QUALITY ASSURANCE ELEMENTS OF STANDARD OPERATING PROCEDURES FOR ENVIRONMENTAL MEASUREMENTS OF RADIOACTIVITY

Kathleen S. Moroney
U.S. Environmental Protection Agency
Environmental Monitoring Systems Lab
P.O. Box 93478
Las Vegas, NV 89193-3478

ABSTRACT

Federal agencies have ordered more detailed quality assurance documentation in procedures used for environmental measurements of radioactivity. Although regulatory guidelines and other studies discuss the topic, no centralized source of quality assurance elements was available for inclusion in standard operating procedures. A limited number of existing guidelines and studies with direct application to the topic were reviewed and contrasted, and recommended elements were compiled. The result is an easy-to-use "menu" format which summarizes elements that can be included in standard operating procedures for environmental measurements of radioactivity. The scope is broad enough to address all types of operations commonly performed in radioactivity measurements.

INTRODUCTION

Federal agencies have ordered more detailed quality assurance documentation in procedures used for environmental radioactivity measurements at radiological work sites throughout the United States. Quality assurance (QA) is a system for assuring the reliability of monitoring and measurement results. Although regulatory guidelines and previous studies discuss the topic, no centralized source of quality assurance elements for environmental radioactivity measurements was available.

A study was performed to develop a simple protocol for selecting appropriate quality assurance elements (practices, requirements, or components) for inclusion in standard operating procedures (SOPs) for measuring environmental radioactivity. A standard operating procedure is a written document which details and prescribes methods for performing defined routine or repetitive tasks.

After compiling a list of these elements, my next goal was to produce a guideline in "menu" format that could be easily used by any writer of technical procedures regardless of that individual's level of expertise in quality assurance. The scope of the resulting information is broad enough to include quality assurance elements for all types of measurements and operations commonly performed in radioactivity measurements; yet presents detailed recommendations in a compact, concise, and logical manner.

The existing quality assurance guidelines published by federal agencies with responsibility for radiation safety were compared and contrasted. The comparison was done using a limited number of sources with direct application to the topic; no attempt was made to perform a complete literature search of the entire field.

BACKGROUND

Work involving the use of radioactive materials in the United States is highly regulated by federal agencies, including the Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA), and the Department of Energy (DOE). These agencies mandate programs to monitor radioactivity at nuclear work sites in order to protect public health and the environment.

These programs can include the collection of air, soil, water, vegetation, sediment, and/or animal tissues, which are analyzed for radioactivity in specialized laboratories. Analytical results are compared with baseline studies (previous measurements of naturally-occurring ambient levels of radioactivity) to detect releases with potential adverse effects.

Positive analytical results are frequently used as the basis for calculating projected dose (the amount of exposure to radiation) to members of the public resulting from nuclear work performed at the monitored site. This derived population dose estimate is used to assess the risk of adverse health effects to populations and individuals exposed to environmental radioactivity.

The maximum allowable dose to a member of the general public is specified by federal law or agency directive. It follows that measurements of environmental radioactivity are subject to close scrutiny, and play a key role in assessing the effectiveness of radiation protection programs (formal integrated systems to protect people and the environment from exposure) at nuclear work sites.

The EPA has recently reduced the legal limits for maximum exposure to a member of the public. In consequence, environmental monitoring programs are attempting to quantify ever smaller amounts of radioactivity. The need for consistent application of quality assurance prin-

ciples to assure the reliability of monitoring and measurement results is vital.

METHODOLOGY

SOPs are commonly accepted in the nuclear industry and scientific community as an essential part of an effective QA program. They prescribe the way that tasks will be performed, and serve as formal documentation of the method used.

A study was performed to compare the QA guidelines (as they apply to SOPs for environmental radioactivity measurements) of several agencies with responsibility for oversight of nuclear work. The objective of the study was to effectively summarize QA criteria, highlight any differences between agencies, and recommend elements that could be selected from a "menu" format, according to their proposed application, for inclusion in generic SOPs.

