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**CENTRO DE CARACTERIZACIÓN DE MATERIALES**
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# *HANDBOOK OF THE MATERIALS CHARACTERIZATION CENTER, INC.*

## *January 2019*

### The Materials Characterization Center (MCC)

**MCC** is an independent not-for-profit but self-supporting corporation affiliated to the University of Puerto Rico offering specialized analyses and the corresponding technical and scientific expertise, on a fee basis, to clients in industry, government and academia. The principal techniques offered by MCC are Nuclear Magnetic Resonance, Mass Spectrometry and MS coupled with various separation techniques, Surface Microscopy and Spectroscopy and Crystallography.

In offering these services, which are not available elsewhere in Puerto Rico, the MCC seeks to strengthen industrial activity by providing expeditious and reliable solutions to situations faced by manufacturing operations that would otherwise require lengthy referrals to Research & Development (R&D) centers outside of Puerto Rico. MCC also seeks to reinforce the academic offerings of the public and private universities by making available to scholars and students services and facilities not available at any other one institution. In this manner, the MCC also promotes closer interaction between industry and academia, to their mutual benefit.

Some typical applications of MCC's facilities include: determination of the chemical structure of unknown compounds, mixture analysis, analysis and identification of impurities, studies of polymorphism in drug products, characterization of surface impurities, identification of trace compounds, and characterization of chemical deposits on surfaces, among others.

MCC is located within the Río Piedras Campus and the Molecular Science Research Center (MSRC) of the University of Puerto Rico. The administrative office is at the Facundo Bueso Building (FB-247) at UPR-Río Piedras Campus. By virtue of its location within the Natural Science Faculty, the MCC has access to the Faculty's technical and instrumentation capabilities and to the infrastructure of the MSRC and may thus complement its own capabilities in order to offer a wider range of services and support.

## MCC's Mission and Vision

- **Mission**: The Materials Characterization Center (MCC) strengthens the relationship between industry and academia and thereby enhances the environment for scientific research and development in Puerto Rico, by providing state-of-the-art analytical services and scientific expertise, not readily available through commercial laboratories, to clients in industry, academia, and government.

- **Vision**: The Materials Characterization Center (MCC) envisions itself as a non-profit, self-supporting entity which strengthens and improves Puerto Rico's scientific and technological infrastructure. This infrastructure is important in retaining and attracting new high technology industries and thus contributing to the economic development of Puerto Rico.

## Brief History of MCC

The MCC was created in 1995 by a joint effort of INDUNIV (Industry University Research Center Inc.), and the University of Puerto Rico with the key collaboration of professors from the College of Natural Sciences, and with support from the government in the form of a grant from the Science and Technology fund. The four professors who initiated the idea were **Dr. José A. Prieto**, who also served as MCC's first Director, **Dr. Osvaldo Rosario, Dr. Carlos R. Cabrera, and Dr. Antonio Martínez**. The first three from the Chemistry Department and Dr. Martínez from the Physics Department.

Until mid-1999, the Center was governed by the Executive Board of INDUNIV, but in May 1999, MCC was incorporated as a separate entity based on a decision by INDUNIV's board and a Resolution of the Board of Regents of the **University of Puerto Rico (UPR).** The Center is now ruled by its own Board of Directors on which are represented private industry and the University of Puerto Rico.

The Center receives samples for testing separately from the academic activities and under strict confidentiality criteria. Analyses are conducted by MCC's scientists and technicians, but a client's own technicians may participate in the analytical process. This offers greater flexibility in responding to unexpected findings arising during the analysis and allows expanding the process while on the job, potentially saving time and expenses to the client.

## Organization and Staff

MCC is governed by a Board of Directors. The President of the Board is the Past vice-president for Academic Affairs and Research of the University of Puerto Rico and the Director of Resource for Research Center. The other four members are appointed by the President of the University of Puerto Rico. Currently these persons are:

- *Dr. José A. Lasalde Dominicci*, President of the Board and Vice-President of UPR
- *Eng. Carlos del Río*, Industrial Private Sector
- *Dr. Ismael Pagán Trinidad,* Dept. of Civil Engineering, Mayagüez UPR
- *Dr. Samuel Hernández,* Industrial Private Sector
- *Dr. Noemí Santiago,* Industrial Private Sector

The Center's day-to-day activities are coordinated by an Executive Director who reports to the Board. **Edgard Resto Rodríguez, PhD** has been the Director since February, 2002. He is assisted by Lic. Neiza Hernández, M.Sc., MBA (Licensed Chemist) in client services, projects management, quality assurance and others; also Mrs. Evelyn García and Mrs. Gladys Varela assist the director in accounting and administration among others administrative assistance (part time basis). Outside services include an accountant: Mr. Andrés Hernández and an external quality assurance consultant, Lic. José H. Lebrón, who was also responsible for the initial development of the *Master Validation Plan.*

Analytical instruments (see brochures) are housed in three laboratories manned by MCC personnel. A professor, knowledgeable in the particular area of analysis serves as the laboratory's scientific and technical advisor and assists in the management and supervision of the facility.

