9.9 Slovenia

EXPERIENCES WITH IAEA PROJECT: TC Regional Project on Quality Control and Quality Assurance for Nuclear Analytical Techniques RER/2/004

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Abstract

In the *TC Regional Project on Quality Control and Quality Assurance for Nuclear Analytical Techniques RER/2/004*, 12 laboratories from east and central European countries participated. Within this project 4 workshops, 2 audit inspections and 2 proficiency tests were organized. The aim of this project was to help these laboratories to implement quality assurance system based on the ISO 17025 standard [1] and to help them on the way towards accreditation.

1. INTRODUCTION

The Gamma-Ray Spectrometry Group, which works within the Laboratory for Radiological Measurement Systems and Radioactivity Measurements at Jožef Stefan Institute performs among other activities also routine measurements of activities of radionuclides in environmental cylindrical homogenous samples. Before joining this project, the Gamma-Ray Spectrometry Group had been building the quality system based on the EN 45001 standard [2] with the bottom up approach. At that time the quality system on the management level was not in place yet. The members of the group participated in courses on quality assurance organized in Slovenia. The process of establishing the quality system was quite slow and no time constraints from outside were imposed, nor did we state them ourselves.

2. ACHIEVEMENTS DURING THE PROJECT

2.1. Overview of Progress Reports

Within this project we had to evaluate our progress every half year and we had to send it in the prescribed form to the Agency. The layout and the quality indicators were assessed separately. The overview of Progress Reports (Quality Indicators) is presented in Table 1. For the layout we achieved the highest score in all reports.

TABLE I. EVALUATION OF PROGRESS REPORTS (Quality Indicators)

Progress Report No.	Score	Percentage
0	66 / 108	61 %
1	78 / 108	72 %
2	104 / 108	96 %
3	106 / 108	98 %
4	108 / 108	100 %

2.2. Overview of Audit Reports

Within this project two audits inspection took place, the first one approximately one year after the beginning of the project, the second one at the end. Skilled auditors carried out the audits; all the aspects of the quality system according to the ISO 17025 standard were checked. Results of both audits are presented in Tables II, III and IV.

2.2.1. First Audit Inspection – April 2000

TABLE II. EVALUATION OF 1st AUDIT

Management requirements	**Score / Max**	**Technical requirements**	**Score / Max**
Organization and management	34 / 40	General	*0 / 0*
Quality System	11 / 20	Personnel	9 / 20
Document Control	**50 / 50**	Accommodation and environment	22 /25
Review of requests and contracts	19 / 20	Test methods and validation	6 / 75
Subcontracting	*0 / 0*	Equipment	45 / 55
Purchasing	14 / 20	**Measurement traceability**	**25 / 25**
Service to the client	4 /5	**Sampling**	**20 / 20**
Complaints	**5 / 5**	Test items	18 / 20
Control of non-conforming work	9 /10	Quality Control	10 / 40
Corrective action (CA)	16 / 20	Reporting	33 / 40
Preventive action	6 / 10		
Control of records	44 / 50		
Internal audits	23 /30		
Management review	0 /10		
Total	**9.85 / 290**		**243 / 6.2**

2.2.2. Second Audit Inspection – August 2001

TABLE III. EVALUATION OF 2nd AUDIT

Management requirements	**Score / Max**	**Technical requirements**	**Score / Max**
Organization and management	37 / 40	General	*0 / 0*
Quality System	17 / 20	Personnel	18 / 20
Document Control	**50 / 50**	**Accommodation and environment**	**25 / 25**
Review of requests and contracts	**20 / 20**	**Test methods and validation**	**75 / 75**
Subcontracting	*0 / 0*	Equipment	53 / 55
Purchasing	10 / 15	**Measurement traceability**	**25 / 25**

Service to the client	**5 / 5**	**Sampling**	**20 / 20**
Complaints	**5 / 5**	**Test items**	**20 / 20**
Control of non-conforming work	**10 /10**	Quality Control	25 / 40
Corrective action (CA)	**20 / 20**	Reporting	39 / 40
Preventive action	**10 / 10**		
Control of records	**50 / 50**		
Internal audits	27 /30		
Management review	9 /10		
Total	**12.24 / 285**		**8.46 / 320**

In both tables not-applicable requirements are indicated by *italics*, the requirements that fulfill the standard requirements are indicated by **bold**.

