**Form Q-21**

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| Date of Qualifying Inspection: | |  | | | | Name(s) of the Inspector(s): | |  | | |
| Name of the Third-party Inspection Agency: | |  | | | | | | | | |
| ICC-ES Report, Listing or File No.: | | | | |  | | | | | |
| Name of the Applicant: | |  | | | | | | | | |
| Address of the Applicant: | | |  | | | | | | | |
|  | | | | | | | | | | |
| Contact Person and Title: | | |  | | | | | | | |
| Phone: |  | | | Fax: | | |  | | E-mail: |  |

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| Name of Inspected Facility (if different from applicant): | | |  | | | | | |
| Address of Inspected Facility (if different from applicant): | | |  | | | | | |
| Product(s) Inspected: | | |  | | | | | |
| Manufacturer’s Representative and Title: | | | |  | | | | |
| Phone: |  | | | Fax: | |  | E-mail: |  |
| Signature of Manufacturer’s Representative: | | | | |  | | | |
| Signature(s) of Inspector(s): | |  | | | | | | |

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| *Use this space to record names and titles of persons present at opening meeting:* |
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| *Use this space to record names and titles of persons present at closing meeting:* |
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| Name of the ICC-ES Staff Person Reviewing the QC Documentation: |  |

Initials Date

**Instructions**

**Introduction:** This qualifying inspection report is for evaluating whether the manufacturer has effectively implemented the quality system described in the manufacturer’s quality system documentation. Inspectors should note that they are to end the inspection immediately if it becomes apparent, early in the process, that the manufacturer is not actually ready to be inspected.

**The Qualifying Inspection:** During the inspection, indicate, in Part A, whether the information provided to ICC-ES and copied to the inspector is accurate, and in Part B whether the manufacturer has actually documented and implemented a quality system that meets the noted specific requirements of AC10 (the ICC-ES Acceptance Criteria for Quality Documentation). Check “Yes” if the required documentation exists and is effectively implemented. Check “No” if the documentation is lacking or is not effectively implemented.

If the inspector writes “No” in any section of the report, an explanatory comment needs to be included.

**It is important to note that the inspector is responsible not only for determining if the specific areas of the quality system are implemented, but also for determining if the implemented process is reasonably effective. The inspector needs to have objective evidence that the manufacturer’s quality assurance process ensures that product quality is consistent and acceptable. If the manufacturer is unable to provide to the inspector evidence of effective implementation of the quality system, corrective action must be requested.**

**The Report:** The inspector will complete the attached report during the inspection. If there is a deficiency (finding), the finding will be detailed in the inspection report, and a Corrective Action Request (CAR) will be issued. CARs will clearly state what is required by AC10 and the quality system and what the inspector actually found. The Qualifying Inspection Report must be signed by the manufacturer’s representative and the inspector. A copy of the report (form Q-21) will be given to the manufacturer at the conclusion of the inspection. A copy of the completed Q-21 form (or an equivalent) must be forwarded to appropriate ICC-ES personnel by the inspector.

**Resolution of CARS:** The manufacturer must respond to each CAR noted on this form within 30 days of the inspection. CARs related to Part A of this form must be resolved by the manufacturer and/or report holder to the satisfaction of appropriate ICC-ES staff. CARs related to the quality system (Part B of this form) must be resolved by the manufacturer to the satisfaction of the inspector. ICC-ES reserves the right to require a reinspection when such is deemed necessary.

When applicable, the inspector shall note any deviations from this inspection instruction in the Summary of the Inspection section.

Indicate in the appropriate section below whether the information provided by ICC-ES on Form Q-20, relating to Items 1 through 8 of Appendix A of AC10, is accurate. Note any discrepancies in the space provided.

**The inspection should not be conducted until the inspector has received a Form Q-20 from ICC-ES. Date of Q-20:**

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| **APPENDIX A INFORMATION** | **INFORMATION VERIFIED**  **DURING INSPECTION**  **(YES/NO)** | **DESCRIPTION OF DOCUMENTATION**  **USED TO VERIFY** | **DATE OF DOCUMENT USED TO VERIFY** |
| 1. Product name | **Yes No** |  |  |
| 2. Components or constituents | **Yes No** |  |  |
| 3. Manufacturing location(s) | **Yes No** |  |  |
| 4. Manufacturing process | **Yes No** |  |  |
| 5. Specifications | **Yes No** |  |  |
| 6. Quality testing | **Yes No** |  |  |
| 7. Inspection agency  (when applicable) | **Yes No** |  |  |
| 8. Product labeling | **Yes No** |  |  |

