



LABORATORY QUALITY MANUAL

Pace Analytical Services, LLC

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Description	Manufacturer	Model No.	Serial Number	Service Date	Condition	Location	Internal ID	Manual location
Gamma Counter (out of service)	Ortec Module	DSPEC Jr 2.0 V.046	10071606	Oct-08	New	Rad	Detector #3	NA
Gamma Counter (out of service)	Ortec Module	DSPEC Jr 2.0 V.046	06116387	Mar-06	New	Rad	Detector #2	NA
Gamma Counter (out of service)	Ortec Module	DSPEC Jr 2.0 V.046	06053268	Mar-06	New	Rad	Detector #5	NA
Alpha Spec	Oxford Tennelec	S5HP	37959	Feb-04	used	Rad	Detectors 25 through 40	GFPC count room
Sodium Iodide Detectors	Ortec	Digibase Unispec	14346852 (Detector 1)	Apr-15	New	Rad	#1	GFPC count room
Sodium Iodide Detectors	Ortec	Digibase Unispec	14346844 (Detector 2)	Apr-15	New	Rad	#2	GFPC count room
Sodium Iodide Detectors	Ortec	Digibase Unispec	14346843 (Detector 3)	Apr-15	New	Rad	#3	GFPC count room
Sodium Iodide Detectors	Ortec	Digibase Unispec	14346847 (Detector 4)	Apr-15	New	Rad	#4	GFPC count room
Survey Meter	Ludlum Measurements Inc.	3019	25014380	Jul-17	New	Rad	25014380	NA

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8.0 ADDENDUM: PROGRAM REQUIREMENTS

Program specific information provided in this addendum supplements the main body of this manual. Each subsection is stand-alone, meaning the requirements for the quality management system in each subsection only apply to the program referenced. Additionally, only program requirements for the quality management system that are more stringent than the content of the main body of the manual are included.

8.1 DoD/DOE

PAS-Greenburg maintains accreditation for DoD Environmental Laboratory Approval Program (ELAP).

This addendum outlines additional policies and processes established by this laboratory to maintain compliance with DoD/DOE program specific requirements as outlined in the DoD/DOE Consolidated Quality Systems Manual (QSM) for Environmental Laboratories. The QSM incorporates ISO/IEC 17025 and the TNI Standard and includes additional program-specific requirements for laboratories that perform analytical testing services for DoD and DoE and which must be followed for DoD / DoE projects.

Section 4.2.5: Supporting Documents

Technical SOPs used for DoD/DoE testing must also include instructions for equipment and instrument maintenance, computer software/hardware, and troubleshooting.

The review frequency for technical SOPs used for DoD/DoE testing is annual, instead of every 2 years.

Section 4.4: Review of Analytical Service Requests

If the DoD/DoE customer requests a statement of conformity, the standard used for the decision rule must be communicated to and agreed on with the customer and identified in the final test report.

Laboratory requests to deviate from the requirements specified in the DoD/DoE QSM must be requested on a project-basis and include technical justifications for the deviation. These requests are submitted to and approved by the DoD/DoE project chemist or contractor, however name, in addition to the PAS client.

For DoD / DoE projects, will also seek clarification from the customer when the customer has requested an incorrect, obsolete or improper method for the intended use of data; the laboratory needs to depart from its test method SOP in order to meet project-specific data quality objectives; and information in project planning documents is missing or is unclear.

Section 4.5: Subcontracting

In addition to written client approval of any subcontractor for testing, the customer is notified of the laboratory's intent to use of a subcontractor for any management system element (such as data review, data processing, project management or IT support) and consent for subcontracting is obtained approved in writing by the DoD/DoE customer and record of consent kept in the project record. Subcontracted laboratories performing analytical services must be accredited and meet the requirements of the DoD/DoE QSM.

Section 4.6: Purchasing and Supplies

The laboratory procedure for records of receipt of materials and supplies used in testing also include a specification to record the date opened (DoE only).



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Section 4.9.3: Nonconforming Work

The laboratory's procedure for client notification includes the 15 business day DoD/DOE time-frame for notification of the problem and the 30 business day time-frame for submission of the corrective action plan or corrective actions taken. This procedure also includes the DoD/DOE requirement for AB notification of discovery.

