# QUALITY ASSURANCE MANUAL GUIDELINES FOR MIAMI-DADE COUNTY APPROVED MANUFACTURERS

## 1. SCOPE

1.1 This guideline defines the overall requirements for documenting the quality assurance program of manufacturers holding a Notice of Acceptance issued by the Miami-Dade County Department of Regulatory and Economic Resources, Product Control Section.

### 1.2 DEFINITIONS

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| a) NOA: | A document prepared by the Department of Regulatory and Economic Resources, Product Control Section accepting the applicant's request. Notices of Acceptance are only issued to manufacturers of a product and/or a system. |
| b) Quality Assurance Manual: | The documentation which comprises the quality assurance program. |
| c) Quality Assurance Entity: | Quality assurance entity means an entity approved by the Florida Building Commission pursuant to subsection 61G20-3.008(5)(d), F.A.C., to provide oversight and determine that the product or system is being manufactured or assembled, per the submitted description, test results, or calculations to establish continual product performance. |

### 1.3 REFERENCE DOCUMENTS:

a) Section 553.842 Florida Statutes

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

c) Miami-Dade County Administrative Order 10-3

d) Chapter 61G20-3.008(50(d)F.A.C.

e) ANSI / ISO / ASQ Q9001:2015 guide

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## 2.0 QUALITY MANUAL

2.1 A Quality Assurance Manual shall be provided by the applicant and contain a management statement on its policy, and objectives for, and commitment to, quality. Evidence shall be provided that approved products, methods, or systems of construction are being manufactured under a Quality Assurance Program.

2.2 Each manufacturing site shall have a Quality Assurance Manual. The Quality Assurance Manual shall clearly identify the manufacturer's name, street address, phone-numbers, email address and legal status and contact information for the member of the organization identified in 3.1.

2.3 In the event that several manufacturing sites exist for one company, and the same manufacturing processes exist for each manufacturing facility, it is acceptable to submit one Quality Assurance Manual. This shall not preclude said company from providing separate Quality Assurance Manuals for each plant.

2.4 If a Quality Assurance Manual is submitted for all manufacturing facilities that produce Miami-Dade County approved product(s); then that Quality Assurance Manual shall specify the NOA number and the description of the NOA product.

2.5 The Quality Assurance Manual shall require that the Product Control Section be notified of any and all changes to the manufacturer's legal status, address, contact persons and their phone numbers, and/or the location of manufacturing for each NOA.

## 3.0 PERSONNEL, RESPONSIBILITY AND AUTHORITY

3.1 The Quality Manual shall define and indicate a member of the organization, irrespective of other duties, that shall have responsibilities and authority that includes:

3.1.1 Ensuring that processes are established, implemented and maintained,

3.1.2 Reporting and resolving quality assurance issues related to third parties on matters related to the quality assurance program.

3.1.3 This person shall have direct access to top management.

3.1.4 There shall be a management statement assigning the person designated in Section 3.1.

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3.1.5 There shall be a relevant job description of personnel assigned to the quality assurance program.

3.1.6 There shall be a policy statement on qualification and training of personnel.

## 4.0 DOCUMENTATION REQUIREMENTS

4.1 The Quality Assurance Program needs to provide means to ensure that the Quality 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 Manual are controlled to ensure that only current documentation is used in processes directly affecting the quality system.

## 5.0 IDENTIFICATION AND TRACEABILITY

5.1 The Quality Assurance Manual shall provide consideration to the quality control of approved products and it shall clearly identify them in accordance with the product approval NOA.

5.2 The Quality Assurance Manual shall control and record how the product is to be identified. The Quality Manual shall clearly identify how products comply with label requirements consistent with the information noted in the labeling section of the NOA.

5.3 The Quality Assurance Manual shall provide means for the finished product to be traced back to the production and quality control records at the manufacturing facility.

## 6.0 PRODUCT REALIZATION

6.1 The Quality Assurance Manual shall include a production flowchart or a description of production methods, describing the process by which the product is manufactured.

6.2 The Quality Assurance Manual shall contain products description, specifications, assembly drawings and manufacturing tolerances.

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6.3 The Quality Assurance Manual shall ensure that product realization is conducted according to planned and developed processes needed to achieve conformity to product requirements.

### 7.0 QUALITY AUDITS AND INSPECTIONS

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

7.2 All third-party audit or inspection reports, when applicable, are to be filed with the Product Control Section no later than ten (10) days after the actual date in which they were conducted.

7.3 All corrective action responses when requested are to be addressed in writing to the Product Control Section. Corrective actions taken shall eliminate the cause of any nonconformity in order to prevent recurrence.

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

7.5 A copy of the entire NOA shall be available and provided to the auditor and/or inspector upon request at the manufacturing facility, distribution center, or at the field.

### 8.0 CONTROL OF INCOMING MATERIALS

8.1 The manufacturer shall define the process(s) used for verifying that the purchased products conform to the requirements established in the Miami-Dade County Notice of Acceptance (NOA).

8.2 It shall be the responsibility of the manufacturer to retain all purchasing records of incoming materials including but not limited to; inspection and mill test reports, certificates of compliance, measurements, etc… The manufacturer shall have these records readily available for inspection.

### 9.0 PRESERVATION OF PRODUCT

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9.1 The manufacturer shall provide means to ensure the conformity of the product and its constituent parts including identification, handling, packaging and protection.

### 10.0 CONTROL OF NONCONFORMING PRODUCT

10.1 The manufacturer shall provide means to ensure that product that does not conform to the product requirements is identified and controlled to prevent unintended use or delivery of a nonconforming product.

10.2 The control of nonconforming products shall be defined in the documentation system.

10.3 All nonconforming products shall be segregated from production until disposition of the product is made by a relevant authority.

### 11.0 MONITORING AND MEASUREMENT OF PRODUCT

11.1 The quality manual shall provide for means to determine the monitoring and measurements to be undertaken, and the monitoring and measuring devises needed to provide evidence of product conformity to predetermined requirements.

11.2 Where necessary to ensure valid results and measurement, the manufacturer shall identify adequate measuring and test equipment. Equipment shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measuring standards. Where no such standard exist or the calibration is done by a computer software, the basis used for calibration or verification shall be recorded.

### 12.0 CONTROL OF DOCUMENTS AND RECORDS

12.1 The Quality Manual shall ensure that all documents and records related to the quality assurance of the product are controlled. All documents shall be legible and readily identifiable.

12.2 Records shall be maintained to provide evidence of conformity to product requirements. Records shall remain retrievable and legible.

12.3 The manufacturer shall establish a documented procedure for the identification, storage, protection, retrieval, retention time and disposition of records.

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12.4 All records pertaining to third-party audits and inspections shall be maintained for a minimum of three (3) years.

12.5 Advertising of a Miami-Dade product approved on any media shall be in compliance with the NOA page requirements. The NOA number shall always be preceded the words Miami-Dade County, Florida, and followed by the correspondent expiration date. If displayed, the NOA document shall be shown in its entirety.

### 13.0 CONTROL OF DESIGN AND DEVELOPMENT CHANGES

13.1 Design and development changes for product that have been issued an NOA shall be identified, and records shall be maintained. All changes shall be reviewed, verified and issued a revised NOA by the Miami-Dade County Building Code Compliance Product Control Section before implementation.

13.2 Records of the result of the review of changes and any necessary actions shall be maintained for a minimum of ten (10) years.