
6. **Data Management and Traceability**		
• Do you have formal procedures for the management and traceability of lab data, test records, and sample identification?	**Yes** ☒	**No** ☐

If yes, please provide the following information/documents:

- Copies of relevant procedures for recording lab data.
- Copies of relevant procedures that describe the retention period for lab data and records. *Note: ExxonMobil data retention guidelines requires that all data be retained for 10 years.*
- Copies of relevant sample identification procedure (e.g. how do you number samples).
- Two example of typical sample labels used for ExxonMobil samples.

Auditor Comment: Samples are received with a completed COC, reviewed for completeness and acceptability, and logged into the ELEMENT LIMS system. Each project and each sample are given a unique ID and samples are labeled. Once analysis is complete, all data undergoes a three tier review: tier I by the analyst; tier II by a second qualified analyst or QA officer; and tier III by the QA Manager or other laboratory management. The review process includes raw data, calculations, data transcriptions. QC acceptance, manual integration, calibrations and reasonableness. The review process is documented. Once complete, reports are prepared for electronic distribution. Report formats can be chosen by the client to include anything from simply end data to a full data package with all QC, calibration records and raw data. All electronic records are backed up biannually, and kept indefinitely. Paper records are maintained for 10 years and then destroyed. See QA Manual sections 7-10 for details.

7. Corrective Actions

	Yes	No
• Do you have formal Corrective Actions procedures in place? **If yes, please provide the following information/documents**: ➢ Which of the following would result in a corrective action: Audit finding ☒ Proficiency Testing Outlier ☒ Customer complaint ☒ ➢ Provide at least one example of a recent completed corrective action arising from key activities such as internal audits, calibration failures, or maintenance work. Auditor Comment: The QA Manual sections 11.4, 11.5 and 11.6 define the policies and procedures for handling nonconformances, preventive actions and corrective actions. Discussion with the laboratory indicated 25-30 corrective actions per year. They do not track numbers for nonconformances but there are records included for these in each laboratory. The corrective action system appears to address all appropriate elements and documentation, including the tracking of corrective action progress. Full corrective action closure that includes follow-up review, typically takes about one year to allow time to verify the effectiveness of actions. Initial actions are typically completed in weeks to months.	☒	☐

8. Test Methods and Performance Compliance

	Yes	No
• Do you have a list of the test methods used for ExxonMobil work in your lab? **If yes, please provide the following documents**: ➢ Copy of current test method list Auditor Comment: By accreditation records	☒	☐
• Are the test methods used in your lab the latest promulgated version? • How do you ensure that you have the most current version of the test method (e.g., ASTM alerts, subscription service, corporate process, etc.): Through DOD and other audits and through manual review of websites.	☒	☐
• Does the lab ensure that the designated test methods are followed as published?	Yes	No

If yes, please provide the following documents: ➢ Attach one of the following documents as evidence: ➢ Internal audit report detailing results of test method audits/assessments (includes witnessing of method performance), or ➢ Documented requalification/training for staff on specific test method. Auditor Comment: SOPs are reviewed annually to verify compliance with published procedures. There is no Test Method Assessment process that includes the a review of the bench procedures. All staff are required annual re-qualification that is documented via routine QC or PT samples.	☒	☐
9. Quality Control (QC) Programs and Performance		
• Do you have quality control procedures in place that cover the test work performed for ExxonMobil? *Typical quality controls could include the use of Certified Reference Materials, check samples with accepted reference values, Statistic Quality Control (SQC) charts or other statistical evaluations of control data.* **If yes, please provide the following documents**: ➢ Two examples of your relevant quality control practices (for example, 2 recent SQC charts or results of check samples for a given test). ➢ Which of the following quality controls are routinely run with each batch (20 or less) of samples? Sample blank ☒ Field blank ☒ Calibration Verification Std ☒ Duplicates ☒ QC Sample (Lab Control Sample) ☒ Matrix Spikes ☒ Matrix Spike Dups ☒ Auditor Comment: The routine QA/QC procedures for all test methods are outlined in the Quality Systems Manual section 8. Instrument QC includes all the elements required by EPA SW846 methods. The program includes control charting of most of the key analytes. The control charts represent comingled data from multiple instruments and multiple extraction mechanims.	Yes ☒	No ☐
10. Calibration Records & Performance		
• Do you have a calibration program in place? **If yes, please provide the following documents**: ➢ Two calibration records pertaining to key equipment and/or standards (e.g., instrument calibration, thermometers, balances). ➢ How do you determine your method detection limit? Procedure equivalent to 40 CFR Appendix B, part 136 as determined by telephone conversation with lab director. ➢ Evidence of method detection limit determinations for 2 tests (e.g., benzene in volatile organics for soil) Reviewed MDL / LOD / LOQ records for various TO-15 procedures. Auditor Comment: The calibration procedures and requirements are outlined in the Quality Systems Manual section 4.2. It includes instrument calibration as well as routine calibrations and verifications of support equipment (balances, weights, thermometers, dispensers etc). Instrument calibration is completed using a minimum of 3 points, and always 5 points for GCMS. All calibrations are supported with independent calibration verifications using a second source standard. Reference	**Yes** ☒	**No** ☐