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| |  | | --- | | Note discrepancies here (please do not shade this area): | |

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| **2.1.1** | Is the quality system documentation signed and dated by an authorized representative of the manufacturer? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.2** | Are the facility street address, telephone number and contact person noted in the documentation correct? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.3** | Does the manufacturer have provisions for reviewing the quality system documentation? (It is required to be reviewed a minimum of once every two (2) years) Are there provisions for documenting revisions to the quality system? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.4** | Is the product labeling consistent with what is described in the quality documentation and in Item 8 on Form Q-20? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.5** | Using the identification that is applied to the finished product, conduct a traceability study by taking a finished product and tracing it back to the production and quality control records. Is traceability adequate?  List identification used in Comments section below (Applicable only to listing report for Canadian certification). |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.6** | Is the product flowchart or description of production methods contained in the quality documentation representative of the actual production flow and process, and consistent with information noted in Item 4 on Form Q-20? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.7** | Does the quality documentation have provisions for documenting of product changes, evaluation of product changes and notification of the appropriate parties? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.8** | Does the quality documentation include an organizational chart and are the duties and responsibilities of key positions in the quality program identified? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.9** | Does the quality documentation contain necessary information about packaging and storage, if such information is critical to product performance? |  |  | **Yes No** |

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| **Comments:** |

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| **2.1.10** | Does the manufacturer have a process (1) for keeping records of all significant complaints about the product(s) covered in the evaluation report; (2) for taking appropriate action with respect to such complaints; and (3) for documenting the actions taken? |  |  | **Yes No** |

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| **Comments:** |

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| **2.2** | Does the manufacturer have documented procedures for inspection or testing of incoming materials? Are they conducting the inspections and tests as required? Are the procedures and actions consistent with Item 6 of Form Q-20? |  |  | **Yes No** |

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| **Comments:** |

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| **2.3** | Is the manufacturer conducting inspections and tests, as required in the quality documentation, for in-process quality control? Do these inspections or tests appear to be effective in ensuring consistency of product quality? Are the procedures and actions consistent with Item 6 of Form Q-20? |  |  | **Yes No** |

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| **Comments:** |

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| **2.4** | Is the manufacturer conducting the final inspections or tests, as required in the quality documentation, prior to final approval and labeling of the finished product? Do these inspections and tests appear effective in ensuring that the product receiving the label complies with the applicable specifications and design values? Are the procedures and actions consistent with Item 6 of Form Q-20? |  |  | **Yes No** |

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| **Comments:** |

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| **2.5** | Are nonconforming materials segregated from conforming materials as directed in the quality documentation? Is there a specific area for quarantine of noncompliant material (whether it is raw material, in-process material or finished material) that did not meet the minimum specifications? |  |  | **Yes No** |

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| **Comments:** |

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| **2****.6.1** | Does the manufacturer maintain a list of critical measuring and test equipment? Does this list include all the critical measuring and test equipment that is in use? |  |  | **Yes No** |

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| **Comments:** |

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| **2.6.2** | Is the critical manufacturing and test equipment from item 2.6.1, above, properly calibrated at the intervals stated in the quality documentation? Is there traceability to nationally recognized standards when appropriate? Are the calibration and maintenance records readily available?  List the equipment and calibration date reviewed during inspection in the Comments section below (Applicable only to listing report for Canadian certification). |  |  | **Yes No** |

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| **Comments:** |

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| **2.7.1** | Is the manufacturer actually using the forms, checklists and reports identified in the quality documentation for recording manufacturing and quality processes? |  |  | **Yes No** |

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| **Comments:** |

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| **2.7.2** | Are the quality records as noted in 2.7.1, above, approved by responsible personnel as required by the quality system? |  |  | **Yes No** |

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| **Comments:** |

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| **2.7.3** | Are all manufacturing and quality records maintained for a minimum of two years? (Examples of these records include reports resulting from the manufacturer’s own product tests and/or inspections.) |  |  | **Yes No** |
| **Comments:** | | | | |

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| **Summary of the Inspection** |
| Was the inspection conducted **remotely**? YES  NO  If “YES”, did technology used allow you to achieve your inspection objectives?  YES  NO\*  (\*Please provide details )  Inspector should note general observations on the manufacturer’s quality system, facility and product manufacturing process.  *(Please do not shade this area)* |

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**CORRECTIVE ACTION REQUEST NO.**

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| AC10 Section: | Quality Documentation (Doc. and Page No.): | Document Date: |
| Details of Inspection Findings | | |

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| Requirement: |
| Findings: |

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| Requirement: |
| Findings: |

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| Requirement: |
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(Make additional copies, if needed)