1. Objective

1.1. This directive details procedures for the evaluation and issuance of a production approval and contains direction and guidance relating to the following three types of Production Approvals (hereinafter – Production Approvals [1]) to be used by CAAI Manufacturing Inspectors:

1.1.1. Production Certificate (PC).

1.1.2. Parts Manufacturer Approval (PMA).

1.1.3. Israeli Technical Standard Order Authorization (ITSOA).

1.2. This procedure is also used whenever the Production Approval Holder (PAH) changes the quality management system that may affect the inspection procedures or the airworthiness of the product, whenever the PAH asks to amend the certificate issued by Israel Civil Aviation Authority by adding a type certificate or model or both, or change the production location or add new production location.

2. General

2.1. See Appendix B for definitions pertaining to this directive.

2.2. Production Certificate (PC), Parts Manufacturer Approval (PMA) and Israeli Technical Standard Order Authorization (ITSOA) are documents issued by the CAAI to a person. These Production Approvals allow the production of a product for which the applicant is the holder of a current Type Certificate or Supplemental Type Certificate, or has the right to the benefits of a type certificate under a licensing agreement with the TC holder, or access to other approved design data.

[1] These approvals all constitute a "production certificate" as referenced in articles 52-53 of the Air navigation law.

2.3. An Applicant for a Production Approval will typically need to provide the CAAI with the following documents:

2.3.1.1 Approved Design Data supporting the production approval;

2.3.1.2 A Quality Manual for CAAI approval showing compliance with the quality requirements listed in this document;

2.3.1.3 A description of the Production Processes, equipment and the facilities where those processes are implemented in, for CAAI Approval.

2.3.1.4 List of Sub Contractors and their scope of work, for CAAI acceptance[2].

2.3.1.5 List of suppliers of finished Parts and Articles for CAAI acceptance.

2.3.1.6 List of critical parts for CAAI acceptance, as specified in the Airworthiness Limitations section of the maintenance manual or Instructions for Continued Airworthiness.

2.4. **These documents shall serve to prove the applicants' compliance with the following requirements:**

2.4.1. **Quality system requirements**: In order to meet the requirements of chapter 7 (production Certificate), 10 (Parts Manufacturer Approval) and 14 (ITSOA) of Air Navigation Regulations (Procedures for the Documentation of Aircraft and Aircraft Parts),1977 (hereinafter – ANR.DOCUMENTATION), an Applicant for a production approval must establish and maintain a quality system. This requirement is in accordance with Article 53(c) to the Air Navigation Law that authorizes the Director General of the CAAI to set conditions and terms in manufacturer license[3].

[2] For a review of the distinction between CAAI approval and acceptance, please review the definitions in appendix B of this document.

[3] The requirement for QA system from PMA applicant is not withstanding ANR.Documentation regulation 100 which set a requirement for quality control system, and lists the requirements for such a system. CAAI is acting to amend the regulations to reflect the changing requirements for PMA holders.

The applicant's quality system must meet the following requirements:

2.4.1.1 *Design data control.* Procedures for controlling design data and subsequent changes to ensure that only current, correct, and approved data is used.

2.4.1.2 *Document control.* Procedures for controlling quality system documents and data and subsequent changes to ensure that only current, correct, and approved documents and data are used.

2.4.1.3 *Supplier control.* Procedures that—

2.4.1.3.1. Ensure that each supplier-furnished product or article conforms to its approved design; and

2.4.1.3.2. Require each supplier to report to the production approval holder if a product or article has been released from that supplier and subsequently found not to conform to the applicable design data.

2.4.1.4 *Manufacturing process control.* Procedures for controlling manufacturing processes to ensure that each product and article conforms to its approved design.

2.4.1.5 *Inspecting and testing.* Procedures for inspections and tests used to ensure that each product and article conforms to its approved design. These procedures must include the following, as applicable:

2.4.1.5.1. A flight test of each aircraft produced unless that aircraft will be exported as an unassembled aircraft.

2.4.1.5.2. A functional test of each aircraft engine and each propeller produced.

2.4.1.6 *Inspection, measuring, and test equipment control.* Procedures to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of each product and article to its approved design. Each calibration standard must be traceable to a standard acceptable to the CAAI.

2.4.1.7 *Inspection and test status.* Procedures for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.

