



THE QUALITY ASSURANCE MANUAL FOR FLIGHT PROCEDURE DESIGN

VOLUME 1 –FLIGHT PROCEDURE DESIGN QUALITY ASSURANCE SYSTEM

Notice to Users

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Advance edition (unedited)

1. PREFACE

The *Quality Assurance Manual for Flight Procedure Design* (Doc xxxx) consists of four volumes:

Volume 1 – *Flight Procedure Design Quality Assurance System*;

Volume 2 – *Flight Procedure Designer Training*;

Volume 3 – *Flight Procedure Design Software Validation*; and

Volume 4 – *Flight Procedures Design Construction*

Instrument flight procedures based on conventional ground-based navigational aids have always demanded a high level of quality control. However, with the implementation of area navigation and associated airborne database navigation systems, even small errors in data could lead to catastrophic results. This significant change in data quality requirements (accuracy, resolution and integrity) has led to the requirement of a systemic quality assurance process (often part of a State Safety Management System). The *Procedures for Air Navigation Services — Aircraft Operations* (PANS-OPS, Doc 8168) Volume II, Part 1, Section 2, Chapter 4, *Quality Assurance*, refers to this manual and requires that the State take measures to ‘control’ the quality of the processes associated with the construction of instrument flight procedures. To this end, this manual has been assembled to provide guidance in attaining these stringent requirements for quality assurance in the procedure design process. All four volumes address crucial areas related to the attainment, maintenance and continual improvement of procedure design quality. Data quality management, procedure designer training, and validation of software are all integral elements of a quality assurance programme.

Volume 1 – *Flight Procedure Design Quality Assurance System*, provides guidance for quality-assurance in the procedure design processes, such as procedure design documentation, verification and validation methods, guidelines about the acquisition/processing of source information/data. It also provides a generic process flow diagram for the design and the implementation of flight procedures.

Volume 2 – *Flight Procedure Designer Training*, provides guidance for the establishment of flight procedure designer training. Training is the starting point for any quality assurance programme. This volume provides guidance for the establishment of a training programme.

Volume 3 – *Flight Procedure Design Software Validation*, provides guidance for the validation (not certification) of procedure design tools, notably with regard to criteria.

Volume 4 – *Flight Procedures Design Construction* (to be incorporated later).

Note.— In the independent volumes, when a reference is made to the term "manual", in the context of this document, without any further specification, it is presumed to refer to this volume of the Quality Assurance Manual for Flight Procedure Design.

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3. ABBREVIATIONS

AIP	Aeronautical Information Publication
AIS	Aeronautical information service
AIRAC	Aeronautical information regulation and control
ANSP	Air navigation service provider
ATM	Air traffic management
ATS	Air traffic services
ANS	Air navigation services
CAA	Civil aviation authority
CAD	Computer aided design
CNS	Communication, Navigation and Surveillance
COTS	Commercial off the shelf
FAA	Federal Aviation Administration
FPD	Flight procedure design
GNSS	Global navigation satellite system
HMI	Human machine interface
ICAO	International Civil Aviation Organisation
IFP	Instrument flight procedure
ISO	International Standards Organisation
QMS	Quality management system
RNAV	Area navigation
RNP	Required navigation performance
SARPS	Standards and Recommended Practices
TLS	Target level of safety

4. DEFINITIONS

Consultation. A conference between two or more people to consider a particular question.

Conceptual design. High level graphical and/or textual description of the designer's interpretation of the stakeholders' requirements.

Designer. A person adequately trained who performs the design of an instrument flight procedure.

Flight procedure design. The complete package that includes all the considerations that went into the development of an instrument flight procedure.

Flight procedure design process. The process which is specific to the design of instrument flight procedures leading to the creation or modification of an instrument flight procedure.

Instrument flight procedure. A description of a series of predetermined flight manoeuvres by reference to flight instruments, published by electronic and/or printed means.

Instrument flight procedure process. The overarching process from the data origination to the publication of an instrument flight procedure.

Integrity (aeronautical data). A degree of assurance that an aeronautical data and its value has not been lost or altered since the data origination or authorized amendment. (e.g. Annex 15 — *Aeronautical Information Services*, Chapter 2, *Definitions*).

Process. A "set of interrelated or interacting activities which transforms inputs into outputs" (ISO 9000:2000 "Quality management systems – Fundamentals and vocabulary", section 3.4.1); hence "flight procedure design (FPD) process" or "instrument flight procedure process".

Procedure. A "specified way to carry out an activity or a process" (ISO 9000:2000 "Quality management systems – Fundamentals and vocabulary", section 3.4.5).

Quality record. Objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. Quality records normally are audited in the quality evaluation process.

Review. An activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives" (ISO 9000:2000 "Quality management systems – Fundamentals and vocabulary", section 3.8.7).

Validation. Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (Annex 15). The activity whereby a data element is checked as having a value that is fully applicable to the identity given to the data element, or a set of data elements that is checked as being acceptable for their purpose.

Verification. Confirmation through the provision of objective evidence that specified requirements have been fulfilled (Annex 15). The activity whereby the current value of a data element is checked against the value originally supplied.

