OmniAir Certification Program Policies Manual, V 2.1

Reference Identification

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Approval and Revision History

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Document Owner – Executive Director of OmniAir

Endorsement Notice:

The contents of this document have been approved by the Board of Directors of the OmniAir Consortium in its entirety. (Holder statement until approval given)

Contents

Foreword

OmniAir Consortium is a 501(c) (6) nonprofit trade association advancing the deployment of standards-based, interoperable wireless transport technologies that improve mobility, safety and efficiency on ground transportation networks. Members include Connected Vehicle, Intelligent Transportation Systems (ITS) and Road Tolling technology device manufacturers, ITS deployers, automotive OEMs and suppliers, testing laboratories and other stakeholders, all promoting the proliferation of certified, interoperable devices. OmniAir Consortium is the owner of a family of conformity assessment certification programs for specific intelligent transportation industry products.

For the certification programs under its ownership, OmniAir Consortium appoints the responsibility of conformity assessment certification activities management and operation to the OmniAir Technical Director. Private or government entities such as IBTTA, USDOT, ITS America, SDOs (Standards Development Organizations), or State DOTs may appoint or contract OmniAir as the certification body for other specific certification programs. These certification body activities include exclusive certification decision review of evidence and issuance of "OmniAir Certified" Certifications to devices that fully demonstrate conformance to a certification program's specific requirements.

This ISO/IEC 17065 based document has been prepared by the collaborative volunteer members of the OmniAir Consortium Certification Working Group.

1.0 Purpose and Scope

The concept of impartial, third-party certification is to provide attestation of a product's conformance with standards based requirements through an objective evaluation. ISO/IEC 17065 is internationally recognized as the publication establishing conformity assessment – certification body requirements.

This document, the OmniAir Program Policies Manual, has foundational elements and formatting based on ISO/IEC 17065. The document's purpose is to define product certification program policies and procedures for all OmniAir owned or appointed certification programs with the goal of providing competent, impartial and consistent certification. The various individual programs may be governed by additional published manuals along with this overarching document.

OmniAir Certification and the "OmniAir Certified" Trademark in no way imply conformance to other product assessments such as those for regulatory conformance, cellular network conformance, environmental, durability or reliability testing, product safety or other consortia certifications. However, other certifications or evidence of conformance may be required to fulfill OmniAir certification program requirements.

The key objective of OmniAir certification is to provide confidence that a product bearing the OmniAir Certified Trademark:

- Fulfills program specified mandatory requirements.
- Has basic interoperability with other products implementing specific similar protocols or features.
- Can be used as evidence of device maturity in procurement processes.
- Is a differentiating factor for manufacturers whose products are certified by OmniAir.

Other related benefits

- Speeding market acceptance of the technology by establishing industry-wide, common performance requirements to which new devices must conform.
- Inform end users' considering their purchasing decisions, and contribute to market acceptance.

2.0 Normative References

The following referenced documents are necessary for the application of the present document and to assist the user with regards to a particular subject area.

[1] ISO/IEC 17000, “Conformity Assessment – Vocabulary and general principles”.

[2] ISO/IEC 17020, “Conformity Assessment – Requirements for the operation of various types of bodies performing inspection”.

[3] ISO/IEC 17065, “Conformity assessment – Requirements for bodies certifying products, processes and services”.

[4] ISO/IEC 17067, “Conformity Assessment – Fundamentals of product certification and guidelines for product certification schemes”.

[5] ISO/IEC 17025, “General requirements for the competence of testing and calibration laboratories”.

[6] OmniAir Authorized Test Laboratory Program Manual

[7] OmniAir Certification Mark Production and Usage Guidelines

[8] OmniAir Manual for Document Management

3.0 Terms, Definitions and Abbreviations

The following terms and definitions for this document are drawn from ISO/IEC 17000, ISO/IEC 17065, and ISO/IEC 17067.

3.1 Terms and Definitions

Applicant – The legal entity or individual who applies for the certification of a specified product. This party is contractually and financially responsible for the cost of the conformity assessment evaluation process. This entity also has rights on the information generated during the evaluation and the authority to withdraw a certification listing. An applicant must be a member in good standing with the OmniAir Consortium.

Authorized Test Laboratory – An independent entity or entities authorized by OmniAir to execute testing for applicants for the certification program. The Authorized Test Laboratory is listed according to the specific certification programs for which it has been evaluated and found to meet OmniAir authorization requirements.

Certification Agreement – A legally binding and enforceable agreement between the applicant and the certification body in regards of party responsibilities, legal considerations and certification activities.

Certification Body – A legal entity or defined team within a legal entity which functions as a third-party conformity assessment body and operates certification programs.

Certification Requirement – Specified requirements established by the certification body or certification program that shall be fulfilled by the applicant as a condition for establishing or maintaining certification. These may also include product requirements.

Certification Review Board (CRB) – The OmniAir Consortium's appointed and authorized group that functions as an advisory and operational review board for OmniAir certification programs. The CRB may advise on aspects of interpretation of the OmniAir Program Policies Manual, the individual certification programs and general knowledge of certification bodies, operation of certification programs or laboratory testing activities. CRB responsibilities can include review and mitigation of confidentiality practices, reported unsatisfactory feedback, and appeals resolution. Members of the CRB are a diverse representative pool to assure that one area of interest does not dominate.

Certification or Conformity Assessment Program – The specific foundational governance, procedures and management to conduct conformity assessment of a product to standards based requirements.

Certification Owner – The organization or individual responsible for the developing and maintaining a specific certification program.

Certification Staff – Collective term for OmniAir staff or staff under OmniAir organizational control or under contract who directly participate in OmniAir certification activities. This includes Executive Director, Technical Director, inspection and administrative support personnel.

Certification Working Group – Entity that develops policies relating to the operation of the certification body, the individual certification programs and defines the operational guidelines and processes.

Conformance Requirement –Specified requirements established by the certification body or certification program that shall be fulfilled by the applicant as a condition for establishing or maintaining certification. These may also include product requirements directly applicable to a product or its implementation features.

Conformity Assessment – The activities determining a product's compliance with defined and relevant requirements.

Consultancy – The act of assisting with the design, manufacturing, installing, maintaining, or distributing of an OmniAir certified product or a product submitted for OmniAir certification.

Evaluation – May include activities such as the initial application information gathering, the development of a test plan, the performance of testing, the witnessing of testing, and all other activities associated with evaluating compliance of a product with the applicable requirements, including any evaluation activities performed prior to the certification application.

Executive Director -- OmniAir staff position whose responsibilities include managerial responsibilities of OmniAir personnel including the Technical Director, Marketing and Administrative staff, review of the Certification Decision Report prepared by the Technical

Director and has sole signatory authority for granted certification certificates. The Executive Director also supervises the finances of the OmniAir Certification programs.

Impartiality – An objective status with freedom from conflicts of interest, bias, and prejudice to promote neutrality and fairness.

Product – A manufactured electronic submitted for conformity assessment. This can be a device, integration, module, re-labeled device or variant. See individual conformity assessment certification programs for further definition.

Product Requirement – A requirement that is specified in standards, normative documents or a certification program that is directly applicable to a product or its implementation features.

Qualified Test Equipment (Test Systems and Test Tools) – Test systems and test tools designed and verify the requirements' functionality and conformance used by authorized test laboratories. The test systems and test tools are validated and certified by OmniAir's subject matter expert(s) and engineering practices to the standards and requirements.

Surveillance Personnel – Competent persons who perform the surveillance procedures as defined by the certification body and/ or the program.

