Instituto Nacional de Tecnología Industrial
ARGENTINA

QMS supporting CMCs in Inorganic and Organic Chemistry

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0. Introduction

INTI`s technology offer (calibrations, measurements, tests, legal verifications and type approvals, qualified technical assistance, developments and product certification) is mainly structured through more than 40 R&D Centers that form a dynamic operational network. This structure integrates industrial and social sectors into institutional activities, thus allowing active involvement of all stakeholders (companies, trade chambers, public and private entities, etc.), intense interaction with society, ongoing identification of evolving technology demands and continuous improvement of the response to such demands.

Based on the previous concept, the Centers have deployed and currently maintain their own quality management systems for the purpose of ensuring their technical competence and reliability to the community. These QMSs follow IRAM 301 standard (national standard equivalent to ISO/IEC 17025). Also, a (global) Integrating Management System was implemented, having the aim of monitoring and assessing the calibration, measurement and testing services of the whole INTI

The metrological capabilities are self-declared under the CIPM-MRA framework, and subject to technical peer reviews.

0.1. Scope of this presentation

This presentation is the focused in the QMSs supporting stated CMCs in the following two areas:

-CMCs in Inorganic Chemistry, as performed by the R&D center in Chemistry of INTI (INTI-Química), and

- CMCs in Organic contaminants, as performed by the R&D center in Environment of INTI (INTI-Ambiente)

Both systems were approved by QSTF in Santiago, Chile, in March 2008. So, this presentation tends to achieve the corresponding 5 year re-approval. However, some entries to the CMCs spreadsheet are new (see Ap A). They are subject to reviews by the SIM chemical working group review, and by CCQM.

1. Quality Management System Structure, Objectives, Policies and Responsibilities

1.1. Integrated system

The structure, scope, objectives, policies and responsibilities of the Integrated Management System of whole INTI, as well as the organizational chart of INTI, did not change since the last presentation to QSTF, in November 2012. So, their main aspects can be seen in the documentation submitted for the previous meeting:

http://icdb.nist.gov/qs/simqstf/Costa%20Rica%2011-12/INTI-elec-freq/

file: *INTI_QS_2012_11_08.pdf*, pages 3 to 14

Also, the Global Management Manual (In English and Spanish) and main administrative procedures (only in Spanish) can be found in the following files, which are available in the same webpage:

INTI-Global QM-eng.pdf	Quality Manual, English
INTI-MC Global-esp.pdf	Quality Manual, Spanish
DP 01 (Spanish).pdf	Document and record control
DP 02 (Spanish).pdf	Non-conformity control and treatment
DP 03 (Spanish).pdf	Corrective and preventive actions
DP 04 (Spanish).pdf	Internal Audits
DP 05 (Spanish).pdf	General Management Review
DP 06 (Spanish).pdf	Complaint management
DP-07 (Spanish).pdf	Harmonization of procedures
DP-08 (Spanish).pdf	Crossed audits
IP 01 (Spanish).pdf	Document and record management

1.2. QMS within the R&D centers

A general description of the QMS maintained in each R&D center involved in this report can be found in the following of the current presentation:

INTI-Quimica QMS documentation.pdf,
INTI-Ambiente QMS documentation.pdf

They include objectives, scope, responsibilities, organizational charts, contents of the respective Quality Manuals as well as the lists of administrative and technical procedures,
The complete Quality Manuals of both centers (in Spanish) can be found in the files:

