



Advisory Circular AC146-1

Aircraft Design Organisations

**Revision 2
01 July 2016**

General

Civil Aviation Authority Advisory Circulars (AC) contain information about standards, practices and procedures that the Authority has found to be acceptable for compliance with the associated rule.

Consideration will be given to other methods of compliance which may be presented to the Authority.

When new standards, practices or procedures are found to be acceptable they will be added to the appropriate AC.

In addressing a subject the use of the imperative *must* or *is to*, terms not normally welcome in an AC, is because it is associated with mandatory provisions of the Rule itself.

Each reference to a number in this AC, such as 146.15, is a reference to a specific rule within Part 146.

Purpose

This Advisory Circular (AC) provides methods acceptable to the Authority for showing compliance with the aircraft design organisation rules set out in Part 146.

Focus

This material is intended to assist organisations in gaining and maintaining certification to carry out design development and approval in Mongolia.

Related Rules

This AC relates specifically to Part 146, Aircraft Design Organisations – Certification.

Change Notice

Subject to “Memorandum for Technical Cooperation” between the CAA of Mongolia and Mongolia on mutual cooperation in implementation of Assembly Resolution A29-3: Global Rule Harmonization, 29th ICAO Assembly, 1992, which urges States to promote global harmonization of national rules, dated 6th of May, 1999, Mongolian Civil Aviation Safety Regulation has been reconciled to the Civil Aviation Regulation of Mongolia.

Amendment 164 of Annex 1 to the Chicago Convention on International Civil Aviation urges flight crew members, ATC personnel and aircraft maintenance engineers to comply with the language proficiency requirements; and

Under Article 14 of the Civil Aviation Law of Mongolia 1999, "Use of foreign language in civil aviation" the AC has been released in English version only, in order to prevent any mistranslation and misuse of the aviation safety related documents.

This AC146-1 was developed based on NZ AC146-1 revision 2, dated on 24 July 2007.

Introduction

The objective of Part 146 is to provide for the certification of organisations in Mongolia to provide design expertise to the aviation industry. In some cases individuals in these design organisations will be able to approve design changes without further reference to the Civil Aviation Authority.

The majority of Mongolia aircraft are imported from other countries. The Mongolia aviation design industry is therefore based not around aircraft development, although this has occurred, but around the development of modifications that aid in the application of aviation to other industries. Examples of this development are the modifications incorporated on aircraft to support farming, agriculture, and tourism.

Parts 21 and 146 provide for the control of designs and design changes, including modifications and repairs, and provide a framework that reflects the larger overseas authorities procedures and the state of art of the aircraft design industry.

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General

To assist readers with cross referencing, the numbering of the paragraphs contained within this circular correspond generally with the numbering of Part 146.

Definitions

The following terms are used in this advisory circular. Additional definitions may be found in Part 1.

Appliance means any instrument, mechanism, equipment, part, or accessory that is used, or is intended to be used, in operating or controlling an aircraft in flight, or is installed in or attached to the aircraft, that is not part of the airframe, engine, or propeller:

Design change means a change to a type design or a change to any other part of a type certificate or type acceptance certificate that if incorporated would require the modification or repair of a product, its components, or an appliance:

Product means an aircraft, aircraft engine, or propeller:

Technical data are drawings, instructions or other data required to be used for product certification, approvals, and authorisations under Part 21 or for the maintenance, modification, and repair of products, their components, and appliances under Part 43.

Subpart A — General

146.1 Applicability

The Civil Aviation Regulations required firms to be approved to carry out construction, maintenance, design, processing, and supply. The organisational rules in the current Civil Aviation Rules system have replaced most of these regulations. The requirement for a design firm to be approved has been replaced with a requirement for them to be certificated as a design organisation under Part 146.

Part 146 applies to an organisation—

- seeking certification as an aircraft design organisation
- maintaining its aircraft design organisation certification

An aircraft design organisation may carry out design activities covering all aspects of aviation and this is controlled by the certification and continued compliance requirements of Part 146.

Part 146 should be read in conjunction with the appropriate subparts of Part 21 and Part 43 as the three rule parts are mutually supportive.

146.3 Reserved

This rule is normally used for definitions found only in Part 146. As there are no specific definitions the rule is reserved.

146.5 Requirement for certificate

The Civil Aviation Rules require designs and design changes to be approved before use. The approval of these designs and design changes requires development work, and this development should be carried out in a controlled environment.

The control of the design environment is provided by the certification of an organisation for aircraft design activities under Part 146. An organisation that has been certificated is provided certain privileges to conduct design activities

146.7 Application for certificate

This rule prescribes the form of the application to be submitted and allows an applicant to apply without providing any further detailed information. The application can then be registered with the CAA and assistance in developing the organisation can be provided against this application.

146.9 Issue of certificate

There are several requirements to be met for the issue of the certificate. Primarily, the applicant must meet the requirements of Subpart B of the Part to be issued a certificate.

To be assessed as meeting the requirements of Subpart B the applicant's documentation will be checked for compliance with each of the rules and suitability for the type of design tasks the applicant is proposing to carry out.

After the documentation is accepted as satisfactory an inspection of the applicant's facilities and resources will be made and may include interviews with key staff members.

Once the Authority is satisfied with the organisation the certificate is issued. A certificate may be issued for a temporary period and a compliance audit required before full certification is granted. This decision will be made after assessing the type of design work proposed, the adequacy of resources, and the experience of the applicant and the organisation's staff.

146.11 Privileges of certificate holder**Certificate ratings**

The certificate is issued with ratings reflecting the level of design work the organisation will be considered competent to perform. These ratings include—

- D1 for the design of products and components of those products. This would commonly be for the larger, more complex items such as complete aircraft and

engines

- D2 for the design of modifications and repairs on those products above
- D3 for the design of appliances and modifications and repairs for those appliances. These would commonly be for the smaller type of item

Whilst the ratings are general abilities, the detailed capability of an organisation should be stated in its exposition. This detailed capability will largely be dependent on the facilities the organisation has access to and the experience of the personnel the organisation employs. An applicant should not detail activities the organisation will not be able to provide.

Holder of a delegation to approve design changes

If a design organisation wishes to approve design changes without prior reference to the CAA it must employ a holder of a delegation. This holder of a delegation must be employed as a senior person in the design organisation.

Appendix A provides the details for the holding and use of a delegation. Appendix A requires—

- A delegation holder to be employed by a design organisation to retain the delegation
- The design organisation to employ the delegation holder as a senior person if the organisation wishes to approve design changes without further reference to the CAA
- The design organisation to authorise that delegation holder to approve design changes

Additional limitations and qualifications on a certificate

The Director may prescribe limitations and conditions on a design organisation certificate. These additional limitations placed upon the certificate may include classes of design changes, limitations based on the applicable requirements of Part 21, or general qualifications of the design activities considered appropriate.

Classes of design changes are based on the approval abilities of a delegation holder. These abilities will be detailed on the delegation itself but also can be used to define the organisation's abilities. For the purposes of defining the abilities of the design organisation, design changes are classed as follows—

- Class A are those design changes that require comprehensive engineering justification, assessment, and substantiation
- Class B are those design changes that do not require comprehensive engineering justification, assessment, and substantiation

Additional qualification of the scope of design development a certificated organisation may perform may include, but is not limited to, the following—

- Structures, including load determination and stress analysis
- Systems, hydraulics, electrical, control, pneumatic, and fuel

- Flight test and performance determination
- Radio and navigation system installations

Part 21 defines the process for, and details of, design and design change approvals. The design organisation may be limited further to specific areas of design work identified in accordance with the subpart of Part 21. For example, a design organisation can be limited to modification and repair design work only, and not supplemental type certificates. This limitation will be reflected by reference to Subparts C and M of Part 21 on the certificate.