Section 4.13: Control of Records

Technical Records: The laboratory's procedure for logbooks includes measures to prevent the removal of or addition of pages to the logbook (applies to both hardcopy and electronic). Hardcopy logbooks are version controlled, pre-numbered and bound. Initials and entries are signed or initialed and dated by the person making the entry and the entry is made at the time the activity is performed and in chronological order. Each page of the logbook must be closed by the last person making the entry on the page. Closure is recorded by the initial and date of the person making the last entry.

Section 5.4.7: Control of Data

The laboratory will assure LIMS passwords are changed at least once per year.

An audit of the LIMS will be incorporated into the laboratory's annual internal audit schedule.

The laboratory will have procedures in place to notify DoD/DoE customers of changes to LIMS software or hardware configurations that may impact the customer's integrity of electronic data.

Section 5.8.9: Sample Disposal

For DoE projects, the record of disposal must also include how the sample was disposed and the name of the person that performed the task.

Appendix E: Support Equipment Calibration

Mechanical Volumetric Pipette: In addition to the quarterly verification check, pipettes used for DoD/DoE projects are checked daily before use using the same procedure and criteria specified for the quarterly check.

Water Purification System: The performance of the water purification system is checked daily prior to use in accordance with laboratory SOP ENV-SOP-GBUR-0008 *DI Water and Suitability*.

Radiological Survey Equipment: The performance of the radiological survey equipment is checked daily prior to use in accordance with laboratory SOP ENV-SOP-GBUR-0103 *Radiation Safety Compliance*.

Additional: (DoE): Section 6.0 of the QSM outlines additional management system requirements for the management of hazardous and radioactive materials management and health and safety practices. The laboratory, if approved for DoE, will work with the PAS Health and Safety Director to establish plans, policies and procedures that conform to these comprehensive specifications and incorporate these documents into the quality management system.



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9.0 ADDENDUM: RADIOLOGICAL REQUIREMENTS

9.1 Estimate of Analytical Uncertainty

Radiological tests often report uncertainty and the manner in which it is derived are in accordance with Multi-Agency Radiological Laboratories Analytical Protocols Manual (MARLAP) and Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (GUM). The means by which these criteria are applied can be found in the method SOPs.

9.2 Radiological Equipment Calibration

Radiological calibrations may follow one of several methodologies based on technology of the counting; these can include efficiency curves, energy calibrations and quench curves. The various calibrations should ensure that the range chosen encompasses the activities expected in the client samples.

Radiological Equipment should be calibrated at the appropriate frequency and whenever the equipment undergoes maintenance. In the case of liquid scintillation counters the equipment shall be recalibrated when a significant move has taken place.

Calibrations can vary with equipment; in the case of gas flow proportional counters standards that range the expected residue range for gross alpha and beta shall be used, with efficiency curves developed to encompass the range of client sample residues. Any samples outside of this range shall be evaluated and the aliquot changed to accommodate the curve if necessary. Beta emitters, or isotopes that are shown to have less than a 2% efficiency change with residue that are known to not experience self attenuation may be calibrated by using a least 3 standards of known activity and comparing the efficiency results to ensure all agree to a relative standard deviation of less than 5%.

Quench factors for liquid scintillation counters shall be prepared by adding varied amounts of quenching agent. Any sample displaying a quench factor outside of the curve shall be evaluated. If the quench factors are shown to not vary in efficiency by greater than 2% then an efficiency calibration can be established using at least 3 standards of known activity and comparing the efficiency results to ensure all agree to a relative standard deviation of less than 5%.

Cross talk factors must also be evaluated when samples are known to contain more than one beta or an alpha and beta emitter.

All detectors must pass various daily tests depending upon the technology. The criteria of these various tests should be known to the analyst. Any detector that does not pass the daily check must be re-checked. If the daily test fails a second time the detector must be taken out of service for that day. Any detector that fails two daily checks must be evaluated and serviced if required. In most instances two passing daily checks are required to put a detector back into service.

9.3 Matrix Spike/Matrix Spike Duplicate (MS/MSD)

For radiochemical analyses, tests that do not incorporate the use of a carrier or tracer for yield assessment must contain an associated MS and MSD (or sample duplicate) using the same matrix collected for the specific DOD project. Gamma spectroscopy analyses are excluded from the MS/MSD requirement as the test does not require chemical processing of samples for analysis.