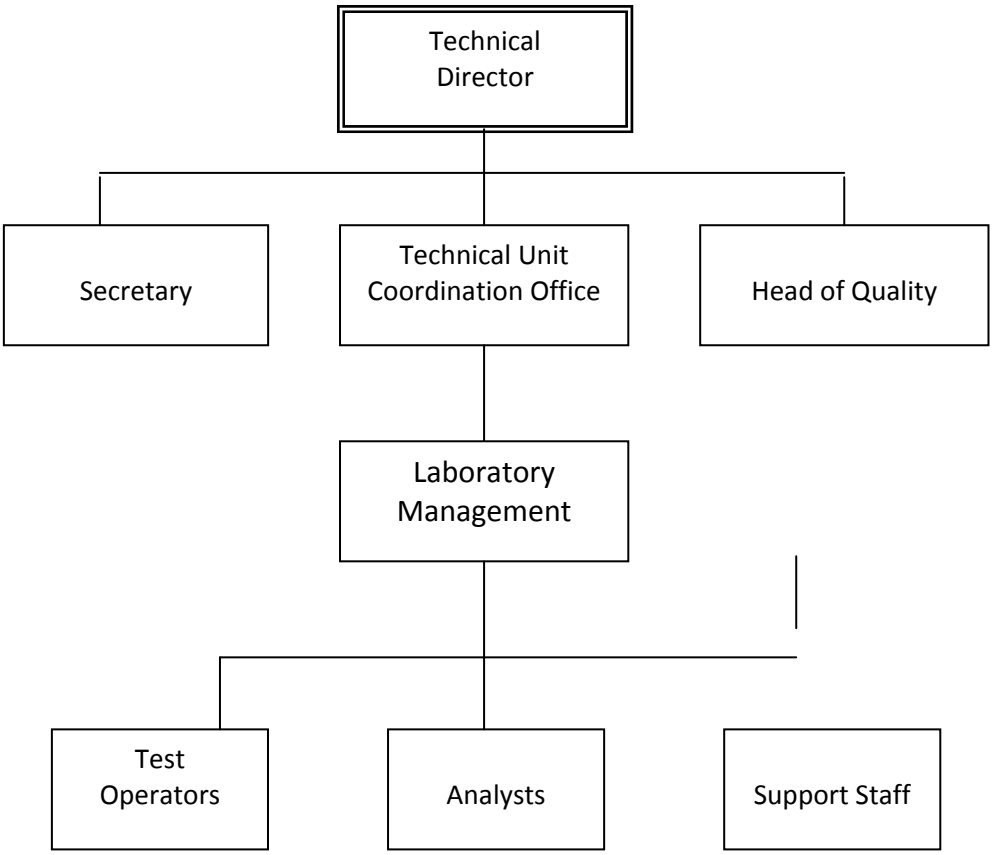
Organic Contaminants:

Organizational Chart:

Organizational structure of the Centre.



Policy Statement

"Centro INTI-Contaminantes Orgánicos" (INTI-Organic Contaminants Centre) is part of the National Institute of Industrial Technology's Centre System and as such, adheres to the Quality Policy of this Institute, which applies as its own, adapting its Quality Management System (QMS) to meet IRAM 301:2005 Standard (ISO/IEC 17025:2005) requirements

Centro INTI-Contaminantes Orgánicos performs research and development studies for organic contaminant detection in packaging, materials, environment, biomedical supplies, and food.

For this purpose, the Centre has set the following objectives:

- Meet user demands in due time and form applying its implemented Quality System, which is maintained and continually improved;
- ensure the entire staff is fully knowledgeable of the contents of this Manual, and that the policies and procedures defined there, as well as in related documents, are observed at all times;

- perform research and development studies for organic contaminant detection by analytical determinations based on national, regional or international methods, previously agreed upon with users and validated at the pertinent laboratory;
- ensure accuracy of measurement results through the use of drugs and/or reference standards, and their performance by duly qualified and committed staff, with good professional practices;
- protect the environment by using the right test and sample disposal and/or treatment.

Responsibilities and authorities: The following is a description of the Centre's staff main functions and the actions they are accountable for, as well as their respective authorities.