5. FOREWORD

5.1 OVERVIEW

The International Civil Aviation Organization is charged with the duty of promoting the safety, efficiency and economy of international air transportation. The instrument flight procedure is an essential component of the aviation system. Every day and during every flight, thousands of aircraft around the world are flying instrument departure, arrival, or approach procedures to airports in every country. The safety and quality of these procedures is often taken for granted by aviation professionals. The flying public assumes that they will get to their destination safely, and for the most part do not even realize that instrument flight procedures exist. Flight procedures are such an integral part of everyday flight operations that their quality cannot be left to chance. As a part of every State's Air Navigation Services Safety Management System consideration must be given to this critical element of the system.

This document addresses two levels of processes. A high level process, called the instrument flight procedure (IFP) process, covering all elements from the initial decision to the publication of the procedure and the relevant maintenance, safety and flight inspection activities. The process is not terminated with the publication. The feedback from the users must be considered in the improvement process.

A second specific process, for the design of the instrument flight procedure – the flight procedure design (FPD) process, is part of the IFP process.

Although not always specifically mentioned in the document, all process steps are followed by a verification and validation step, in order to guarantee the quality of the resulting elements of each step.

The implementation of procedures is the responsibility of Contracting States, which implies that the State authorities have the final responsibility for the procedures published within their territory. The FPD process may be carried out by States themselves or by delegation from States to third parties (ATS providers, private companies, other State, etc.). The *Procedures for Air Navigation Services— Aircraft Operations* (PANS-OPS, Doc 8168) requires that the State takes measures to control the quality of the process used to apply procedure design criteria. These measures must ensure the quality and safety of the procedure design product through review, verification, coordination, and validation at appropriate points in the process, so that corrections can be made at the earliest opportunity in the process.

States must establish quality systems for the entire IFP process. This system may consist of an overall quality assurance, including all steps from origination to final publication, as well as a more focused quality assurance process for the design of procedures. For any portion of the IFP process, that is accomplished by a third party, an adequate quality system is required.

In all cases, including when third parties are involved in the IFP process; the State carries the ultimate responsibility for the procedures published in their national AIP.

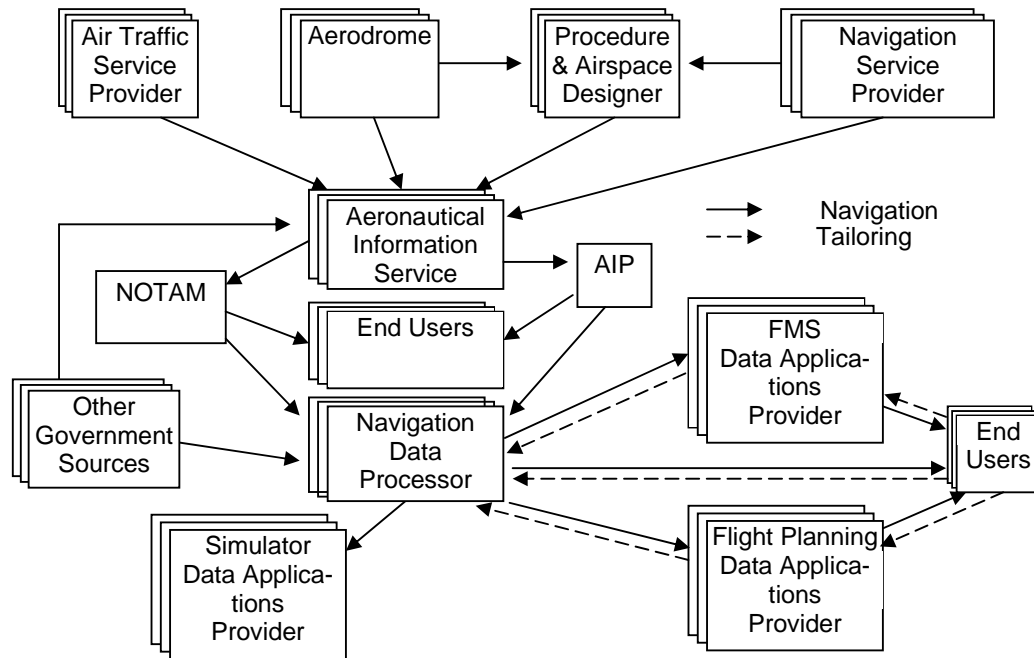
This manual has been developed to provide guidance to Contracting States in developing a system to ensure the quality of the flight procedures they publish. The manual provides one means, but not the only one, for quality assurance implementation throughout the FPD process. The manual may also be of interest for any person or organization involved in the procedure design domain.

5.2 THE NEED FOR QUALITY

With the advent of new navigation systems, the IFP process and its products have become key enablers of the worldwide air traffic management (ATM) system. They must therefore be managed effectively to ensure that quality assured procedures are provided in support of ATM operations.