Personnel at present are as follows:

**MS Lab:**
- Dr. Osvaldo Rosario, Advisor
- Ms. Mildred Rivera Isaac, M.Sc.
- Other Research Assistance

**NMR Lab:**
- Dr. José A. Prieto, Advisor
- Lic. José Martínez, BS

**SMS & Crystallography Lab:**
- Dr. Carlos R. Cabrera, Advisor
- Dr. Antonio Martínez, Advisor
- Lic. Cristina Díaz, BS, Quality Control
- Lic. Loraine Soto, PhD, Quality Control
- Other Research Assistance

## MCC's View of Industrial Regulations

Many of MCC's clients belong in the category of regulated industries, pharmaceutical and medical devices as for example. For this reason we are often visited and audited by personnel from these industries. MCC welcomes and promotes this activity and is keenly aware of its own characteristics, its assets and limitations. Our organization is committed to follow sensible, safe, and sound procedures which will result in good scientific data which is useful to our clients. Concepts such as GMP's, GLP's, and validations have periodically been discussed in relation to the operations of MCC. In spite of the very special and specific nature of MCC's operations, adherence to these rules and regulations is always attempted. Following is our view of the MCC's role:

***What the MCC does and does NOT:***

- **MCC** is a laboratory dedicated to perform specialized analytical testing and provide the scientific and technical expertise related to these analyses.

- **MCC** will consider all clients as allies and consider itself as an extension of their scientific and technical capabilities.

- **MCC** performs testing as part of investigations which may result in releasing products. The release, however, is not based on MCC's laboratory analyses alone, but on the result of a written investigation done by the client which may include test results performed at MCC as well as their own analyses and those of other laboratories.

- **MCC** in general does not perform routine testing and analyses such as those prescribed in USP/NF, EPA regulations, AOAC and other compendial works which describe specific analytical methods. MCC's essence is precisely to perform the kind of testing which is not routine and thus not available in industrial or commercial laboratories.

- **MCC** does not perform any testing with the purpose of directly release products or materials *except in cases where highly specialized instrumentation is required* such as X-Ray diffraction or high resolution Nuclear Magnetic Resonance, techniques which may not be available in the industry or in commercial laboratories.

- **MCC** does not manufacture any products, intermediates or raw materials, does not carry out any sampling activities and does not perform any microbiological testing or testing in humans or animals.

- **MCC** shares laboratory space and instrumentation with the University research community, especially with the professors who serve as scientific advisors and their corresponding research groups. Thus MCC recognizes and is ready to co-exist with

other scientists that may be available for consultation and add knowledge and expertise to MCC's operations.

- **MCC**, as an organization, does not perform research to discover or develop new products but may assist others in doing so.

The concepts which will be briefly discussed below may or may not be mandatory but essentially all make "good science". It is in this essence that MCC wishes to focus on GMP's, calibrations, ISO Guide 17025 and other quality concepts considering these practices as helpful to ensure the quality, exactness and preciseness of the work performed in MCC's laboratories.

## Good Manufacturing Practices (GMP's)

21 CFR Part 210 describes the "Current Good Manufacturing Practice in Manufacturing, Processing, Packaging or Holding of Drugs", and 21 CFR Part 211 describes the: "Current Good Manufacturing Practice for Finished Pharmaceuticals". Although MCC as an organization does not fall into any of these categories it strives to operate as if it did. A review of cGMP's indicates that it would make common sense and good science for MCC to adhere to the following sections and subsections:

*Subpart B: Organization and Personnel*

- Define a Quality Control Unit responsible to overview the quality aspects of the analyses and reports prepared at MCC.
- Prepare and follow Standard Operating Procedures regarding quality issues and in general the performance of the work typically carried out at MCC.
- Ensure that personnel follow suitable sanitation and health habits.
- Qualify and document correspondingly the technical staff of MCC.

*Subpart I: Laboratory Controls*

- Establish general test procedures and controls tempered by the nature of the analytical techniques and of the instrumentation.
- Prepare procedures to handle samples, standards and calibrations where applicable.

*Subpart J: Records and Reports*

- Establish procedures to manage records, notebooks and information regarding projects.
- Establish procedures to investigate anomalous or aberrant results.

## Good Laboratory Practices (GLP's)

GLP's (21 CFR 58) relate exclusively, and need to be followed only, for preclinical research to determine the safety of a drug candidate. FDA does periodically inspect those facilities that perform GLP toxicology studies. MCC does not perform this kind of activity. However, in as much as possible MCC will comply with GLP's since it makes good science.

## Validation

Validation is the totality of the activities designed to prove and document that a process, method, instrument, and other devices, do what they are supposed and meant to do in a consistent and well defined manner. The concept of validation typically applies to activities which are performed in a repetitive fashion such as, for example, a manufacturing process or a routine analysis. The tests and analyses carried out in the MCC are not routine operations, but on the contrary, our instrumentation and techniques allow for a myriad of different variations. This is what makes MCC's instrumentation so powerful. In the MCC a different testing sequence or protocol is used for every sample that is submitted.

In a complete validation protocol, three distinct stages are considered: Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). At MCC we have the documentation to demonstrate completion of IQ and OQ. But because of the nature of the various techniques, types of samples and approaches to situations, the preparation of a classical PQ is impracticable since our processes are not routine or pre-prescribed. We do, however, have documentation available to show that instruments perform in a consistent and correct fashion.

Certify by,

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**Edgard Resto Rodríguez, PhD**
Executive Director
Materials Characterization Center, Inc.

# Handbook of the

# MATERIALS CHARACTERIZATION CENTER, INC.

# Appendices

- Organizational and Structure Charts
- MCC's FDA Registration – FEI Number 3005053832
- List of Standard Operating Procedures
- MCC general information and brochures