

EM 200-1-1
1 Jul 94

APPENDIX C

INFORMATION

FOR

COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES

UNDERGOING VALIDATION

BY

THE U.S. ARMY CORPS OF ENGINEERS

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(SAMPLE LETTER)

Dear Laboratory Director:

Your laboratory has been submitted as a candidate for validation/revalidation in support of the U.S. Army Corps of Engineers (USACE) hazardous, toxic, and radioactive waste (HTRW) response activities. Prior to the field studies or sample analyses, your laboratory must be validated by the USACE. Enclosed for your information and action are:

- (1) Information about the USACE Project(s) that leads to this validation/revalidation process,
- (2) Information for Commercial Analytical Chemistry Laboratories Undergoing Validation by the USACE,
- (3) Guidelines for Analyzing and Reporting Performance Evaluation Samples (Appendix D), and
- (4) Preliminary Questionnaire (Appendix E).

If you decide to obtain a USACE HTRW laboratory validation, please be sure that:

- (1) All instructions, including all time deadlines, are read and followed carefully.
- (2) The preliminary questionnaire is completed and returned with original verification signature(s) within ten working days from receiving date.

I hope that the information provided in this packet will be helpful to you and answer any questions you may have. If you have any questions regarding this information or the USACE HTRW laboratory validation program in general, please contact the Laboratory Validation Coordinator at (402) 221-7494.

Sincerely,

Chief, Environmental, HTRW Division
HTRW and Engineering Directorate

4 Enclosures

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TO: Laboratory Director/Manager
FROM: USACE HTRW MCX
DATE: 01/21/92

SUBJECT: USACE HTRW Projects and Laboratory Validation

Listed below is some basic information about the USACE HTRW project(s) that your laboratory will provide analytical chemistry services. For the details, please contact the primary contractor and/or refer to the approved final Work Plan.

Laboratory Name: ABC Analytical Laboratory State: MD

1. Project Name: Elmwood County Landfill State: NJ
Contract No: DACW01-91-C-2345
Sampling Date: 09/01/91 (approximate)

AE/Contractor: DEF, Inc. State: PA

USACE TM: John Dow
Phone No: (222) 333-4444

HTRW Analyses: VOA, BNA, PCB, PEST, TAL METALS, TRPH, CN.

2. Project Name: Any AFB; Fire Fighting Training 2A State: AZ
Contract No: DACA01-91-B-1234
Sampling Date: 04/15/92 (approximate)

AE/Contractor: Any Environmental Services, Inc. State: CA

USACE TM: Paula Smith
Phone No: (333) 444-5555

HTRW Analyses: RCRA METALS, TRPH, AVO, TPH (Mod. 8015) .

Remarks: The HTRW analyses may involve samples of various matrices.

Figure C-1 Sample Laboratory Evaluation Request

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INFORMATION FOR COMMERCIAL ANALYTICAL CHEMISTRY LABORATORIES
UNDERGOING VALIDATION BY THE U.S. ARMY CORPS OF ENGINEERS

Please retain this information and a copy of your completed preliminary questionnaire in your file for future reference.

WHO NEEDS VALIDATION?

According to USACE Engineer Regulation 1110-1-263, CHEMICAL DATA QUALITY MANAGEMENT FOR HAZARDOUS WASTE REMEDIAL ACTIVITIES:

Laboratory validation shall apply to all commercial laboratories directly or indirectly providing chemical analyses to support USACE HTRW investigative and remedial activities.

All commercial laboratories that support USACE HTRW response activities must obtain a USACE laboratory validation prior to field studies or sample analyses and must maintain the validated status throughout the contract/project/task order(s) (hereafter referred to as the contract or project) for the HTRW response activities.

WHAT IS THE VALIDATION PROCESS?

The laboratory validation process consists of three major sequential steps: (1) review of the laboratory's qualification documents, (2) analysis of performance evaluation (PE) samples, and (3) on-site inspection of laboratory's facility, instrumentation, operation, and management.

