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# LABORATORY QUALITY ASSURANCE

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Sir: Quality control (QC) has been used for many years to provide degrees of assurance about the reliability of products. During the past decade, a broader concept called quality assurance (QA) has come into prominence, especially within the aerospace and nuclear industries. The importance of quality assurance to the nuclear industry is indicated by the paper of Randers, Morris and Pomeroy (1).

Quality assurance normally is associated with major manufacturing, fabrication, or construction projects and the involvement of the analytical chemistry laboratory is primarily through the measurements made for certifying and accepting materials used in those projects. Too often, however, the laboratory is thought of merely as a supplier of that service (usually called inspection and tests) without much further concern about how the laboratory should fit into the basic QA program. By applying the principles of QA to the operation of the laboratory itself, the laboratory becomes fully integrated into the QA program, giving a more effective program. This has been done within the analytical chemistry laboratory at the Hanford Engineering Development Laboratory (HEDL).

More important, quality assurance can be applied to the operation of an analytical chemistry laboratory whether or not that laboratory is involved in an outside QA program. Laboratory quality assurance can be an effective tool for indicating the competence of a laboratory and for helping to upgrade that competence if necessary. The purpose of this correspondence, therefore, is to acquaint analytical chemists with the concept of laboratory quality assurance, particularly as we use it at HEDL, which may encourage its use in other analytical chemistry laboratories. Hopefully quality assurance will become as familar to analytical chemists as quality

control, which is just one type of activity within the broader framework of QA.

## DEFINITION OF QUALITY ASSURANCE

A generally accepted definition of quality assurance is as follows: "The planned and systematic actions necessary to provide adequate confidence that a material, component, system, or facility will perform satisfactorily in service." The key phrases in this definition are planned and systematic actions, to provide adequate confidence, and will perform satisfactorily. The phrase "planned and systematic actions" embodies the essence of QA.

The above definition can be changed somewhat to apply to the laboratory as follows: "The planned and systematic actions necessary to provide adequate confidence in each analytical result reported by a laboratory".

## LABORATORY QUALITY ASSURANCE

Analytical chemists, for the most part, have thought of their involvement in quality assurance as being suppliers of measurements used by others in the certification and acceptance of materials. Actually, analytical chemists use many quality assurance practices regularly. Most of the elements of quality assurance are used in well-run laboratories, even though these elements may not be recognized or formalized in terms of a quality assurance program plan.

A major problem in proposing that analytical chemists apply the concept of quality assurance to laboratory operations is that the concept has little meaning when presented in terms used by quality assurance engineers who apply QA to design, development, procurement, fabrication, manufacturing, construction, operation, and testing project (2). What must be done is to identify the elements

of QA and then put them into terms used by analytical chemists. Such an interpretation was done when laboratory quality assurance was first established at HEDL in 1971 (3).

The elements of laboratory quality assurance that are used in the analytical laboratory at HEDL, based upon a recent QA laboratory manual (4), are discussed briefly in the following paragraphs.

Qualification of Analysts. A system is used for qualifying analysts that is based upon demonstrating proficiency in performance and that specifies requirements for education, training and experience. The system also includes a designation of responsibilities for training and for certifying qualification. Qualification of each analyst is documented via an analyst's qualification form, which must be updated whenever a change in qualification status occurs. A yearly review of all qualifications is mandatory.

Written Methods. Written methods document the procedures used to make analyses, provide guides for the analysts, provide information for training analysts, and describe the technological bases of the methods. The format used includes sections on application, technology involved, bibliography, apparatus, reagents, standards, safety, quality control, analytical procedure, and calculations. Each method is reviewed and approved by laboratory management and provisions are established for revising and updating the methods periodically or as needed. A controlled copy of each method is kept in the laboratory in which it is used.

Sample Receiving and Storage. Whereas analytical results are the product of an analytical laboratory, samples are the incoming or feed material from which the product is obtained. This analogy to a process

or manufacturing operation points to the importance of including samples in the laboratory quality assurance scheme. Requirements are established at HEDL for receiving and storing samples. That includes identification, labeling, and inspection upon receipt. Reagents and chemical standards are included also in the identification and storage requirements.