Application for a type certificate

Part 21, Subpart B requires that the applicant for a type certificate be a design organisation. This requirement ensures that the support for the product or equipment is available during design, introduction to service, and continuing use.

Once certificated with the appropriate rating, normally D1, a design organisation may apply for a type certificate.

146.13 Duration of certificate

The all aviation documents issued to organisations should terminate. The report proposed a maximum validity of five years and this has been reflected in the rule.

Where the certification of an organisation will require checking after a period of initial operation the certificate may be issued only for a temporary period. After a satisfactory compliance audit, full certification should be achieved.

The initial compliance audit should ensure that the organisation is complying with their exposition and that the exposition accurately reflects the organisation's activities. Future audits will examine similar compliance requirements and any other relevant matters.

146.15 Notification of ceasing design

As well as ensuring the CAA has an accurate picture of the aircraft organisations in operation in Mongolia, there are continuing airworthiness responsibilities that must be addressed when a design organisation ceases to operate.

If an organisation decides to cease design work the CAA is required to be informed. A letter should be sent to the CAA within 30 days of ceasing design activities. The letter should request the revocation of the certificate but, in practice, the letter should include the certificate itself.

146.17 Renewal of certificate

An organisation should allow sufficient time for the renewal process to be planned and carried out. The time involved will vary according to the level of design activity the organisation is certificated for, and carrying out, as well as the period the certification

has been in force.

Where a certificate has been in force for the full five years a re-entry application and audit process will be required to be followed. This process will ensure that all facets of the organisation comply with the rule. The extent of this re-entry process will depend on the organisation's conduct to date, any changed circumstances, and results of safety audit findings over the period of validity.

146.19 Exemptions

The Director may exempt organisations from the requirements of this Part if a suitable submission is made and the Director finds the grounds for the submission are supportable. Part 11 covers all aspects of exemptions.

146.21 Overseas applications

Organisations located outside Mongolia will only be certificated if the service they provide requires them to be certificated or the Director considers it necessary.

A request for certification by organisations outside Mongolia is considered a remote possibility but may result from an organisation providing design services to a Mongolia organisation.

Subpart B — Certification Requirements

146.51 Personnel requirements

One basis for certification will be an adequate staffing structure from the Chief Executive position to the design personnel.

In smaller organisations the Chief Executive and the senior persons may be the same individual but in all cases there should be clear definitions of the position's responsibilities. The individual undertaking one or more functions in the organisation should have a clear understanding of the division of the responsibilities and be able to show this to the CAA.

The organisation should establish procedures to assess and maintain the competence of all staff. This may require staff to undergo familiarisation training before embarking on particular design activities.

Assessments should be determined on the following factors—

- Academic qualifications
- Licences, certificates, or approvals held
- Employment records
- Written, oral, or practical examination

The procedures for the maintenance of an employee's competence should be shown in the organisation's documents. Continuation training should consider the type of work

the employee is undertaking. For example, a person holding a delegation to approve designs and whom is authorised by the organisation would have different training considerations from those of a draughts person.

Many industry bodies, institutes, and associations require a certain level of continuing professional development (CPD). Examples of these bodies that required CPD are the Institute of Professional Engineers Mongolia. Organisations should consider the CPD of its employees when structuring the continuation training procedures.

The Chief Executive

The Chief Executive must have the authority within the organisation to ensure the activities are performed in accordance with the applicable requirements, and the financial responsibility to support this.

If an organisation has several independent business units then it may be appropriate to apply for certification independently. If this is the case a Chief Executive will be required to be identified for the design unit specifically.

If, on the other hand, an organisation retains one identity the Chief Executive should be clearly shown to have an appropriate level of authority. This may occur where an organisation is certificated for other tasks such as maintenance or manufacture and only one top level exposition is used for all functions.

The senior persons

The person or persons nominated will represent the management structure of the organisation and are required to be acceptable to the Director. The senior persons should be suitably qualified for the positions held and should be given the responsibility for the conduct of the design activities of the organisation. The Chief Executive should ensure that the senior persons are readily available to their respective staff members to assist and direct the organisation's activities.

Titles may vary between organisations, but the requirements are for management representatives for design control, for inspection and testing, and for internal quality assurance. If a particular area is specifically excluded, or specifically included, in the exposition the responsibilities required to be addressed may vary.

In particular, a design organisation may elect not to employ a delegation holder. In this case the organisation must submit all designs and design changes to the CAA for approval.

Design Control

The senior person for design control has the following responsibilities—

- The design control system is implemented and running effectively
- Designs are processed in accordance with the requirements of the Civil Aviation

Rules

- Concessions are processed in accordance with the exposition and any CAA requirement
- The drawing system is effective in providing for the design activities of the organisation
- The continued airworthiness facilities for any design produced are provided
- Support systems are effective in providing for the activities of the design teams
- Any corrective action relating to the design control system resulting from the internal quality assurance programme is quickly and effectively carried out

Inspection and testing

The senior person for inspection and testing has the following responsibilities—

- Any inspections and tests carried out are implemented and running effectively
- Inspections and tests reflect the current state of the art of the aviation industry and provide the results necessary to show compliance with airworthiness requirements
- Suitable arrangements with providers of testing equipment and facilities are established and reflected in the exposition
- Support systems are effective in providing for the activities of the inspection personnel
- Any corrective action relating to the inspection and testing resulting from the internal quality assurance programme is quickly and effectively carried out

Internal quality assurance

The senior person for internal quality assurance has the following responsibilities—

- The organisation remains in compliance with Part 146
- The exposition and the associated procedures remain adequate for the scope of the organisations activities
- Any exemptions required are processed in accordance with the organisation's procedures and Part 11
- Personnel meet the initial and on-going training and qualification criteria defined in the exposition
- Staff are authorised appropriately for performing certifications on behalf of the organisation
- Support systems are effective in providing for the activities of any internal quality assurance personnel
- Any corrective action relating to the exposition, procedures, qualifications, personnel, or support systems resulting from the internal quality assurance programme is quickly and effectively carried out

The delegation holder

The responsibility for the approval of designs and design changes resides with the Director. The Director may delegate some of the design change approval functions to a person meeting the requirements of Part 146, Appendix A.

The applicant for a delegation will have to undergo an interview that will determine the limitations and privileges the delegation holder will have. This interview requires the applicant to show an understanding of design concepts, airworthiness requirements, type conformity, and any other topic the Director considers necessary to show competency.

The delegation holder must be employed by a design organisation to ensure that sufficient support systems are in place to complete the design approval function.

Whilst the delegation holder acts as the Director for the design change approval functions, they are required to be authorised by the organisation to exercise their privileges. This ensures that control remains with the organisation maintaining the design control system. The organisation cannot authorise the delegation holder for functions beyond their delegation.

The requirements for the approval of design changes are explained in Appendix A and are further expanded in Part 21, Part 43, and their associated advisory circulars.

