

QUALITY ASSURANCE/QUALITY CONTROL FROM AN ACADEMIC PERSPECTIVE

T. O. TIERNAN

Department of Chemistry and Toxic Contaminant Research Program
Wright State University, Dayton, Ohio 45435, U.S.A.

ABSTRACT

This paper describes the changing requirements for Quality Assurance/Quality Control in academic research laboratories involved in environmental analyses which have been dictated by recently-enacted environmental legislation in the U.S.

INTRODUCTION

Analytical chemistry has been widely applied for characterizing environmentally-related samples by academic, industrial, and government laboratories for some years. Traditionally, academic research laboratories have been primarily concerned with the development and demonstration of analytical methods which are useful for such purposes, and in some cases, for the implementation of these methods for exploratory environmental studies. The latter have included such objectives as characterizing chemical residues in the environment and determining the transport, fate, and adverse effects of these chemicals from the standpoint of achieving an overall understanding of the environment. More recently, however, such measurements and assessments conducted by academic laboratories in the U.S. have sometimes been used as indicators of environmental pollution, and evidence of violations of environmental regulations established by the U.S. Environmental Protection Agency (EPA), and/or by various States and other regulatory agencies. In some instances, such data, obtained by academic laboratories in the U.S., have been used in legal proceedings instituted by the government against parties not in compliance with environmental regulations. In these instances, Quality Assurance and Quality Control (QA and QC), with respect to analytical data obtained and procedures employed, are important issues. Increasingly, therefore, academic laboratories involved in such work must be concerned about QA/QC and conformity with mandated QA/QC practices and standards which are established for environmental laboratories by government regulations. The present paper describes some of these requirements from the perspective of academic laboratories in the U.S. In addition, the role of such academic laboratories in environmental analytical studies under the present regulatory scheme is discussed.

EFFECTS OF U.S. ENVIRONMENTAL LEGISLATION ON ANALYTICAL LABORATORIES AND QA/QC PRACTICES

Various environmental laws enacted in the U.S. in the past few years, including the Clean Air Act, the Water Pollution Control Act, the Toxic Substances Control Act (TSCA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response Compensation and Liability Act (CERCLA, sometimes called the "Superfund" Act) have imposed upon industry and other generators requirements for analyses of large numbers of environmental samples (water, soils, sediments, biota, air) and have also dictated analyses of wastes, effluents, and various products for hazardous constituents which may pollute the environment. These requirements have, in turn, spawned a sizable number of commercial analytical laboratories to address the large number of samples which are needed to demonstrate environmental compliance and to assess pollution problems. In order to ensure that these laboratories generate analytical data of uniform consistency and quality, the U.S. EPA and other regulatory agencies have established numerous analytical methods or protocols which must be used for analysis of environmental and related samples which are conducted in connection with regulatory requirements. These methods generally include provisions for QA/QC procedures. The availability and use of such detailed analytical methods (including QA/QC measures) by laboratories analyzing these types of samples also helps to ensure that data obtained will be legally defensible and usable in court, if this is required.

The regulation of laboratories conducting environmental analyses by the U.S. EPA and other such agencies has not been limited to the imposition of analytical methods, but has been extended to cover the entire range of laboratory practices. Thus, "Good Laboratory Practices," to which such laboratories must conform, have been defined in some instances (1-3). These cover virtually everything from detailed procedures for safe receipt and handling to generation of the final data report, and require that elaborate written documentation of all laboratory activities be maintained. Laboratories not in compliance with these rules can be subjected to legal action and penalties.

QA/QC REQUIREMENTS FOR ACADEMIC ANALYTICAL LABORATORIES

From the foregoing discussion, it is apparent that increasingly, the analyst's discretion with respect to the implementation of analytical procedures and QA/QC associated with these is no longer acceptable in the case of analyses of environmental samples having regulatory implications. Rather, the analyst is constrained to follow a codified set of detailed requirements. It is clear, therefore, that academic laboratories conducting work of this type must also be fully cognizant of official methods and procedures and must adhere to the same laboratory practices and standards as those which bind their commercial laboratory counterparts. However, most academic laboratories are unlikely to become involved in high volume analyses of a routine nature (that is, which utilize standard protocols). Rather, the research-oriented nature of the academic investigator makes it probable that his laboratory will undertake developmental studies. In developing new analytical methods and procedures which may ultimately be adapted for routine use by commercial or contract laboratories, the academic scientist must nevertheless, incorporate appropriate QA/QC measures. Until such newly developed methods are collaboratively tested and adopted by appropriate regulatory agencies for use by their laboratories, academic laboratories may experience

difficulties in having use of these procedures officially sanctioned.

In addition to developing new analytical methodology, another possible role of the academic analytical laboratory is to serve as a referee laboratory for validating methodology, or independently corroborating analytical results obtained by other organizations. Here again, the QA/QC measures applied by the academic laboratory are important in such inter-laboratory comparisons.

Still another requirement of the QA/QC programs imposed on analytical laboratories by some governmental agencies is that for establishment of an independent QA/QC organization within the laboratory structure which has the authority to review, and reject or accept, analytical results, independent of the laboratory management. Because of their generally small size, academic laboratories may find this requirement difficult to implement.

In undertaking any environmental study having regulatory implications, an academic laboratory must prepare an overall QA/QC project plan which addresses the QA/QC measures associated with all phases of the investigation. In terms of analyses, such a plan will specify target objectives in terms of precision, accuracy, and other criteria which the data obtained must satisfy.

REFERENCES

1. *Toxic Substances Control Act (TSCA) Good Laboratory Practice Standards*, U.S. Federal Register, 54, 34034 (1989)
2. Garner, W.Y., and M.S. Barge, Eds. (1988), *Good Laboratory Practices, An Agrochemical Perspective*, ACS Symposium Series 369, American Chemical Society, Washington, D.C.
3. Dux, James P. (1989), *Handbook of Quality Assurance for the Analytical Chemistry Laboratory*, Van Nostrand Reinhold, New York