Technical Director – OmniAir Certification Staff position whose responsibilities include day to day operation of OmniAir certification programs, oversight of OATL application, authorization and continued fulfillment of OATL contractual obligations, interpretation of program requirements, review of applicant provided information, delivering a certification requirement fulfillment decision, issuance of certification letters and OmniAir Certified Trademark usage authorization.

In this Program Policy, the following verbal forms are used:

"Shall" indicates a requirement.
"Should" indicates a recommendation.
"May" indicates permission.
"Can" indicates a possibility or a capability.

3.2 Abbreviations

CRB	Certification Review Board
DOT	Department of Transportation
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Organization for Standardization
ITS	Intelligent Transport Systems
OATL	OmniAir Authorized Testing Laboratory
OA - CPPM	OmniAir Certification Program Policies Manual
OQTE	OmniAir Qualified Test Equipment
SAE	Society of Automotive Engineers
SDO	Standards Development Organization4.0 General Requirements

4.0 General Requirements

4.1 Legal and Contractual Matters

4.1.1 Legal Responsibility

OmniAir Consortium is the legal entity responsible for all certification activities it has authorized or delegated to the Technical Director to operate and manage.

4.1.2 Certification Agreement

4.1.2.1 OmniAir Consortium shall create a legally enforceable Certification Agreement for the provision of defining the rights, terms, conditions and responsibilities of both OmniAir and the applicant, which will contract with OmniAir for the certification activities. The Certification Agreement may vary in content and appropriateness based on the individual certification program.

4.1.2.2 OmniAir Consortium Certification Agreements are framed to include applicable ISO 17065 Section 4.1.2.2 applicant compliance requirements. These requirements may also include reference and conformance to a specific certification program. A Certification Agreement is a required element of a certification application and shall be executed prior to commencement of any OmniAir certification activities.

4.1.3 Use of License, Certificates and Marks of Conformity

4.1.3.1 OmniAir Consortium owns the rights, control of usage, intellectual property and registered trademarks associated with OmniAir and/or OmniAir Certified Trademarks indicating a device is certified. Permitted usage is subject to the terms of the specified certification

agreement, certification program and the OmniAir Certification Trademark Production and Usage Guidelines.

4.1.3.2 OmniAir Consortium shall oppose and take action against incorrect, misleading or fraudulent references of a device meeting program requirements, certification, or usage of certification marks. This applies to incorrect claims on websites, marketing brochures, product packaging, documentation and/or claims in a public forum. Incorrect usage or observed infringement of OmniAir certification or its trademarks can be reported using the OmniAir Feedback, Appeal and Dispute Incident Reporting Form.

4.2 Management of Impartiality

4.2.1 Impartiality shall be exercised for all OmniAir certification activities and a mechanism for safeguarding impartiality is further defined in Section 5.2 of this document.

4.2.2 Commercial, financial or other circumstances shall not interfere with the responsibility or execution of impartial OmniAir certification activities.

4.2.3 The Technical Director shall identify risks to impartiality or potential conflicts of interest that could affect certification body responsibilities. Process activities, organizational relationships and personnel relationships will be actively monitored. CRB members will be asked to provide impartiality risk input at annual impartiality review meetings.

4.2.3.1 Disclosure is a key element in evaluating impartiality risk. The Technical Director, individual members of the CRB or other OmniAir staff under its organizational control shall self-review, monitor and disclose actual or potential threats to impartiality to certification activities or management of a program.

4.2.4 Should an impartiality risk be identified that has not already been previously addressed by OmniAir policy, the Technical Director shall document in Annex A Impartiality Management Addendum and devise steps to eliminate or minimize the identified risk. Any Annex A additions will be discussed at the next CRB review meeting or as need determines.

Identified Risks to impartiality, conflicts of interest and objectivity which could cause real or perceived bias in conducting certification responsibilities and activities include:

a) Self-interest.
b) Self-review (conflicts from previous certification evaluations or consultancy).
c) Representation (advocacy -- paid or voluntary) for or against an applicant of OmniAir certification.
d) Previous familiarity (using past involvement /knowledge rather than evaluating objective evidence and result).
e) Intimidation (real or perceived threats of consequence).

f) Competition (between applicant and OmniAir legal entity or OmniAir representative).

4.2.5 The Technical Director and the top level OmniAir executive management providing oversight shall be committed to impartiality of OmniAir certification activities.

4.2.6 OmniAir staff and personnel of legal entities under its organizational control involved with a specific certification application, review or decision shall not without prior authorization:

a) Be the designer, manufacturer, manufacturer of a competitive product, installer, distributer or maintainer of the applicant certified product.
b) Provide consultancy to the applicant of the product submitted for OmniAir certification.
c) Provide management system consultation or auditing to the applicant of the product submitted for OmniAir certification.

4.2.7 The Technical Director shall ensure that relationships established with separate legal entities or entities within OmniAir do not compromise the impartiality of certification responsibilities and activities.

4.2.8 In the situation where the separate legal entity in 4.2.7 produces an OmniAir certified product (including products submitted for OmniAir certification) or provides consultancy, the Technical Director, OmniAir executive management and persons involved with certification application, review, and decision activities shall not be affiliated with the separate legal entity. Likewise, personnel of the separate legal entity shall not participate with the management, application, review and decision activities of OmniAir certification programs or processes.

4.2.9 The OmniAir certification activities shall not be marketed or offered in conjunction with the consultancy services of OmniAir legal entities or separate legal entities. The Technical Director, staff involved with certification activities, publicly available information or marketing material shall not imply or declare a potential or real benefit of achieving OmniAir certification through usage of a specified consultancy service.

4.2.10 In past activities, should the Technical Director or staff involve with certification activities provided consultancy services on a particular OmniAir certified or submitted for certification product, this individual is prohibited from participating in the application, review or decision activities of the product or other products submitted by the same applicant organization for a period of one (1) year from the date of termination of the pre-existing relationship. CRB will address if conflict of interest occurs.

4.2.11 The Technical Director shall take action to address any risk to its certification activity impartiality arising from other persons, enterprises or organizations.

4.2.12 All OmniAir staff, personnel of entities under OmniAir's control, OmniAir Working Groups or Committees who could influence OmniAir certification shall practice and act impartially.

4.2.12.1 Violations of the impartiality policy are considered a serious matter. Reported incident or allegation of violating the impartiality policy involving the Technical Director or staff under OmniAir organizational control or involved with the certification activities will be thoroughly investigated through the CRB and, if confirmed, may result in disciplinary action including possible termination.

4.3 Liability and Financing

4.3.1 The certification activities of the OmniAir Consortium shall have adequate resources such as insurance policies or reserve funds to address potential operational liabilities that could arise from its activities.

4.3.2 The OmniAir Certification activities shall have the resources and financial foundation necessary to conduct and operate its certification activities.

4.4 Non-discriminatory Conditions

4.4.1 The guidance policies and operational practices of the OmniAir certification programs shall be non-discriminatory and promote access of certification services to eligible applicants. The policies and practices should not create barriers to certification.

4.4.2 OmniAir certification shall be accessible to all eligible applicants whose submittals are within the scope of the certification programs for which OmniAir owns or is appointed.

4.4.3 The OmniAir Consortium is an industry collaboration organization promoting interoperability in transportation. The certification programs under its ownership shall be accessible to OmniAir Members in good standing or to non – OmniAir Members with an additional application fee equivalent to the Affiliate Membership rate.

Certification programs for which OmniAir enters into a contractual agreement as the appointed administrator and operator shall abide by the program's eligibility requirements for certification application or consideration.

