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Draft Consultants' Report

CONSULTANTS' MEETING ON REQUIREMENTS REGARDING THE HARMONIZATION OF LABORATORY QUALITY ASSURANCE SYSTEMS 2 - 5 May 1995, Vienna, Austria

INTRODUCTION

For more than thirty years the International Atomic Energy Agency) has been assisting laboratories in Member States in maintaining and improving the reliability, i.e. the quality of analyses of nuclear, industrial, environmental, and biological materials, and materials of marine origin. Through the Analytical Quality Control Services (AQCS) the Agency initiates and supports improvements in the accuracy of analytical chemistry and radiometric measurements and their traceability to basic standards. Part of these activities are world-wide or regional inter-comparison exercises and distributing reference materials as listed in the 1995/96 AQCS catalogue. The AQCS program focuses on the determination of radionuclides, major, minor, and trace elements, stable isotopes, and groups of organic contaminants and agrochemical residues with nuclear, atomic and other analytical techniques.

Since results of analytical measurements may be the basis upon which economic, ecological, medical or legal decisions are taken, the assurance of quality is critically important for laboratories in Member States in order to achieve highly acceptable and compatible output from these laboratories. The assistance provided to Member States by the Agency to the improvements in the quality of analytical results help laboratories to compare data with fully accredited laboratories. Ultimately accurate analytical data will become available world-wide based on traceable measurements assisted by an extensive system of reference and intercomparison materials that serve the assessment and control of quality in each individual laboratory.

Considering on the one hand that CIPM/CCQM (and IUPAC) are working on fundamental aspects of the internationally structured system for traceable chemical measurements (a system likely to be set up in the next decade), it is conceivable that such structure should be useful and applicable to all countries, hence, including all IAEA Member States. Considering on the other hand that the IAEA has an United Nations mandate for assistance and technology transfer in general and wants to support its Member States in their analytical measurements in particular, it becomes apparent that there is a high degree of complementarity between the two undertakings. It is therefore necessary to realize this complementarity by developing a harmonized approach in helping Member States setting up their analytical measurement structures in parallel to the international efforts.

To advise the Agency on the realization of a harmonized approach to internationally compatible quality assurance systems the consultants were requested to consider the following questions:

1) What actions should be taken by the Agency to aid the development and implementation of measures to assess and assure the quality of laboratories that provide data in Agency projects and programs as well as for their national or regional programs?

2) What are the needs for the Agency to implement and promote the internationally discussed guidelines on production and certification of reference materials (ISO-

REMCO); are they relevant for all producers and all kinds of analytical quality control materials?

3) Is there a role of the Agency as an important international organization with activities in analytical quality assurance to be a focal point for promoting and maintaining the quality of reference materials and intercomparison runs?

4) Which are the key requirements to assure traceability of analytical measurements; how are these requirements applied in the production and certification of Reference Materials, how can traceability of AQCS materials be achieved?

5) Which type of reference and intercomparison materials (for programs relating to nuclear, industrial, environmental and human health measurements) are most urgently required by laboratories in Member States, which of these are uniquely provided by the Agency, which are available from other sources?

6) What are the future challenges in analytical chemistry investigations, what are the future requirements for service by Member States, how can AQCS respond?

PRESENTATIONS

Consultants from Brazil, Belgium, Germany, Switzerland, and the United States of America, representing also the European Union and the International Standards Organization, and IAEA staff members (RIPC, RIHU, RIFA, RIAL and RIML) were in attendance (Appendix I). The detailed agenda as it was accepted by the Consultants for the meeting is listed in Appendix II. Under the Chairmanship of Mr. Krug, the Responsible Officer and Secretary, Mr. R. Zeisler, summarized the present status of the AQCS program and the broad objective of this meeting:

- The role of the present AQCS program in the frame of Agency's program and budget and in the light of the needs in Member States
- The current objectives of the program and its relation to international standards and guidance
- The way and means in which the program is handled
- The recent technical accomplishments and development goals for the intercomparison and reference materials services
- The need for the development of approaches to training and technology transfer with Member State's laboratories.