INTI-Quimica QM.pdf
INTI-Ambiente QM.pdf

2. QUALITY SYSTEM IMPLEMENTATION

2.1. Customer feedback management

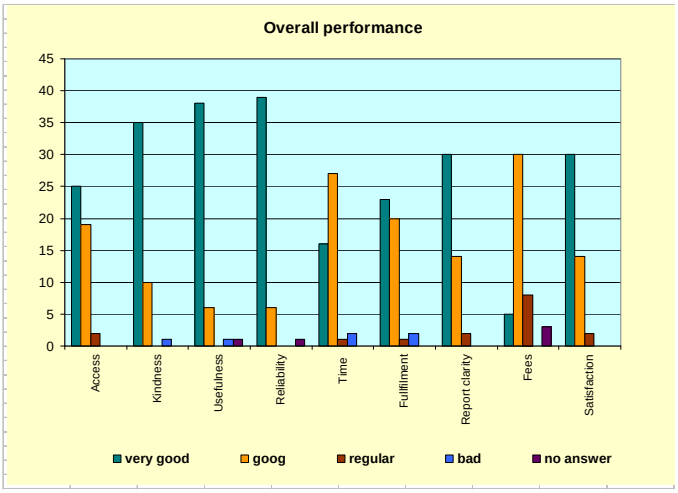
2.1.1. Policy, procedures and Actions

From the beginning of the relation with actual or potential consumers of its services, INTI actively and constantly cooperates with them by maintaining ongoing communications through all the available means (in person, by telephone, mail, electronic media, etc.) to receive their requests or respond to their queries, provide advice or technical assistance, clarify doubts and/or solve any potential discrepancies that might affect the quality of the Institute's technology services. These mechanisms are applied before, during and after services are provided, gathering and analyzing the feedback received from said activities and applying it to process improvement.
Users also have a toll-free line (0800 444 4004) and an e-mail address (consultas@inti.gob.ar) to send their requirements from any location in the country to INTI's the centralized Customer and Public Service Office. All service requests are then forwarded to the pertinent R&D center for processing.
If appropriate, and with prior approval of each R&D center's leadership, INTI allows user access to its labs whether for educational or follow-up purposes regarding ongoing tests or calibrations, provided, however, that such access will not jeopardize any confidentiality obligations to other users and the safety conditions are met in the involved work areas.
In this context, each R&D center establishes and maintains adequate procedures to manage these user-driven services, by defining the tools applied on a case-by-case basis.

Under this framework, an institutional survey was carried out in all the centers. Random samples of customers were extracted, proportionally to the total amount of them. The following issues were enquired.

- **Access to INTI**: how easy or difficult was to arrive to the required person / laboratory / center.
- **Staff kindness:** attitude for the services (friendless, courtesy, interest, communication, etc.)
- **Service usefulness:** level of benefit, use or advantage related to he previous expectation
- **Reliability of the results:** confidence in the supplied information
- **Time, period of response**
- **Fulfillment of the agreed periods**
- **Clarity of the report:** clearness and lack of ambiguity in the content of the report
- **Fee**

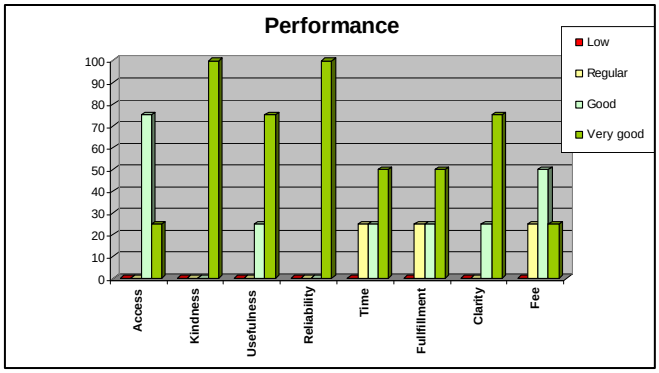
2.1.2. Survey results. INTI-Química



A sample of 52 users was extracted from a total volume of 364 users. The survey results were presented and discussed in the management review

2.1.3. Survey results. INTI-Ambiente

A random sample of 15 users was extracted. The survey results were presented and discussed in the management review



2.2. Managing customer complaints

2.2.1. Quality Management philosophy and procedures of handling customer complaints, nonconforming work, and corrective and preventive actions

Each Institute's R&D center defines policies and procedures for the reception, treatment and resolution of complaints, objections or claims from direct or indirect users, and keeps a record of the measures adopted with regard to them. In general, these actions are deemed to be non-conformities and are managed as such after assessing their relevance, and the appropriate action is taken subsequently. Corrective actions are implemented when applicable to minimize or eliminate the root cause for the deviation.

In addition, users may submit their complaints or claims directly to the Metrology and Measurement Quality Program or to the Institute's President through regular institutional channels. In this case, and based on the type of claim received, the highest authority establishes the steps to be taken to solve the issue.

*The **"DP 06 - Gestión de Quejas y Reclamos" (Complaint and claim management)** document defines the actions to be taken in these situations within the scope of the Metrology and Measurement Quality Program*

2.2.2. Statistics of Complaints in 2012

No customer complaints were received in 2012 in INTI Quimica.