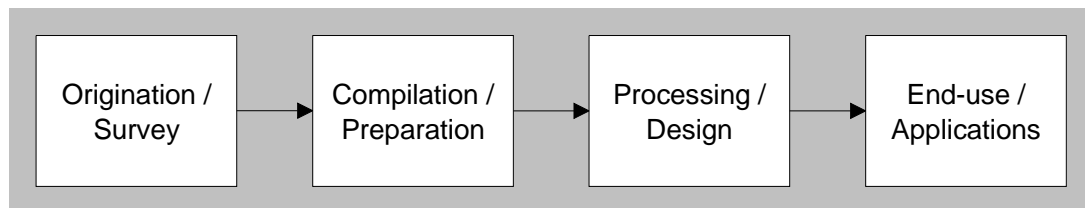
The quality of an instrument flight procedure is flight critical. The enroute structure, departure, arrival, holding and approach procedures are derived from an IFP process, which covers various steps from collection of user requirements, to State publication and the integration into airborne systems. In consequence, the FPD and the resulting instrument flight procedure, from data origination through publication to incorporation into an end-user system must be quality assured.

Note.— This chain involves various organizations which should apply quality assurance processes as stated in the existing applicable Standards, notably Annex 15 for the origination of data and EUROCAE ED-76 / RTCA DO-200() for the processing and release of aeronautical data (also see the figure below).



The development of an instrument flight procedure follows a series of steps from the origination of data through survey to the final publication of the procedure and subsequent coding of it for use in an airborne navigation database (refer to Figure &xx). At each step there should be quality control procedures in place to ensure that the necessary levels of accuracy and integrity are achieved and maintained. The main steps in the development process are illustrated in Figure &xx.

The procedure design chain is as follows:



Checks must be carried out throughout the whole chain by each "participant" (organization) to ensure that the final procedure meets quality requirements. In particular, the accuracy, resolution and integrity of data elements, together with any changes to the data, need to be addressed. The preferred method for the transmission of the data elements is by electronic means, as this preserves the integrity of the data.

5.3 PURPOSE AND SCOPE OF THE MANUAL

As stated in Annex 15, the area navigation implementation, the development of area navigation (RNAV) applications has a significant impact on the role and importance of aeronautical information and data, which become an essential part in the overall safety of air navigation. Annex 15 recognizes this trend as follows: “The role and importance of aeronautical information/data changed significantly with the implementation of RNAV, required navigation performance (RNP) and airborne computer-based navigation systems. Corrupt or erroneous aeronautical information/data can potentially affect the safety of air navigation.”

Among the most critical information/data are those derived from the FPD process. In order to support air navigation operations in the context of the CNS/ATM concept, it is thus necessary to ensure that both the IFP and FPD processes are consistently quality-assured. To this end, ICAO decided to develop a quality assurance manual to assist States in implementing quality assurance in the IFP process.

This volume provides a detailed description of a quality-assured instrument flight procedure and a flight procedure design process, including requirements for procedure design documentation, verification and validation methods, and guidelines about the acquisition of source information/data.

6. INSTRUMENT FLIGHT PROCEDURE PROCESS

6.1 OVERVIEW

The instrument flight procedure process encompasses the initiation and collection of requirements and constraints, the acquisition of data, the FPD, ground validation, flight validation and flight inspection (when required), approval and publication.

This process includes review, verification and validation processes, which are necessary to minimize the possibility of errors. It considers the safety analysis necessary prior to implementation. The process also incorporates the periodic review of data, criteria and feedback from operational implementation.

The process covers the entire lifespan of an instrument flight procedure, from the initial development up to the withdrawal, recognizing that some of the process steps might belong to other organizations such as AIP publication and procedure regulation.

It is recommended this process should be periodically reviewed to ensure continuous improvement, particularly after the release of updates to the reference material.

This process, supported by the other volumes of the *Quality Assurance Manual for Flight Procedure Design* and properly applied, should provide consistent results with an appropriate level of quality.

6.2 OUTPUT OF THE QUALITY PROCESS

Although the process covers the entire lifecycle of an instrument flight procedure, from the original requirement to the final withdrawal, the aim of the process is not the decommissioning of Instrument flight procedures.

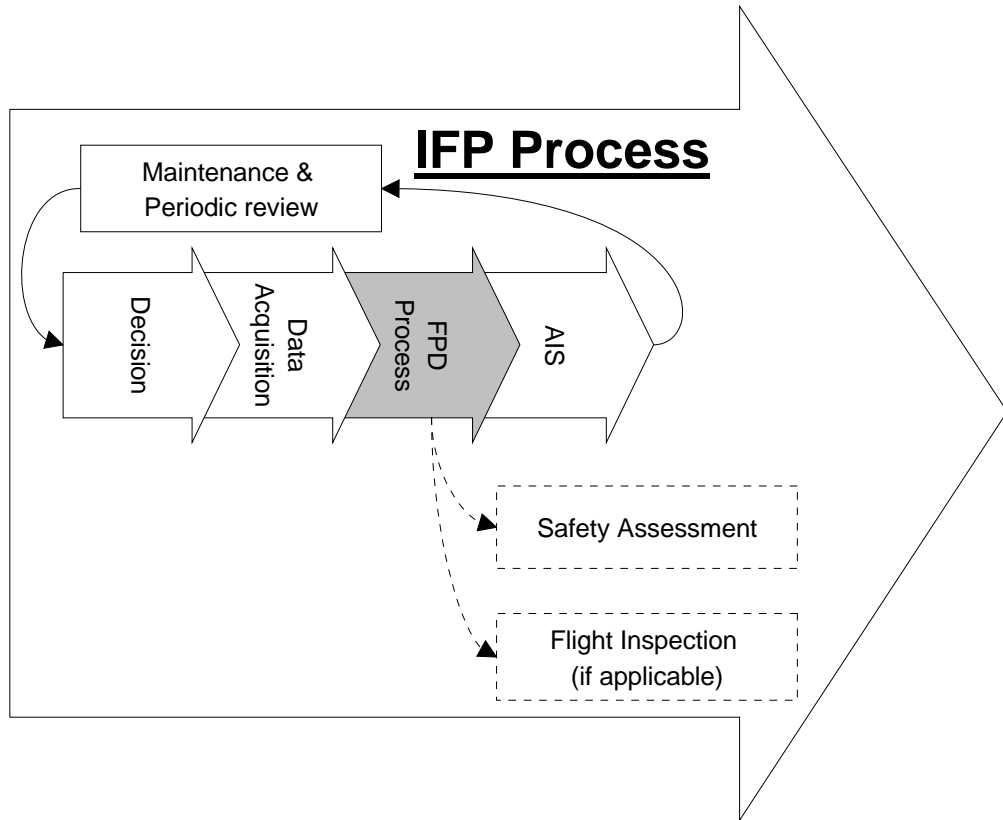
The closure of the decommissioning is the termination of the quality process (except for the archiving requirements).