4.4.4 The Technical Director and affiliated persons involved with OmniAir Certification activities shall follow program specific policies, procedures and requirements for application, evaluation, review, certification decision, and surveillance (if applicable).

4.5 Confidentiality

4.5.1 OmniAir Consortium through the specific program's Certification Agreement is legally committed to the requested confidentiality of the applicant. Proprietary marked information submitted for certification and certification communications, files and records will be considered confidential. Publicly available applicant, product information or specific information agreed to in writing information between the applicant and OmniAir are exempt from confidentiality consideration.

The identity of an applicant undertaking OmniAir certification along with applicant provided information, excluding information that is publicly available, is considered confidential. All certification activities are covered by the confidentiality provisions in the applicable OmniAir Certification Agreement and the individual certification programs.

The Technical Director shall notify the applicant in advance of releasing specific information regarding certification in a public forum.

4.5.2 Within a specific program Certification Agreement and the corresponding certification program manual indicate some information may be disclosed to third parties under certain conditions. Unless prohibited by law, the applicant or concerned party shall be notified of the information provided.

4.5.3 Information regarding an applicant, obtained from a source other than an applicant, such as a regulatory authority or publicly submitted feedback shall not be considered confidential information under this Section 4.5.

4.6 Publicly Available Information

OmniAir Certification Programs shall maintain and when requested provide information on the following:

a) Certification program information such as the process of submitting products for certification evaluation, the policy guidelines and actions for granting, for maintaining, for changing the scope of certification (modifications, additions or reductions), for denying, suspending or withdrawing certification.
b) General information on certification fees charged to applicants.
c) Information on the limitations and permitted use of certification documentation and OmniAir Certified Trademarks including the rights and responsibilities of applicants and Marks of Conformity.
d) Information on the process for handing feedback, incidents and appeals.

5.0 Structural Requirements

5.1 Organizational Structure and Top Management

5.1.1 To promote impartiality, OmniAir certification activities shall be framed and segmented accordingly.

5.1.2 OmniAir Certification programs are structured as follows:

OmniAir Executive Director -- The Executive Director has managerial responsibilities of OmniAir personnel including the Technical Director, Marketing and Administrative staff, review of the Certification Decision Report prepared by the Technical Director and has sole signatory authority for granted certification certificates. A formal organization chart is maintained by the OmniAir Executive Director.

OmniAir Technical Director – Responsibilities and duties are highlighted in Section 3.1 Terms and Definitions of this manual. The Technical Director is a certification fulfillment role and therefore segregated from financial transactions.

Administrative staff – Has certification responsibilities of documentation preparation and handling of financial transactions.

Certification Review Board – Certification Roles are defined in Section 3.1 Terms and Definitions of this Program Policies Manual.

5.1.3 Additional Authorities and Responsibilities for operating and maintaining certification body activities are defined below:

a) The Certification Working Group develops policies relating to the operation of the certification body; the individual certification programs define the operational guidelines and processes.

b) The Technical Director supervises the implementation of certification policies and procedures.

c) The Executive Director supervises the finances of the OmniAir Certification programs.

d) The Certification Working Group develops certification activities from a policy and process perspective for individual certification programs.

e) The Technical Working Group under Technical Director develops program conformance requirements, product features forms, test suites and procedures /use cases for programs.

f) OmniAir Authorized Test Labs are responsible for evaluation activities (see Section 7.4 of this document).

g) The Technical Director is responsible for review activities considering inspection, testing, informational documentation and reports as conformance evidence (see Section 7.5 of this document).

h) The Technical Director is responsible for the decision on certification and prepares the Certification Decision Report documenting the decision (see Section of this 7.6 manual).

i) The Executive Director and Technical Director have the authority to delegate tasks to committees or personnel, as required, to undertake defined activities for the certification programs.

j) The Executive Director has the authority and responsibility of contractual arrangements.

k) The Executive Director along with the OmniAir Board of Directors provision adequate resources for certification activities.

l) The Technical Director responds and handles reported feedback, incident and appeals.

m) The Executive Director and the Technical Director are responsible for personnel competence requirements.

n) OmniAir Consortium is responsible for the management system of the certification activities (see Section 8 of this manual).

5.1.4 When applicable or the need arises the Executive Director can appoint and delegate the Technical Director or CRB members as alternate signatories for agreements as long as confidentiality, impartiality provisions are maintained. This authority can be revoked at any time.

5.2 Mechanism for Safeguarding Impartiality

5.2.1 Technical Director shall adhere to the mechanism for safeguarding impartiality detailed in this section to maintain integrity and fairness with its appointed certification body activities. This mechanism includes:

a) The policies and practices pertaining to impartiality such as the appointment of mechanism members, maintenance of impartiality and keeping of records;
b) Preventing or limiting tendencies of commercial or other influences on the consistent and unbiased execution of certification responsibilities or activities;
c) Matters such as disclosure and openness that can affect impartiality and trust in the OmniAir certification activities and process.

5.2.2 The OmniAir Technical Director shall as an impartiality mechanism conduct an internal annual audit of the certification activities to evaluate:

a) Impartiality controls are implemented and effective.
b) The level of possible threat is acceptable.
c) Risk awareness is reinforced to certification staff.
d) Review of potential impartiality threats to identify compromise concerns.
e) The need for creation of an independent impartiality mechanism within the consortium consisting of members of the Certification Review Board, certification Working group of other members for a diverse stakeholder pool.

5.2.3 If the top management or certification staff does not follow the input from this mechanism, this mechanism shall have the right to initiate an independent audit investigation with the CRB to review practices and advise on appropriate or corrective measures. The confidentiality requirements of Section 4.5 of this OA-CPPM shall be followed in regards to involved parties.

Feedback from the mechanism that is in conflict with the operating procedures of the OA-CPPM should not be followed. The Technical Director should document and maintain a record of the items considered if not adopting or following input of the mechanism.

5.2.4 If this mechanism lacks a balanced proportion of viewpoints on impartiality, the Technical Director may extend invitations to suitable parties to participate in the impartiality mechanism's activities.

6.0 Resource Requirements

6.1 Certification Body Personnel

6.1.1 General

6.1.1.1 OmniAir shall have an adequate number of employees or contracted personnel to operate its owned or appointed certification programs.

6.1.1.2 The certification operations staff shall have the technical knowledge and experience necessary to carry out the responsibilities assigned to them including contributing to and implementing policies and making technical judgments.

6.1.1.3 Any personnel affiliated with OmniAir's certification activities shall keep confidential all information obtained or created for the purpose of conducting certification activities, except as

directed by the individual certification program or as required by law. All personnel can include, OmniAir Technical Director, certification support staff, committee members, persons of other organizations under the authority of or acting on behalf of OmniAir.

6.1.2 Management of Competence for Personnel Involved with the Certification Process

6.1.2.1 Management of Personnel Competencies Procedure will be developed.

6.1.2.2 OmniAir staff assigned to manage human resource responsibilities shall maintain the records described below on the personnel involved in OmniAir certification activities (see Section 7 of this manual):

a) Personal information of name and address.
b) A history of previous employer(s) and positions held.
c) Personnel records on educational qualification and professional credentials.
d) Applicable past experience, experience while employed by OmniAir and training.
e) An assessment of competence for certification program they support.
f) Performance reviews and appraisals.
g) OmniAir and certification program authorizations.
h) Generate and maintain the date of the most recent updating for each record.

6.2 Resources for Evaluation

6.2.1 Internal Resources

When evaluation activities using internal OmniAir resources or resources under its control are utilized the following International Standards shall provide the foundational basis.

