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LABORATORY QUALITY ASSURANCE AND ITS ROLE IN THE SAFEGUARDS ANALYTICAL LABORATORY EVALUATION (SALE) PROGRAM

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ABSTRACT

Since the late 1960's, strong emphasis has been given to quality assurance in the nuclear industry, particularly to that part involved in nuclear reactors. This emphasis has had impact on the analytical chemistry laboratory because of the importance of analytical measurements in the certification and acceptance of materials used in the fabrication and construction of reactor components. Laboratory quality assurance, in which the principles of quality assurance are applied to laboratory operations, has a significant role to play in processing, fabrication, and construction programs of the nuclear industry. That role impacts not only process control and material certification, but also safeguards and nuclear materials accountability. The implementation of laboratory quality assurance is done through a program plan that specifies how the principles of quality assurance are to be applied. Laboratory quality assurance identifies weaknesses and deficiencies in laboratory operations and provides confidence in the reliability of laboratory results. Such confidence in laboratory measurements is essential to the proper evaluation of laboratories participating in the Safeguards Analytical Laboratory Evaluation (SALE) Program.

INTRODUCTION

Quality assurance (QA) is an important concept to the nuclear industry. It was introduced through the US Breeder Reactor Program and light water reactors in the late 1960's and early 1970's. With experience in its use, understanding of its function, and its demonstrated worth, quality assurance has become widely accepted and acknowledged as a valuable tool in providing safe, trouble-free equipment and facilities and in reducing costs. This is evidenced by the papers, such as the one by Randers, Morris, and Pomeroy, presented in a seminar on nuclear fuel quality assurance held in 1976 at Oslo, Norway.[1,2] Quality assurance is an integral part of nuclear technology and nationally established quality assurance standards are in use by the industry, such as ANSI/ASME NQA-1.[3,4]

The role of the analytical chemistry laboratory in quality assurance is significant because the measurements provided by the laboratory are vital in assessing the quality of materials. Yet, too often the laboratory is associated with the quality assurance function merely as the supplier of a service that is usually called inspection and test. Instead, for the overall QA program to be fully effective, the principles of quality assurance must be applied to the operation of the laboratory itself. An example of such application was in a fuel program for fast reactor fuel in which laboratory quality assurance played an important role.[5]

The purpose of this paper is to show how quality assurance can play a meaningful role in providing reliable data for the SALE Program from a wide variety of laboratories using several different measurement methods and materials.[6] Those measurements, which are for uranium and plutonium content and isotopic abundance, provide a basis for the continuous and comprehensive performance evaluation of laboratories participating in the SALE Program.[7] Proper evaluation of participant data may be hindered when adequate laboratory quality assurance practices are not used.

DEFINITIONS 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."

ROLE OF LABORATORY QUALITY ASSURANCE

The basic function of the analytical chemistry laboratory is to provide measurements that describe and characterize materials in terms of chemical composition and physical structure. Its role, therefore, is a supportive one in development, testing, fabrication, processing, and construction operations.

The role of laboratory quality assurance is established in a broad sense by the definition given previously. More specifically, it provides the mechanisms for having sound operating procedures established in the laboratory, for promoting the correct use of analytical methods by laboratory personnel, and for monitoring and controlling laboratory performance. These activities help to ensure confidence in the measurements made by the laboratory, which in turn adds to the confidence in the quality of the materials analyzed by the laboratory. Thus, laboratory quality assurance gives a degree of back up assurance within the overall quality assurance activities associated with any program requiring laboratory support.

The role of laboratory quality assurance referred to previously relates to process control and material certification, which are common associations of quality assurance with an operation. Another aspect that is peculiar to nuclear fuels and most important to international nuclear non-proliferation policies, however, is safeguards and nuclear materials accountability. Quite often analytical chemistry measurements made for process control, or more likely for material certification, are used for purposes of safeguards and nuclear materials accountability. Thus, laboratory quality assurance also has a significant role in the control and accountability of nuclear materials, which is as important to nuclear fuel cycle operations and nuclear safeguards programs as is the quality of the fuel itself.