The American National Standards Institute (ANSI) standard for nuclear work most frequently cited by the NRC requires that "activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances," but does not indicate or recommend specific QA elements for inclusion.(1)

Similarly, EPA's principal QA document for program plans requires that, "SOPs should be developed and used to implement routine quality requirements in all monitoring programs. . .and measurements. . .".(2) DOE's environmental protection program directive states, "the QA program shall include, but not be limited to. . .program design and procedures. . .".(3) Again, neither document recommends specific QA elements for inclusion in SOPs.

It is apparent that agencies acknowledge the unique requirements of each facility, and intended flexibility when controlling regulations were imposed. All three regulatory agencies do require SOPs for environmental measurements to assure quality results, and have accepted many organizational formats. Nevertheless, procedures must be comprehensive and contain sufficient QA elements to assure (and document) that work is performed to acceptable standards of quality.

One example of an outline format for an SOP for environmental measurements of radioactivity is shown in Table I. This format is used by the EPA's Nuclear Radiation Assessment Division in Las Vegas, and by several commercial radioanalytical laboratories throughout the United States. The format is especially useful for technical applications which will be subject to exceptional scrutiny during extensive program audits, where meticulous documentation is advisable.

The procedural paragraph headings in the figure are accompanied by associated elements that can be included in the SOP as subheadings. Important procedural checkpoints, calibrations, required actions, quality assurance measures, and safety precautions should be specifically noted and/or highlighted in the body of all SOPs. The SOP must be detailed enough to allow for completion of the defined task by an individual knowledgeable in the field using only the SOP as a reference. Applicable agency regulations and industry standards must be comprehensively referenced. All steps required to complete the task must be clearly stated, making sure that full compliance with referenced standards is prescribed.

RESULTS

The study identified two sources which address QA elements for SOPs. The EPA's Environmental Monitoring Systems Laboratory QA Program Plan lists selected procedural functions for which SOPs should be written, along with "possible associated elements," and "documentation requirements".(4)

In addition, T.L. Rucker's presentation at the annual meeting of the Health Physics Society in Albuquerque, New Mexico (June, 1989) discussed quality factors that could affect environmental monitoring for radioactivity.(5)

These two sources served as the primary basis for producing a "menu" formatted guideline for selecting QA elements for inclusion in SOPs for measuring environmental radioactivity, presented in Table II. To use the chart, first identify the procedural function requiring inclusion in the SOP, and then note which QA elements are associated with the specified application. The table is designed to provide convenient examples, and lead readers to further elaborate on their own.

As Rucker stated, "A quality environmental monitoring program depends upon quality analytical results; and quality analytical results depend on quality analytical procedures".(5) Effective calibration of instruments and measurement systems is a crucial element in producing quality analytical results. It is imperative to mandate full compliance to appropriate standards and criteria for instrument or measurement system calibrations in all SOPs which include their use.

Where monitoring or laboratory analytical support is to be supplied by a contractor, it is essential to document specific quality assurance elements (such as system calibrations or prescribed methods) that will be required for the given task prior to placing the contract out for bid. Selection should depend upon the contractor's qualifica-

TABLE I
STANDARD OPERATING PROCEDURE FORMAT

Procedural Paragraph Heading	Associated Elements
1.0 Purpose	Reason for SOP
2.0 Applicability	Discussion of when SOP will be used and its scope.
3.0 Definitions	Explanation of technical terms.
4.0 References	List of pertinent requirements, directives or standards.
5.0 Discussion	Summary of the method, analysis, procedure, or principle; including limitations/interferences.
6.0 Responsibility	Delegation of assignments or specific duties of all personnel assigned to task, including special training.
7.0 Equipment	Calibration requirements and procedures.
	List of materials, forms, scientific apparatus, tools, model numbers, chemicals and reagents.
	Specially noted required safety equipment/cautions.
8.0 Procedure	Step-by-step "walkthrough" of the task which clearly differentiates between required and recommended actions, and corresponding documentation.
	QA and quality control steps, system checks, critical points, notification requirements.
	HIGHLIGHTED SAFETY WARNINGS
0.9 Records and Reports	Description of what to record, format to use, who to copy, where to store, how long to keep, and who will have access to records/reports.