2.4.1.8 Nonconforming product and article control.

2.4.1.8.1. Procedures to ensure that only products or articles that conform to their approved design are installed on a type-certificated product. These procedures must provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming products and articles. Only authorized individuals may make disposition determinations.

2.4.1.8.2. Procedures to ensure that discarded articles are rendered unusable.

2.4.1.9 *Corrective and preventive actions.* Procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system.

2.4.1.10 *Handling and storage.* Procedures to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.

2.4.1.11 *Control of quality records.* Procedures for identifying, storing, protecting, retrieving, and retaining quality records. A production approval holder must retain these records for at least 5 years for the products and articles manufactured under the approval and at least 10 years for critical components.

2.4.1.12 *Internal audits.* Procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system. The procedures must include reporting results of internal audits to the manager responsible for implementing corrective and preventive actions.

2.4.1.13 *In-service feedback.* Procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must

include a process for assisting the design approval holder to—

2.4.1.13.1. Address any in-service problem involving design changes; and

2.4.1.13.2. Determine if any changes to the Instructions for Continued Airworthiness are necessary.

2.4.1.14 *Quality escapes.* Procedures for identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.

2.4.2. Access to Design data requirements:

2.4.2.1 According to article 53(a)(1) of the Air Navigation Law, an applicant for a production approval must either be the holder of a CAAI approved TC, or have a signed licensing agreement with the holder of a TC, STC, or TSO authorization holder of the article in which the applicant's part is intended to be installed. This licensing agreement serves as written permission for the applicant to use the design data to apply for a Production approval. A “production approval assist letter” or similar evidence authorized by the TC, STC, or TSO authorization holder is sufficient for showing evidence of a licensing agreement.

Note: A licensing agreement alone is insufficient to issue a production approval. The applicant must meet all the requirements of ANR.DOCUMENTATION Chapter 7, 10 and 14, as applicable.

2.4.2.2 The “Production approval assist letter” must include the following information:

2.4.2.2.1. Product model, name, and TC/STC/TSO number.

2.4.2.2.2. A statement that the Production approval applicant is authorized to use the design data as identified by article name and drawing number.

2.4.2.2.3. Information describing the authority of the Part approval applicant to use the TC or STC holder's part number and other article marking information, if applicable.

2.4.2.2.4. Information on the article's eligibility for installation (product make, series, model, and if appropriate, the serial number per the TCDS).

2.4.2.3 The Applicant must provide sufficient data to support discretionary conformity inspections in their application letters. Holders of the TC, STC, or TSO authorization may add this information to their assist letters. These data include:

2.4.2.3.1. The revision level of the article's drawing to baseline the design for future approved changes.

2.4.2.3.2. A statement as to whether design changes to the article and disposition of nonconforming articles will be controlled through the TC, STC, or TSO authorization holder's quality system. The statement also should describe how design change information will flow to the applicant, and consequently, to the CAAI.

2.4.2.3.3. Information that establishes the life limits or airworthiness limitations of the article.

2.4.2.4 Identicality Finding. Based on the review of the "Production Approval assist letter" that contains the information specified in paragraph 2.4.2.2 of this order, the Manufacturing Department will make a finding of identicality by showing evidence of a licensing agreement. The MD also will review the Production Approval supplement prepared by the applicant.

2.4.2.5 Life-Limited Articles. The MD will forward applications for life-limited articles to the certificating ED engineer to verify completeness of design data. The MD should ensure that the application includes a continued operational safety plan.

2.4.3. Marking Requirements.

2.4.3.1 **Type Certificated products - Regulation 55 of** Air Navigation Regulations (registration and marking of aircraft), 1973 (hereinafter – ANR.Registration) specifies the marking requirements for articles produced for installation on TC products, STC products, and TSO articles.

2.4.3.2 **Parts to be installed in Type Certificated products under PMA -** In accordance with regulation Par. 57 of ANR.Registration, articles produced under a PMA must be permanently and legibly marked in a manner that will enable persons to identify that it is a PMA article, the manufacturer, and the part number. The issuance of the PMA letter authorizes and requires the holder to mark articles as prescribed in Par. 57.

2.4.3.2.1. Marking Critical PMA Articles. In addition to the marking requirements of Par. 57, a PMA article with a critical characteristic(s) must be permanently and legibly marked with a serial number. The CAAI must confirm that the marking location and the associated process will not affect airworthiness.