The delegation holder will have their responsibilities explained in their delegation, but as a senior person in a design organisation they will have the following responsibilities—

- Any inspections and tests fulfil the requirements they specify before approving a design change
- Design change descriptive and supporting data is assembled and distributed as required by the exposition
- They can supervise the design work and be readily available, in person, for consultation with those performing the work
- Each complete design complies with the airworthiness requirements
- They only approve design changes in areas that they are competent
- Where the proof of compliance depends on calculations alone, and these calculations are extensive or are based on other than fundamental technical procedures, checking is done by competent persons other than those originally performing the work
- They prescribe relevant limitations and conditions to design changes to ensure an adequate level of safety is maintained
- Support systems are effective in providing for their delegated privileges
- Any corrective action relating to the approval of design changes resulting from the internal quality assurance programme is quickly and effectively carried out

146.53 Facility requirements

Office accommodation should provide for the management, planning, records, quality, design, and other staff. In most cases a design organisation will consist of only this office accommodation and it should be sufficient to meet the requirements for the scope of design work to be undertaken.

As there is an ongoing requirement to retain design records the provision of storage and the methods of cataloguing and preventing deterioration of this material is required.

Whilst a design organisation may not have the testing facilities at their principle place of work, they may own and maintain calibrated and critical equipment. This test and measurement equipment should have adequate protection and control.

143.55 Equipment, tools, and data

It is recognised that design organisations may not have the facilities to perform all the required calculations, testing, and inspection to confirm a design conforms to a design standard.

The requirements extend to the following provisions—

- Design data from organisations such as libraries, Mongolia Standards, the CAA, the military, and other design organisations
- Tools and testing facilities requiring hanger, workshop, or other specialised environments
- Equipment including measurement, drawing, and computer support equipment

In undertaking design work the organisation should ensure that it identifies the testing locations it intends to use regularly in its exposition. If tools and equipment are located at the testing premises then controls should be in place to ensure the equipment is controlled and calibrated as necessary.

Outside organisations, or organisations certificated under other Civil Aviation Rules, may be acceptable to provide the equipment, tools, and data facilities. In these instances a contractual arrangement would be expected and this agreement should be referenced in the exposition. Subcontracting is addressed in Appendix G of this advisory circular.

Calibration

The calibration of tooling and equipment is a critical factor in ensuring a repeatable product, test, or service.

Tooling and equipment should be calibrated by recognised organisations that provide conditions for testing appropriate to the calibration required. Appropriate conditions include—

- Competent staff
- Suitable environment
- Technically appropriate procedures
- Full traceability of calibrations

An organisation may calibrate equipment itself if it has the correct reference items or may use a suitable body to carry out calibration activities. When contracting a calibration facility, organisations should note that ISO 9000 certification does not in

itself constitute laboratory accreditation. Laboratory accreditation for calibration purposes is carried out against ISO Guide 25 that includes the above requirements.

For reference, Testing Laboratory Regional Council Mongolia and list similar policy requirements for organisations to conduct calibration of inspections, measuring, and test equipment. Acceptable organisations include—

- National Measurement Laboratory, Mongolia
- Measurement Standards Laboratory, Industrial Research Limited, Mongolia
- National Physics Laboratory, United Kingdom
- A metrology or calibration laboratory accredited for the equipment required to be calibrated by—
 - the National Association of Testing Authorities ,Mongolia
 - the Testing Laboratory Regional Council , Mongolia
 - NAMAS, United Kingdom
 - Other national standard laboratories recommended by, or accredited to, the above organisations

146.57 Design control system

The design control system can be likened to the internal quality system but is more specific in its application. The Joint Aviation Authority require a design assurance system to be established and maintained for the control and supervision of the design work. It is considered appropriate to follow this approach.

The design control system should ensure—

- Design control procedures are published, maintained, and followed
- Designs and design changes comply with the applicable airworthiness requirements and have no unsafe features
- Subcontracted work is identified and the design organisation exercises control over its performance
- Responsibilities for issuing documents are clearly identified and personnel are given clear descriptions of the scope of their authorisations

To ensure that there are no unsafe features in a design or design change may practically be impossible to achieve. For example, changes incorporated subsequent to the design entering service may introduce problems with the original design unforeseen by the designer. A design organisation should include procedures that ensure designs have no unsafe features that could have reasonably been identified during the design process. The organisation should take all possible compromises to airworthiness into account and may subsequently use limitations, conditions, operating instructions, and incorporation procedures to limit the effect of any otherwise unsafe features.

The design control system does not specify a requirement for a totally separate checking system. This allows the small design organisations consisting of few individuals to be certificated. Since the certificate can be limited in its scope, the smaller organisations may be required to rely on a degree of CAA involvement for the tasks

that require independent checking. Such certificate limitations will be dependent upon the competency of the applicant's staff.

146.59 Design control procedures

The design control procedures form an integral part of the design control system. As part of the system there should be adequate copies of all technical data necessary to carry out the design activities for which the organisation is certificated.

In providing this information, the organisation should make the relevant data available to personnel requiring to use it. When computer systems are used, the number of terminals and the types of software should be adequate to provide for use by the relevant staff members. In providing electronic information the organisation should ensure that the necessary software and information updates are scheduled to enable the correct reference material to be accessed.

The drawings produced by a design organisation ultimately define a design and there is a requirement for drawing control procedures. Appendix B of this advisory circular details more considerations for the drawing production and control system.

As well as control of the drawings, a design organisation has a requirement to provide document control procedures. These procedures should ensure that the correct reference materials are current and authorised for use in the design activities. These requirements extend to computerised records and documents as well as software updates. The procedures should include an electronic information control section if this is utilised by the organisation.

The design control procedures include the requirement for methods for the inspection and testing of specimens of the design to demonstrate compliance with airworthiness requirements. The inspection and test procedures may not apply to all designs and design changes developed by the organisation and the design control procedures should include methods to determine when testing is required.

Documentation

The design control procedures should include systems to control the documentation used by the organisation.

The documentation required to be addressed in the procedures includes all company procedures, test procedures, technical data, and reports. The documents should be available to all employees requiring the information and should be reviewed prior to use.

The rule requires that each item of documentation is identifiable so that only that information relevant to the design is used. Documentation otherwise considered obsolete may therefore be required for a design task. If a design or design change is still in current use, then the documentation should not be considered obsolete. The rule

however recognises that otherwise superseded data may be appropriate to a design activity.

When utilising documentation that is otherwise considered obsolete, the organisation should ensure procedures provide for confirmation of the relevance of that documentation. This confirmation would normally be by the person approving the design or issuing the statement of compliance. In accepting that documentation the appropriate person should ensure—

- The design activity cannot be carried out with otherwise acceptable documentation
- The documents are directly relevant to the product to which the design activity relates
- The level of safety is equivalent to those standards considered acceptable for the type of operation the product is to be submitted to

Proprietary information

In determining the procedures to be employed by the design organisation the issue of commercial- in-confidence and proprietary information is raised.

The actions up to and including the statement of compliance can be taken as being commercially sensitive and owned by the developing design organisation.

The approval however, even if completed by the design organisation's delegation holder, is carried out by the Director and becomes publicly available information. This means that any pages containing the approving signature become public information. One particular example of this is any supplemental pages for flight manuals, where they do not form the design change approval itself, but are however approved as part of the delegation holder's functions.

Figure 1 shows the relationship between design organisation commercial information and public information.