3 customer complaints were received in INTI Ambiente in the last period. All of them are related to mistakes in the report of results. Corrective actions were implemented and verified

2.3. Management of non-conformities

2.3.1. Policy and procedures

In the event a non-conformities are detected in a work or any part of them, the Research Centers act pursuant to the effective procedures stated in their respective quality systems, by identifying such non-conformities, assessing their relevance and/or risk for the user, defining any applicable containment or corrective measures and notification, if necessary, to the affected user. This applies to any test, measurement, verification or calibration conducted by INTI to the extent any of them does not comply with the stated requirements or user requests.

The same procedure also applies to the management of any non-conformities arising from the application and maintenance of quality systems.

In this regard, the Metrology and Measurement Quality Manager has implemented the "**DP 02 - Non-conformity control and treatment**) document within its area of competence, which describes the appropriate methodology to detect, identify and treat any non-conformities arising in the INTI - QMS.

2.3.2. Statistics of Nonconformities in 2012 (Corrective actions carried out in all the cases)

INTI-Quimica: All the following nonconformities were managed by means of corrective actions, which were implemented and verified. The statistics classified by topics is as follows

		Quimica	Ambiente
4.2/4.3	Documentation / QMS	20	8
4.4	Contract review		2
4.6.	Suppliers	1	
4.9.	Nonconforming works	1	
4.14	Audits		1
5.2	Job descriptions	1	
5.2	Lack of training		1
5.2	Non authorized person	2	
5.3	Facilities	1	1
5.4.5.	Method validation	4	1
5.4.6.	Uncertainty	1	1
5.6.	Traceability		1
5.6.	Use of non-calibrated equipment	1	
5.4.7.	Data Control		1
5.9.	Quality Control		1
5.10	Report of results		4
	Total	**32**	**22**

2.4. Corrective and preventive actions

The Institute's Research Centers included within the scope of the INTI – Integrated QMS have specific policies and procedures to manage, implement and verify the efficiency of corrective or preventive actions in order to avoid the repetition of non-conformities (by analyzing and eliminating their causes) or prevent their occurrence.

Similarly, the Metrology and Measurement Quality Program's **"DP 03 - Acciones correctivas y preventivas" (Corrective and preventive actions)** procedure sets forth the policies and guidelines as to their responsibilities within the framework of operational supervision under the INTI - QMS.

2.5. Improvement

Each center performs, on a regular basis and in accordance with the relevant methodology, critical analyses of the evolution of their quality management systems in order to continuously improve their effectiveness.

To that effect, and keeping INTI's vision, mission, quality policy and goals as reference, the Research Centers study, resolve and plan the implementation of the necessary measures to improve their own systems' performance, based on substantial information acquired during their maintenance while trying to eliminate any weaknesses found (whether actual or potential).

The centers may base their analyses on management review conclusions, the results of the internal and external audits to which they were subject, analyses of trends in the management indicators defined, the main corrective and preventive actions taken, users' feedback, comparative information (internal or external), improvement opportunities and potential changes in their technical or organizational environment.

Based on the results of this information, each center defines an action plan to update the quality management system applied.

3. ASSESSMENTS

3.1. Internal and crossed audits.

An internal audit is an audit performed by auditors from the same center that the audited area.
A crossed audit is an on site peer assessment performed by an auditor internal to INTI but independent and outside the management chain of the laboratory being reviewed. So, crossed audits are considered.
Yearly crossed audits are mandatory for managerial aspects in all the centers.
Yearly internal or crossed audits are mandatory for technical aspects in all the centers in which external peer reviews are carried out once each 5 years.
The audits are yearly planned by the Metrology Management of INTI. The Institute has a significant number of auditors with the required profile, who are specifically trained for this function and have enough expertise in quality management and technical aspects. The crossed audits are planned and implemented in order to further ensure the auditors' independence and unbiased conclusions regarding the areas or activities audited by them. The selection of auditors takes into account these considerations.