2.4.3.2.2. Marking Detail Parts of PMA Assemblies. PMA article markings required by Par. 57 are applied to the top-level assembly of the approved replacement or modification article. Marking subassemblies or individual detail parts is not required. For example, if the PMA were approved for a hydraulic pump, the PMA marking would be affixed to the completed assembly. It is not required that each individual subassembly or detail part within the assembly be marked with "CAAI-PMA," unless it is being produced under its own PMA. If a PMA is granted for an assembly, individual detail parts of the assembly sold separately, except those produced under their own PMA, must be accompanied by a shipping

document containing the information required by Par. 57 and must identify the detail part as a subcomponent of a PMA assembly. The article marking requirements for detail parts that are sold by the original PMA holder for installation into its related PMA assemblies may be found within the applicable design data for the assembly. This provides traceability of the individual detail parts to their related PMA assemblies.

Note: There is no need to reissue previously issued PMA letters that require detail parts of an assembly sold separately to be marked in accordance with Par. 57.

2.4.3.3 Part Numbering. Except as provided in paragraphs above, the applicant's article should be numbered such that it is distinguishable from the corresponding TC holder's part number. The TC holder's part number with a prefix or suffix is sufficient for this purpose, as long as use of such a prefix or suffix will not cause confusion with the part marking practices of the TC holder. The requirement of Par. 57 (to mark with the name, trademark, or symbol of the applicant) may be satisfied by the use of a prefix or suffix, if the prefix or suffix is consistent across the applicant's product line. Each article also must be marked with "CAAI-PMA".

2.4.3.4 Supplier Part Number. Some applicants are suppliers to PAHs. Often these PAHs use the supplier part numbers in their approved designs. When these suppliers later apply for PMA, they may continue to use their original part numbers, provided they also meet the requirements of Par. 57.

Note: PAHs and suppliers should be advised that when articles are marked only with PAH part numbers, the PAH is responsible for the design and quality of the article and any compliance and enforcement actions. Likewise, when the supplier is manufacturing under its PMA and has marked its article in accordance with Par. 57, they are responsible for the design and

quality of the article(s) and any compliance and enforcement actions.

2.4.3.5 Articles Manufactured Under Licensing Agreement. When the PMA is based on the applicant showing evidence of a licensing agreement, the PMA article may have the same number as the type-certificated article, provided the applicant also meets the requirements of Par. 57.

2.4.3.6 Articles Impractical to Mark. If the CAAI finds the article too small or impractical (because of characteristics) to mark all (or any) of the information on the article, the information not marked on the article must be attached to the article or its container in accordance with Par. 57.

2.4.3.7 Supplier Marking of PMA Articles. Suppliers to PMA holders may identify articles with PMA markings provided the PMA approval holder adequately controls those suppliers as part of its quality system. Suppliers that mark articles should be treated the same as any other supplier furnishing articles or services, using supplier control procedures as part of the quality system. MDs may require that specific article marking controls be included in these procedures, along with any additional conditions that may be necessary for suppliers with direct-ship authorization.

3. Reference Material

3.1. Article 53, 54 to the air Navigation law, 2011.

3.2. Israeli Air Navigation Regulations (Procedures for the documentation of aircraft and aircraft parts), 1977 (hereinafter – ANR. DOCUMENTATION) chapters 6, 7, 10 & 14.

4. Process

4.1. Application

4.1.1. The documents listed below must be submitted to the CAAI Manufacturing Department for review and acceptance or approval[4] as detailed:

4.1.1.1 Approved Design Data;

4.1.1.2 Quality Manual for CAAI approval which complies with the requirements of 2.4 above;

4.1.1.3 Production Processes and the facilities that those process are implemented in, for CAAI Approval;

4.1.1.4 List of Sub Contractors and their scope of work, for CAAI acceptance;

4.1.1.5 List of suppliers of finished Parts and Articles for CAAI acceptance.

4.1.1.6 List of critical parts for CAAI acceptance, as specified in the Airworthiness Limitations section of the maintenance manual or Instructions for Continued Airworthiness.

4.2. Quality Manual Evaluation.

4.2.1. Upon receipt of the documents the Manufacturing Department evaluate the documents in to determine compliance with the requirements of 2.4 above. General guidance for evaluating documents is included in appendix A of this document.