2.2.3. Evaluation of Audit Inspections

TABLE IV. COMPARISON OF FINAL RESULTS OF BOTH AUDITS

		1st Audit	**2nd Audit**
	Score / Max	478 / 610	570 / 605
	Percentage	78 %	94 %
Management Requirements	Score / Max	235 / 290	270 / 285
	Percentage	81 %	95 %
Technical Requirements	Score / Max	243 / 320	300 / 320
	Percentage	76 %	94 %

2.3. Proficiency Tests

2.3.1. Achievements by the laboratory

In frame of this project two proficiency tests were performed.

The fist proficiency test was performed in April 2000; the report was finished in September 2000. Radionuclides in spiked soil sample and in standard solution were determined; 6 radionuclides were determined in each sample. Comparing our results with the agency's, our results were biased from –2.9% to –7.88%. Regarding u-test 6 results out of 12 differ for more than 1.95 from the expected value. Two results out of 12 were rejected according to the accuracy and precision criteria. One of them failed accuracy criteria and one of them precision criteria. The last case was due to a typing error. At the same time the laboratory participated at a proficiency test organized by EML, USA, where 4 different samples were analyzed. Those results did not have any bias, therefore no corrective action was undertaken with the aim of improving the agreement.

The second proficiency test was performed in June 2001, the results were finalized in September 2001. Gamma ray emitters in spiked matrix and standard solution were determined. The relative bias of 9 radionuclides reported was from +4.56 to –4.35, the highest reported u-test score was 1.55, therefore all of them meet criterion $u<1.64$ (the reported result does not differ significantly from the expected value) and all results passed accuracy and precision criteria.

2.3.2. Achievements within the Project

The overview of the results of all participating laboratories for the second proficiency test were worse than the results for the first proficiency test. This can be attributed in part to the more demanding spectrum analysis, but it can nevertheless be concluded that the results of the second test would not be significantly better in case of an equivalent analysis. This may reflect the well-known fact that the results of accredited laboratories in proficiency tests are not significantly better from non-accredited laboratories. The introduction of a quality system itself usually does not improve the results in proficiency tests. Namely, establishing and maintaining the quality system requires development of a working culture, which is linked to the way of thinking, the way of performing work, the attitude towards the result of the work, the relation towards changes in the working process etc., but not directly to the technical performance.

3. EVALUATION

From the point of view of the participating laboratory, the assessment of Progress Reports versus Audit Reports shows that the amount of information on how to improve the quality system and working process is much larger in the audit reports. The Progress Reports shows how much the documentation has been settled, but it is the audit inspection which checks if it has been implemented in practice and to what extent. The audit visits in the laboratories are of very high value, the assessors can seek out weak point in the laboratory's QA system and in work performed on the spot and can immediately give suggestions on how to improve the quality of work.

We believe that for the duration of the project of three years two visits are sufficient, but more assessor visits are required in case of an extended duration on the project.

The end of the project does not mark the moment when the laboratory has completed its QA/QC system. This only happens when the accreditation has been granted, therefore the Agency can learn much from staying in touch with the laboratory. We recommend to the Agency not to severe the links with the laboratory after the project finishes. Agency should remain in contact with the laboratories at least until the accreditation has been gained. Possible information, which can be obtained from these links, is:

(1) How the interaction between the laboratory and accreditation body takes place; this interaction may not be analogous to the interaction with the Agency's assessment team.
(2) What happens with the laboratory after finishing the project. Does the laboratory continue the development of the QA system? If not, is the reason an internal or an external one, etc?

All these information could be collected by a **fact finding mission** of one person, one day after e.g. 1.5 years after finishing the project. The other possibility is that the Agency carries out one more audit inspection.

3.1. Achievements of the laboratory

From the financial point of view:

(1) up to now no new contracts,
(2) up to now no extra funding,
(3) this may change with accreditation: accredited laboratories may have greater possibility not to lose old customers and to compete with other laboratories on the market.

