Transport Canada Aviation Transports Canada Aviation

AMA: **561/1**

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AIRWORTHINESS MANUAL ADVISORY (AMA)

Subject: Manufacturer Approval Requirements

Purpose

This advisory provides information concerning Chapter 561, Subchapter A of the Airworthiness Manual and sets forth acceptable means, but not the sole means, of compliance with its requirements. It covers only those sections where further discussion, information and examples would be helpful. The numbering of the paragraphs of this advisory refers to the applicable sections of Chap-ter 561, Subchapter A.

561.105 Aeronautical Products

One of the conditions under which a DOT manufacturer approval may be granted for a product and its components is that the product be type approved either by DOT or a foreign civil aviation authority. The inclusion of the clause "have the rights to the benefits of (approvals) under a licensing agreement" recognizes the manufacturer who obtains from the holder of a product Type Approval, through legal process the right to manufacture the approved product and/or its components. With this right the manufacturer should have the rights to all current design data, process specifications and other related information, and in some cases, production equipment, test equipment and other devices required to manufacture the product. He should also have made an arrangement, as part of his licensing agreement, whereby the holder of the product Type Approval will provide him with the design change data essential to the continuing airworthiness of the product or component so that the manu-facturer can have the capability of incorporating such changes.

561.107 Manufacturing Facilities

The organization of a company and the functions of all company departments responsible for manufacturing an aeronautical product should be clearly defined. Full and effective coordination should exist within departments and between related departments. A

separate department should be established to ensure that all operations affecting quality and airworthiness are effective and properly coordinated.

Although DOT does not, in any way, impose requirements regarding the manufac-turing methods and facilities used, there should be adequate space for all fabrication and assembly operations, with proper lighting and proper environ-mental conditions, such as air cleanliness and controlled temperatures. There should be adequate space for the movement of assemblies and parts throughout the plant, and if necessary, environmentally controlled storage space suffi-cient to ensure that materials are properly separated, identified and protec-ted, and that nonconforming material can be isolated to prevent intermingling or unauthorized use. A manufacturer should have adequate manufacturing/ inspection tools and equipment and a sufficient number of qualified and compe-tent personnel.

561.109 Quality Program

A manufacturer need only be concerned with those aspects of a quality program which are applicable to the aeronautical products which he produces.

The extent of a quality program may vary greatly. In the case of a simple component, final inspection with a minimum of written procedures or instruc-tions may be adequate. In the case of components or products, where the manu-facturing processes are not excessively complex, an inspection system with related procedures and instructions should suffice. In the case of an air-craft, aircraft engine, most appliances, and most major assemblies, a full quality program will be necessary so that manufacturing processes are control-led, procedures are established and carried out, and a complete inspection system is utilized.

An effective quality program should be planned and implemented with the full cooperation of all departments within the organization. Engineering may be responsible for quality program procedures providing for the control of such things as design specifications and engineering drawings. Manufacturing could be responsible for procedures to control fabrication and assembly operations. Another department may be responsible for procedures to control the receipt, storage and distribution of all components, whether acquired from outside sources or produced internally. The coordination of all such functions should be carried out by a quality assurance department operating and reporting at the same management level as other functional departments. The head of the department should report to senior management, and the personnel in the de-par-tment should have the authority and organizational freedom to identify quality problems and to recommend and implement satisfactory solutions.

The quality of computer software is determined primarily in the type approved phases of a product, at which time a software design quality assurance program should include such items as design specifications, design reviews and other documentation including flow charts, testing, and configuration control. The quality program during manufacture

should be mainly concerned with ensuring that products in which software is imbedded or for which software is required, meet the approved design data. In regard to the software itself, the quality program

should ensure that the software delivered are exact copies of the approved software design. The program should include strict control over master discs and tapes, the incorporation of changes and the generation and custody of new print-out data.

561.109(d)(1) Quality Program Manual

A well prepared quality program manual is an asset to a manufacturer. It can provide the top levels of management with an overview of how quality is achieved and verified, and it should show which departments and persons are responsible for quality. It should assist in assuring a prospective customer that the manufacturer is capable of producing high quality products and compo-nents. Information and guidance for the format and contents of a typical quality assurance manual is given in AMA 561/4.