4.2.2. The Manufacturing Department manager shall issue a Letter of Acknowledgement, informing the applicant that a manufacturing Inspector has been designated to initiate an evaluation to determine compliance with applicable regulations.

[4] For a review of the distinction between CAAI approval and acceptance, please review the definitions in appendix B of this document.

4.2.3. Any non-compliance with applicable regulations will be notified to the applicant in writing.

4.2.4. After the Quality Manual has been reviewed, and any applicable corrective actions taken, Manufacturing Department will Approve the Quality Manual submitted by the applicant. The approved Quality Manual will be retained in the Manufacturing Department files.

4.3. Audit

4.3.1. After completion of the evaluation phase, the Manufacturing Department will make arrangements to conduct an Audit within 30 days. The Audit Team will Audit the applicant's implementation of all Quality Manual Procedures that approved by the CAAI.

4.3.2. The audit may take the form of a QSA in accordance with appendix 2 of CAAI Procedure MFG 2.4.001.

4.3.3. The audit criteria listed in appendix B of CAAI procedure MFG 2.4.001 may be used to audit the facility, but note that some of the criteria there will not be applicable for a first-time certification audit.

4.4. Notifying the Applicant.

4.4.1. Upon completion of the audit, Manufacturing Department will formally notify the applicant as to any corrective actions needed to comply with the regulations.

4.4.2. When one or more of the documents listed above are not in compliance with the requirements toward a production approval, CAAI may issue a letter of Approved Production Inspection System (APIS) that allow the applicant to continue the production until reaching PC, without the privileges granted by PC:

4.5. Issuance of a production Approval

4.5.1. After the audit team found that the production approval applicant's Quality System, Production Processes, the facilities that those Processes are implemented in, List of Sub Contractors and their scope of work and the List of suppliers of finished Parts and Articles, are in compliance with the requirements listed above, the Manufacturing Department will issue PC or ITSOA.

Note: When a PC is issued based on a licensing agreement that is for a specific period of time, it must be indicated on PC under "Duration."

4.5.2. Assignment of the Production Approval Number. The MD inspector will assign a Production approval number (PC, PMA, or ITSOA) to all original production approval

letters in accordance with the existing project assignment number procedures. The Production Approval number should be unique to each PAH and be carried forth on subsequent approved supplements for that Production Approval. The MD will sign the Production Approval supplements affirming production approval after completing validation of the quality system.

4.5.3. Production Approval Letter.

4.5.3.1 The MD inspector will prepare the following Production Approval documents:

(1) A production approval letter for the initial issuance of the PA.

(2) A transmittal letter for all subsequent issuances of PAs, including all supplements.

4.5.3.2 The original(s) should be presented to the manufacturer, and the MD should retain one copy.

4.6. Post-Production approval Activities

4.6.1. Additional Article Approvals. If a PAH wishes to produce additional articles under the existing approved quality system, an application must be made and the holder must show compliance with the requirements listed in chapter 2 of this document. If the new articles' production does not require any significant change in the operation or capabilities of the PAH, the MD will then issue a Production Approval supplement that adds the new articles to the original approval with no further review. If the new articles' production constitutes a significant change in the operation or capabilities of the PAH, the MD will conduct a review of the holder's production and quality systems.

4.6.2. Initial Risk-Based Resource Targeting Assessment. Subsequent to the issuance of the PMA, the MD will

conduct an RBRT assessment of the PMA holder. The results will determine the initial basis for conducting ongoing CM responsibilities, as summarized in CAAI procedure MFG 2.4.001

4.6.3. Transferability.

4.6.3.1 A production approval is not transferable to another person, company, or location. The regulations do not preclude revising approval letters to show a change in name only if the holder provides evidence there is no change in the quality system, management, ownership, or location of the principal facility. However, the design portion of a production approval based on an STC may be sold, licensed, or otherwise transferred. If the STC holder or a licensee intends to manufacture articles, it must apply for a new production approval.

4.6.3.2 In the event a production approval holder is acquired by another company, with no resulting change in the legal status of the PMA holder, the acquiring company will not be required to apply for a new PMA. However, the PMA holder must:

(1) Retain possession of the production approval,

(2) Retain the same quality system, and

(3) Continue to operate at the same location with the same core management officials.