From the material point of view:

(1) **new equipment**: station for monitoring the environmental parameters was bought,

(2) **additional people** joined the Gamma-ray spectrometry group for new duties connected with the capture 5.9 *"Assuring the quality of measurements results"* of the ISO 17025 standard for:
   - building-up a data base of results for detecting trends, correlations, testing hypotheses etc. Practical use can be seen in connection with models in the field of radioecology,
   - research in statistical analysis of time series (flow charts) - Westgard rules and their generalizations. Practical use can be new publishable knowledge,
   - performing measurements of blind samples, replicate tests, retesting, etc. These measurements give the possibility for improving the analysis procedure.

From the subjective point of view (influence on personnel):

(1) new knowledge was gained,
(2) awareness and felling of necessity for:
   - critical attitude towards own results,
   - perception to meet the needs of costumers,

(3) awareness that by establishing the QA system laboratory gains the ability for improvement by conducting QA activities (e.g. by preventing nonconforming work) was gained,
(4) spin-off of the above to other laboratories in the country.

The greatest achievement of the laboratory has been that we have applied for the accreditation at the Slovenian Accreditation body on 28th of August 2001.

3.2. Publications

From the time the laboratory has started participating in this project, the knowledge acquired in the field of assuring the quality of work in the laboratory has been published in the following scientific articles:

1. M. Korun, Propagation of uncertainties in sample properties to the uncertainty of the counting efficiency in gamma-ray spectrometry, Appl. Radiat. Isot. 55 (2001) 685-691.
2. D. Glavič3. -Cindro, M. Korun, B. Vodenik, Quality assurance of automated gamma-ray spectrometric analysis, Appl. Radiat. Isot. 53 (2000) 237-241.
4. D. Glavič5. -Cindro, B. Vodenik, M. Korun, R. Martinč6. ič7. , Quality control of gamma-ray spectrometry measurements, Appl. Radiat. Isot. 52 (2000) 765-770.
8. D. Glavič9. -Cindro, M. Korun, M. Korun, Analysis of non-conforming work as a tool for status analysis and continuous improvement, submitted for publication in Accred. Qual. Assur.
10. D. Glavič11. -Cindro, M. Korun, Verifiability of gamma ray spectrometric results, IRPA Regional Congress on Radiation Protection in Central Europe – Radiation Protection and Health, Dubrovnik, 20-25 May 2001, in press.
12. D. Glavič13. -Cindro, M. Korun, R. Martinč14. ič15. , B. Vodenik, Quality Assurance of automated high-resolution gamma-ray spectrometry analysis, in Proceedings of the IRPA Regional Congress on Radiation Protection in Central Europe, Budapest 23-27 August 1999.

During this time our work has been presented orally or as posters at these scientific conferences:

1. D. Glavič2. -Cindro, M. Korun Quality control of gamma-ray spectroscopy measurements, *12th International Conference on Radionuclide metrology ICRM'99*, Prague, 1-11 June, 1999, Book of abstracts, p.12, poster presentation.
3. D. Glavič4. -Cindro, M. Korun Quality assurance in gamma-ray spectroscopy measurements, Book of abstracts, p.16, *IRPA Regional Congress on Radiation Protection in Central Europe*, Budapest 23-27 August, 1999, poster presentation.

5. D. Glavič6. -Cindro, M. Korun Quality assurance in gamma-ray spectrometry, *Conference on Low Level Radioactivity Measurements*, Mol, Belgium, 18-22 October, 1999, Book of abstracts, p.88, oral and poster presentation.
7. D. Glavič8. -Cindro, M. Korun, M. Korun, Pareto analysis of non-conforming work in a gamma-ray spectroscopy laboratory, *12th International symposium "Spectroscopy in Theory and Practice"*, Bled, 9-12 April, 2001, Book of abstracts, p.32, oral presentation.
9. D. Glavič10. -Cindro, M. Korun, Verifiability of gamma ray spectrometric results, *IRPA Regional Congress on Radiation Protection in Central Europe – Radiation Protection and Health*, Dubrovnik, 20-25 May, 2001, Book of abstracts, p.211, poster presentation.