561.109(d)(2) Written Procedures

Quality program procedures are required to ensure that the methods of carrying out the various quality functions are developed, established and carried out in conjunction with other related activities. The procedures should be in writing so that each function will be performed in a consistent manner regard-less of change in personnel. The procedures should be reviewed and updated as necessary.

The procedures referred to in section 56l.l09(d)(2) do not include manufac-turing or inspection instructions, although they may provide for the control of such instructions. The following paragraphs provide for most of the func-tions affecting quality, but are not intended to be all-inclusive or restric-tive either in content or in the functions covered.

Engineering and Data Control

The engineering department is usually responsible for ensuring that all design requirements are clearly defined in drawings and specifications. The depart-ment usually originates, coordinates and implements, through appropriate docu-mentation any changes to a product or component, whether the change is origin-ated by the manufacturer for product improvement, as a result of feedback from within the facility, or from reports received from users of the product or components.

Each change should be implemented by issuing a drawing or specification change. All changes should be coordinated with other appropriate departments to ensure that the change does not significantly alter the type approval de-sign data, and does not adversely affect other requirements or functions, particularly those affecting quality and airworthiness.

A common practice is to maintain a technical data control system to record data and changes to the data, and to ensure that only approved drawings and drawing

changes are issued to manufacturing and inspection personnel. All unauthorized, inappropriate and obsolete data should be removed promptly from manufacturing and inspection areas and destroyed or segregated to prevent inadvertent use.

A drawing change control system should ensure that all changes are issued in writing and may be in the form of a drawing change notice or a drawing change. A drawing should be reissued when control becomes difficult because of too many changes. Changes to all documents should be issued promptly to all af-fected areas and a positive recall system should be instituted to ensure the removal of obsolete documents from all points of issue and use.

A change control system should also provide for the issue of engineering change notices or manual amendments to users when a user is affected.

Nonconformance and Corrective Action

A material review system should be established to provide for the reporting of nonconformance, unsatisfactory performance or failure of a product or compo-nent during manufacture; an analysis of the product or component and its sup-porting data; the determination of whether to accept as is, rework, repair, or scrap the article; and the measures to be taken when corrective action is required.

If a minor nonconformance is revealed during manufacture, and is due to fail-ure to adhere to drawings, specifications or instructions, the system should provide for immediate corrective and preventive action within the area respon-sible for that stage of manufacture. If, however, form, fit, function, qual-ity or airworthiness may be affected, the problem should be reported in detail to the appropriate department for material review action. All nonconforming articles should be segregated and held in quarantine areas, or be clearly identified, to prevent use pending disposition.

When a full investigation of nonconforming materials is required a Material Review Board should be assembled by the quality assurance department, with representation from all departments involved, to determine whether an article may be used as is, reworked, or scrapped. If the decision necessitates a change in the design of the article, changes to existing documentation should follow the procedure covering technical data control.

Articles held in quarantine should be reworked or re-issued as appropriate, and returned to the production line or to stores. Articles which must be scrapped should be removed from all manufacturing and storage areas.

Charts or records should be used to show the extent and effectiveness of defect reporting and Material Review Board action.

A manufacturer may delegate Material Review Board privileges to a subcontrac-tor. The extent to which the subcontractor's review board may make decisions regarding the

disposition of material is the prerogative of the manufacturer, except that DOT should be advised of the delegation.

Material Handling

To prevent abuse, misuse, damage or deterioration, a system should be imple-mented to provide for the identification, segregation, handling and storage of all articles from the time of receipt from a supplier or fabrication within the facility, through the manufacturing processes to the point of delivery. Particular care should be taken to protect all articles being moved within the plant from physical or environmental damage. Secure storage areas or stock rooms should be available and all articles should be properly identified and protected from intermingling or contamination pending use or shipment.

Defective articles or articles under investigation should be clearly identi-fied, segregated and quarantined until acceptability is established or other disposition arranged.