3.1.1. Summaries of the current cycle of crossed audits in the involved centers

The summary, including dates, scopes, auditors, findings, corrective actions and verification if applicable, can be seen in the following files:

INTI Quimica internal and crossed audits.pdf
INTI Ambiente crossed audits.pdf

3.2 Management reviews

3.2.1. Policy, Scope, Responsibilities, Frequency

Each center has implemented procedures to conduct management reviews within their own areas of competence. A copy of reports and records generated from reviews is submitted to the Metrology and Measurement Quality Program for information and evaluation purposes.
The Program may participate in management review meetings at each of the Research Centers comprised within the scope of this Manual.
*The **"DP 05 - Revision General por la Dirección" (General Management Review)** document also includes regular reviews of substantial quality system activities performed under the Metrology and Measurement Quality Program.*

3.2.2. Summary of recent Management Reviews

The reports of the last MRs performed at the involved centers are available in:

INTI-Quimica MR.pdf
INTI-Ambiente.pdf

3.3 Peer reviews

3.3.1. Policy about peer reviews

External technical peer reviews are carried out each 5 years, in the fields related to the claimed CMCs. The reviewers should have experience in assessing QMS and knowledge and experience assessing the technical requirements of ISO/IEC 17025 related to the CMCs

3.3.2. INTI-Quimica Peer review

An on-site peer review was held on June 25-27 2012, by Dr. Heidi Goenaga-Infante, LGC (UK). Its scope was the stated CMCs in Chemical Inorganic Analysis Methods mentioned in Ap A

The peer review report is in *INTI Quimica PR report*.pdf
As a conclusion, the following paragraph is extracted:

> ***"Attestation***
> *The INTI has the capabilities and competences to carry out the services it is claiming to deliver to its customers in the scope of the CIPM MRA.*
> *The quality system, as far as it could be reviewed, is in compliance with ISO/IEC 17025:2005 and covers the near future claimed CMCs.*
> *No Non-Compliances have been found, however a few minor non-compliances have been observed. Those are detailed in further sections of this report. A number of recommendations for further improvements are, therefore, added in the peer review report."*

The reviewer has mentioned 19 recommendations. All of them were considered and actions were defined and were or are being executed. The detail can be found in the file:

INTI-Quimica Action Plan.pdf

3.3.3. INTI-Ambiente Peer review

An on-site peer review was held on June 4-5 2012, by Dr. Dr. Mariana Arce Osuna, CENAM (México). Its scope was the stated CMCs in Organic Contaminants mentioned in Ap A

The peer review report is in *INTI Ambiente PR report*.pdf
As a conclusion, the following paragraph is extracted:

"Executive Summary

> *…….*
> *In general, the measurement methods applied are adequate. Measurement uncertainty evaluation is based on the GUM and related EURACHEM documents. In some cases the claimed uncertainty seems to be on the optimistic side and should be reconsidered, of course taking into account the results of pilot studies and other bilateral comparisons and in particular of key comparisons. Thorough method validation is still necessary addressing all potential uncertainty components. Taking into account some reconsideration as mentioned above, the claimed calibration and*

measurement capabilities as proposed to become published in the Appendix C of the CIPM MRA are acceptable and seem to be reliable. "

The reviewer has mentioned 2 non-confirmities and 19 recommendations. All of them were considered and actions were defined and were or are being executed. The detail can be found in the file:

INTI-Ambiente Action Plan.pdf

4. CMCs Vitality

Evidences of the CMCs vitality can be found in the following files

INTI-Quimica vitality evidences.pdf
INTI-Ambiente vitality evidences.pdf

5. Appendices

Appendix A. CMCs under review

INTI Quimica: see the files

Ap A - INTI Quimica CMCs (approved).pdf and
Ap A - INTI Química CMCs (new).xls

INTI Ambiente: see the file

Ap A - INTI Ambiente CMCs.xls

Appendix B. Bios of internal and crossed auditors. The crossed and internal auditors bios can be seen in the following files

AP B - Bios Gladys Mastromonaco.pdf
Ap B Bios Pablo Álvarez.pdf
Ap B - Bios Mabel Puelles.pdf
Ap B Bios Alejandra Rodriguez.pdf

C. Bios of peer reviewers. Their reviewers bios can be seen in the following files

Ap C - bios Mariana Arce,pdf
Ap C - bios H Goenaga-Infante,pdf

D. Cross reference. It can be shown in the following files

Ap D - cross reference INTI-Quimica.pdf
Ap D - cross reference INTI-Ambiente.pdf