REGIONAL TECHNICAL COOPERATION MODEL PROJECT, IAEA- RER/2/004 " QUALITY CONTROL AND QUALITY ASSURANCE FOR NUCLEAR ANALYTICAL TECHNIQUES"

P. Arıkan

Turkish Atomic Energy Authority, Ankara Nuclear Research and Training Center, Ankara, TURKEY

INTRODUCTION

An analytical laboratory should produce high quality analytical data through the use of analytical measurements that is accurate, reliable and adequate for the intended purpose. This objective can be accomplished in a cost-effective manner under a planned and documented quality system of activities [1].

It is well-known that serious deficiencies can occur in laboratory operations when insufficient attention is given to the quality of the work [2]. It requires not only a thorough knowledge of the laboratory's purpose and operation, but also the dedication of the management and operating staff to standards of excellence. Laboratories employing nuclear and nuclear-related analytical techniques are sometimes confronted with performance problems which prevent them from becoming accepted and respected by clients, such as industry, government and regulatory bodies, and from being eligible for contracts.

The International Standard ISO 17025 has been produced as the result of extensive experience in the implementation of ISO/IEC Guide 25:1990 and EN 45001:1989, which replaces both of them now. It contains all of the requirements that testing and calibration laboratories must meet if they wish to demonstrate that they operate a quality system that is technically competent, and are able to generate technically valid results. The use of ISO 17025 should facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures [3].

IAEA model project RER/2/004 entitled "Quality Assurance/Quality Control in Nuclear Analytical Techniques" was initiated in 1999 as a Regional TC project in East European countries to assist Member State laboratories in the region to install a complete quality system according to the ISO/IEC 17025 standard. 12 laboratories from 11 countries plus the Agency's Laboratories in Seibersdorf have been selected as participants to undergo exercises and training with the assistance of 3 external and 5 agency staff auditors. This very demanding project required the submission of 6 monthly progress reports, two external audit inspections and participation in two proficiency tests rounds [4].

Nuclear Analytical Laboratories (NALs) (gamma, x-rays and alpha/beta) of Ankara Nuclear Research and Training Center were selected by IAEA to participate fully with appropriate staff and facilities in the model project.

The NALs made reasonable progress in the implementation of its Quality Assurance (QA) system during the two-year span of the RER project. Besides the increase in the number of QA related documents and SOPs, significant progress and benefits were noted in the following areas: Critical technical variables, control charts, performance checks, trackability, traceability, sample custody and coding, method validation, qualification of personnel and quality manual.

QUALITY SYSTEM OF NUCLEAR ANALYTICAL LABORATORIES

There is generally an accepted plan for a establishing laboratory quality assurance program that principles and methods are transferable from one situation to another with only minor modifications. The proper and complete identification of quality elements is an important consideration in establishing a quality assurance program [1]. Some of these elements are given in Table 1.

Table 1. Some Elements of a Quality Assurance Program

Management's policy statement
Control of samples and records
Method evaluation
Reports to management
Personnel practices
Sample custody
Statistical considerations
Audit inspection
Corrective actions
Laboratory design
Training

International Standard of ISO 17025 specifies the minimum expected technical and management requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods and laboratory-developed methods [3].

The responsibility for planning the quality system was divided among three groups: top management, the supervisory staff and operating personnel. Management of Center has decided to establish a program and support it financially and administratively. Existing laboratory operations and practices were evaluated with respect to quality assurance needs and the QA checks and procedures currently in place. From the very beginning the entire laboratories staff was involved in planning and developing the program, with consensus approval obtained at various steps from key affected personnel.

Establishment and improvement of the quality system for NALs was based on quality indicators of Agency according to ISO 17025. The layout and the quality indicators for analytical and organizational requirements were assessed separately. The program of QA/QC was perfectly applied and time of important points was kept. With this project we had to evaluate our progress every half year and we had to send it in the prescribed from to the Agency. An overview of Progress Reports (quality indicators) and audit reports is presented in Table 2. The steady progress in implementation was clearly reflected in the increasing marks the IAEA auditors gave to both the progress report and audit reports.