Figure 1. Proprietary Information

Any submission to the CAA for approval is treated in a similar manner and the approval itself is the only document generally available.

Design stages

There are three broad stages of design development and each has its final certification requirements. These stages are shown in Figure 2.

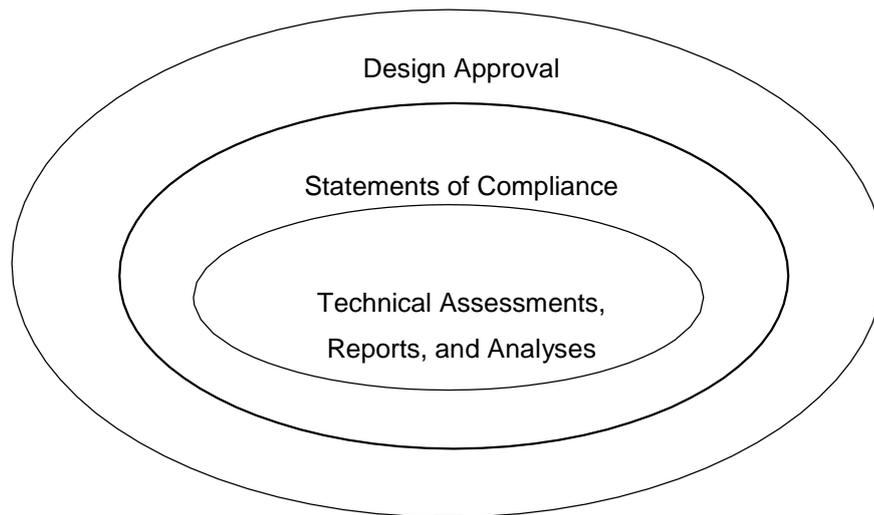


Figure 2. Design Stages

Technical assessments, reports, and analyses

This area forms the majority of the design organisations tasks. The technical assessment should examine all facets of the design or design change and conclude with a statement that the design meets the intended requirements.

At this stage this is not a certification of anything other than the fact that the design has been developed, all reports supporting the design are available, and any stress analyses or other testing has been concluded.

The format of technical assessments and reports is up to the organisation but standard layout should be used and identified in the exposition or other design control manuals. The layout should include the following sections—

- The name of the organisation and a reference number for the assessment
- The description of the items affected
- A brief description of the design change
- Technical data that includes—
 - descriptive data
 - substantiating data
 - amendment requirements
 - other supporting data such as weight and balance calculations

Statements of compliance

This is the confirmation by an authorised company person that the design has been checked, complies with the airworthiness requirements, and is acceptable for approval.

The terms *compliance* and *conformance* are often used interchangeably. This is not strictly correct.

Conformance generally refers to the conformity of a design to an applicable type design. It is correct, therefore, that a statement of conformity attests to the design showing conformity with the type design.

Compliance has a much broader meaning and better reflects the entire design concept. A design comprises several parts and conformance to the type design is only one aspect.

A design or design change must meet the relevant airworthiness requirements including the following—

- Conformity to the type design
- Applicable design standards
- Special conditions by the CAA
- General safety aspects of the design
- The design's fitness for use

The statement of compliance therefore refers to the wider considerations a design must take into account.

A design organisation may utilise the services of an outside agency to provide for some of the design activities. In these cases the details of the authorisations issued to other persons is a requirement of the exposition. It is appropriate that a design organisation use contractual arrangements to formalise these authorities.

Aspects for consideration when setting up contracts are included in Appendix G.

Commonly used subcontractors should be listed in the exposition and be acceptable to the Director. The scope of the tasks assigned to these subcontractors should be dependent on their competency and the assessment of the organisation. Most examples of these arrangements will be for testing requirements that may be met by recognised laboratories and testing establishments.

In all cases a design organisation should require statements of compliance or written reports attesting to the satisfactory completion of the contracted tasks.

Design approval

Design approval considerations are detailed in Appendix A and are further expanded in

Part 21, Part 43, and their associated advisory circulars.

The design approval is the final stage of the design process and may or may not be required by a design organisation. If a design organisation wishes to approve designs they must employ a delegation holder as described earlier. This person should be authorised by the organisation so that positive control of the approval function is retained with the organisation.

After design change approvals have been issued, copies should be forwarded to the CAA for their records. This is an important requirement for two reasons. Firstly the CAA retains a complete picture of the products, components, and appliances in use or available in the Mongolia aviation environment. Secondly, in approving the design change, *as the Director*, the delegation holder has carried out a CAA function.

The procedures for the issue of design change approvals should detail the requirements the organisation expects to be met to enable the delegation holder to sign the approval. These requirements would likely take into account commercial-in-confidence issues, corporate image issues, and other considerations that may not directly relate to the development of the design.

146.61 Continued airworthiness

The design organisation has a responsibility to ensure that the designs produced are monitored and supported. As with manufacturing organisations, part of this monitoring includes the investigation and analysis of defect incidents reported by operators of the organisation's products.

The organisation should ensure that procedures are in place that address the continuing airworthiness responsibilities. The international Civil Aviation Organisation (ICAO) Document 9642-AN/941, Continuing Airworthiness Manual, contains information relating to the continued airworthiness of aircraft.

Defects that have no effect on safety, in any form, can be considered to be economic or ease-of-use defects. By this we mean that to correct the defect may aid production or make the item easier to use. In turn this may result in an economic advantage to the organisation.

Defects that may result in injury, accidents, or hazards to other aviation activities are considered defect incidents. As the manufacturer has a responsibility to keep the users of their products informed of associated improvements, the design organisation has a responsibility to ensure users of their designs are informed of any improvements.

The defect reporting responsibility of a design organisation will generally cover those design features that are causing a problem. That is, an inherent design fault rather than poor manufacturing or maintenance practices. Defect reporting to the CAA is covered in Part 12 and its advisory circular.

As part of the documentation of a design, particular a product design, there is a requirement for Instruction for Continued Airworthiness. These instruction may be developed in conjunction with a maintenance or manufacturing organisation if the design organisation requires those organisation's assistance.

146.63 Records

Design records are required to be kept in an easily accessible form so type conformity and compliance with airworthiness requirements can be assessed later if required. These documents also form an important part of the reference material for other design tasks, staff training, and continued airworthiness responsibilities.

Records can be kept electronically but systems should ensure the information security, integrity, and retrieval. A system of backing up electronic data would be considered appropriate. Procedures for electronic record and document keeping should consider the following—

- Avoidance of data loss in the event of power interruptions
- Software control, including amendments and prevention of corruption
- Unauthorised access
- Audit trail facilities
- Archiving of data in a similar manner to hardcopies, and for a similar period
- Backup of critical information, preferably once a day, with storage for that backup information
- Data verification, on entry and retrieval
- Publication provision
- Staff training
- Amendment and protection of stored data
- Problem report register including the problem details and solutions

For ease of access records may also be microfilmed or magnetically stored but the original documents should be retained in a secure environment.