3.3. Working in a scientific environment

Working in a scientific environment brings along some advantages and some disadvantages for our laboratory. Jožef Stefan Institute is a state-owned research institute with strong links with the University. In such an academic environment routine work is not especially highly valued, yet it is this routine work which is the subject of accreditation. Our workers are employees of the state with fixed salaries. Substantial increases in salary can only be achieved through promotion. The quantitative criteria for promotion are connected with articles, patents and students. Accreditation and quality are not even mentioned. When the Gamma-Ray Spectrometry Group started to build its quality system it was recognized that research connected with quality can be done and that the results of the research can be published. This recognition made the work on the quality system compatible with the scientific environment and motivated the research staff.

From the above stated facts another recommendation to the Agency follows: in the audits during meetings with the management the assessors should ask them about the role of quality and accreditation in the promotion of workers. According to the answer they should stress the necessity for motivation and recognition of good quality routine work.

The assessors should bear in mind that especially in the transition economies the academic community is under pressure to produce knowledge, which can be directly used to serve the industry. The research in quality, when it is connected with specific routine measurements, fulfills this condition. The message should be, that routine measurements of good quality (quality means among others continuous improvement) are compatible with an academic environment. This recognition is not wide spread and it should be stressed at the meeting of assessors with the management of the institutes.

4. CONCLUSIONS AND PERSPECTIVES

With the help of this project the QA/QC system in the Laboratory for Radiological Measurement Systems and Radioactivity Measurements at Jožef Stefan Institute has finally been established, during this time we have completed the Quality Manual and the awareness of importance of the quality system in the laboratory has increased.

The project had strict dead lines and by completing our duties within those time limits the quality system in the laboratory has been established much more quickly as it would otherwise have been. During audits the management was faced with the QA system and auditing in practice. The Institute management gained higher commitment to the QA system in the laboratory and probably also recognized the necessity for implementing a QA system on the Institute's level according to the ISO 9001 standard.

It was felt during the workshop that the commitment of the management to quality and accreditation may be in some cases only verbal. Even if this feeling is not justified the commitment may be of undue origin, as for example:

- QA/QC is fashionable: everybody wants it, so I want to have it as well, especially since QA/QC supports work according to written procedures, which will relieve me of some control duties.

We therefore recommend to the Agency to organize courses or workshops for management, where skills such as how to promote the laboratory, sell the services to the outside world, how to compete on the open market etc can be addressed. However, the Agency should bear in mind that the managers may resist to participate in such courses, since they have their own ideas and priorities. In process of persuading the management the statement of management commitment should be used.

In our mind, the greatest achievement of the laboratory was the establishment of a self sustained system for managing non-conforming work, which can lead to a self-sustained system of continuous improvement of the work in the laboratory in the future.

5. REFERENCES

[1] ISO/IEC 17025:2000, General Requirements for the competence of testing and calibration laboratories, ISO, Geneva.

[2] EN 45001:1989, General criteria for the operating of testing laboratories, CEN/CENELEC, Brussels.

9.10 Slovakia

EXPERIENCES OF RADIOCHEMICAL LAB OF FACULTY OF NATURAL SCIENCES, COMENIUS UNIVERSITY, BRATISLAVA SLOVAKIA WITH IMPLEMENTATION OF QA/QC SYSTEM.

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Radiochemical laboratory, which was participating in the project quality assurance and quality control (QC/QC) was creating from the staff of the Department of Nuclear Chemistry, Faculty of Natural Sciences, Comenius University.

Our Lab was oriented to measurement of pure alpha and beta radionuclides and as necessary tools was gamma spectrometry for determination of gamma emitters in samples as an important step before separation process mainly for samples from radioactive wastes from NPP. After determination of gamma radionuclides concentration in sample it was possible to determined necessary decontamination factor for radiochemical separation and determination of pure beta radionuclides with good results. Our lab had more experience from nuclear waste samples from Slovak NPP, for which high contamination with ^{137}Cs is typical. We started with measurement since 1980. After 1990, new system of measurements was organized and more organization (firms) starts to measure radioactivity as a routine service for NPP. Slovak Nuclear Regulatory Authority and NPP start to require accreditation or authorization measurement for radioactivity as an inevitable for participation in measurement of radioactivity for them. From the demands of clients it was clear that only accredited laboratory will leave and survived on the market. For our Lab it was important to be accredited in as short time as possible. In the year1999 we couldn't get any contract due to the fact that we were not accredited.