Purchased Supplies and Services

The manufacturer of a DOT approved product is responsible for each article used in his product, and therefore he should ensure that all products, compo-nents or services obtained from suppliers conform to approved design data. When the supplier holds a DOT manufacturer approval for the articles being purchased it should only be necessary for the manufacturer to ensure, on receipt, that the articles have been properly identified, inspected and certified by the supplier, and have not been damaged in transit.

When the supplier produces components on a subcontract basis the manufac-turer's quality program should be extended, as necessary to the subcontrac-tor's facilities if the components cannot or will not be fully inspected on receipt. In this case the supplier's capability should be evaluated by the manufacturer prior to award of the subcontract, and surveillance and inspec-tion may be necessary throughout the duration of the subcontract. Minimal surveillance or inspection is required when a reliable supplier provides a certificate of conformance and data which show objective evidence that the design data and quality standards have been met.

Subcontractors should be advised that their facilities, quality program, per-sonnel and articles supplied are subject to evaluation and inspection by DOT as well as by the manufacturer, since in effect the subcontractor's facilities are an extension of the manufacturer's facilities.

A system of rating supplier's capabilities and performance can assist a manu-facturer in selecting his suppliers and in determining the extent to which

he should maintain surveillance at the supplier's facility, and determining the amount of receipt inspection required.

An effective purchasing system would ensure that the subcontractor is provided with, as applicable:

(a) Specifications and other design data in the detail necessary to ensure that all design and airworthiness requirements will be clearly identified;

(b) Requirements for approval or qualification of material;

(c) Requirements for a specific quality program;

(d) Requirement for certification, and inspection records;

(e) Requirements for batching and identification; and

(f) Shipping instructions.

If articles are purchased from foreign suppliers, care should be taken to ensure that either:

(a) The supplier's capability is evaluated by the manufacturer, and that surveillance and inspection is carried out as necessary throughout the dura-tion of the contract; or

(b) There is an agreement between DOT and the foreign civil aviation author-ity whereby the foreign civil authority certifies that each article conforms to approved design data and is in a condition for safe operation; or

(c) The foreign civil aviation authority issues an export airworthiness ap-proval.

Manufacturing

All fabrication and assembly operations should be carried out under controlled conditions, using documentation to provide the essential criteria for fabrica-tion, assembly and, when appropriate, for standard processes such as plating. Documentation may take the form of drawings, instructions, travellers, check lists or similar data. Manufacturing documents should include a requirement for inspection and tests to be conducted in proper sequence throughout all phases of the manufacturing process. If physical inspection of each article is not feasible, control may be obtained by process monitoring. In some cases both process monitoring and inspection may be the best way of ensuring effec-tive control of quality.

Standard Processes

Processes and services that are additional to those normally used during fab-rication and assembly should be closely controlled by the manufacturer, whether performed in his own facility or at a subcontractor's facility. A system for controlling standard processes or services such as welding, plating, heat treatment or nondestructive testing would provide for the use of specifications which form part of the approved type design data and definitive requirements for trained and certified personnel and, when applicable, the periodic inspection of specialized equipment gauges or solutions, and the calibration of monitoring devices.

Identification and Traceability

When required by a customer or specified in approved design data a system may be required throughout the manufacturing cycle to identify each article with its design data

and its inspection lot and job number to allow for tracing of items from the finished product back to the source of materials.

When traceability is required parts may be identified by using a lot numbering system on a batch-by-batch basis which should provide for the transfer of the identification of the lot from shop, to stores, to assembly line, with a record being kept of their installation on a serial numbered product, includ-ing an aircraft. An approved manufacturer's record system should provide for serial number traceability.

Inspection Equipment

All inspection equipment used throughout a facility should have the necessary capability, reliability and accuracy to provide assurance that products and components conform to approved type design data. A system should be estab-lished and maintained to check and calibrate all inspection equipment at times and intervals adequate to ensure that measurements taken during inspection are of known accuracy. The same system should be used for production jigs, fix-tures, tools and other such devices used for inspection. All calibration devices must be calibrated against standards traceable to Canadian or foreign national primary standards.