Technical Director's Responsibilities:

- Ensure laboratory measurements are performed according to a Management System that meets all requirements in force, as per the latest revision of the ISO 17025 Standard.
- Establish Quality Policies, annual objectives and the Quality System to be followed at the Centre.
- Determine the Centre's organizational chart.
- Define the scope of the Quality System.
- Provide the necessary resources to ensure the quality required for laboratory operations is achieved, and implement the corresponding Quality Policy, based on the Quality System in place.
- Manage the resources provided for that purpose, as well as other operational aspects to Quality and Chemical Metrology.
- Appoint a member of the staff as the Head of Quality. Apart from all other pertinent obligations and responsibilities, this person shall also be responsible for ensuring, and granted sufficient power to enforce, the implementation and full time observance of the ISO 17025 Standard.
- Perform the yearly review of the Quality Policy, the annual objectives and the Quality System to be applied at the Centre.
- Approve the Quality Manual.
- Implement and enforce the provisions set forth in this Manual for the Laboratory's daily operations.
- Ensure the Centre's staff is fully aware of the significance and relevance of their activities and how they contribute to the achievement of the management system goals.
- Ensure the implementation of proper communication procedures within the laboratory.
- Ensure communication on the effectiveness of the Management System.
- All technical operations executed at the Centre, including Chemical Metrology activities, as described in this Manual.
- Sign technical reports, attesting to the accuracy of stated values.
- Define and approve functions and positions, as well as the required profile to fill in each position.
- Approve the incorporation of new staff into the Centre.
- Evaluate by function.
- Approve QMS documents.
- Approve handwritten modifications introduced to documents.
- Authorize QMS deviations.

- Determine if a non-conformity is to be managed as a correction or if a corrective action is to be implemented.
- Appoint a person responsible for dealing with a correction or non-conformity.
- Approve audit schedule and request unscheduled audits, if deemed required.
- Evaluate, approve and select providers.
- Determine provider requirements and evaluation forms.
- Approve purchase orders and supply requisitions.
- Approve the general Training Plan.
- Approve the list of authorized signatures for test/measurement reports.
- Issue reports.
- Decide on work referral to other laboratories.

Head of Quality's Responsibilities:

- Ensure the Quality Management System is implemented and followed at all times.
- Develop, implement, and update the Quality System.
- Verify Quality System implementation and compliance.
- Schedule, plan, and set up Quality System Internal Audits.
- Verify and validate the effectiveness of implemented Corrective and Preventive Actions.
- Establish specifications for measuring equipment calibration, verification, and maintenance.
- Regularly report on Quality System performance.
- Oversee and organize training on Occupational Health and Safety.

Responsibilities established for Chemical Metrology activities:

- Promote the concept that the Quality System implementation and the changes introduced as a result of its continual improvement, both contribute to the compliance with Chemical Metrology's policies and activities.

The Coordination Office of the Technical Service and Chemical Analysis Development Unit **(Coordinación de Unidad Técnica Servicios y Desarrollos Analíticos --CUT)** is responsible for:

- Monitoring compliance with laboratory's test/measurement specifications.
- Overseeing and training key technical and support staff.
- Defining functions and positions, as well as the profile required to fill in laboratory job positions.
- Rating the qualification of analysts and test operators to perform tests and/or particular calibrations and use specific equipment.
- Overseeing staff during their training.
- Promoting and developing new analytical techniques.
- Signing technical reports, attesting to the accuracy of reported values.
- Cooperating with the Director in controlling the Centre's management.
- Approving the annual calibration, verification, and inspection program.
- Determining evaluation criteria for each test/measurement.
- Designing and approving test/measurement method validations.
- Specifying values for non established parameters as a requirement to be complied with in a validation method.
- Evaluating validation reports.
- Approving validated analysis methods.
- Authorizing deviations in the compliance with established criteria as parameters in test/measurement performance.
- Approving modifications to test/measurement methods so as to meet criteria established for the particular method, and work continuation.
- Evaluating, approving and selecting providers.
- Validating purchase orders and supply requisitions.
- Approving and receiving purchases and supplies.

Responsibilities established for **Chemical Metrology** activities**:**

- Implement Chemical Metrology policies indicated by the Technical Director, thus ensuring compliance with all BIPM's requirements applicable to laboratory measurement capabilities.
- Coordinate and supervise Chemical Metrology activities in the laboratory.
- Contribute to chemical traceability dissemination in INTI-declared measurement capabilities.
- Survey and report to the Technical Director on opportunities to participate in pilot or key comparisons organized by the BIPM or SIM.