The rule requires the ideal retention of records to be 2 years from the date of the withdrawal of the last example of the product from service. This is a very onerous requirement but ensures that the information is available no matter how long the product remains in service. The rule recognises the need for varying this time limit in special cases. The cases that may support the reduction of this period will vary considerably but may include, but not be limited to, the following—

- The only examples of the product being operated are on limited experimental operations
- The number of products is finite and the necessary information can be provided to each owner for inclusion in the product's service records
- The only known examples of a product are operated in countries not contracted to ICAO
- Although products still exist, the likelihood of restoring an operating example

- of the product is considered extremely rare
- The type certificate is cancelled and the owners of each example of the product informed as to the non-type certificated nature of the product

146.65 Internal quality assurance

Quality assurance is the process of self checking which assures management that the complete system relating to airworthiness is effective. The quality assurance system should provide a system of internal checks which will ensure the integrity of the quality control system. The quality assurance system should also take account of occurrences which may not involve the quality control system but which may indicate the level of quality of the service. These could include the continuing airworthiness requirements relating to accidents, incidents, and defects affecting users of the product.

The level of self checking will depend largely on the size and activities of the organisation. The holder of a design certificate should decide what statistics and other information will provide the best assurance that the quality control system is effective.

Compliance with MNS 9000 series of standards would be an acceptable means of meeting the requirements of Part 146. MNS 9004 (ISO 9004) also provides guidance information for establishing quality systems.

The requirements for the internal quality assurance programme are extensively detailed in the rule and AC00-3 expands on the procedures a system should include.

A complete quality control system would provide control over all phases of design. A totally integrated quality control system should consider the following—

- Data control
- Subcontractor control
- Prototype manufacturing control
- Special processes dependent on the skill of staff
- Design equipment control
- Inspection and testing control
- Dealing with inadequate designs
- Identification of designs
- Protection of designs
- Storage and security
- Statements of compliance with the airworthiness requirements
- Issue of approval documents
- Retaining records relating to quality control
- Dealing with service difficulties

The holder's internal quality assurance procedures should ensure—

- Items requiring checking are checked and the level and frequency of the checks detailed
- The identification of personnel who will carry out required checks

- The documentation of the checks and the communication of the results to management
- The identification of those persons responsible for reviewing the results of the checking and taking the action necessary to rectify any deficiencies found
- The identification and appropriate reference to supplementary data such as—
- copies of all inspection and acceptance forms and check-lists for designs and completed prototypes, together with instructions for their use
- the identification of the various inspection and process certifications required, and their meaning
- schedules of inspections for design, testing, and inspection equipment
- listings of manufacturing processes which are relied upon to assure quality, conformity, and safety of the completed product

The single person operation could achieve internal quality assurance in a number of ways.

The individual could pick up the senior person responsibilities in respect of quality assurance but in order to achieve the necessary independent overview the organisation would need to have in place very specific procedures to spell out the task. The person responsible would need to convince the CAA that they were able to separate this function from any other tasks. It may also be necessary for the CAA to be more active in overseeing this type of organisation.

Alternatively the individual could contract an independent quality assurance person specifically to carry out the internal quality assurance task. It should be clearly understood that this person is not an auditor but is in fact a senior person responsible for quality assurance and would carry out the senior person responsibilities detailed in this advisory circular.

146.67 Design organisation exposition

The exposition is the publication that governs the operation of the organisation. An organisation already certificated under another Civil Aviation Rule may have only require an additional top level document that references procedures manuals common to both types of organisation. An example would be a single quality assurance manual for a combined maintenance and design organisation.

The exposition includes details of, or references to, the following—

- The management definition of the organisation
- Senior persons
- Organisational structure
- Work locations
- Capabilities of the organisation and the design activities to be performed
- Procedures used in the provision of the design activities
- Control and availability of the exposition

An advisory circular may be issued in the future to explain what the CAA is expecting in an exposition.

Subpart C — Operating Requirements

146.101 Continued compliance

The organisation is required to comply with their exposition and the procedures and systems included in it. The exposition should ensure that the organisation maintains compliance with Part 146.

A design organisation is primarily certificated to develop and approve, in some case, designs and design changes. In the completion of these tasks the design organisation should ensure that their designs comply with the applicable airworthiness requirements, have no unsafe features, and are fit for embodiment.

146.103 Continuation of designs

Designs are normally non-terminating in nature. That is, once a design is approved for use it remains approved for use forever, provided any restrictions or limitation imposed upon it are complied with.

146.105 Changes to certificate holder's organisation

An organisation should always ensure that its exposition remains an accurate description of the organisation and its activities. When there are changes to staff, structure, location, or documented procedures the organisation should ensure the exposition reflects these changes.

The organisation is required to provide a copy of any amendment to the Director as soon as practicable after its incorporation. As a rule, *as soon as practicable* means by the next practically available standard postal method.

Prior acceptance by the Director is required for the following changes to an exposition—

- The Chief Executive
- The listed senior persons
- The design activities
- The locations at which work is carried out, including the design tasks and the testing and prototype manufacture locations

146.107 Safety inspections and audit

One function of the CAA is to monitor adherence to the safety and airworthiness standards. The Civil Aviation Act empowers the Director to require and carry out safety inspections and audits. Certificated organisations should comply with any reasonable audit requests from the Director.

The safety audit programme will normally be agreed with the organisation at the time of issue of the certificate, and be reviewed at regular intervals.

Appendix A — Delegation for the approval of design changes

As discussed in this advisory circular, the responsibility for design approvals is retained by the Director as this reflects other international requirements. In accordance with delegation of director's functions or power to persons outside authority of the Civil Aviation Act, the Director may issue delegations to persons meeting certain criteria to enable design changes to be approved without further reference to the CAA. This appendix prescribes the qualifications and experience, and the privileges and limitations associated with, the grant of a delegation for the approval of design changes.

Privileges and limitations

The design delegation holder is not permitted to carry out their delegated approval function outside a design organisation. This ensures that the support structure is available for that person to satisfactorily approve design changes. Therefore, the design delegation holder relinquishes their delegation if they leave a design organisation.

It would be acceptable for a design delegation holder to move from one design organisation to another and retain their delegation. If the organisations had different ratings or design activities the delegation may require amendment to reflect the scope of the new organisation.

Design changes are divided into two classes for the purpose of approval by delegation holders—

- Class A design changes that require full engineering investigation
- Class B design changes that do not require full engineering investigation

In conjunction with design change approvals it is appropriate that a delegation holder can approve flight manual supplements. There is a limitation on this ability however. The delegation holder may only approve those flight manual supplements that result directly from a design change the organisation develops and the delegation holder approves. Flight manual amendment alone should be referred to the Aircraft Certification Unit of the CAA.

Flight manual supplements are further described in Appendix A to the advisory circular. Flight manuals and their approval is detailed in a Part 21 advisory circular, AC21-5.

Qualifications

The qualification requirements are clearly laid out. The applicant for a delegation will be expected to meet the academic qualifications as a minimum to be considered for a delegation interview.

The interview for the delegation holder is considered a critical assessment of their understanding and experience with respect to designs and design changes. This

interview will determine the scope and any limitations or restrictions that may be placed on the delegation.

Subsequent to the issue of the delegation, the holder would be expected to maintain some form of CPD. This is considered important to ensure that the delegation holder remains current with up to date technologies and the application of professional standards to their work. Delegation holders should examine the organisation's procedures and ensure that CPD is available and supported by the organisation.

Appendix A – Design approvals

Design approval is an important stage of development as it finalises the product, component, or appliance for manufacture and modifications for incorporation. The approving person for a design is the Director although certain design changes may be approved under design delegations.