Inspection equipment schedules and records should be maintained so that each piece of inspection equipment is calibrated, as necessary, prior to initial use and inspected and calibrated at periodic intervals established by the manufac-turer on the basis of utilization and records which are used to deter-mine the rate at which equipment becomes inaccurate and requires adjustment or replace-ment. Inspection equipment should be marked to indicate the date that the next calibration is due, and should be removed from work areas or conspi-cuously identified to prevent usage after expiration of the calibration due date.

Quality Audits

Regular or progressive audits should be conducted by the manufacturer to ensure the effectiveness of his quality program. Each function of his program should be audited at least once a year. Audit procedures should be estab-lished to detail the method of audit, the records to be maintained, responsi-bility for the analysis of audit results, and the use to be made of the audit data for corrective action.

561.109 (d) 3. Inspection System

An acceptable inspection system should be capable of producing objective evidence

that a product or component meets approved design and airworthiness standards. The system should, as a minimum provide for the detection and removal of nonconforming articles prior to, or at the latest stage of, fabri-cation, assembly or manufacture where a characteristic can be observed or measured. The system should include inspection carried out at a supplier's facility.

Inspection Planning

The effectiveness and efficiency of an inspection system depends, to a great extent, on how well the inspection is planned. As part of production plan-ning, the manufacturer should determine what inspection is required, where in the production process it should be carried out, acceptance limitations, records required and how the inspection status of materials is to be indi-cated.

Subcontractor Inspection

When purchasing aeronautical products or services which do not require a full quality program the manufacturer should ensure that the subcontractor is pro-vided with engineering and quality requirements and instructions, including the need for batching, identification, inspection records and certification. Surveillance may be necessary at the subcontractor's facility to ensure that inspection is carried out as required and that components conform to design data requirements.

Incoming Inspection

All material provided by subcontractors should be held in a separate area until it can be identified and inspected. Each incoming shipment should be checked against purchasing documentation to ensure that it is the product ordered and, when applicable, that batching identification, inspection records and certifi-cation has been included with the shipment. Inspection should be carried out, the extent of which should depend on the inspection carried out by the subcontractor, on the past performance of the subcontractor and the complexity and criticality of the product. Incoming inspection may vary from complete inspection to a minimum of inspection to verify the inspection results provided in the subcontractor's records. When identified and inspec-ted, acceptable material should be placed in stores with proper identification and batching information. Material found not acceptable should be segregated for follow-up action.

Process Inspection

Throughout fabrication and assembly operations, inspection should be carried out as required by production documentation and data. Inspection to determine conformity of any design characteristic should be carried out prior to or at the latest stage of production at which that characteristic can be identified and measured. Records should be kept of the results of all inspection whether the record is used only to confirm that a process is in control, or whether the record is used as evidence that the product or component, at that stage of production, conforms to design standards and is to become part of the accumu-lated data required for final inspection.

Final Inspection

All products and components should be subjected to final inspection by the manufacturer. Part of final inspection should be the review of the records of all previous inspections to ensure that inspection has been carried out at specific points in the manufacturing process and that the design requirements of specifications and drawings have been met.

In the case of a complete aircraft, in addition to ensuring that all compo-nents and installed products conform to design and airworthiness standards, physical inspection and

functional tests should be carried out on the com-pleted aircraft prior to flight testing. This should include checking flight controls for proper operation, ensuring that installed appliances and acces-sories are functioning properly and performing engine run-ups when necessary.

The manufacturer should ensure that means for levelling an aircraft are pro-perly installed and that the empty weight and the centre of gravity for each completed aircraft are accurately determined. The holder of a manufacturer approval may submit for DOT consideration, a proposal based on a reliable statistical plan and evidence of product uniformity if he desires to utilize an average empty weight and centre of gravity, in lieu of weighing each air-craft.

Each completed aircraft will be subjected to a production flight test in ac-cordance with an approved flight test procedure, as part of the quality pro-gram data. DOT engineering test pilots may carry out some of the production flight tests on an auditing basis. The DOT office responsible for approving the quality program will arrange with the Chief, Test Flying, Airworthiness Branch for the approval of the flight test procedure.