(1) Step 1. Upon request, a commercial laboratory should submit its qualification documents within five working days to the USACE Laboratory Validation Committee (hereafter referred to as the Committee) for review. This submittal may be in the form of an off-the-shelf quality assurance manual or in some other format that provides proper laboratory-specific information for the Committee to assess the laborator's technical capabilities. The information includes, but is not limited to, laboratory floor plan, organization chart, list of major instrumentation, copy of staff resumes, laboratory certificates, standard operating procedures for nonstandard/modified standard chemical testing, quality assurance/quality control (QA/QC) policy and practice, etc. If it appears that a laboratory has the adequate capabilities to meet project requirements, the Committee will initiate Step 2.

(2) Step 2. The Committee will provide a laboratory with project-specific PE samples for performance evaluation. A laboratory may volunteer for additional non-project-specific PE samples at its own cost. Arrangements will be made with the laboratory for the analysis and reporting of these samples. Enclosure 3 is a general guidance for PE sample analysis and reporting. Sample-specific instructions will be sent along with the PE samples and should be followed wherever applicable. Failure to analyze these samples correctly or within the required time frame may result in termination of the validation. The results are considered passing if the results of a particular method are within statistically established acceptance limits as determined by the USACE and no procedural problems are found during the Step 3 follow-up laboratory inspection. Normally, only one set of PE samples will be sent to each laboratory. A laboratory must pass more than 50 percent of all PE samples within 40 working days from receipt of the PE samples or the validation process will be terminated. Prior to an on-site inspection, a laboratory shall submit to the Committee a concise written statement describing the problems, solutions, and corrective actions taken or to be taken for the analytical parameters failed in the first attempt.

(3) Step 3. Two Committee representatives will inspect a laboratory only after Steps 1 and 2 have been successfully completed. The on-site inspection which generally takes eight hours involves:

- (a) An entrance interview with the upper laboratory management staff (including laboratory director, managers, QA officer, and project personnel) to discuss upcoming USACE project(s), the USACE QA program, the USACE review comments on the laboratory's qualification documents, the PE sample results, and the laboratory's previous performance on USACE projects, if applicable.
- (b) A laboratory tour to determine the adequacy of laboratory organization, personnel, facility, and equipment and the implementation of adequate analytical quality and document control, including use of proper analytical methodology, control charts, data and sample handling, documented corrective action measures, chain-of-custody, etc.
- (c) An exit interview to discuss any deficiencies noted during the inspection and recommended corrective actions with the laboratory management staff. The corrective actions may include the analysis of a second set of PE samples for failed parameters.

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During the exit interview, a laboratory will be requested to submit written responses with supporting documentation to the deficiencies within ten working days from the inspection date. The Committee will evaluate and determine the validation status. A laboratory must rectify any deficiencies noted during the inspection prior to approval for a full validation status.

WHAT ARE VALIDATION CRITERIA?

The USACE basically follows Federal and/or State laws, regulations, and guidelines and good laboratory practices to evaluate laboratory performance. The validation status of a laboratory depends on whether the laboratory's PE sample results are within USACE established acceptance criteria and no procedural problems are found during a follow-up laboratory inspection. The laboratory's PE sample results will be compared in the following manner: (1) with the prepared concentrations of PE samples that are used as the absolute recovery comparators, and (2) with the statistical mean and standard deviations reported by a group of referee and/or peer laboratories. The acceptance limits for analyte quantitation will be established statistically at 95 percent confidence based on peer group results.

WHAT DOES A LAB NEED TO PREPARE FOR THE INSPECTION?

Prior to the USACE on-site inspection, a laboratory should be familiar with all the materials that have been provided by the USACE. Laboratory key personnel including laboratory director/manager, QA officer, group supervisors, etc., should be residing and available for answering questions during the inspection.