4.6.3.3 The MD inspector should conduct an on-site visit to ensure that the PAH has complied with the requirements in Procedure MFG 2.4.001. In addition, the acquiring company should provide a letter to the MD indicating its status as the new owner of the production approval holder and any future plans affecting the status of the production approval holder. The MD inspector should update the project files to include documentation indicating the acquisition.

4.6.3.4 In the event that the status of the PMA changes (for example, the PMA holder is disbanded or absorbed into the acquiring company) or the PMA holder transfers or relinquishes its production approval, the MD will ensure that a new application for PMA is submitted for processing by the CAAI.

4.7. Changes in a Production Approval[5]

4.7.1. **Changes requiring CAAI approval**. After issuing Production Approval by CAAI, the following changes to the PAH's capabilities and / or approved documents are subject for review and approval prior its implementation:

4.7.1.1 Changes in the PAH's access to approved design data (e.g. if the PAH's licensing agreement expires or is amended).

4.7.1.1.1. In case of changes intended to be introduced to ITSOA holder design data, CAAI is to be notified using CAAI Form EN-81a (Located at CAAI website).

4.7.1.2 Any changes to the approved quality system; specifically, whenever the PAH wishes to introduce any changes that may affect the Inspection, Conformity, or Airworthiness of its Product or Article, the PAH must immediately notify CAAI in writing and seek the CAAI's approval. These changes should include, but not limited to, the following:

[5] The requirement for approval of any changes to a PMA is not withstanding listed in ANR.Documentation, which such a requirement for approving changes for PC and ITSOA. This requirement is in accordance with Article 53(c) to the Air Navigation Law that authorizes the Director General of the CAAI to set conditions and terms in manufacturer license. CAAI is acting to amend the regulations to reflect the changing requirements for PMA holders.

4.7.1.2.1. Significant reduction/reassignment of quality system personnel.

4.7.1.2.2. Changes or revisions to quality system data and related procedures approved by CAAI.

4.7.1.3 Any changes in production operations, specifically:

4.7.1.3.1. Resumption of production after being discontinued for an extended period of time for other than normal periods of time, such as vacation periods.

4.7.1.3.2. Changes in the Production Processes, equipment and production operations.

4.7.1.4 Changes in location of Principal Manufacturing Facilities:

An applicant's manufacturing complex would normally consist of a principal facility and all associate facilities using the same quality system approved by the CAAI, for the particular TC Product(s), Approved Part, or ITSOA article(s).

When a PAH moves the principal Manufacturing Facility to a new location, **the production Approval is no longer effective**. In this case the PAH must reapply for a production approval as per the instructions of this document.

The Production approval issued to applicant will specify the principal manufacturing facility that controls the design and quality of the Product(s) or Article(s) for which the Approval was granted, as well as associate facilities. The Principal Facility address will be listed under the “business address” and all associate facility addresses will be listed under “Manufacturing Facilities” on the Production Approval. A mailbox address is not acceptable for a facility since the actual location must be identified. Such addresses, however, may be used as supplemental to the actual address when desired for such uses as corresponding to and from CAAI offices.

4.7.1.1 **Changes requiring CAAI acceptance**[6]. The following changes are to the PAH's capabilities and or documents may be accepted CAAI: Changes to the list of sub contractors and their scope of work.

4.7.1.2 Changes to the list of suppliers of finished Parts and Articles.

4.7.1.3 Changes to an associate facility: When the PAH seeks CAAI Acceptance to move an Associate Facility or add a new Production Facility, the CAAI may, if deemed necessary, conduct a Preliminary Audit at the new Production Facility or moved facility. If an Audit is deemed necessary, a satisfactory Audit result must be obtained before the facility can be Approved for Production. The Production Approval also must be amended to reflect this change.

5. Task Outcomes

5.1 The end result of the process: issue of Production Certificate, Israeli Technical Standard Order Authorization or Parts Manufacturer Approval.

5.2 Future Activities**:** None

[6] For a review of the distinction between CAAI approval and acceptance, please review the definitions in appendix B of this document.

Appendix A. Evaluation of a PAH's Quality System

1. Purpose. This appendix, in conjunction with the applicable ANR.DOCUMENTATION requirements, provides guidance to review all data submitted by a PAH that describe the quality system required for the applicable production approval. These data will include a quality manual describing the PAH's quality system in accordance with Par. 53. Any inadequacies in the data submitted must be identified to the PAH for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MD will approve the data, as applicable.