Testing – If testing is performed internally within OmniAir as part of an evaluation, ISO/IEC 17025 shall be applicable. The specific certification programs will detail the evaluation policy and process of testing.

Inspection – When inspection is conducted as part of an evaluation or surveillance activity, ISO/IEC 17020 shall be applicable. The individual certification programs will detail the policy and process of inspection.

6.2.2 External Resources (Outsourcing)

6.2.2.1 OmniAir shall utilize an authorized test laboratory system of independent testing organizations to fulfill the evaluation functions of its certification programs. Testing shall be performed by a laboratory that is;
a) ISO 17025 accredited; or

b) Audited and authorized by OmniAir ensuring the quality system implemented is conformant with ISO 17025.
c) A member in good standing with the OmniAir Consortium.
d) Capable of demonstrating use of OmniAir Qualified Test System to OmniAir Test Specifications and maintains internal training records and documentation.

If audit and/or inspection services for certification surveillance are required per the individual certification program, the parties involved shall meet the applicable requirements of ISO/IEC 17020. These external resources and the associated evaluation staff shall adhere to the OmniAir impartiality policies. Please refer to The OmniAir Test Laboratory Authorization Program and individual certification programs for additional details.

6.2.2.2 OmniAir shall not outsource its certification testing activities to entities other than OmniAir Authorized Test Laboratories.

6.2.2.3 To facilitate the authorized test laboratory relationship, OmniAir shall have legally binding contracts with the OATLs. These agreements shall include content covering responsibilities, authorized scope of work, impartiality and confidentiality policies and practices.

7.0 Process Requirements

7.1 General

7.1.1 OmniAir owns (Certification Owner) or is appointed by non-OmniAir entities to operate conformity assessment certification programs for the purpose of conducting certification activities for said programs.

7.1.2 The requirements to which the submitted products of an applicant are to be evaluated are stated within specific certification programs, standards or normative documents.

7.1.3 The individual certification programs should provide explanation as to the applicability of identified normative documents and standards to the product requirements. If requested, OmniAir shall provide explanation or may refer inquiry to persons/organizations capable of providing explanation.

7.2 Application

The applicant shall contact OmniAir at www.omniair.org and complete the Contact Us Form or directly contact the Technical Director to request a specific certification program's Application Packet.

An Application Packet may include:

- Certification Application Instruction Letter.
- OmniAir Membership Evidence in Good Standing.
- Program Specific Application Form with Certification Agreement.
- Program Device Features & Use Cases Form.
- Invoice for OmniAir Application fee.
- List of OmniAir authorized OATLs for the specific program.

OmniAir shall request and obtain the required information to complete a test plan for program evaluation and testing activities. Required information may include:

- Executed Certification Agreement.
- Completed Device Features & Use Cases Form.
- Device Data Specification Sheet &/or Overview.
- User Manual and Operating Instructions (Laboratory).
- Internal and External Pictures of Device and Labelling.
- Hardware, Firmware & Application Software versions under Revision Control.
- Product Samples for Inspection, Validation and Repository (Laboratory).
- Evidence of additional certification, if available.
- Verification of payment of OmniAir Application Fee.

7.3 Application Review

7.3.1 The individual certification programs and the program specific Certification Application Instruction Letter shall describe the details of how and what required information to submit for the application review to further the certification activity.

7.3.2 The individual certification programs shall have a scope of applicable products to determine if an applicant product is outside of the specific program's scope. Information in the application packet shall also be evaluated to determine the level of OmniAir experience, knowledge of the product type or normative document to provide certification services.

7.3.3 OmniAir shall ensure certification staff has the technical competence and other certification body resources to conduct the certification activities it undertakes. This includes documenting the justification to commence certification activities and the creation of the applicable Test Plan for Conformance Testing.

7.3.4 Should OmniAir be presented with a certification application for which it lacks the required competence or capability, OmniAir shall decline the undertaking of this certification activity.

7.3.5 The individual certification programs shall address how previously granted certifications to a particular applicant are utilized for the purpose of omitting any certification activities. These actions and previous record references shall be documented. If requested by the applicant, OmniAir shall provide justification of such activity omission.

7.4 Evaluation

7.4.1 The individual OmniAir certification programs will define the evaluation process for specific programs.

7.4.2 The OmniAir Test Laboratory Authorization Program (OA-TLAP) establishes the foundational requirements for independent testing organizations to apply and obtain recognition as an OmniAir Authorized Test Laboratory (OATL). These independent OATLs conduct the testing phase of a certification program. An applicant shall choose an OATL listed as authorized for the specific program for which they are seeking certification.

7.4.3 When the applicant declares the OATL to provide testing services, the Technical Director will forward pertinent documentation including the OmniAir applicable Test Plan for Conformance Testing to the chosen OATL for execution.

7.4.4 The individual OmniAir product certification programs will state the conformance requirements for products which fall under the scope of certification. The OATL will produce a conformity assessment result (Test Report Record) which will list verdicts (pass fail) for each tested requirement listed in the Test Plan.

7.4.5 OmniAir may utilize evaluation results from previous OmniAir certifications when possible for the purpose of fulfilling a new certification application, such as relabeling and variant. The source of the results shall be an accredited OATL in good standing, other nationally recognized certification organization or notified body. In the event previous results are unavailable in the OmniAir records and attempts to secure the previous evidence are unsuccessful, the applicant or original OATL will be requested to provide a copy of the original test report and certification authorization to review.

7.4.6 Non-conformities - Applicants whose submitted product receives an unfavorable test (non-compliant) or inspection result shall be notified in writing of the non-conforming result for mandatory test results by the OATL or during the review phase of certification information.

7.4.7 If the applicant of a non- conforming candidate product desires to continue with OmniAir certification, OmniAir shall provide a list of additional evaluation tasks to be completed at the applicant's expense in order to undergo a subsequent certification review. Evidence, such as re-test data, shall be presented to verify that the nonconformities have been corrected and are now compliant.

7.4.8 If the applicant agrees to proceed with the additional evaluation tasks, the process outline within this Section 7.4 of this OA-CPPM and the individual program's evaluation process shall be repeated prior to certification review.

7.4.9 The results of all evaluation activities shall be classified as certification records and stored in accordance with the OmniAir Manual for Document Management (OA_MDM).

7.5 Review

7.5.1 The OmniAir Technical Director shall only consider and accept conformity assessment results from testing entities on the specific OATL List or as stated in individual certification programs. All other testing, inspection or auditing information or reports will not be reviewed for OmniAir certification. Certification review shall be conducted by the Technical Director. The certification review function and responsibility shall not be outsourced.

7.5.2 Upon receipt of the program's certification submittal package from the applicant, (the package is defined in the individual certification program) and test report from OATL, the Technical Director shall review the application and inspection/testing evaluation evidence for completeness. It is the Technical Director's responsibility to verify fulfillment of a program's conformance requirements, make the certification decision and recommend granting OmniAir certification. The results of the review and certification decision are documented in a Certification Decision Report.

7.6 Certification Decision

7.6.1 Award of the OmniAir Certified Trademark solely constitutes an OmniAir judgment that a product has met or exceeded the specified program requirements.

7.6.2 The Technical Director shall have technical competency to review submitted certification package evidence for completeness and conformance and to render the certification decision to grant OmniAir certification.

7.6.3 The Technical Director shall be an employee of OmniAir or another entity under organizational control by OmniAir.

7.6.4 Other entities under organizational control by OmniAir can be classified by the following conditions:

- Wholly owned or majority ownership of the other entity by OmniAir
- Documented authority of the other entity to OmniAir through ownership or Board of Director's control linkage
- OmniAir majority participation on the board of directors of the other entity

7.6.5 Personnel under contract with or under OmniAir organizational control shall be required to adhere to the same certification program policies and individual certification program requirements as the certification staff directly employed by OmniAir.