Results of any USACE PE samples should be reviewed prior to the inspection. Special attention should be placed on unacceptable results. Documented corrective actions for unacceptable results should be made available to the USACE inspector(s) during the inspection. Any data or information requested in advance by the USACE inspector(s) should be made readily available.

The preliminary questionnaire should have been filled out and returned within ten working days from receipt or at least one week before the inspection. A map and/or directions for getting to the laboratory should also be submitted along with the preliminary questionnaire.

HOW MUCH TIME DOES VALIDATION TAKE?

The entire process of laboratory validation generally takes up to 12 weeks depending on a laboratory's performance and responsiveness. A simplified flow diagram for the entire validation process is shown in Figure C-2 (Pages C-9 thru C-10).

WILL A CERTIFICATE BE ISSUED?

USACE will not issue a certificate for validated laboratories. However, a letter and a copy of inspection report will be sent to each validated laboratory. The letter will specify the methods and matrices, the project(s), and the time period (usually 18 months) for which the validation is granted.

IS THE VALIDATION UNIVERSAL?

The validation is a parameter, method, and matrix-specific approval and only applies for USACE HTRW program. However, for each new contract awarded during the 18-month validation period, a project-specific evaluation is still required. The Committee will check the laboratory's validation status and previous performance to determine if any additional actions are needed. If different parameters, methods and/or matrices are involved, only those PE samples will be sent. If work done for the USACE by the laboratory has been satisfactory, no further actions will be necessary.

HOW ABOUT SUBCONTRACTING?

A validated laboratory may not subcontract any USACE samples to a second laboratory without the knowledge and approval of the USACE TM/COR and the concurrence of the Committee. The second laboratory must also be validated for methods, parameters, and matrices corresponding to the subcontract. Subcontract of PE sample analysis is totally prohibited.

WHAT ARE THE FEES REQUIRED FOR VALIDATION?

There are no direct fees for the laboratory besides the cost for additional PE samples required for failed parameters or non-project-specific parameters. The cost for any additional or non-project-specific PE samples range from \$100 to \$300 per analytical parameter, per matrix, and per shipment. The cost shall be reviewed annually and adjusted as necessary without

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notice to reflect currency value fluctuations or changes in program administration costs. The USACE will not pay the cost for analysis of PE samples and preparation of any qualification documents.

HOW TO RENEW VALIDATION

On a monthly basis, the Committee will notify USACE TM/CORs of laboratories with expiring validation (i.e., within three months). If the USACE TM/CORs intend to use those laboratories beyond the expiration dates, the USACE TM/CORs will request revalidations. For a commercial laboratory with an expired validation status, its validation will be renewed when next contract is awarded. After considering use of the laboratory and its previous performance, the Committee will determine which of the three steps will apply to the revalidation process.