These deliberations were complemented by a contribution on the goals of the RIML part of the AQCS program presented by Mr P. Povinec.

In the plenary session the Consultants presented their viewpoints and position papers in relation to the initial questions, reflecting the international efforts and their own experiences in analytical quality assurance. This was complemented by technical presentations on the RIAL and RIML components of the AQCS program The relevant position papers are collected in Appendix III.

DISCUSSION

The Consultants, under consideration of the progress made since last year's Consultant's Meeting on Requirements for Reference Materials and Intercomparison Runs - IAEA Program on Analytical Quality Control Services (AQCS), 17-21 April 1994, Kona, Hi, U.S.A., recognized that certain areas of the current Agency program need clarification in definition and strengthening of implementation. The Consultants made the potential benefits to Member States, to the Agency, and to a world-wide harmonized chemical measurement system the core of their discussions and recommendations.

An Agency program, considering the requirements regarding harmonized laboratory quality assurance systems, must, at a minimum,

a) ensure that the main components of the Agency's mission are at the core of the program,
b) ensure that internationally accepted standards are applied internally (to serve as model for Member States) and externally (to improve complementarity and compatibility of projects and programs),
c) provide feedback mechanisms between Member States and Agency activities (to minimize deficiencies and to provide quantifiable measures for implementation).

A number of International Standardizing Organizations are producing the reference protocols and definitions that aid the implementation of the above. These established (in industrialized countries - G7 countries) organizations could provide valuable resources and backup to the Agency program with the aim to extend partnership to Member States' laboratories.

The Consultant's Committee accepts that:

a) <u>For the AQCS program</u>
The basic IAEA mission is requiring more attention to training and interaction with counterpart laboratories. Also the scope of the activities may have to be extended as needs for quality assurance in food analysis may result in new Agency activities; the demand for new reference materials is rapidly increasing.

b) <u>For internal and external laboratory quality assurance</u>
The Agency Laboratories need to implement (or finalize implementation) as rapidly as possible Total Quality Management Systems that can form the basis of accreditation, similar efforts are appropriate for counterpart laboratories in Member States. The output must be compatible with that from leading international laboratories and organizations.

c) <u>For the Agency's technology transfer activities</u>
In the world-wide Agency efforts to establish (nuclear) analytical capabilities the intensive utilization of AQCS would not only assist in improving the quality of the laboratories but would also provide documented and quantifiable feedback on the implementation.

The consultants recognize that full implementation will require new resources, nevertheless consider the core recommendations as indispensable. Some internal measures (of which more continuity in the Agency Laboratory's program staffing may be a key factor) should take highest priority in the implementation of the current program as to avoid investments in activities of unknown quality.

RECOMMENDATIONS

The Consutants feel that the Agency's programs need to consider in the area of laboratory quality assurance requirements the high degree of complimantarity in their own efforts to the undertakings of the internationally appointed organizations. Harmonization is indicated of the Agency's internal and external interactions to achieve technology transfer, training and analytical data with measurable success and compatible results.

A. Mission Statement

To promote the goals of the IAEA by supporting the measurement infrastructure of the analytical laboratories in the Member States in order

- to achieve internationally credible and comparable measurements;
- to maintain and improve the quality of their analytical measurements.

Realization of this mission will be attempted by achieving the following goals:

- to assist Member States in education and training in analytical measurements;
- to support the transfer of measurement technology and its application in Member States;
- to monitor the effectiveness of the assistance provided.

B. Acceptance/Accreditation of the Agency's Laboratories as CRM producer

The Consultants' Committee recalls that the Agency has been producing Reference Materials (CRMs) in the last twenty years. These were important tools for intercomparison purposes among Member States' laboratories. Many Reference Materials produced by the Agency are unique and are indispensable.