2. Data Review. All quality system data submitted to the MD must be reviewed to ensure that:

a. The described quality system will adequately provide for the consistent acceptance of only those products or articles which are in conformity with the approved design data and in a condition for safe operation.

b. The quality system is adequately described, meets the intent of the pertinent rules, and can be realistically implemented. Be cautious of data that are overly descriptive, since such data may often be difficult to implement.

c. The data are identified by title, revision, and date, and contain the signature of the appropriately authorized person in the PAH's organization.

d. The data are well organized, unambiguous, and not subject to misinterpretation.

e. Inspection procedures are well organized and easy to understand and implement.

f. The quality system adequately defines when a product or article has officially left the control of the quality system.

g. The quality system adequately describes the process of re-introducing, back into the quality system, new products or articles that have left a PAH's quality system. The process must ensure the following criteria are met:

(1) The products or articles are traceable to the PAH that manufactured them.

(2) The products or articles meet the type design and are in a condition for safe operation.

> **Note:** Depending on their complexity, a visual inspection may be adequate for determining that the products or articles meet their type design. When a determination cannot be made by a visual inspection, the products or articles must be re-introduced to the quality system at a point where functional testing is possible.

h. New products and articles that leave the control of a PAH and fail on initial installation and/or testing are considered to be nonconforming. Those nonconforming products and articles that are returned to the PAH must be processed utilizing the PAH's quality system.

i. Statistical sampling plans are clearly documented. The Manufacturing Inspector must ensure that sampling plans based on valid consensus standards do in fact comply with those standards (for example, MIL-HDBK-683, Statistical Process Control (SPC) Implementation and Evaluation Aid; MIL-HDBK-1916, Companion Document to MIL-STD-1916; "Zero Acceptance Number Sampling Plans," by Nicholas Squeglia, ASQ Quality Press). Sampling plans that are not based on valid consensus standards should be closely examined to determine their statistical validity (Juran & Gryna, *Quality Control Handbook*, may be used as an aid in determining this validity). Regardless of the basis of the sampling plans used, the PAH is responsible for ensuring that all products or articles conform to the approved design data. Therefore, the Manufacturing Inspector should ensure that the acceptance/rejection criteria will not allow for acceptance of nonconforming product or articles. If specific experience or expertise is required to review sampling plans, the PI should advise the MD manager. The following should be considered when reviewing sampling plans:

(1) Controlled process. Prior to implementing a sampling plan, objective evidence must exist that demonstrates and ensures that the process(es) used to manufacture sampled characteristics are documented, controlled, repeatable, and consistent.

(2) Characteristics classified. Each characteristic that will be part of the sample plan must be identified, evaluated, and properly classified. Characteristics are classified based upon the effect they may have on safety or usability of the product or article.

(3) Proper and reasonable sample sizes. Specific sample sizes should be chosen based upon the lot/batch size, the characteristic classification and criticality, the design tolerances being measured, and the probability of accepting nonconforming products or articles.

(4) Unbiased sample selection. The plan should fully describe how samples are selected. The sample method must be unbiased; that is, the sample selection method does not unfairly weight a particular timeframe, production sequence, tooling configuration, operator(s), batch, etc. To ensure an unbiased representative sample, the lot, batch, or group should be homogeneous (that is, consisting of the same characteristics, type, grade, class, composition, and manufactured under the same data and conditions, and manufactured at approximately the same time).

(5) Samples controlled. When sampling is used, the results of the selected sample apply to the entire lot, batch, or grouping. The lot, batch, or group should be clearly identified and segregated throughout the entire sampling, inspection, and possible disposition process. In the event that any characteristics are found to be nonconforming in the sample, the entire lot, batch, or grouping must be withheld pending additional analysis, ensuring that there are no other nonconforming articles. Should this analysis indicate the possible existence of additional nonconforming articles, the entire lot, batch or grouping must be dispositioned in accordance with the PAH's approved material review procedures. In all cases, the PAH is responsible for ensuring that all products and articles conform to the approved design data.