Throughout the elaboration and the lifecycle of the procedure, several outputs are generated and evolved to a next level in the "production line".

The main outputs of the process would be, listed as from the beginning of the process:

- conceptual design, including planned implementation dates, needed resources to achieve the task;
- the flight procedure design (FPD), including the procedure layout, the relevant calculation outputs, coordinates and a textual description of the intended procedure;
- validation and verification reports for the instrument flight procedure;
- the approval of the procedure by the regulatory authority;
- the publication throughout the various stages to the input into the publication process; and
- finally, the released AIP publication (charts, texts, coordinates, path terminators and any other pertinent information relevant to the procedure)

At the end of the lifecycle, a decision to withdraw the procedure will be issued (and documented). All changes permitting the withdrawal will be included in the quality documentation, but will also be part of the replacement procedures' documentation.



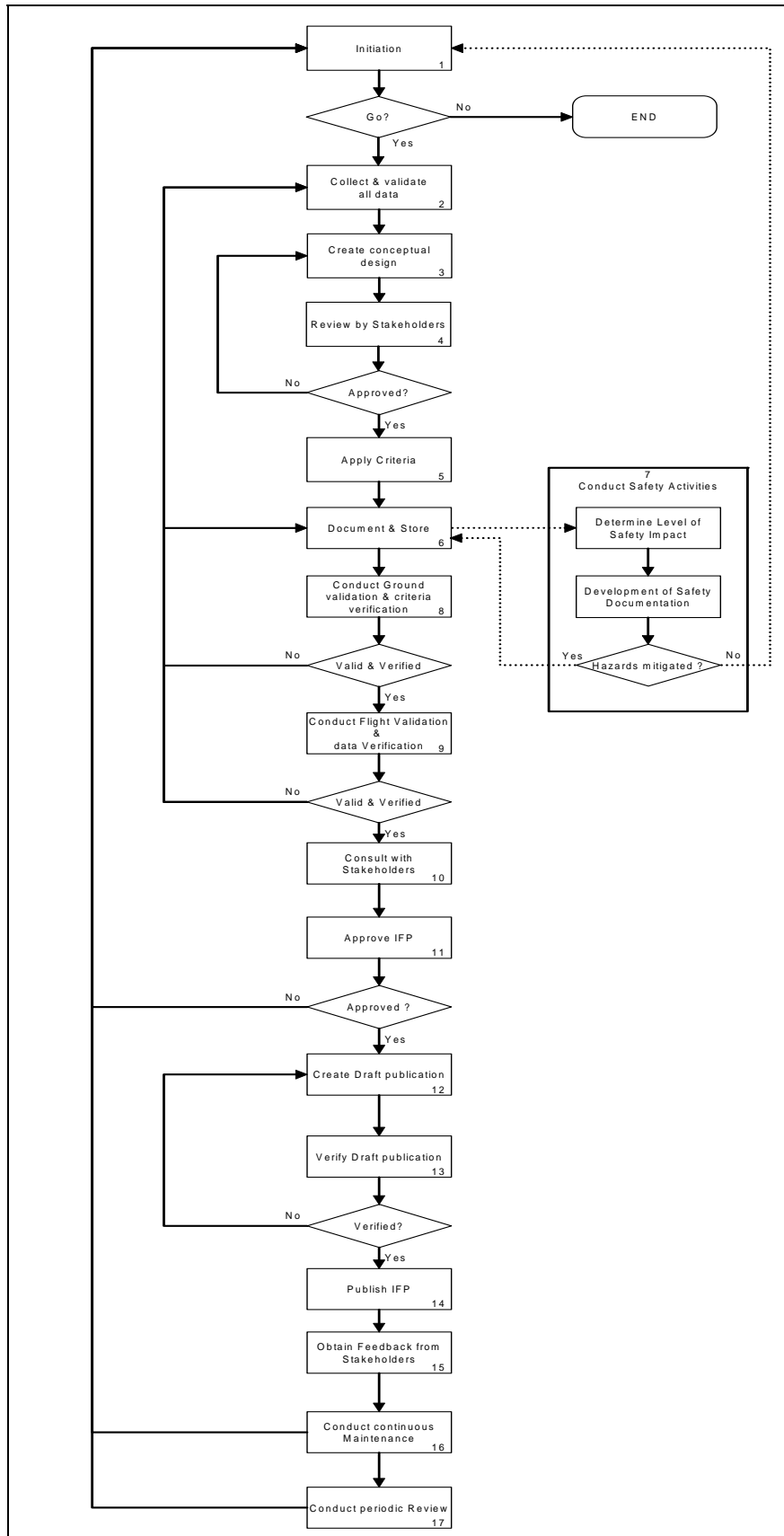


Figure 1. IFP process flow diagram

6.3 PROCESS DESCRIPTION

STEP	DESCRIPTION	INPUT	OUTPUT	PARTIES INVOLVED	QUALITY RECORDS	REFERENCES
1	<p>INITIATION</p> <p>This starting point is when a 'pre-design' request is made for a new FPD or a 'modification' request to an existing FPD resulting from feedback, continuous maintenance or periodic review (see Steps Nos. 12 to 14). Justification for the FPD must be clearly stated and must be in accordance with the airspace concept and the State navigation strategy. This is a managerial responsibility to make a decision at this point to 'go' or 'no go'....</p>	<ul style="list-style-type: none"> • Request from a stakeholder for a new or a modified procedure. • Review of an existing procedure. • Navigation strategy considerations. • Resource planning. • Feedback on existing procedure. 	<ul style="list-style-type: none"> • Managerial decision to set up the procedure design process or to discontinue the activity. 	<ul style="list-style-type: none"> • Stakeholders. 		<ul style="list-style-type: none"> • ISO 9001:2000: section 7.2.1 "Determination of requirements related to the product", section 7.2.2 "Review of requirements related to the product", section 7.3.1 "Design and development planning" and section 7.3.2 "Design and development inputs".

<p>2</p>	<p>COLLECT & VALIDATE ALL DATA</p> <ul style="list-style-type: none"> • Specific ATS stakeholders requirements: local traffic patterns (altitude, direction, airspeed), feeder/transitions, arrival/departures, preferred routes, ATS routes, communication facilities, time, restrictions and any ATS needs, restrictions or problems. • The designer is to collect from recognized sources, validate for resolution, integrity, reference geodetic datum and effective dates, and incorporate the following data into a design file. • Terrain data: electronic raster and/or vector data or paper cartographic maps. • Obstacle data: man made and natural (tower/tree/vegetation height). • Aerodrome/heliport data: ARP/HRP, runway, lighting, magnetic variation and rate of change, weather statistics, altimetry source. • Aeronautical data: airspace structure, classifications (controlled, uncontrolled, Class A, B, C, D, E, F, G, name of controlling agency), airways/air routes, altimeter transition altitudes/flight levels, other instrument procedure assessed airspace, area of magnetic unreliability. • Navaid data: coordinates, elevation, service volume, frequency, identifier, magnetic variation. • existent waypoints significant to the planned navigation. 	