The Consultants recommend

1. The Agency should declare its commitment to TQM (Total Quality Management) principles as defined in the International Standard ISO 8402:1994.
2. The Agency's Laboratories should seek the help of short term (2-3 months) consultants for peer review of its preparations for certification in accordance with ISO 9001, ISO/IEC Guide 25 as a first step and also with ISO Guide 34 at a later stage.
3. The Agency's Laboratories should seek co-operation with other top CRM producers to achieve mutual, international acceptance (through mutual analysis).
4. The responsibility for the declared reference values should be clear and personalized.
5. Having attained these goals the Agency's Laboratories can be accredited by the Director General of the Agency.

C. Harmonization of internal / external QA procedures applied to AQCS Intercomparison and Reference Material production

The Consultants stress the necessity for consistent quality of the work procedure within the Agency's AQCS and between the service and collaborating laboratories. To achieve this goal following steps should be undertaken:

- Appointment of an AQCS co-ordinator as a link between Units[1]
- Preparation of common AQCS QA-Manual based on ISO standard 9001 covering the main organizational topics
- Preparation of separate Laboratory QA-Manuals based on ISO Guide 25 and ISO Guide 34 covering the specific tasks and standard operating procedures of each Unit involved
- Exchange of information between Units regarding preparation of Intercomparison and Reference Materials, evaluation of Intercomparison Runs and certification for Reference Materials
- Uniformity of relevant AQCS documentation
- Harmonization between AQCS and collaborators (ISO Guide 34) should be established and monitored.

D. Promoting and maintaining the quality of Reference Materials and Intercomparison Materials

The Consultants' Committee recognizes the importance of promoting and maintaining the quality of the RMs (including CRMs) and ICMs produced by the AQCS in support of the Agency mission. This importance is derived from:

- the international importance of "Quality" in analytical measurements as used in health, science and commerce;
- the support given to the Member States from the AQCS;
- the need to maintain the current investment in the analytical measurement infrastructure of the Agency and in the Member States;
- the Agency's credibility among users and suppliers of RMs and ICMs.

The quality of the RMs and ICMs can be promoted and maintained by

- link program activities with national and international bodies engaged in similar activities by participating in measurement intercomparisons and co-operate measurement projects on a routine basis;

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[1]Divisions, Sections and Units of the Agency involved in AQCS are:
Division of Human Health, Division of Physical and Chemical Sciences, Agency's Laboratories Seibersdorf - Chemistry Unit and Isotope Hydrology Unit, IAEA Marine Environment Laboratory, Monaco - Marine Environment Studies Laboratory and Radiometric Measurement Laboratory)

- demonstrate an appropriate quality program;

- produce RMs and ICMs according to accepted guidelines and standards;

- maintain links to appropriate international activities as ISO-REMCO, BIPM/CIPM, EURACHEM, etc.;

- provide permanent professional leadership for the program in order to assure quality and continuity.

E. Quality/Classification of Certified Properties of AQCS Materials

To support the mission as outlined under A, the Consultants underscore that AQCS should

- continue its intercomparison programs and

- produce and maintain a supply of suitable reference materials

taking due note of the recent CIPM/CCQM directions in chemical measurements. However an appropriate transition period ~~must be taken into account for the latter to be put into effect.~~

Since the intercomparisons are intended to provide proficiency testing for the participating laboratories, it is mandatory to have or create a reference value and its uncertainty range for each substance under investigation in the intercomparison sample. The "mean" values of Proficiency Test programs - in whatever "statistical" way they are derived - are not appropriate as reference value.

There are three procedures leading to a "reference value":

1. the Agency Laboratories build up their own expertise to determine themselves the (SI traceable) reference values;

2. the Agency extracts a reference value from a selected set of results of those participants who fulfill well-defined quality criteria (e.g., traceability to SI);

3. the Agency requests acknowledged measurement laboratories to deliver an SI traceable value for use in its interlaboratory comparisons.

Prerequisites for the first procedure are that:

a) a QA system is established at the Agency's laboratories;
b) the Agency takes part in intercomparisons with laboratories producing reference materials;
c) the Agency demonstrates traceability to internationally acknowledged standards;
d) the Agency equips its laboratories with highly skilled permanent staff and primary methods of measurement (CCQM definition).