Participation in the SALE Program does not in itself qualify as a quality assurance program. Participation does provide, however, a management tool to assess the quality and status of a laboratory's measurement capability and this activity constitutes elements of quality assurance, which are Test Control and Inspection, Test, and Operating Status (Basic Requirements 11 and 14 in ANSI/ASME NQA-1).[3]

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. It is becoming increasingly important, however, for

laboratories to certify their performance by formalizing, documenting, and implementing a quality assurance program. This is especially true in the area of nuclear materials safeguards measurements.

Various laboratory operations, as they may be used in analytical laboratories, are discussed briefly below. These operations constitute elements of quality assurance and they are related to and can be identified as combinations of the 18 basic QA requirements found in ANSI/ASME NQA-1.[3] That standard has become the basic QA standard for the nuclear industry and basing a laboratory QA program on that standard enhances the program's credibility. Those basic requirements of NQA-1 applicable to the laboratory operations discussed are listed at the end of each paragraph.

Qualification of Analysts

A system is used for qualifying analysts, which includes training and proficiency in performance and which specifies qualification requirements in terms of 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.

NQA-1: 2. Quality Assurance Program, Personnel Qualification.

Written Methods

Written methods document the procedures used to make analyses, provide guides for the analysts, provide information for training analysts, and establish 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.

NQA-1: 5. Instructions, Procedures, Drawings and 6. Document Control.

Sample Receiving and Storage

Whereas analytical results are the product of an analytical laboratory, samples are the incoming or feeding 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 for receiving and storing samples, which include identification, labeling, and inspection upon receipt. Reagents and chemical standards are included also in the identification and storage requirements.

NQA-1: 10. Inspection and 13. Handling, Storage, and Shipping.

Quality Control

As used in this paper, 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. These procedures prescribe frequency of 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.

NQA-1: 11. Test Control, 12. Control of Measuring and Test Equipment, and 14. Inspection, Test, and Operating Status.

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. It has been found 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; many outside auditors lack such knowledge.

NQA-1: 16. Corrective Actions and 18. Audits.

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 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.

NQA-1: 6. Document Control, 8. Identification and Control of Items, and 17. Quality Assurance Records.

QUALITY ASSURANCE PROGRAM

Quality assurance is established in the laboratory through a quality assurance program that specifies how the elements of quality assurance are to be implemented. This program can be presented in the form of a laboratory quality assurance manual. This is an excellent way to present such a program. In addition, the written analytical methods can be assembled into method manuals, which become supporting documents for the QA manual.

The quality assurance program covers the overall operation of the laboratory. A provision, called a quality assurance plan, should be included to permit quality assurance practices to be tailored for each customer's program. Preparation of a 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 plan is important to avoid unneeded QA effort since not all programs require the same degree of assurance.

The laboratory QA manual can include 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. If there is a company-wide QA manual, the laboratory QA manual should contain references to appropriate requirements in the company manual.

BENEFITS

An immediate benefit in designing a laboratory quality assurance program is the identification of weaknesses that relate to sound laboratory practices and the discovery of deficiencies in methods used. With the implementation of the program, weaknesses found will be strengthened 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 few in number.

Experience has confirmed the above statements. For example, at both the Hanford Engineering Development Laboratory and the New Brunswick Laboratory, the analytical laboratories have benefited in the following ways: deficient laboratory practices were found and eliminated; already adequate record systems were improved even further; outside auditors have found only a few deficiencies in laboratory operations. In addition, the laboratory quality assurance program has given management added confidence in the output of the analytical laboratories.

Adequate laboratory quality assurance will not be a burden to analytical laboratories; rather it will be a useful tool in the application of analytical chemistry for supporting nuclear programs. The resulting high quality measurements from those laboratories participating in SALE will add credibility and reliability to the evaluation of data from the SALE Program.

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