<ul style="list-style-type: none"> • All stakeholder requirements. • Previous designs. • Data from State recognized sources. • All other data. 	<ul style="list-style-type: none"> • Preliminary work file, containing summary of stakeholder requirements, summary of all data. 	<ul style="list-style-type: none"> • Designer. • ATM, AIS, • Stakeholders. • Data sources (e.g. surveyors, charting agencies, MET offices, etc.) 		<ul style="list-style-type: none"> • <i>Safety Management Manual</i> (Doc 9859). • <i>Quality Assurance Manual for Flight Procedure Design</i> (Doc xxxx). • ISO 9001:2000. • Annexes 11, 14, 15. • <i>World Geodetic System-1984 (WGS-84) Manual</i> (Doc 9674). • ED 76/RTCA DO 200. • ED 77/RTCA DO 201. • ED 98/RTCA DO 276. • Eurocontrol Doc P357/DO 002-2. • ISO 9001:2000. • <i>Guidelines for electronic terrain, obstacle and aerodrome mapping information</i> (Doc 9881) .
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3	<p>CREATE CONCEPTUAL DESIGN A conceptual design is drafted with the key elements considering the overall strategy.</p>	<ul style="list-style-type: none"> • Preliminary work file. 	<ul style="list-style-type: none"> • Conceptual design. 	<ul style="list-style-type: none"> • Designer. 		<ul style="list-style-type: none"> • Doc 8168 (or applicable criteria) ISO 9001:2000: section 7.3.1 "Design and development planning".
4	<p>REVIEW BY STAKEHOLDERS Formal agreement and approval of the conceptual design is sought at this stage. If agreement and approval are not possible then either the designer must redesign the conceptual design or the stakeholders must reconsider their requirements.</p>	<ul style="list-style-type: none"> • Work programme to serve as basis for decision, including the scope of the activity to be performed. • Conceptual design. 	<ul style="list-style-type: none"> • Formally approved conceptual design or formal decision to discontinue, updated with any consequential changes, if applicable. • Planned implementation AIRAC date, based on available resources and any other technical / operational / training constraints. 	<ul style="list-style-type: none"> • All concerned stakeholders. • Designer and management. 	<ul style="list-style-type: none"> • Formally approved conceptual design or formal decision to discontinue, updated with any consequential changes, if applicable. 	<ul style="list-style-type: none"> • ISO 9001:2000: section 7.3.1 "Design and development planning" and section 7.3.4 "Design and development review".
5	<p>APPLY CRITERIA Using the stakeholder approved conceptual design, apply criteria.</p>	<ul style="list-style-type: none"> • Preliminary work file. • Formally approved conceptual design. • Planned implementation AIRAC date. • Resource allocation for the design and planning for publication. 	<ul style="list-style-type: none"> • FPD. • Draft procedure layout. • Report. • Calculation outputs • Coordinates.. • Textual description of the procedure. 	<ul style="list-style-type: none"> • Designer. 		<ul style="list-style-type: none"> • Doc 8168 Volumes I and II or applicable criteria ISO 9001:2000: section 7.3 "Design and development".