WHAT TO DO WITH THE PRELIMINARY QUESTIONNAIRE

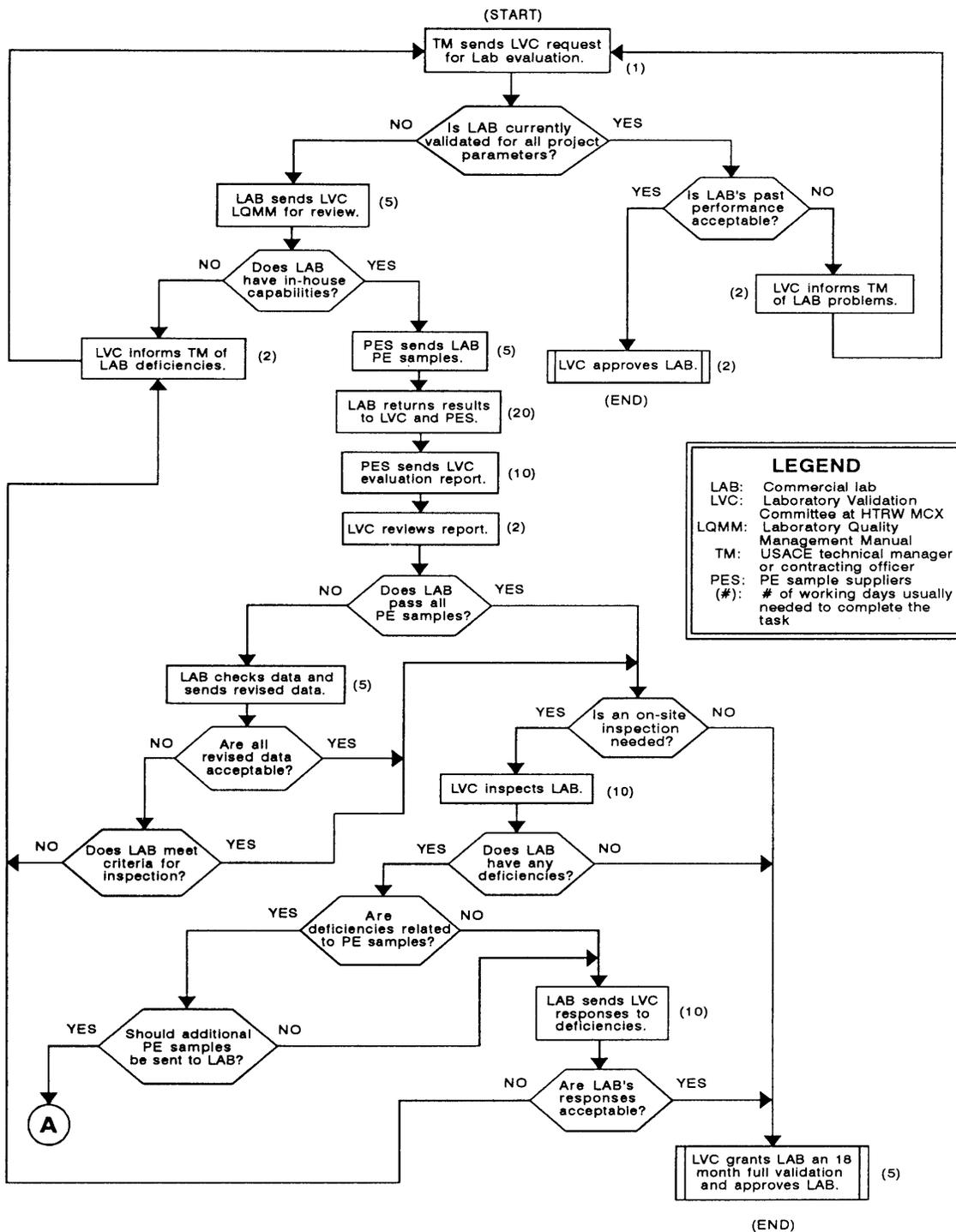
The enclosed preliminary questionnaire shall be completed and returned to the Committee within ten working days from the date of receipt. Any supporting documents should be attached if available.

WHERE TO GET MORE INFORMATION

The Laboratory Validation Committee at the HTRW Mandatory Center of Expertise (MCX) of the USACE is responsible for all aspects of the USACE HTRW laboratory validation program. Any questions concerning the validation program can be directed to the Laboratory Validation Coordinator.

U.S. Army Corps of Engineers
HTRW Mandatory Center of Expertise
ATTN: CEMRD-ED-EC (Laboratory Validation Coordinator)
12565 West Center Road
Omaha, NE 68144-3869

Voice: (402) 221-7494
FAX: (402) 221-7403



LEGEND
 LAB: Commercial lab
 LVC: Laboratory Validation Committee at HTRW MCX
 LQMM: Laboratory Quality Management Manual
 TM: USACE technical manager or contracting officer
 PES: PE sample suppliers
 (#): # of working days usually needed to complete the task