Table 2. Evaluation of Progress and Audit Reports

Progress Report No.	Score	Percentage	External Audit Inspection
0	30	27 %	
1	55	51%	48 %
2	68	63%	
3	86	80%	75%
4	100	93%	

TECHNICAL REQUIREMENTS

Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include

- Human factors
- Accommodation and environmental conditions
- Test and calibration methods
- Method validation
- Equipment
- Measurement trace ability
- Sampling
- Handling of test and calibration items [3]

The following techniques were selected for participation in the project

- γ Spectrometry
- X-ray fluorescence spectrometry
- Alpha and beta counting

Twelve NAL staff members were fully committed to the project. Most routine analytical methods were based on established standard methods. All routine methods were thoroughly validated and authorized before use in laboratory. Methods and projects were reviewed annually. Quality control samples were analyzed with each batch of samples to ensure the validity of the analytical results. The results were used to identify problems within a sample run. If a problem was identified, corrective actions were taken. Control standards and samples, blanks, standard reference materials were employed as quality control protocols.

All instruments were verified before sample analysis. The instrument response must be within specified limits (performance check of equipment). To ensure rapid turn-around at all times, instruments were properly maintained. Significant progress and benefits were noted in the following areas: preparation and utilization of control charts (for critical variables and environmental factors), improved knowledge of method validation, trackability, uncertainty budget and traceability. Data on background, FWHM, repeatability, reproducibility and efficiency are collected in a routine way.

In one frame of this project, to evaluate the participants' performance in the determination of selected radionuclides of environmental importance and to validate the accuracy and precision of the measurements, two proficiency tests were performed. Radionuclides in a spiked soil sample and in a standard solution were determined. IAEA uses the statistical u-test for the evaluation of all participants' results. Table 3 shows one example of IAEA treatment for our laboratory's results. [4] The analysis results are presented in Table 4. [5,6]

Table 3. Results of Evaluation Criteria of IAEA (4)

Radionuclide	Accuracy			Precision		Final Status
	Difference Value	Uncertainty	Status	%	Status	
^{57}Co	0.92	4.06	passed	3.3	passed	passed
^{60}Co	3.98	9.08	passed	3.0	passed	passed
^{65}Zn	3.45	10.0	passed	11.5	passed	passed
^{134}Cs	1.23	8.79	passed	3.6	passed	passed
^{137}Cs	2.35	8.15	passed	2.9	passed	passed
^{241}Am	10.2	25.1	passed	8.2	passed	passed

Table 4. Results of The Proficiency Tests

Working group	Sample type	Radionuclide	No. of passed results/total result
Gamma lab.	Soil	^{57}Co, ^{60}Co, ^{65}Zn, ^{134}Cs, ^{137}Cs, ^{241}Am	6/6
Gamma lab.	Solution	^{57}Co, ^{60}Co, ^{65}Zn, ^{134}Cs, ^{137}Cs, ^{241}Am	4/6
Alpha/beta lab.	Soil	^{90}Sr	3/4

CONCLUSION

Demonstrable and measurable improvements were made in the organizational and analytical performance of Nuclear Analytical Laboratories (NALs) at Ankara Nuclear Research and Training Center in accordance with internationally harmonized requirements, as specified in the ISO 17025 standard. The proper objectives of the quality assurance program were clearly stated and understood by both management and project staff while the quality program was functioned efficiently. Supervisory staff of NALs provided the technical expertise, technical advice and guidance and performed writing and reviewing of assigned parts of the Quality Assurance Program.

Performance indicators show increased scoring from 48% to 75% according to the audit inspections for NALs of Ankara. In addition, the scoring for the biannual progress reports increased from 27% to 93% in two years period for γ, α/β and X-rays labs of Ankara. From the point of view of all participants in RER/2/004 the project was very successful. About 80% of the participants managed to establish a functional quality system to a level which would enable them to approach their national accreditation body for accreditation as well.

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