QUALITY ASSURANCE MANUAL GUIDELINES FOR MIAMI-DADE COUNTY APPROVED LABORATORIES

1.0 SCOPE

1.1 This document specifies the general requirements for establishing a Quality Assurance Program for laboratories holding a Certification from the Miami-Dade County Department of Regulatory and Economic Resources, Product Control Section.

1.2 Definitions:

a) Laboratory Certificate: An approval document issued by Miami-Dade County's Department of Regulatory and Economic Resources, Product Control Section to testing laboratories performing tests and listing the tests that can be performed. Approved engineers for laboratories are also listed on the Laboratory Certificate.

b) Laboratory Quality Assurance Manual: Documentation made up of the laboratory's Quality policies, organizational structure, and responsibilities of key staff.

c) Quality Assurance Audit: Assessment to the organizational compliance of specific requirements to determine if quality control processes are effectively implemented and maintained.

1.3 **Reference Documents:**

a) ISO/IEC/EN 17025 Guide

b) Florida Building Code, Testing Application Standard (TAS 301-94) HVHZ

c) Section 8-40 of the Code of Miami-Dade County

d) Miami-Dade County Administrative Order 10-3

d) Chapter 9N-3.008(5)(d)F.A.C.

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2.0 DOCUMENTATION REQUIREMENTS

2.1 A Quality Assurance Manual shall be provided by the applicant and contain a management statement on its policy, objectives for, and commitment to, quality. Evidence shall be provided that approved methods for test/calibration are being used under a Quality Assurance Program.

2.2 The Quality Assurance Manual shall clearly identify the Laboratory's name, street address, phone-number(s), email address, and contact information for the member of the organization identified in 3.1.

2.3 The Laboratory's organizational and management structure shall be included within the Quality Assurance Manual.

2.4 The Laboratory shall operate under a documented Safety Control Program.

3.0 PERSONNEL, RESPONSIBILITY AND AUTHORITY

3.1 The Quality Assurance Manual shall appoint a member of the organization, irrespective of other duties, that shall have responsibilities and authority that includes but not limited to:

3.1.1 Ensuring that The Quality Assurance Program is established, implemented, and maintained.

3.1.2 This person shall have direct access to top management.

3.1.3 The job description of personnel assigned to the Quality Assurance Program.

3.2 The Quality Assurance Manual shall include a policy statement on the qualifications and training of technical personnel involved in the test and calibration processes.

3.3 The Laboratory shall provide evidence that a Florida Registered Professional engineer is part of the Laboratory's permanent staff or under contract and that said engineer does not have any financial interest with the products being tested.

3.4 Records of relevant qualifications, training, skills and experience of technical personnel shall be maintained by the laboratory.

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4.0 DOCUMENTATION REQUIREMENTS AND MANAGEMENT REVIEW

4.1 The Quality Assurance Program needs to provide means to ensure that the Quality Assurance Manual is reviewed at planned intervals not to exceed 12 months to ensure the continuing suitability, adequacy and effectiveness of the system.

4.2 The Quality Assurance Program shall also provide means to ensure that changes or revisions to the Quality Assurance Manual are controlled to ensure that only current documentation is used in processes directly affecting the quality system.

5.0 TECHNICAL REQUIREMENTS

5.1 The Laboratory shall document methods and procedures before, during and after the test inside or outside its facility within the scope of tests in the laboratory certificate.

5.2 The Laboratory shall have a documented inventory of all the equipment required to perform tests and/or calibrations including name, model number and serial numbers.

6.0 SAMPLING

6.1 The sampling of tested products shall include the identification, handling, transporting, packaging, protection, disposal, and reference to any applicable standard used.

7.0 ACCOMODATIONS AND ENVIRONMENTAL CONDITIONS

7.1 The Laboratory's environmental condition shall not affect the outcome of any tests performed. If any environmental condition exist for a particular test that condition shall be documented together with the project file.

7.2 The Laboratory shall ensure that proper accommodations are established to facilitate accurate testing.

7.3 The Laboratory's safety procedures shall be established in accordance with the regulatory standards and the safety procedures used for the test.

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8.0 EQUIPMENT, CALIBRATION & VERIFICATION

8.1 The Laboratory test equipment and other equipment shall be kept clean and free of debris. Equipment shall be cleaned and maintained in accordance with the manufacturer's specifications.

8.2 Laboratory equipment shall be operated only by the qualified personnel.

8.3 Testing equipment shall be calibrated in accordance with the manufacturer's schedule and requirements. Equipment requiring calibration shall be identified with its corresponding label.

8.4 Laboratory shall ensure that all the equipment is calibrated and prevent the usage of any out of calibration equipment engaged in any testing activity.

8.5 The use of independent calibration of equipment shall be traceable to nationally recognized standards when appropriate. When the calibration is performed by the Laboratory, the procedures used shall be traceable to international standards or national measuring standards. Where no such standards exist or the calibration is done by computer software, the basis used for the calibration or verification shall be recorded.

8.6 The Laboratory shall provide means to ensure that subcontracting of tests and/or calibrations are done with the use of competent and approved contractors.

8.7 Records of the result of the calibrations shall be maintained with calibration certificates.

9.0 CONTROL OF DOCUMENTS AND RECORDS

9.1 The Quality Assurance Manual shall establish a documented procedure for the identification, storage, protection, retrieval, retention time, and disposition of records.

9.2 Records shall be maintained to provide evidence of conformity to standards requirements. Records shall remain retrievable and legible. Records shall be available at the request of officials during inspections.

9.3 Records of test result and amendment letters to any test report shall be kept a minimum of (10) years.

9.4 All records pertaining to audits, calibration certificates, training, and complaints, shall be maintained for a minimum of four (4) years.

9.5 Reports of test results shall include information such as, but not limited to: client information, specimen identification, standards used to perform the test, date when the test was performed, calibration date, calibration agency when applicable, and signature and seal of professional engineer listed on the laboratory certificate.

9.6 Laboratory shall have a procedure to notify clients or other entities whenever notification is required by the authority having jurisdiction prior to conducting a test.

10.0 QUALITY AUDITS AND INSPECTIONS

10.1 The Quality Assurance Manual shall specify the frequency of the quality audits and inspections that are conducted by third-party agencies. The Laboratory shall use the records of audits and inspections to demonstrate its ability to correct and prevent nonconformance issues.

10.2 The laboratory shall expect and allow unannounced visits from the authority having jurisdiction on the facilities holding a Laboratory Certificate from the Miami-Dade County Product Control Section.

10.3 All corrective action responses, when requested, shall be addressed in writing to the Miami-Dade County Product Control Section. Corrective actions taken shall eliminate the cause of nonconformity recurrence.

11.0 NONCONFORMING TEST AND COMPLAINTS

11.1 All complaints involving Miami-Dade County approved laboratories brought by a Building Official, manufacturer, customer or member of the general public, shall be addressed and documented by the laboratory. All complaints shall be investigated and submitted to the Miami-Dade County Product Control Section addressing the root cause of the problem and the corrective action.

11.2 Any suspect test results or data from a test verified to be incorrect, or any portion of the testing found not to conform to the test method shall be immediately defined as invalid and any corrective action will be specified.