materials are obtained from a supplier recognized under ISO/IEC 17025 wherever possible. All equipment is calibrated by an ISO/IEC 17025 accreditied supplier. In-house verifications for balances and dispensors were reviewed and found acceptable.		
11. Proficiency Testing Programs		
• Do you participate in inter-laboratory cross checks or external proficiency evaluation programs? ➢ Please provide details of your proficiency testing activities? Records provided show volatiles in soil and water, GRO and DRO, and air using TO-15 and TO-17. ➢ Please identify any tests/matrices which you are not rated proficient: All 2015 data provided show acceptable results with few non-acceptable data points.	**Yes** ☒	**No** ☐

H and P Mobile Geochemistry, Inc. is a network of one fixed laboratory facility and 6 mobile units. They concentrate mostly on air testing, with a very small amount of soil testing. All work is GC and GCMS. They offer several variations of EPA TO-15 (ambient air and soil gas) and an air version of EPA SW846-8260.

ExxonMobil uses these laboratories for some third-party work, mostly for on-site soil gas testing. All of the laboratory units are accredited under CA ELAP and DoD for the fields of testing used by ExxonMobil. This Tier III audit was completed using records submitted by the laboratory electronically. A follow-up telephone call with the Laboratory Director Janis Villarreal on July 26, 2016 supplied information needed to complete some issues not completely addressed by the electronic records.

The reviewer, not the laboratory completed this checklist, therefore the signature line for Laboratory Manager remains blank. The reviewer considers this laboratory PREFERRED for the limited and type of work performed for ExxonMobil.

Two areas in need of improvement if this laboratory were to receive much work from ExxonMobil would be:

- The inclusion of test method assessments that reviewed actual bench practices as well as a paper review of the SOP
- Construction of control charts specific to each instrument; they currently reflect comingled data from all instruments per test and matrix.

Christine A. Kearney
Kearney and Associates

August 1, 2016

Low Risk Self Assessment (Tier III Checklist) Audit Process

This section to be reviewed and completed by ExxonMobil approved auditors only.

Audit Performance Categories (Audit Ratings)

Please review the audit rating choices described below and complete the Audit Rating Summary box at the end of this page.

3rd Party Contract Lab Audit Ratings:

ExxonMobil expects 3rd Party Contract laboratories to comply with the requirements of the ExxonMobil Data Integrity Assurance Framework (DIAF) and relevant sections of the Quality Practices & Guidelines standard (QP&G v5.3b, May 2011). The lab's performance against these requirements will be rated as:

- A **PREFERRED** Lab shall have answered "**Yes**" to all of the above 10 sections.
- A **CONDITIONAL** Lab shall have answered "**No**" to one or more of the above 10 questions/sections but the lab is willing to act promptly to develop an action plan and work to correct the identified deficiencies within 6-12 months, depending on business line audited. When the actions are completed to the satisfaction of the auditor, the lab can be upgraded to **PREFERRED** and registered in the QP&G Audit database after EMBSI review and approval. The businesses will still allow these labs to be used while audit findings are being actioned and Supplemental QC performance samples / review activities are at the submitter's discretion.
- A **NOT PREFERRED** Lab shall have answered "**No**" to any of the above the above 10 questions/sections and have indicated that although they may have a relatively good quality program they are reluctant (or refuse) to correct the deficiencies that were noted in the audit. The business line is not recommended to use these laboratories.

Audit Rating Summary:

Name of Auditor: Cindy Smelser/Christine Kearney
Audit Date: August 24, 2016
Audit Rating: Preferred