3. Data Approval/Acceptance Standards for a PC, PMA, or TSO Authorization Holder. The MD will determine the adequacy of the data reviewed in accordance with paragraph 2 of this appendix. Any inadequacies in the data submitted must be identified to the PAH for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MD will prepare a letter approving the PAH's quality system data and forward it to the PAH. These data, ANR.DOCUMENTATION and the CAAI-approved design data comprise the standards with which the PAH must show continued compliance.

Appendix B - Definitions

Approved. Unless used with reference to another person, means approved by the CAAI or any person to whom the CAAI has delegated its authority in the matter concerned, or approved under the provisions of a bilateral agreement between the Israel and a foreign country or jurisdiction.

Article. A material, part, component, process, or appliance. Articles may include sealants, modified standard parts, brake assemblies, etc.

Associate Facility. A facility that has been approved as an extension to an original PAH. This facility is owned and operated by the same corporate management as the original PAH that controls the design and quality of the product or article(s), except for companies participating in joint-production and/or co-production business agreements. The associate facility must be listed as a manufacturing facility on the PC or the letter of authorization for other production approvals, for example, PMA or TSO authorization.

ANR. Air Navigation Regulations of Israel.

Audit. A systematic and independent examination to determine compliance of an established supplier system, inspected product or article(s), or processes with purchase order requirements, technical data, or specifications.

Auditor. An individual the CAAI appoints to perform audits on its behalf.

CAAI. Civil Aviation Authority Israel

CAAI-Approved Data. Data specifically approved by the CAAI or CAAI-delegated representatives, including any document referenced therein. These data may include design drawings, manuals, procedures, and specifications.

CAAI Acceptance – "Accepted" is used to describe a document, manual, or checklist that does not have, or is not required to have, CAAI approval. Certain documents required an applicant for a Production approval "accepted" by the CAAI – in effect, considered approved unless otherwise formally notified by the CAAI within a set time limit of 45 days, which can be further extended by CAAI notification. If the CAAI concludes that an accepted section document is not in compliance, the CAAI must formally notify the applicant / PAH of the deficiency within 45 days. Upon notification, the applicant / PAH must take action to resolve the deficiency.

Certificate. A document (that is, a certificate or approval) issued by the CAAI that recognizes an applicant's or PAH's established quality system and allows for the production of products or articles in accordance with an CAAI-approved design.

Commercial Part. A part not specifically designed or produced for applications on the aircraft. For the purpose of ANR.DOCUMENTATION,

a design approval holder may designate an article as a “commercial part” if the CAAI finds the part:

(1) Is not specifically designed or produced for applications on aircraft, and

(2) Is produced only under the commercial part manufacturer’s specification and marked only with the commercial part manufacturer’s markings.

Corrective Action. The measures taken to resolve unsatisfactory conditions and to prevent reoccurrence.

Days. A reference to calendar days, unless otherwise specified.

ED. Engineering Department of CAAI

Established Industry Practice. A widely followed method of operating that achieves consistent performance of specific functions. Examples of established industry practices include a calibration recall system and an internal audit system.

Facility. A physical location where a PAH or associate facility performs all or part of the system element functions relevant to the approval authority granted by the CAAI.

Foreign Manufacturer. A person other than a CAAI-issued PAH who causes a product or article(s) to be produced outside the Israel.

ITSOA. A document issued by CAAI to persons who desire to manufacture an article that meets a specific TSO.

Licensing Agreement. A commercial agreement between a TC or STC holder and a PAH (or applicant) formalizing the rights and duties of both partners to use the design data for the purpose of manufacturing the product or article.

MD. Manufacturing Department of the CAAI.

Manufacturing Inspector (MI). A manufacturing inspector who has been assigned CM responsibility of a particular PAH or associate facility.

Manufacturer. A person who causes a product or article(s) to be produced. A manufacturer may be a PAH or a supplier to a PAH.

Noncompliance. A PAH’s or associate facility’s operating practice that is found to be inconsistent with ANR, CAAI-approved data, or internal procedures. A supplier’s operating practice found to be inconsistent with a PAH’s or associate facility’s purchase order requirements is considered to be a noncompliance by the PAH or associate facility.

Objective Evidence. All the means by which any alleged fact tends to be established or disapproved. These means must be factual, convincing, relevant, valid, reliable, and complete. Examples of objective evidence include interview statements, photographs, charts, maps, diagrams, documents, and records. Documents and records include items such as work travelers, inspection documents, CAAI-approved drawings, PMA and

TSO approval letters, airworthiness approval tags (CAAI Form 8130-3, Airworthiness Approval Tag), and calibration logs.