7.6.6 In accordance with the individual certification program, applicants whose submitted product receives an unfavorable certification decision shall be notified of the reason(s) for not granting certification by the Technical Director.

7.7 Certification Documentation

OmniAir Certification documentation shall be detailed in the individual certification programs. Basic documentation includes:

1. An OmniAir Certified Authorization Letter declaring the OmniAir program under which certification is granted and the type of surveillance, if any, that applies. The letter shall bear the name and signature of the OmniAir Executive Director, the unique certification documentation number, the effective date of certification, certification scope embodied in relevant test requirements, expiration dates if applicable, hardware/firmware/application versions and all applicable addresses for OmniAir and the applicant.

2. The Certification Decision Report shall be delivered and serve as evidence of the product meeting the specific program's conformance requirements.

3. The executed OmniAir Certification Agreement and specific OmniAir Certified Trademark.

Upon completion of testing, one sample will be returned to applicant and shall be stored (by the applicant) for a period of three (3) years from date of report issuance in an "as is" condition (the state at which the device was submitted for certification testing). No modifications or updates are permitted to hardware or software of the storage sample. During the retention period, OmniAir may request the storage sample for verification purposes. A second sample may be retained by test laboratory for future conformance/regression (ECO) and interoperability testing.

7.7.1 Certification Information that may be disclosed on OmniAir On-line Directory of Certified Products

1. Name of Applicant.
2. Certification Program and version.
3. OmniAir certification number.
4. City, State and Country of Applicant.
5. Product name, model number, hardware, firmware and/or software version.
6. Product evaluated to the following certification scope.
7. Date the listing was last updated and expiration.

Please refer to the individual certification program manuals for additional Directory of Certified Product information disclosures.

7.8 Directory of Certified Products

The Online OmniAir Directory of Certified Products can be accessed at www.omniair.org. The directory is maintained by the Technical Director. See 7.7. 1 for details on disclosed listing information.

7.9 Surveillance

An OmniAir surveillance program monitors the market to ensure proper use of the OmniAir Certified Trademark and those products issued the OmniAir Certified Trademark maintain conformance to the program requirements. A surveillance program also provides a means of corrective action when a deficiency is encountered. The individual certification programs define associated surveillance activities.

7.10 Changes Affecting Certification

7.10.1 Proposed technical changes affecting OmniAir certification such as changes to normative standards, product requirements, test methods, use cases or non-technical changes shall be defined in the individual certification programs. Further, procedures of communicating the changes to all applicants shall also be defined in the programs. The applicant will be responsible to update their “active” device certification within the specified date of the product requirement’s implementation date.

7.10.2 Applicant initiated changes affecting certification documentation, an engineering change order or other circumstance that may affect conformity to requirements as a condition of certification shall be communicated to the Technical Director for appropriate action as defined in the individual certifications programs. After review and consideration of the changes, the Technical Director will determine the level and direction of administrative update, scope of regression testing or if the changes are deemed as affecting a device’s conformity to the certification requirements. This latter instance may necessitate the device to be submitted for a new and full initial certification evaluation process. Changes affecting certification may incur additional cost payable by the applicant for technical review and resolution to maintain the products compliant certification.

7.10.3 Process guidance to implement the changes affecting OmniAir certification shall be contained in the individual certification programs.

7.11 Termination, Reduction, Suspension or Withdrawal of Certification

The individual certification programs shall establish the policies and procedures for termination, reduction, suspension or withdrawal of OmniAir certification. In general:

Withdrawal (OmniAir initiated) - The OmniAir Withdrawal of Certification notice shall specify the date of notification, the proposed effective withdrawal date and be dispatched to the last known business address.

Termination (per applicant request) of Certification - The applicant has the right to terminate certification with or without cause with prior written notification. A termination notice initiated by the applicant shall indicate the date of notification and effective termination date in accordance with the terms of the Certification Agreement.

Reduction and Suspension are discussed in the individual certification programs. Please refer to those documents.

7.12 Records

7.12.1 All records and communications demonstrating fulfilment of OmniAir certification requirements shall be retained. See Section 8.4 of this OA-CPPM, the OmniAir Manual for Document Management and the individual OmniAir certification programs for details.

7.12.2 OmniAir certification records are considered confidential with exception of publicly available information and handled per the OmniAir Manual for Document Management.

7.12.3 See Section 8.4.2.1of this document regarding complete re-evaluation during a given cycle.

7.13 Feedback, Appeals, Device Incident Process

OmniAir shall adhere to the following feedback, technical appeal or device incident process to receive, investigate, determines necessary action, if any, and resolution outcome by documenting the activities of each step. The individual certification programs may also contain specific handling procedures in addition to those stated below:

Feedback – A formal communication regarding OmniAir certification service fulfilment.

Technical Appeal – A formal communication regarding an OmniAir certification decision or interpretation. A Technical Appeal shall clearly state the OmniAir certification decision or interpretation made, the reason for the appeal and propose a preferred outcome or course of action should the appeal be upheld.

Device Incident - A formal communication of fraudulent or misuse of OmniAir Certified Trademark on packaging, marketing materials. Device incidents may also include unsatisfactory feedback on product performance, interoperability or misbehaviour.

7.13.1 Feedback, technical appeal or device incident shall be communicated by completing and submitting the OmniAir Feedback, Appeal and Device Incident Reporting Form to OmniAir. The form is available by request from the http://omniair.org/contact-us/ link on the OmniAir website.

7.13.2 The OmniAir Feedback, Appeal, and Device Incident Reporting Form shall be evaluated by the Technical Director who will determine if the reporting is related to the certification activities for which OmniAir has ownership or authority.

7.13.3 The Technical Director shall acknowledge receipt of the form.

7.13.4 The Technical or Executive Director shall initiate, compile and verify the necessary records to move the reporting towards a resolution decision.

7.13.5 The review and resolution decision of feedback, appeal or device incident shall be made by the Technical or Executive Director in collaboration with impartial Certification Review Board members.

7.13.6 OmniAir staff involved with a feedback, appeal, or device incident reporting review, decision or decision approval shall not have been employed by nor acted as a consultant for the applicant for a period of one year from the termination of that affiliation to avoid a potential conflict of interest.

7.13.7 When possible OmniAir shall provide a formal notice of feedback or device incident outcome to the party submitting the OmniAir Feedback, Appeal and Device Incident Reporting Form provided the outcome does not breach OmniAir confidentiality, conflict of interest policies or existing contractual agreements. This notice will indicate the closing of the process.

7.13.8 OmniAir Technical Appeal shall provide formal notice of appeal outcome to the party submitting the OmniAir Feedback, Appeal and Device Incident Reporting Form, thus providing notice of the closing of the process.

7.13.9 OmniAir shall undertake any subsequent action should it be necessary to further resolve the feedback or appeal in accordance with the certification agreement of record.

8 Management system requirements

8.1 Options

8.1.1 General

OmniAir shall establish and maintain a management system that promotes a uniform platform for operating and maintaining product conformity assessment programs. This program policy constitutes the management system.

8.1.2 Option A (ISO 17065)

The OmniAir management system is guided by ISO 17065 Option A requirements.

The specific requirements of Option A are:

General Management System Documentation (Section 8.2).
Control of Documents (Section 8.3).
Control of Records (Section 8.4).
Management Review (Section 8.5).
Internal Audit (Section 8.6).
Corrective Actions (Section 8.7).
Preventive Actions (Section 8.8).