Laboratory Management's Responsibilities:

- Organize analysis development and services.
- Oversee measurements performed by analysts and test operators.
- Establish guidelines for handling of chemical substances.
- Oversee waste management activities.

Analyst's Responsibilities:

- Execute tests/measurements, according to documented guidelines in their possession.
- Report any deviation observed to their superior authority.
- Write and sign test/measurement reports, attesting to the accuracy of the reported values.
- Oversee test operators during test performance.
- Validate test/measurement methods.
- Receive and record claims.
- Execute primary maintenance activities on hydrogen generators.
- Perform air compressor filter maintenance activities.
- Perform preventive maintenance activities on gas chromatographs.
- Prepare purchase orders.

Responsibilities established for **Chemical Metrology activities:**

- Receive samples for exercises to be performed during Chemical Metrology activities.
- Keep record of necessary supplies for exercises associated with Chemical Metrology activities.
- Elaborate technical procedures for measurements corresponding to each measurement capability stated to the BIPM.
- Participate in SIM and BIPM's interlaboratory tests and implement corrective actions based on such participations, if so required.
- Assure uncertainty calculations for each stated capability.

Test Operator's Responsibilities:

- Perform tests according to documented guidelines in their possession, under the supervision of an analyst or the CUT.
- Carry out primary maintenance activities on hydrogen generators.
- Perform air compressor filter maintenance activities.
- Perform preventive maintenance activities on gas chromatographs.
- Inform analysts on availability of supplies.
- Prepare purchase orders.

Secretary's Responsibilities:

- Issue invoices corresponding to works performed.
- Follow up on test reports destinations.
- Prepare purchase orders.

Support Staff's Responsibilities:

- Clean Laboratory material and arrange it for later use.
- Perform primary maintenance activities on hydrogen generators.
- Perform air compressor filter maintenance activities.

QMS Documents for Organic Contaminants

1. **Quality Manual - Table of Contents**

Chapter Code	Title
-	Correlation matrix
1	Quality policy
2	Introduction
3	Definitions and abbreviations
4	Organization and management
5	Quality system audits and reviews
6	Personnel
7	Locations and environment
8	Equipment and standard materials
9	Measurement and calibration traceability
10	Test/measurement methods and method validation
11	Agreement review and handling of test/measurement materials
12	Records
13	Reports
14	Test subcontracting
15	Procurement of services and supplies
16	Complaints

2. List of Management Documents:

Code	Title
PG 5.1	Document control and maintenance
PG 5.2	Procedure for non conformities and corrective actions
PG 5.3	Procedure for internal audit performance
PG 5.5	Procedure for preventive actions
PG 5.6	Procedure for management reviews
PG 5.10	Continual improvement
PG 11.1	Reception of samples and work order opening for internal and external clients
PG 12.1	Procedure for record control
PG 12.2	Test records
PG 15.1	Contracting support services and supplier evaluation
PG 15.2	Procedures for supply and equipment purchase, reception and storage
PG 16.1	Complaint management

List of Technical Documents:

Code	Title
PG 5.9	Quality assurance of test results
PG 6.1	Personnel training and qualification
PG 7.1	Emergency action and evacuation plan
PG 7.2	Environment condition control
PG 8.1	Laboratory equipment and instrument identification and maintenance
PG 8.2	Standard material and work standard control
PG 9.1	General procedure for equipment and instrument calibration / verification
PG 10.2	Procedure for measurement uncertainty estimation
PG 10.3	Test method validation
PG 11.2	Sample preservation, maintenance and disposition
PG 11.3	Hazardous waste identification, storage and collection for disposition
PG 13.1	Test reports
PG 13.2	Calibration/ measurement reports
PE 8.1	Gas chromatograph preventive maintenance
PE 9.2	Glassware calibration; volumetric flasks
PE 9.3	Glassware calibration; bulb pipettes
PE 9.4	Analytical balance verification
PE 9.5	Glassware calibration; syringes
PE 9.6	Glass thermometer verification
PE 9.7	Digital thermometer verification
PE 10.39	Determination of aromatic hydrocarbons in methanol
PE10.40	Determination of ethanol