The design package

Designs generally consist of several distinct sections that together make up a package. The design package or modification package should consist of the following sections—

- Descriptive data
- Substantiating data
- Other supporting data and consequential information

The package as a whole should be arranged inductively so that the purposes and summary of the design is provided in a covering document. Each subsequent section should be deductive permitting the person approving the work to follow the logical development of the design in each section.

Descriptive data

The completed design package requires descriptive data that fully describes all aspects of the design or design change for manufacturing purposes.

The descriptive data should include—

- Use and application of the design
- Purpose of the design
- Maintenance, operating, and performance data including any limitations for the use of the design
- Installation properties including any factors that affect the interaction of the design with other equipment
- References to standards and specifications used during the development of the design
- Drawings, diagrams, and other physical descriptions of the design, including—
 - special processes and their required outcomes, such as—
 - heat treatments
 - surface finishes
 - weld quality
 - wiring diagrams
 - an equipment list that details the items that make up the completed item
- A summary of particular manufacturing considerations, including—
 - pressures

- temperatures
- environments
- A list that details the substantiating data for ease of reference

Limited descriptive data

In some cases the descriptive data may not be fully available, or considered required, by the design organisation. Limited descriptive data may be appropriate in the following cases—

- Acceptance by the approving person
- The design change is a trial installation to be used for a limited time and under the direct control of the approving person
- The design change has been previously approved by acceptable military authorities
- Where the design change is inadequately described for manufacture, the design can be fully checked by inspection during manufacture and installation

Substantiating data

The substantiating data makes up the majority of the design package. It contains the supporting calculations and descriptions of special processes chosen to provide compliance with the airworthiness requirements.

Substantiating data should include—

- Load analyses
- Failure analyses
- The requirement and suitability of any special processes chosen
- Installation considerations
- Methodology and results of test as to the interaction and compatibility between existing units and the new items
- For an avionics design—
 - an electrical load analysis
 - a failure analysis ensuring that essential equipment are sufficiently independent to prevent complete system failure
 - the layout and ergonomics of applicable units, in particular instruments
- Performance confirmation
- Crashworthiness assessments

Other supporting data

Other data that a design package should address includes weight and balance data, manufacturing data, manual amendment requirements, and installation or incorporation instructions.

Weight and balance

Unless the design change results in a negligible weight change then weights and moment arms should be calculated in the description of the change. Alternatively a complete reweigh could be requested of the aircraft after embodiment.

What is considered negligible varies dependent on the aircraft size and type. The following are considered acceptable guidelines for weight and balance—

- For aircraft less than or equal to 5700 kg MCTOW—
 - a cumulative weight change of up to 1% is considered negligible
 - a moment arm change of less than 1% is considered negligible
- For aircraft greater than 5700 kg MCTOW—
 - a cumulative weight change of up to ½% is considered negligible
 - a moment arm change of less than ½% is considered negligible

Manufacturing data

The manufacturing details should ensure that the equipment can be produced within the design limits. Considerations should include the application of special processes, particular pressures, temperatures, and environments, and the repeatability of production standards if appropriate.

Manufacturing data for designs that are subsequently sold for incorporation should consider the different environments that production may be conducted. In many cases the ideal production of a prototype will not be achievable subsequently, from either the airworthiness or economic standpoints.

Amendments

Amendments to manuals is an important aspect of a complete design package. Maintenance manuals, illustrated parts catalogues, and flight manuals are three documents that may require amendment when a design is incorporated.

In many cases the manuals will not be controlled by the design organisation and to amend the document would require approval of the issuing organisation. A design package may provide supplements to these types of manuals that would subsequently be provided to the purchaser of the design or equipment manufactured to that design. In many cases, if the design is significant enough to require substantial changes to manuals some liaison with the manual issuer would be expected.

Flight manual supplements may be approved when they form part of the design change. Further details on the responsibilities associated with the approval of flight manuals is contained in an advisory circular to Part 21, AC21-5. As guidance a flight manual supplement should include the following sections—

- **Cover Page**; including—
 - the aircraft type / applicability
 - a contents table
 - a list of effective pages
 - the date and revision status
 - the identification of the design organisation developing the supplement
 - a signature, designation, and delegation reference of the approving person
- **General**; including a description of the application of the supplement, particular special considerations for installation or operation, and a drawing if necessary

- **Limitations**
- **Emergency Procedures**
- **Normal Procedures**; including the installation and performance of pilot maintenance as well as the normal operating procedures
- **Performance**

Installation data

For designs that progress to sale and/or installation there should be some installation data provided. In many cases this is provided in a booklet to assist the person carrying out the work. Although a booklet is not required in all cases, design packages should include considerations for maintenance actions pre and post installation, performance testing when installed, and subsequent operation instructions.

Design Checking

It is important that compliance with airworthiness requirements is adequately proven and checked. In some cases there is no need for the calculations to be checked by independent persons. For example, where structural testing confirms the results of structural calculations an independent calculation check would not normally be required.

Where the proof of compliance depends on calculations alone, and these calculations are extensive or are based on other than fundamental technical procedures, it is important that checking is done by suitably qualified persons other than those originally performing the work.

Design Approval

It is the responsibility of an approving person to ensure the complete design complies with the applicable airworthiness requirements. In approving a design a person should ensure the following—

- Only designs in areas that the person is competent should be approved
- The design changes approved should be those that the person has—
 - personally performed; or
 - supervised and checked to the extent necessary to ensure that it complies with the applicable airworthiness requirements
- The applicable descriptive data is included in the design documentation
- Ready availability in person for consultation with those performing the design, testing, or prototyping when supervising the design work
- A qualification such as *OK by inspection* or *OK by comparison* is provided to indicate how—
 - the final design has been assessed
 - the production units are to be assessed
- Independent checking of calculations that may have a affect on structural airworthiness are carried out
- A determination is made that—
 - a product, component, or appliance incorporating a design change, when

operated in accordance with the flight manual or other prescribe operating limitations and conditions, amended as required by the design change—

- meets the airworthiness design standards, or the provisions not complied with are provided for by equivalent levels of safety; and
- has no unsafe feature or characteristic that makes it unsafe for its intended use; and
- the maintenance data provided is adequate for the proper maintenance of the product, component, or appliance incorporating the change.

Appendix B – Drawing system

The drawing system of a design organisation is a key element in the design control system. Drawings may range from sketches to fully draughted drawings to computer produced drawings. The design organisation should ensure that the media it chooses to use is appropriate for the considerations of the drawing standards the organisation wishes to maintain. The drawing system may use one or more of the following media for drawing it produces—

- Paper
- Acetate
- Microfiche
- Computer

In all instances the design organisation should ensure that the system provides security, safety, integrity, and backup of the design data. Personnel should be fully trained on the system used. A blank or an example drawing would aid in any references to the drawing in an organisation's procedures.

The drawing system detailed in a design organisation's exposition should include the following features—

- A description of the drawing system and the standards the drawings are to, such as BS 5070, Mil-STD 100, or a suitable aviation specific drawing standard
- A method of identification of company drawing sheets
- A definition of the company drawing numbering system. The numbering system should be logical, provide a reference on each drawing to the modification package it is approved under, and utilise, as necessary, international recognised numbering standards such as ATA
- Drawing certification procedures that include—
 - drawing checks
 - stress checks and agreements
 - a list of person authorised to certify company documents
- Procedures for the approval of designs and design changes after a drawing amendment
- The distribution of new or amended drawings to all personnel or customers requiring the use of the information. This may be an update service that identifies those drawing that have changed but should provide sufficient information for the person using the drawing to determine the relevant changes and their consequences
- Temporary drawings control
- Amendment control
- A drawing list that—
 - is adequately identified by the type designation and by the issue number or date
 - lists all drawings or enables all drawings to be traced easily from the listed

drawings

- clearly identifies the types and modifications covered if the drawing list covers more than one type of design or covers optional modifications
- contains the approving persons signature

The drawing list will be identified in any applicable type certificate data sheet but need not be identified by issue number or date. This allows a change of the list without a change of the type certificate data sheet.