Quality Control. As used in laboratory quality assurance at HEDL, quality control involves calibration and control--control in the classical sense of control charts. Calibration includes the standardization of reagents as well as the calibration of instruments and other equipment. In the quality control section of the methods, procedures are given for calibration and control, the chemical standards to use, and the treatment of data. Where possible, those standards are traceable to NBS or to other nationally recognized chemical standards. In the section on standards (written methods), instructions for preparing the chemical standards are often included to ensure uniform preparation with time.

Audit. Audits are used to determine if all requirements are being followed and to detect incorrect practices. Such information will help to find deficiencies before they can become serious. Auditing consists of examining records, inspecting equipment and materials, and observing laboratory operations. Auditing also involves establishing corrective actions for deficiencies found. We have found it beneficial for the laboratory to have its own internal auditing system even if it is subject to outside audits. The laboratory auditor, who has no direct responsibility for the laboratory work, has detailed knowledge of laboratory operations; most outside auditors lack such knowledge.

Documentation. Documentation has three objectives, which are to provide traceability of reported results back to raw laboratory data,

to provide control of samples as they are processed through the laboratory, and to provide records that verify actions taken in the operation of the laboratory. The primary tools used in documentation are forms, some of which are used to carry out functions that provide traceability of results and control of samples. Some typical forms and their functions as used at HEDL are as follows: Analysis Request--to initiate work in the laboratory and to provide sample information to the laboratory; Log Book--to provide a source of consecutive serial numbers for laboratory identification and to serve as a record of sample information; Traveler Card--to transmit sample information to the analysts, to initiate analyses, and to transmit results from the analysts to the analytical report; Data Record--to provide a record of all data generated during the analyses, to document unusual or unexpected occurrences that happen during analyses, and to document who did the analyses and when; Analytical Report--to report analytical results to the sample submitters. Included as a part of documentation are requirements for the retention of laboratory records.

## LABORATORY QUALITY ASSURANCE PROGRAM PLAN

Quality assurance is established in the laboratory through a quality assurance program plan that specifies how the elements of quality assurance are to be implemented. At HEDL the program plan is presented in the form of a laboratory quality assurance manual (4), which is a satisfactory way to present such a plan. The laboratory QA manual includes general requirements relating to calibration and control of equipment and materials, tolerance requirements for calibration equipment and measurements, statistical practices, and definitions of terms used that might not be familiar to all users of the manual.

In designing the quality assurance program plan for the HEDL laboratory, the approach used was to develop a general QA program to cover the overall operation of the laboratory. A provision, called a quality assurance work plan, was included to permit quality assurance practices to be tailored for each customer's program. Preparation of a work plan for a specific program involving analytical chemistry support is a joint effort between analytical chemistry, the customer, and the company QA organization (if appropriate). Preparation involves selecting appropriate QA practices for the specific application. The use of the QA work plan is important to avoid unneeded QA efforts since not all programs require the same degree of assurance.

## BENEFITS

An immediate benefit in designing a laboratory quality assurance program is the identification of weaknesses in laboratory practices arising from inadequate planning and the discovery of deficiencies in methods used. With the implementation of the program, weaknesses and deficiencies will be eliminated. An established laboratory quality assurance program helps the laboratory to make a favorable impression on present and potential customers. Obviously, laboratory quality assurance cannot guarantee that poor results will not be reported, but it will provide confidence that such results will be infrequent.

Experience at HEDL has confirmed the above statements. For example, the analytical laboratory has benefited in the following way: Methods to improve laboratory practices were adopted; an already adequate record system was improved even further; subsequent to implementing laboratory quality assurance, outside auditors have found few defi-

ciencies in laboratory operations. In addition, the program has given management and customers added confidence in the output of the analytical laboratory.

Laboratory quality assurance has not been a burden to the HEDL analytical laboratory; rather, it has been a useful tool in the application of analytical chemistry for the support of various HEDL programs.

## LITERATURE CITED

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(4) W. L. Delvin, "Quality Assurance Manual for Analytical Chemistry Laboratory", HEDL MT-2, November (1975).