8.1.3 Option B (ISO 17065)

N/A – OmniAir does not operate a management system in accordance with ISO 9001 requirements.

8.2 General management system documentation (Option A ISO 17065)

8.2.1 The individual conformity assessment certification programs along with referenced documents and OmniAir policy manuals constitute the management system of each certification program. The Certification Owner and Technical Director shall establish, document and maintain the policies governing OmniAir certification assuring acknowledgment and implementation of the objectives and guidelines by all persons and entities affiliated with OmniAir certification programs.

8.2.2 The Technical or Executive Director shall conduct an annual management review to assure effective implementation of the management system.

8.2.3 OmniAir has defined and delegated the responsibility, authority and management of the following:

a) Technical Director is responsible for ensuring the management system processes and procedures are created, executed and sustained.

b) Technical Director is responsible for monitoring and reporting the effectiveness of the management system and providing recommendations for management system improvements to OmniAir management.

8.2.4 To demonstrate application of ISO 17065 principals, any referenced documents, procedures, or systems, including this program policy shall be noted within the management system documentation.

8.2.5 Persons affiliated with OmniAir certification activities shall have access to the management system documentation appropriate for their appointed role and responsibilities.

8.3 Control of Documents (Option A)

8.3.1 OmniAir shall establish internal and external document control procedures.

8.3.2 The document control procedures are defined as follows:

8.3.2.1 Internal OmniAir certification management system documentation with specified purpose, goals and objectives are drafted within the OmniAir working groups in collaboration with the Technical Director. A document editor is appointed by the working group and this individual is responsible for the development, accuracy of content and maintenance of the document.

The process of creating a management system document follows the procedure as outlined in the OmniAir Manual for Document Management (OA-MDM).

8.3.2.1.1 OmniAir shall use a mnemonics or reference number identification for documents. Please refer to the OmniAir Manual for Document Management (OA-MDM).

8.3.2.2 Every two (2) years or as needed, documents shall be reviewed by the document owner, updated (as necessary) and re-approved. The document owner may assign revision or update task to the applicable working group. The review is documented on the Approval and Revision History page.

8.3.2.3 Documentation review includes the following assurances:

- Changes and the current revision status are noted and accurate.
- Latest version of documents is available in the document control system.
- Obsolete documents are no longer needed or intended for use and therefore should be promptly removed from access points. Obsolete documents may be retained for historical or legal purposes and should be appropriate labelled and stored to prevent usage.

8.3.2.4 External documents are those which are authored outside of OmniAir and deemed necessary to perform working group, organizational or certification activities. External documents shall be noted for origin and controlled in a specified external documents folder in the document control system. External documents are also assigned a document owner whose responsibility it is to review new or revised documents for their possible impact on the organization.

8.4 Control of records (Option A)

Records are defined as a stated result that has been generated or provides evidence of performed activities and are considered a valuable business asset. Certification Records may include, but are not limited to any form of printed materials, electronic documents, e-mails, saved or submitted forms or records contained on digital format storage or data recording media.

8.4.1 OmniAir shall establish the procedures defining the control for the identification, storage, protection, access, retention time and disposition of the records related to the system management of the organization and certification programs.

8.4.1.1 The Executive Director is responsible for assuring the certification document management and retention policies comply with the regulatory and legal requirements.

8.4.1.2 All Persons affiliated with an OmniAir certification program are responsible for keeping accurate and thorough records of their certification activities.

8.4.1.3 OmniAir shall use a mnemonics and reference number combination for certification application and awarded certification records identification. Please refer to the OmniAir Manual for Document Management (OA-MDM).

8.4.1.4 Records shall be kept in confidence and in a secured manner to assure confidentiality during transport, transmission and transfer.

8.4.1.5 Storage – the location of each record shall be documented. Electronic records shall be stored to allow for regular data backup. Access to records is controlled through an explicit permissions process. Persons not authorized for access will be denied access to records.

8.4.2 Retention - OmniAir shall establish control procedures for record retention to illustrate the fulfillment of all certification process requirements. The record retention schedule document is included in the OA-MDM. Please refer to this document for details.

8.4.2.1 If an OmniAir certification program, involves the re-evaluation of a product within the established record retention timeframe the records shall be retained for the balance of the current cycle and the previous cycle to preserve a historical record of the product.

8.4.2.2 Disposition of records is as noted in OA–MDM. Please refer to this document for details.

8.5 Management review (Option A)

8.5.1 General

8.5.1.1 The Technical Director shall establish guidelines and processes to review the OmniAir certification management system to assure stability, appropriateness and effectiveness of stated certification policies and practices.

8.5.1.2 Reviews of the management system shall be conducted once per year and a record of the review shall be maintained.

8.5.2 Review Inputs

Information for the management system review shall include the following:

a) Results from internal or external audits.

b) Feedback from internal and external stakeholders related to certification activities.

c) Feedback on confidentiality and impartiality policies and practices.

d) Updates on preventive or corrective actions.

e) Review and outcome of follow up actions from previous management reviews.

f) Fulfillment of objectives or goals.

g) Possible conditions or situations that could affect the management system.

h) A review of feedback, appeals, incident reports or arbitration.

8.5.3 Review Outputs

The outputs from a management system review shall include:

a) Recommendations or actions needed for process or management system improvements.

b) Recommendations or actions needed to more closely follow ISO 17065 guidelines.

c) Identification of needed resources to conduct certification activities or system management.

8.6 Internal audit (Option A)

8.6.1 The Technical Director shall establish procedures to conduct internal audits with the goal of evaluating certification policies, practices and management system for adherence to ISO 17065 guidelines. An internal audit can also be used to monitor management system effectiveness and to keep the certification activities relevant and current.

8.6.2 Internal audits shall be planned with key areas of focus to promote efficient and thorough review of policies, processes and management systems. A review of previous audit results can be used to guide the areas of focus.

8.6.3 The frequency of an internal audit shall be conducted at least once every 12 months. Changes to the frequency may be made as long as there is historical stability of the management system, policies or practices and adequate documentation recorded to justify how the change decision was derived. Impartial members of the Certification Review Board or Certification Working Group may support audits of the certification management system.

8.6.4 The Technical Director shall ensure that:

a) Internal audits are performed by persons with knowledge of certification, auditing and ISO 17065.

b) Auditors are not allowed to audit their own activities or areas of responsibility.

c) Feedback and findings are reported to the person responsible for the audited area.

d) Internal audit findings are acted upon in a timely and suitable manner.

e) Certification process or policy improvements are identified and reported.

8.7 Corrective actions (Option A)

8.7.1 The Technical Director shall establish a procedure for identifying and managing nonconformities to its policies, practices and management system. This shall be accomplished through usage of a Corrective Action Request initiation upon a documented finding.

8.7.2 As part of the corrective action request process, The Technical Director shall implement plans to mitigate the root cause of the nonconformance finding to prevent reoccurrence.

8.7.3 The nature of the corrective action resolution shall be appropriate to the possible impact of the initial non-conformance finding.

8.7.4 The Corrective action request shall incorporate the following elements:

a) Identify the nonconformity (findings during audits, feedback or improvement suggestions).

b) Investigate root cause of nonconformity.

c) Create an action plan and timing to correct nonconformity.

d) Delegate responsibility to carry out corrective action plan steps.

e) Investigate the need to implement steps to ensure nonconformities do not reoccur.

f) Keep records of actions taken and who carried out actions.

g) Review the effectiveness of the implemented corrective actions.