In the case of an engine, in addition to the review of accumulated records, each engine should be subject to a test run, including:

(a) Verification that engine operating parameters are as specified in the type design data;

(b) Internal inspection as necessary to determine that the engine is in con-dition for safe operation. The extent of such inspection may be based on a sampling plan, recorded evidence of product uniformity, a satisfactory history of previous inspections and tests, and service experience; and

(c) Determination of test instrumentation and power/thrust measuring devices, tolerance and correction, to ensure that no production engine can be delivered with less than its type approved rated power/thrust.

In the case of propellers each variable-pitch propeller would be functionally tested to determine that it operates freely and smoothly throughout the normal range of operation, with minimum and maximum operating forces alternately applied according to design and installation requirements.

In the case of components, in addition to the review of accumulated records if applicable, each completed component should be subject to final inspection to verify conformity with approved design data and airworthiness standards, and to determine that the component is safe for embodiment in an approved product. Final inspection should include, as applicable, verification that the compo-nent is complete, properly identified, adjusted, calibrated, etc. If applic-able each component should be subjected to a functional test to ensure that the operating characteristics meet the approved design provisions.

Sampling

Sampling techniques may be used whenever advantageous in maintaining control of quality and in obtaining maximum effectiveness while employing a minimum of data, time and personnel.

Sampling techniques used during production should not be used to eliminate final inspection but may be used to reduce final inspection, providing the products and processes are shown as being consistently conforming and stable.

Inspection Status

To ensure that only those articles and processes which have been inspected and found to conform are used in the product a means should be provided which will identify the article or the controlling documentation with stamps, marks or any other viable means of showing:

(a) That inspection has been performed;

(b) The identity of the inspector; and

(c) That any lots or batches have been identified to provide for traceabil-ity.

Articles rejected as being unusable should be conspicuously identified and controlled to preclude further fabrication, assembly or use as spares.

Records

Inspection records should be established and maintained, wherever inspections are performed, to determine conformity with design and airworthiness stan-dards. Such records should identify the article inspected, the batch identi-fication if applicable, the applicable characteristics and their limitations, the results of inspections performed and the feedback or corrective action generated by the records.

Packaging and Shipping

To ensure adequate protection, products and components should be preserved, packaged and prepared for shipment in accordance with the applicable design approval data or as otherwise required to provide adequate protection.

561.111 Inspection Personnel

Because of the diverse certification functions regarding the full range of aeronautical products it is not possible to establish across-the-board crit-eria in regard to the knowledge, expertise and experience required of a person authorized to certify products. Manufacturers are therefore expected to es-tablish inspection criteria related to the certification of each of their products, and from that criteria establish the knowledge, expertise, and ex-perience required to perform the certification tasks. Personnel may then be selected and approved to carry out the certification process and, unless dis-approved

by DOT, authorized to certify that specific products conform to ap-proved design data and are in a condition for safe operation.

Manufacturers of aircraft, aircraft engines and propellers, appliances or major assemblies may require the authorization of several inspectors, some of whom will only require specialized knowledge and experience. However, a manu-facturer with a relatively small facility may require only one or two inspec-tors, in which case each inspector should have a broad knowledge of the manu-facturer's complete operation as well as knowledge and skills regarding several components for which he may be responsible.

561.115 Privileges

Only those inspectors who are authorized inspectors or Airworth-iness Inspec-tion Representatives may be authorized, within the scope of their approval, to certify airworthiness documentation required by DOT.

561.119 Record Retention

The need to retain current technical design data for an aeronautical product after manufacturing ceases depends largely on whether, or for how long, the product to which the technical data applies will continue to be used in ser-vice. If the original manufacturer chooses not to produce the product or its components any arrangement regarding the disposition of the technical data should be made with DOT's knowledge.

In the case of quality records the need to retain records beyond three years should be based on their usefulness in investigating unsatisfactory or unsafe performance. In some cases inspection records may be helpful in determining the need for and the nature of product improvement. The need to retain records beyond three years is left to the best judgement of the manufacturer.

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