- Procedures to ensure that—
 - if final drawings are not those used during the prototype stage, the approving person confirms that any new drawings are compatible with the drawing list
 - any amendment of the drawing list to incorporate modifications or to incorporate new models follows the process detailed in the exposition.

Appendix C – Design changes affecting airworthiness

The term *affecting airworthiness* is not used in the rules but it is relevant to explain what the term means for the interpretation of design organisations and delegation holders.

All design changes will affect airworthiness to some degree but it is accepted that the Class A design changes, requiring comprehensive engineering justification, assessment, and substantiation, are most likely to significantly affect airworthiness.

Generally, a design change will be interpreted as affecting airworthiness if it is necessary to substantiate any aspect of the design against the applicable airworthiness standards or it adversely affects safety. The decision as to whether a design will significantly affect airworthiness depends upon the experience and judgement of the design approval delegation holder.

The classes of design changes should not be confused with the major / non-major modification split. Classes of design relate to the approval of data rather than the maintenance actions required for major modifications or repairs. Figure 3 describes the split between approval of data and maintenance actions and highlights the area that Class A and Class B should be considered.

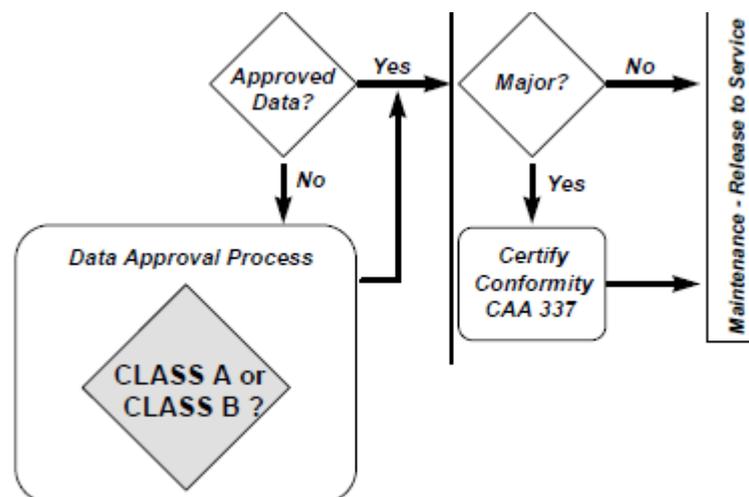


Figure 3. Data approval and application

Where the Class A design change requires comprehensive engineering justification, assessment, and substantiation, a major modification or repair is one that could potentially affect the safety of an aircraft or its occupants where, as a result of its embodiment, one or more of the following incidents may occur—

- Structural collapse
- Loss of control
- Failure of motive power

- Unintentional operation of, or inability to operate, any systems or equipment essential to the safety or operational function of the aircraft
- Incapacitating injury to any occupant
- Unacceptable unserviceability or maintainability

Although the potential for these results normally indicates a Class A design change, this is not always the case. Conversely, a modification may require comprehensive engineering justification, assessment, and substantiation when the modification itself is not considered major.

Class A design changes

Accepting that design changes affecting airworthiness are also design changes requiring comprehensive engineering justification, assessment, and substantiation, Class A design changes include, but are not limited to, the following areas—

- The structure, including—
 - changes to structure supporting design loads
 - changes affecting structural fatigue life
 - changes to structural stiffness or control balance which may create flutter or other aerodynamic characteristics
 - vibration characteristics
- Powerplants, including—
 - engine
 - transmission
 - propeller
 - rotor
- Essential systems and their associated supports, cables, wires, and controls, including—
 - control
 - avionic
 - hydraulic
 - pneumatic
 - air conditioning
 - pressurisation
- Changes to data listed in the type certificate data sheet, flight manual, identification plates, or placards
- The addition of fixed exterior equipment or a change of the exterior shape
- Changes affecting compliance with airworthiness requirements
- The addition, removal, or change of equipment—
 - listed in the type design
 - required by other applicable design standards

- required by specific Civil Aviation Rules
- Equipment installations
- Changes to the empty weight and balance to maintain the c of g within limits, including the addition of ballast that may restrict payload or fuel capabilities.

Class B design changes

The design changes that may not require comprehensive engineering justification, assessment, and substantiation include, but are not limited to, the following—

- Modifications and repairs that would be simple and straightforward in nature when accomplished using acceptable methods, techniques, and practices
- The substitution of materials or standard parts not supplied or specified by the manufacturer that—
 - comply with—
 - approved specifications
 - other airworthiness standards such as a Technical Standard Orders
 - in essential respects are equivalent to those materials or parts replaced
- The incorporation of supplemental type certificates subject to—
 - confirming that the modification is not incompatible in respect of airworthiness design standards with other modifications incorporated
 - provided that flight manual supplements have been approved
- Equipment mounting in accordance with FAA AC43-13-2 Chapter 1
- The installation of radio and navigation equipment in accordance with FAA AC43-13-2 Ch 2 and 3 provided—
 - any required tests are completed
 - flight manual amendments are approved
- The replacement of equipment by equipment of equal or better performance provided—
 - the new equipment meets the same standards as the replaced equipment
 - any required tests are completed
 - flight manual amendments are approved.

Appendix D – Approved data, design standards, and specifications

Technical data

Technical data forms the basis for the design of aviation articles. The basic concept is that all designs and design changes must comply with acceptable technical data, or have data approved as part of the design process.

Advisory circular AC43-9 details the procedures relating to modification approval and the use of the form CAA 337. The approval of a modification or repair in accordance with Part 21 is carried out by the approval of the technical data. The new rules system recognises that incorporation of modifications and repairs to acceptable data is appropriate without further approval. Acceptable technical data is listed in Part 21, Appendix D.

If technical data is not approved or acceptable then the data must be substantiated by design activities. If data is already accepted, design activities may be required to confirm interactions between modifications. This means that data may or may not be acceptable dependent on its use.

Technical data has limitations placed upon its use and these are generally described in any descriptive information supporting the data. The suitability of a modification, even to acceptable data, relies ultimately on the incorporating person's checking the compatibility of any new modifications with existing structure or equipment. Technical data provided by the manufacturer of a component may not be appropriate if it conflicts with data provided by the manufacturer of the product or assembly of which the component is to form a part.

The ability to approve technical data resides with the Director and any appropriate delegation holder. In approving data it should be ensured that—

- an approved type design is complied with
- an approved design change is complied with
- the applicable airworthiness design requirements are complied with

Airworthiness design standards

The basis for aircraft certification is taken in Mongolia largely from the USA Federal Aviation Administration. A list of design standards is in Part 21 Appendix C but other standards may be acceptable to the Director if a design organisation can provide—

- any documentation necessary to define and support the data
- the basis for the suitability of the data as an airworthiness design standard
- confirmation that the data provides an equivalent level of safety to those standards already listed in Part 21, Appendix C and/or for the type of aircraft operation

Advisory circular 21-1 expands on the acceptable standards that may be utilised in design development.