Principal Inspector. A manufacturing inspector who has been assigned CM responsibility of a particular PAH or associate facility.

Principal Facilities. The main facilities located at the address of the applicant.

Procedure. A specific way to perform an activity or function that is documented and usually contains the purposes and scope of the activity or function: what is to be done and by whom; when, where, and how the activity or function is to be done; the materials, equipment, and documents to be used; and how the activity or function is to be controlled and recorded.

Produce. To manufacture, or cause to be manufactured, a product or article(s).

Product. An aircraft, aircraft engine, or propeller.

Production Certificate (PC). A document issued by CAAI to persons who desire to manufacture a complete product.

Parts Manufacturer Approval (PMA). A certificate issued by CAAI to persons who desire to manufacture an article under a PMA.

Production Approval. A document issued by the CAAI to a person that allows the production of a product or article in accordance with its approved design and approved quality system, and can take the form of a PC, a PMA, or a TSO authorization, in accordance with paragraph 51 of the air Navgiation Law, 2011..

Production Approval Holder. The holder of a PC, PMA, or TSO authorization who controls the design and quality of a product or article(s). A person who has been issued a production approval by the CAAI.

Production approval assist letter. A letter accompanying a licensing agreement, specifying the technical aspects of the relationship between the design certificate holder and the applicant for production approval.

Quality System. A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles.

Quality System Data. Data that provide a description of the quality system required by ANR for a PAH. These data would encompass the methods, procedures, processes, inspections, tests, specifications, charts, lists, forms, etc., which the PAH employs to produce products or articles.

Risk-Based Resource Targeting. A structured process designed to support **CAAI** management in determining risk, assigning resources based on that risk, and prioritizing multiple projects.

Supplier. Any person ~~as defined by 14 CFR part 1, Definitions and Abbreviations,~~ that furnishes products, articles or services (at any tier in

the supply-chain) that are used or consumed in the manufacture of, or installed on, aviation products or articles**.**

Quality System. A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles.

Quality System Data. Data that provide a description of the quality system required by the regulations for a PAH. These data would encompass the methods, procedures, processes, inspections, tests, specifications, charts, lists, forms, etc., which the PAH employs to produce products, articles, or parts.

Risk-Based Resource Targeting (RBRT). A structured process designed to support MD management in determining risk, assigning resources based on that risk, and prioritizing multiple projects.

Standard Part. A part manufactured in complete compliance with an established government or industry-accepted specification that contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

(1) **Note:** Examples of specifications include, but are not limited to, National Aerospace Standards (NAS), Air Force-Navy Aeronautical Standard (AN), Society of Automotive Engineers (SAE), SAE Aerospace Standard (AS), and Military Standard (MS).

Standardized Audit Criteria. Questions developed for each system element that the CAAI QSA teams use to plan and document the audit. The applicable the regulations requirements, appropriate CAAI AWs and Aps (Advisory Pamphlets), international standards and specifications, and established industry practices are the basis for these questions. Refer to Appendix B to ~~this Certification procedures~~ the Surveillance procedure 2.4.001 ~~for products and parts.~~

Supplier. Any person as defined by the regulations that furnishes products, articles or services (at any tier in the supply-chain) that are used or consumed in the manufacture of, or installed on, aviation products, articles, or parts.

Supplier Control Audit. A systematic and independent examination to determine compliance of an established supplier system, inspected product, article, or part(s), or processes with purchase procedures for products and parts requirements, technical data, or specifications.

System. An activity or function that may affect the maintenance of an CAAI-approved design, quality data, or the design approval system.

System Element. A specific activity or function that may affect the maintenance of CAAI-approved design or quality data, such as design data control, manufacturing controls, and supplier control. Such activities

are subject to audit of the adequacy and implementation of approved procedures.

Quality System. A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles as described in the Quality Manual.

TSO. Technical Standard Order

TC/STC. Type Certificate / Supplement TC

CRITICAL PARTS. a part for which a replacement time, inspection interval, or related procedure is specified in the Airworthiness Limitations section of a manufacturer's maintenance manual or Instructions for Continued Airworthiness.