8.8 Preventive actions (Option A)

8.8.1 The Technical Director shall establish proactive procedures for reducing the likelihood of potential nonconformities to ISO 17065 principals.

8.8.2 The nature of the proactive actions shall be appropriate to the possible impact of a non-conformance finding.

8.8.3 The proactive actions shall consider the following:

a) Identify potential nonconformities and the possible causes.
b) Consider the need for preventive nonconformity action.
c) Determine appropriate action and implement policy or process.
d) Record any action taken.
e) Review the effectiveness of the implemented preventative measures

ANNEX A – Impartiality Management Addendum

Potential Risk	Reported By	Date	Mitigation Steps

ANNEX B

FIGURE 1 OMNIAIR CERTIFICATION APPLICATION PROCESS

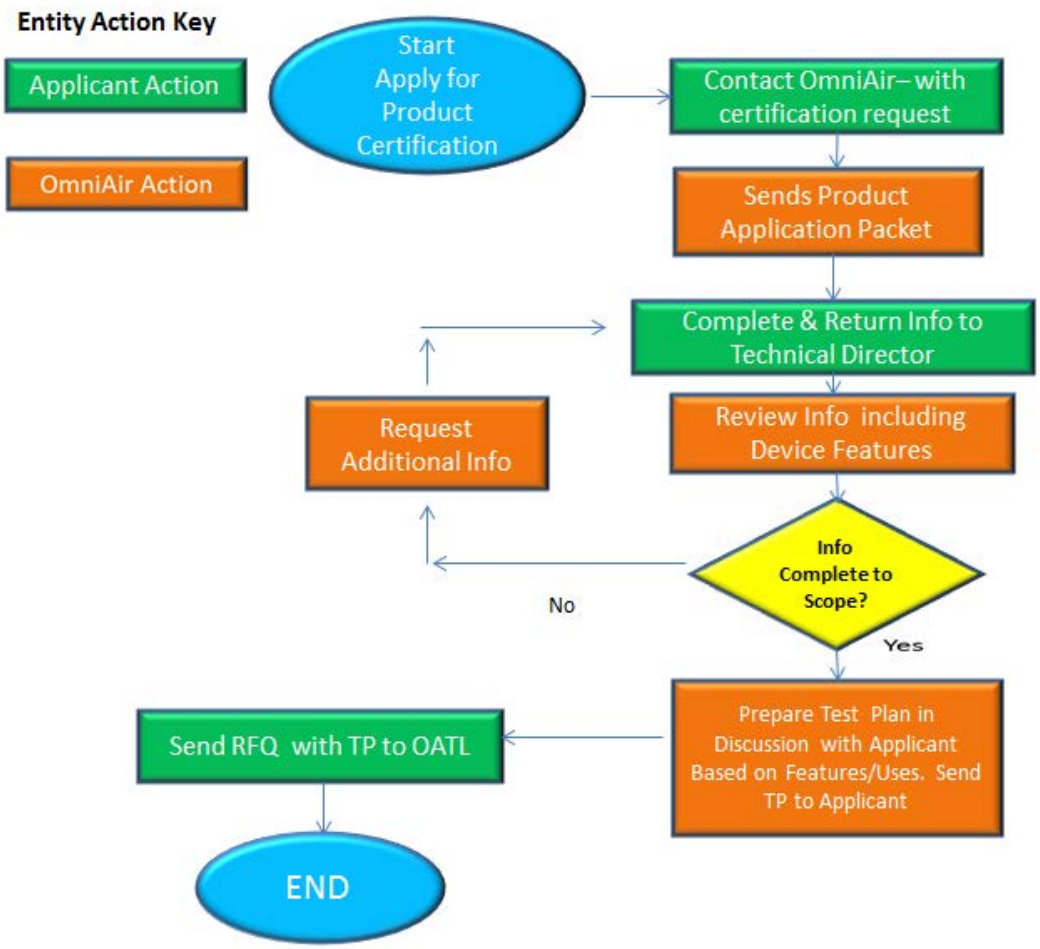


FIGURE 2

TESTING PREPARATION WITH OMNIAIR AUTHORIZED TEST LABORATORY

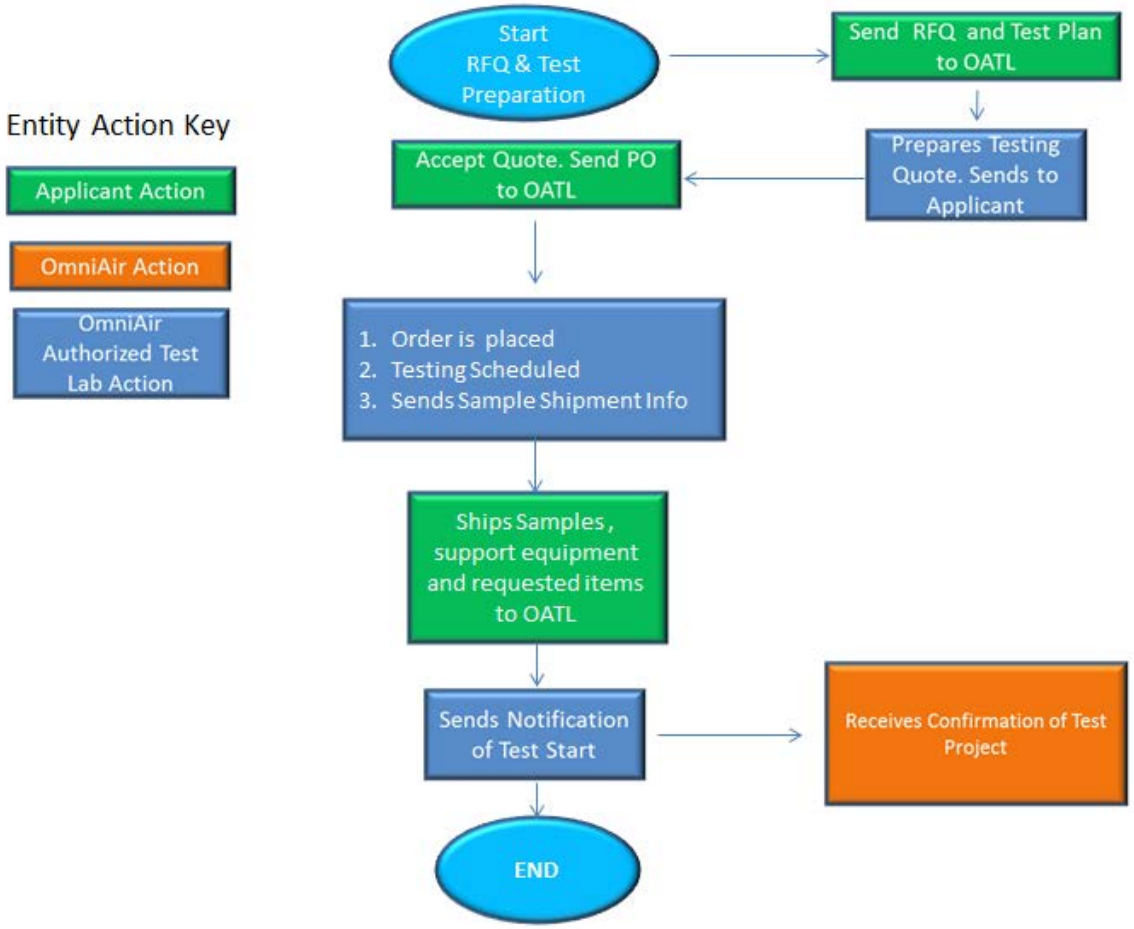


FIGURE 3 OMNIAIR CERTIFICATION TESTING AND EVALUATION PROCESS

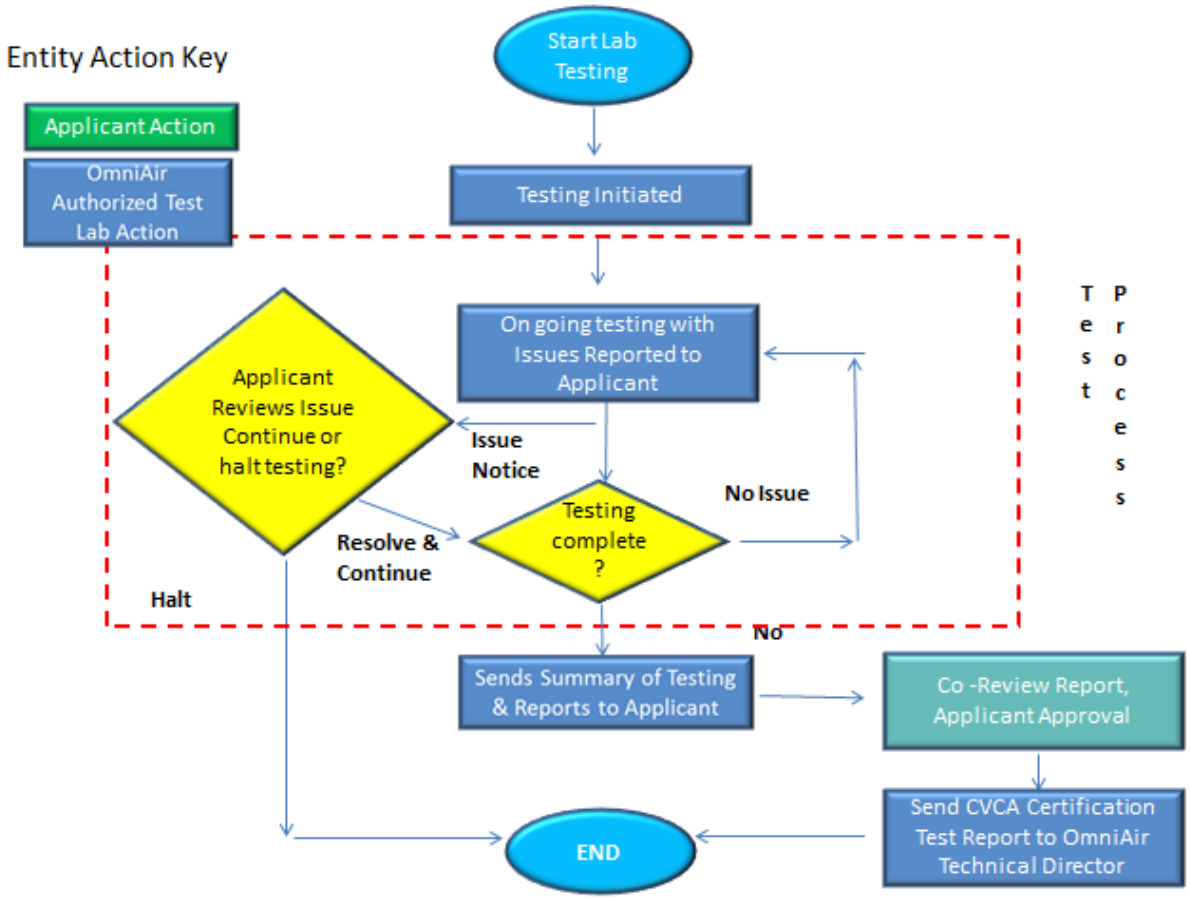
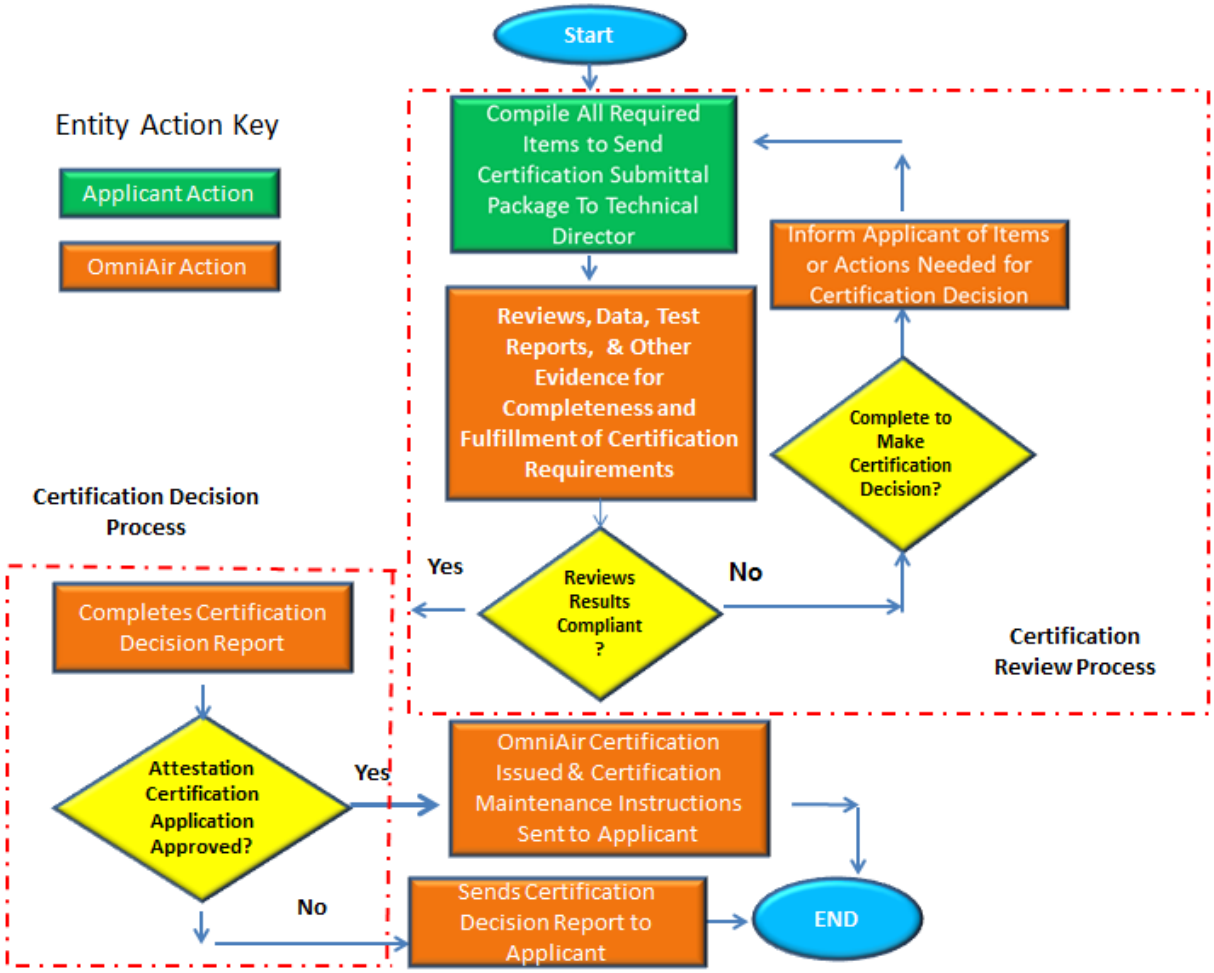


FIGURE 4 – CERTIFICATION REVIEW AND DECISION PROCESS



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