(Rucker, 1989 and Moroney, 1989)

tions and documented willingness to meet these quality assurance specifications.

In summary, the purpose of the study was to develop an easy-to-use protocol to select QA elements for inclusion in SOPs for environmental measurements of radioactivity. Two single-page tables are presented, which together propose paragraph headings and associated procedural or QA elements.

It is recommended that writers of SOPs thoroughly review the functions to be prescribed, and carefully select QA elements for inclusion.

REFERENCES

1. American Society of Mechanical Engineers. Quality Assurance Program for Nuclear Facilities. New York: The American Society of Mechanical Engineers, ANSI/ASME NQA-1 (1986).
2. Environmental Protection Agency, Office of Monitoring Systems and Quality Assurance. Guidelines and Specifications for Preparing Quality Assurance Program Plans. Washington, D.C., QAMS-004/80 (1980).
3. Department of Energy, Office of Environment, Safety, and Health. DOE Order 5400.1: General Environmental Protection Program. Washington, D.C.: U.S. Government Printing Office (1989).
4. Environmental Protection Agency, Environmental Monitoring Systems Laboratory. Quality Assurance Program Plan. Washington, D.C.: U.S. Government Printing Office, EPA/600/X-87/241 (1987).
5. T.L.RUCKER, Quality in Analytical Procedures for Radiological Environmental Monitoring. Paper presented at the Annual Meeting of the Health Physics Society, Albuquerque, NM (1989).
6. C.J.BONZON, Implementation of Environmental QA Practices at a Mixed Waste Site at the Idaho National Engineering Laboratory. Paper presented at the

TABLE II
PROCEDURAL FUNCTIONS WITH QUALITY ASSURANCE ELEMENTS

Procedural Function	Quality Assurance Elements
Purpose	Documentation, measurement, evaluation.
Applicability/Scope	Analysis, maintenance of physical system.
Definitions	Technical and QA terms.
References	QA standards, operator's manuals.
Discussion	Sensitivity, range, detection limits, safety precautions, bias, precision, accuracy, interferences.
Responsibility	Corrective actions, notifications, training, certifications, oversight functions.
Equipment	Calibration requirements and procedures.
	Laboratory notebooks, apparatus, model numbers, manuals, reference tables, maintenance specifications, QA controlled reagents.
Procedure	Blanks, controls, spikes, methods, checkpoints, signoffs, approvals, QA documentation, notifications, calibration methods, storage, collection, handling, marking, labeling, disposal, validation, reduction, formulae, corrective action, safety precautions, analysis, emergency response, caveats, calculations, preparation, schedules.
Records and Reports	Forms, notebooks, dates, approvals, storage, maintenance.

(EMSL-LV, 1987 and Moroney, 1989)

ASQC Energy Division's International Waste Management Conference in Las Vegas, NV (1989).

7. Environmental Protection Agency, Office of Monitoring Systems and Quality Assurance, Office of Research and Development. Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans. Washington, D.C., QAMS-005/80 (EPA-600/4-83-004) (1980).
8. J.E. KENNEDY, Quality Assurance on the Yucca Mountain Project: An NRC Perspective. Paper presented at the ASQC Energy Division's International Waste Management Conference, Las Vegas, NV (1989).
9. D.L. WOLFE, A Comparison of EPA and NRC Quality Assurance Requirements: Environmental vs. Nuclear Quality Assurance, Complimentary or Conflicting. Paper presented at the ASQC Fifteenth Annual Energy Division Conference (1988).