<p>6</p>	<p>DOCUMENT AND STORE</p> <ul style="list-style-type: none"> • For traceability complete necessary submission / calculation forms in paper and / or electronic formats. • Create a draft instrument procedure graphical depiction. • Provide a summary of the logic and decisions used in the step-by-step design of the procedure. • Gather all information used and created in the design of the procedure, and assemble into a submission package. • Obtain traceability of consensus from stakeholders via signatures. • Store submission package in a secure format and area, easily accessible for future considerations. 	<ul style="list-style-type: none"> • FPD. • Draft procedure layout. • Report. • Calculation outputs. • Coordinates. • Textual description of the procedure. 	<ul style="list-style-type: none"> • Data store FPD containing: <ul style="list-style-type: none"> • all calculations; • all forms and reports, including consensus from stakeholders; • all charts / maps • AIRAC textual description; • path terminators (if applicable); and • procedure plate (draft graphical depiction). 	<ul style="list-style-type: none"> • Designer. 		<ul style="list-style-type: none"> • Doc 8168 (or applicable criteria). • Annexes 4 and 15. • <i>Quality Assurance Manual for Flight Procedure Design</i> (Doc xxxx). • State depiction standards. • State forms.
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7	<p>CONDUCT SAFETY ACTIVITIES</p> <p>DETERMINE LEVEL OF SAFETY IMPACT Perform an assessment of the magnitude of change to determine the amplitude needed for the safety case.</p> <p>DEVELOP SAFETY DOCUMENTATION Safety documentation to be provided for the implementation of a new procedure should be agreed at this stage. Normally the Safety Management System to be used is defined for the ANSP affected by the change or by the regulator responsible for the area where the procedure will be implemented.</p>	<ul style="list-style-type: none"> • FPD containing draft procedure layout, report, calculation outputs, coordinates, textual description of the procedure. 	<ul style="list-style-type: none"> • Formal statement on the significance of change, allowing to determine the amplitude of the safety case that needs to be performed. 	<ul style="list-style-type: none"> • Quality and safety officer, affected stakeholders, supported by designers. 		<ul style="list-style-type: none"> • EUROCONTROL Safety Regulatory Requirement (ESARR 4, Section 5). • <i>Safety Management Manual</i> (Doc 9859) • ISO 9001:2000. • European Air Traffic Control Harmonisation and Integration Programme (EATCHIP) Safety Assessment Method . • State Safety Management System documentation (e.g. UK CAA Doc 675).
8	<p>CONDUCT GROUND VALIDATION & CRITERIA VERIFICATION</p> <ul style="list-style-type: none"> • Validate all data used in the procedure design (i.e. data resolution and format). • Validate the ‘intended use’ of FPD as defined by stakeholders and described in the conceptual design • Verify that the criteria has been properly and accurately applied. 	<ul style="list-style-type: none"> • FPD package. • Safety case. 	<ul style="list-style-type: none"> • Ground validated IFP. 	<ul style="list-style-type: none"> • Designer. • Validation team. 		<ul style="list-style-type: none"> • Doc 8168 . • Annexes 4 and 15. •

<p>9</p>	<p>CONDUCT FLIGHT VALIDATION AND DATA VERIFICATION</p> <ul style="list-style-type: none"> • Verify for accuracy of terrain data, obstacle data, aerodrome data, aeronautical data, navaid data. • Validate the ‘intended use’ of FPD as defined by stakeholders and described in the conceptual design. • Validate flyability and/or human factors. • Validate safety case. 	<ul style="list-style-type: none"> • Ground validated IFP. • Safety documentation. 	<ul style="list-style-type: none"> • Validated IFP. 	<ul style="list-style-type: none"> • Designer. • All concerned stakeholders. • Flight inspection organization. 	<ul style="list-style-type: none"> • Flight validation report (if applicable). • Flight inspection report (when performed). 	<ul style="list-style-type: none"> • <i>Manual on Testing of Radio Navigation Aids</i> (Doc 8071)
<p>10</p>	<p>CONSULT WITH STAKEHOLDERS</p> <ul style="list-style-type: none"> • Submit all pertinent information to all relevant stakeholders for consultation. 	<ul style="list-style-type: none"> • Validated IFP. 	<ul style="list-style-type: none"> • Stakeholder endorsement. 	<ul style="list-style-type: none"> • Designer. • Relevant stakeholders. 	<ul style="list-style-type: none"> • Stakeholder endorsement. 	<ul style="list-style-type: none"> • National regulations as appropriate.
<p>11</p>	<p>APPROVE IFP</p> <ul style="list-style-type: none"> • Provide IFP documentation to the designated authority for approval. 	<ul style="list-style-type: none"> • Validated IFP. • Stakeholder endorsement. 	<ul style="list-style-type: none"> • Approved IFP. 	<ul style="list-style-type: none"> • Designer. • Designated authority. 	<ul style="list-style-type: none"> • Formal approval of the FPD for new procedures (or for relevant changes on existing procedures). 	<ul style="list-style-type: none"> • National regulations as appropriate.
<p>12</p>	<p>CREATE DRAFT PUBLICATION</p> <ul style="list-style-type: none"> • Provide FPD package including a graphical depiction, to the AIS to create a draft publication. 	<ul style="list-style-type: none"> • Approved IFP. 	<ul style="list-style-type: none"> • Draft publication. 	<ul style="list-style-type: none"> • Designer. • AIS. 		<ul style="list-style-type: none"> • Annexes 4 and 15 ISO 9001:2000 section 4.2 "Documentation requirements" section 7.3.5 "Design and development verification".