Specifications

Whereas design standards apply to several areas and define overall compliance requirements, a specification is particular. A specification may be included in a design standard and will usually detail performance requirements of a material, part, process, or appliance.

A specifications may be used—

- In a design to specify—
 - materials and standard parts
 - performance standards
 - manufacturing standards
 - quality control standards
 - processes
- As an approved design for standard parts
- To define suitable equipment for manufacture and maintenance including the selection of suitable materials for production or maintenance equipment
- To supplement other specifications provided they do not conflict with the approved design

A specifications may include—

- Composition
- Selection
- Testing
- Heat treatment
- Finish
- Maintenance and support data
- Identification requirements

If a specification does not include these details, any additional information required for the manufacture and incorporation of the design should be included in the design's descriptive data.

Commercial specifications in non critical areas may be acceptable but may require additional testing to confirm suitability.

Specifications can be approved if a design organisation confirms the required information is available to show that the specification meets an acceptable minimum performance standard. An example of an approved specification would be a Mongolia Technical Standard Order. Advisory circular AC21-40 provides more guidance on Mongolia Technical Standard Orders.

A specifications may be accepted if it is appropriate to the aviation environment and—

- has requirements applicable to a particular design standard
- is an established industry specification

- is a Mongolia national specification
- is a foreign national specification

In most cases a design organisation will not be developing a specification and will require access to existing specification. Various sources can provide specification detail that would be considered acceptable, including—

- International Standards Organisation
- Mongolia Standards
- Other national standards organisations
- International Electrotechnical Commission
- Radio Technical Commission for Aeronautics
- British Standards (Aircraft series)
- USA Federal Aviation Administration
- USA Federal government specifications
- USA Society of Automotive Engineering Aerospace Material Specification
- DTD specifications
- Military Specifications (MIL-SPEC, MIL-STD)
- Military handbooks
- Mongolia Defence Force .

Appendix E – Prototypes and testing

Prototypes

The liaison between a manufacturer and a design organisation is critical in the development of a product, component, or appliance. This is particularly true during any prototype phase of design development.

There will be problems during the prototype stage because some manufacture and assembly may occur while the design has not been properly documented. The control of the prototype development needs to be flexible to cater for any problems that may arise but it is essential not to lose sight of the fundamental principle - the final product must meet an approved design.

All stages of the design development should be documented so that the design organisation can analyse the design and the prototype for the development of the production product, component, or appliance.

Ongoing inspection and testing of each stage is required. This inspection should confirm to the approving person the conformity to the design and the suitability for placing into production. If subsequent approval is required by the Director then stage inspections may be required by the Civil Aviation Authority.

In constructing a prototype the design organisation should ensure that the manufacturer or assembler has—

- the necessary drawings and documents to satisfactorily construct the prototype
- a quality control system that ensures the prototype reflects the designer's concept
- procedures to—
 - raise concessions on areas that do not conform to the design
 - raise queries regarding test results, drawing inadequacies, and production and assembly problems with the designer
 - identify required items that have no drawings and raise deficiency reports if necessary
 - require drawing amendment to fulfil their construction function

Testing

With all designs a level of inspection and test is required. This testing ensures that the product, component, or appliance complies with the applicable airworthiness design requirements.

The testing is part of the design process leading up to the issue of a statement of compliance. To issue statements of compliance the tests must demonstrate—

- the product, component or appliance conforms to the type design and any modifications
- an aircraft has been flight tested to the production flight schedule

- any functional checks have been completed
- all additional airworthiness requirements have been met

Tests to show particular compliance with an airworthiness requirement should be witnessed by the approving person, whether the delegation holder or the Civil Aviation Authority.

Final approval of a design or design change may be withheld until flight testing is satisfactorily accomplished.

Critical parts

For use in prototypes some parts may be fabricated to fulfill specific functions during the construction or assembly phase. The parts may be one off designs in themselves and should have drawings included in the design if they are to be used for production units.

If a part is considered critical to the design and that part is a standard, mass produced part there are considerations relating to testing that should be addressed. If the manufacturer of the part is using sampling as their own quality control system the results may not be acceptable for critical situations. In these cases consideration should be given in the prototype and production manufacture to adding a requirement for such parts to be independently tested prior to incorporation.

Appendix F – Concessions

A design organisation should ensure that they have a facility to process concessions from the manufacturing organisation producing the finished product. These concession requests may result from problems or variations related to—

- production processes
- material availability or performance
- supply
- assembly details

A concession may be issued to permit the use of an individual component or number of components that deviate from the design or specification or to allow the temporary use of substitute materials or parts.

It should be shown that for each concession the applicable airworthiness design standards are complied with.

A concession is essentially a design change of limited applicability and as such they may be approved by a delegation holder within the scope of their delegation.

Appendix G – Subcontracting

This appendix details the considerations for any a design organisation in subcontracting design activities to a subcontractor that may or may not be certificated in accordance with Part 146.

This subcontracted work is considered to be an extension of the work carried out by the certificated organisation and under the control of its design control and quality control systems.

The responsibility for providing the necessary documentation and liaison rests with the certificated design organisation.

General Conditions

When design activities are carried out under the subcontract control system the Part 146 certificate has been temporarily extended to include the subcontractor for the duration of that activity. Those parts of the subcontractor's facilities, personnel, and procedures involved with the certificated design organisation should meet Part 146 requirements.

Any design organisation certificated to Part 146 may subcontract design activities to a non- certificated organisation provided there is provision in its exposition for subcontracting.

A Part 146 design organisation may not need to have its own facilities to carry out all the design activities it wishes to subcontract. The organisation should have its own expertise to decide that the subcontractor meets the necessary standards and that any design activity is carried out in accordance with their design instructions.

A Part 146 design organisation may find it necessary to include several specialist subcontractors in its exposition to enable the design and testing of particular products. The organisation should provide the Director with evidence that it has the expertise and procedures to control the subcontractors.

The design organisation is responsible for all design activities carried out by its subcontractors. Where a Part 146 organisation fails to control a subcontractor it may put at risk part or all of its own Part 146 certification.

The extent of the subcontracting is only limited by the expertise and procedures of the Part 146 organisation.

Approval of the subcontract is shown by the Director accepting the exposition containing a specific section on the control of subcontractors and a list of those subcontractors.

Procedures

When creating procedures for the control of subcontractors the following should be considered—

- A pre-assessment procedure under which the certificated organisations' subcontract control section should visit a prospective subcontractor. The visit will determine whether those operations of the subcontractor that it wishes to use meet the requirements of Part 146 before any design work is placed with the subcontractor
- A procedure to ensure the upgrade of the relevant operations of the subcontractor to meet the intent of Part 146, if the contractor internally does not meet the requirements
- An assessment of the extent that the Part 146 design organisation will use the subcontractor's facilities
- Where the subcontracted design will be approved without significant further checking by the Part 146 organisation, procedures for the issue of statements of compliance by authorised staff
- Where the design requires further checking, procedures for the inspection during design development at the subcontractors facility
- Procedures for the control of subcontractors, to record visits to subcontractors, to have a corrective action follow-up plan, and to show when subcontractors are being used

Procedures for the audit of the subcontract control section and for the sampling of subcontractor's performance by the Part 146 design organisation's quality assurance personnel.