In the second procedure, the same prerequisites must be fulfilled by the selected participants who must take open responsibility for their values in the final report.

F. Assistance to Member States by AQCS to establish a network of "Agency Recognized Laboratories".

It is recognized that within the Agency's technology transfer, training, and education mission, a formalized assistance program for Member States' laboratories is of benefit, that will aid laboratories in assessing and improving the measures for analytical quality control. This can be achieved by establishment of an External Quality Assurance Program (EQAP) for laboratories engaged in the determination of amount of substance in environmental or food samples. The scope of specific EQAP projects in the determination of elements, radionuclides or organic compounds in sediments (from fresh water, estuarine, marine environments), biota (bio-accumulators), aerosols or food samples, would be subject to specific EQAP protocol(s).

The Consultants recommended the following approach:

For a laboratory to operate at an internationally acceptable standard, a number of key quality elements must be in place

- staff with the required skills and abilities to undertake the required measurements
- proper equipment to undertake the measurements in a technically sound manner
- an information management system which operates according to documented procedures
- an internal quality control system based on the personal responsibility of each individual staff member

The EQAP's function is to ensure that these factors are in place within the laboratories, that they are effectively utilized and that data are available both to determine performance and effectiveness of actions for improvements. A laboratory with a documented Quality Management System according to the relevant ISO guides or a nationally accredited laboratory would fulfill the above a priori requirements but would have to be subject to IAEA EQAP.

Components of EQAP are:

- Review of conformity with accepted quality standards (questionnaire, external expert)
- Review of internal quality control measures (control charts, RM analysis)
- Formalized proficiency testing (min 2 intercomparison/year)

Results of review and proficiency tests are the basis of Laboratory Recognition.

It is recommended that the IAEA (through AQCS) conducts the appropriate reviews and proficiency tests as well as organizes training on laboratory quality control and assessment. Protocols for such programs still need to be developed and approved. The Agency's Laboratories shall establish a committee that, in co-operation with scientific consultants, reviews and approves the results of these activities

Recognition will be granted by the Agency's Laboratories to laboratories fulfilling above requirements routinely.

Furthermore it is realized that such a program ought to start at a small scale, i.e., in a few laboratories and analytical activities. For that purpose, regional pilot project(s) may be appropriate.

It is also conceivable that in due course a network of recognized laboratories will function as training center or reference for other laboratories, thus passing on the quality standards and their implementation until ultimate "recognition". This would multiplying the initial investment effort.

CONSULTANTS' MEETING AGENDA

Tuesday: **2 May 1995**

8:30 Registration

9:00 - 10:30 **SESSION 1:**
Opening of the Meeting
Brief Self-Introduction of Participants
Election of Chairman and Rapporteur
Adoption of the Agenda

Introduction to the meeting objectives

IAEA's Program on AQCS, a brief status report:
- Aspects of the activities of an international organization
- Technical aspects:
  - Agency's Laboratory Seibersdorf
  - Marine Environment Laboratory, Monaco

11:00 - 13:00 **SESSION 2:**

Presentations by consultants, plus discussions

14:00 - 15:30 **SESSION 2:**

Presentations by consultants, plus discussions

16:00 - 18:00 **SESSION 2:**

Presentations by consultants, plus discussions

followed by **Reception**

Wednesday: **3 May 1995**

09:00 - 13:00 **SESSION 3:**

Group Discussions

14:00 - 18:00 **SESSION 3:**

Group Discussions (continued)

Thursday: **4 May 1995**

09:00 - 13:00 **SESSION 4:**

Presentations, General Discussions

14:00 - 18:00 **SESSION 4:**

General Discussions (continued)

Friday: 5 May 1995

09:00 - 13:00 **SESSION 5:**

Discussion and Formulation of Recommendations

14:00 - 16:00 **SESSION 6 (joint Session):**

Discussion and Adoption of Recommendations

CLOSING OF MEETING