13	VERIFY DRAFT PUBLICATION <ul style="list-style-type: none"> • Verify the draft publication for completeness and consistency. 	<ul style="list-style-type: none"> • Draft publication. • Validated FPD. 	<ul style="list-style-type: none"> • Cross-checked draft publication. • Decision for publication release. 	<ul style="list-style-type: none"> • Designer. • AIS / aviation authority. 		<ul style="list-style-type: none"> • Regional/national regulation. • Doc 8168 Volumes I and II, all applicable Annexes and Docs ISO 9001:2000 section 7.3.5 "Design and development verification" and section 7.3.6 "Design and development validation".
14	PUBLISH IFP AIS initiates the AIRAC process.	<ul style="list-style-type: none"> • Cross-checked draft publication. • Decision for publication release. 	<ul style="list-style-type: none"> • AIP chart, documentation. 	<ul style="list-style-type: none"> • AIS. 		<ul style="list-style-type: none"> • Annexes 4 and 15. •
15	OBTAIN FEEDBACK FROM STAKEHOLDERS <ul style="list-style-type: none"> • Request and analyse feedback from stakeholders on the acceptability of the work performed. • Cross-check of the AIP chart, documentation. 	<ul style="list-style-type: none"> • AIP chart, documentation. • Reports from stakeholders. 	<ul style="list-style-type: none"> • Decision for ongoing activities. 	<ul style="list-style-type: none"> • Manager of the design office. • Stakeholders. 		<ul style="list-style-type: none"> • Standards for processing aeronautical data (EUROCAE ED-76 / RTCA DO-200).

<p>16</p>	<p>CONDUCT CONTINUOUS MAINTENANCE</p> <ul style="list-style-type: none"> • On a continuous basis ensure that: <ul style="list-style-type: none"> – significant changes to obstacles, aerodrome, aeronautical and Navaid data are assessed. – significant changes to criteria and design specification that affect procedure design are assessed. Criteria and charting changes should be assessed to determine if action is required prior to the periodic review. • If action is required return to Step No. 1 to reinitiate process. 	<ul style="list-style-type: none"> • Significant changes in the FPD environment or design criteria changes that are safety related. 	<ul style="list-style-type: none"> • Revision as required. 	<ul style="list-style-type: none"> • Designer. • Regulator. • Procedure owner. • Pilots (when applicable and possible). 		<ul style="list-style-type: none"> • Doc 8168 . • Annexes 4 and 15. • <i>Safety Management Manual</i> (Doc 9859). • <i>Quality Assurance Manual for Flight Procedure Design</i> (Doc xxxx).
<p>17</p>	<p>CONDUCT PERIODIC REVIEW</p> <ul style="list-style-type: none"> • On a periodic basis (periodicity determined by State, but no greater than five years) ensure: <ul style="list-style-type: none"> – that all changes to obstacles, aerodrome, aeronautical and navaid data are assessed; and – that all changes to criteria, user requirements and depiction standards are assessed. • If action is required return to Step No. 1 to reinitiate process. 	<ul style="list-style-type: none"> • All changes in the FPD environment, design criteria or depiction standards. 	<ul style="list-style-type: none"> • Revisions as required. 	<ul style="list-style-type: none"> • Designer. • AIS/Aviation Authority. 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> • Doc 8168 . • Annexes 4 and 15. • <i>Safety Management Manual</i> (Doc 9859). • <i>Quality Assurance Manual for Flight Procedure Design</i> (Doc xxxx).

6.4 RELATED PROCESSES

The FPD and the IFP processes should not be considered as stand alone processes. It is important to consider the supporting processes (mostly activities that are performed once, such as the software validation, or on a regular schedule, such as training) and the upstream and downstream processes that trigger or are triggered by the FPD and IFP processes.

6.4.1 Supporting processes

This describes various activities that should be performed prior to the procedure design process.

6.4.1.1 Use and validation of procedure design software -tools

Software-based tools provide automated functions for calculations and/or designs, layouts and include products such as spreadsheets, commercial CAD packages and custom-made software packages. They can facilitate the design work through a certain level of automation in calculations and procedure layout generation. Procedure design tools may be used throughout the procedure design process, from initial data input to final procedure output, maintaining the data integrity throughout the entire process.