Figure C-2. Flow Diagram of Commercial Laboratory Validation Procedures

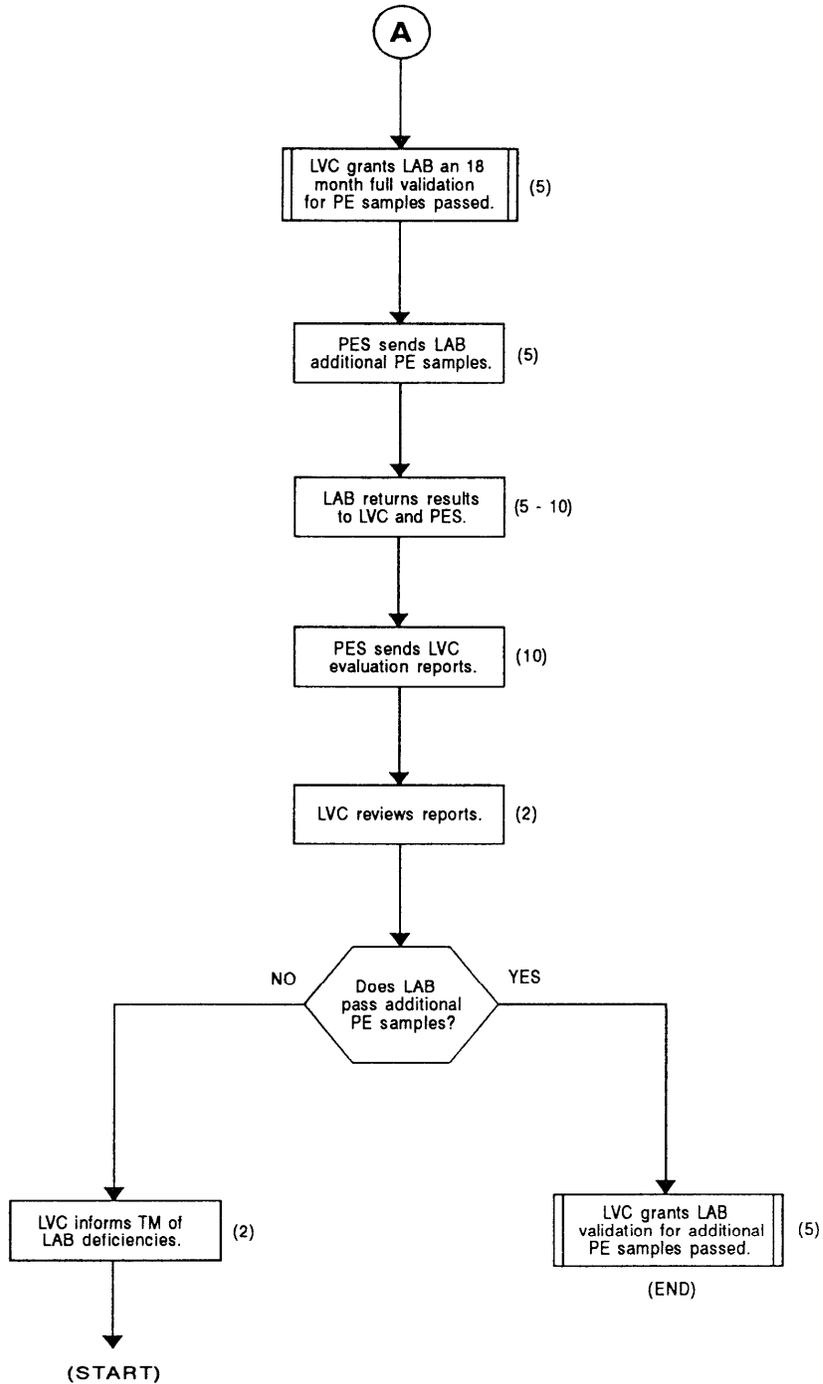


Figure C-2. Flow Diagram of Commercial Laboratory Validation Procedures (continued)