Consequently the use of procedure design tools is encouraged in the framework of the quality process of instrument flight procedure design. However, it is of paramount importance to note that the use of automation does not replace the procedure designer's expertise. Additionally, the use of software should not prevent designers from using manual techniques.

The user requirements (e.g. type of functions, coverage of the tool in reference to the applicable criteria, adequacy of HMI) should be captured and taken into consideration during the selection of the software solution. This selection should consider the needs of the end user and should be based on the volume, the complexity and type of flight procedure(s) to be designed or maintained by the flight procedures design unit.

To address specific issues that might appear later during the operational use of the software, a close relationship between the user and the software provider is encouraged.

Although procedure design tools provide a significant step toward improved quality assurance in FPD, there is a risk that software errors or non-compliance with criteria can result in poor quality, or even dangerous flight procedures. When automation is used during the procedure design process, States must make sure that automation functions have been validated to ensure compliance of the final results with applicable criteria. Volume 3 – *Flight Procedure Design Software Validation*, provides guidance on such validation processes including one means for validation of procedure design tools.

6.4.1.2 Training

Training is a key element of a quality management system (ISO 9001:2000 "Quality management systems – Requirements ", section 6.2.2 "Competence, awareness and training"). Delivering training is one element of a training programme. Other elements include identifying training requirements, developing training curriculum and maintaining training records.

Identifying training requirements is a process that includes defining required competencies (knowledge and skills). Ensuring the competencies are possessed and maintained by procedure design staff requires a

review(s) of an individual's qualifications which may include prior training, education level and experience. As required competencies evolve, new and/or recurrent training may be indicated to ensure that procedure designers maintain the required level of competency. Each procedure design organization must establish required competency levels and maintains records of personnel training, qualification, and experience as one means of tracking individual competency.

Developing training curricula can be accomplished through the use of subject matter experts or by using third party training materials. Volume 2 – *Flight Procedure Designer Training* may be used for guidance. Training curricula should be managed and controlled in the same manner as other QMS documentation to ensure that training is accomplished at a consistent level.

Delivering training effectively requires planning and feedback mechanisms. Planning brings consistency to the effort and is supplemented by defined learning objectives. Feedback mechanisms, such as trainee testing, question/answer periods and course survey questionnaires help identify training improvement opportunities.

Training is a key element of any managed quality system and there are many reference documents that relate methods and systems of providing and maintaining training. Refer to Volume 2 – *Flight Procedure Designer Training* for guidance.

Training records (TRs) provide historical tracking of activities that support the qualification of a person to do a specific task. TRs are the evidence of due diligence by an organization to keep their staff competent for assigned tasks or functions. Training and TRs by themselves, **do not** demonstrate competency. Competency is demonstrated through the actions of performing a task and must be monitored through a management process.

6.4.2 Upstream and downstream processes

This describes various activities that trigger or are triggered by the IFP process.

6.4.2.1 Data origination

Quality assurance for the IFP process starts at the point of data origination. Data origination addresses the functions performed by requesting authorities and originating authorities, surveyors and any other third party organizations supplying aeronautical data to procedure designers. For example, surveying coordinates of the runway end or of navigation aids.

The data origination phase is one of the most critical stages of the data chain, as some errors cannot be easily detected in the subsequent steps of the process.

Historically, most aeronautical data is originated by individual States. Other originators may supplement State-originated data or originate data that is independent of the State. Examples of other data chain participants that may originate aeronautical data include, but are not limited to, airlines, aircraft manufacturers, airport authorities, defence mapping agencies, and communication service providers.

Annex 15 provides the SARPs about the horizontal (WGS-84) and vertical (MSL/EGM-96) reference system as well as terrain and obstacle data. For more details refer to ICAO Doc 9674 (WGS-84 Manual) and *The Guidelines for Electronic Terrain, Obstacle and Aerodrome Mapping information* (Doc 9881)

6.4.2.2 AIS

The FPD process is closely linked to the AIS process, since one of the objectives of the design is to have the procedure published in the AIP. For this purpose, the procedure design process includes a phase

related to the preparation of elements to be published. Depending on the organization in the CAA, these elements can range from basic elements being provided to the AIS office in the preparation of a detailed (draft) procedure chart to be subsequently processed by AIS. The AIS office is responsible for the integration of the designed procedure in the official State publication (AIP and charts), according to the SARPs laid down in Annexes 4 — *Aeronautical Charts* and 15 .

The AIS office may have to process the elements forwarded by the procedure designer in order to make them compliant with the applicable SARPs, and consistent with the national publication standards as appropriate. The outcome from this process may be different from the original submission of the procedure designer. It is therefore essential that the procedure designer reviews the outcome of the AIS process prior to publication. This review must include a check of completeness and consistency of the publication with the result of the FPD.

It is recommended that the processes between the procedure design office and the AIS office are defined and formalized, e.g. through a quality process or through a service level agreement (SLA).

6.4.2.3 *Data integration*

When the completed IFP is published, it should be forwarded to the commercial database suppliers for entering the IFP into a database for airborne applications. The database suppliers enter the IFP according to the ARINC 424 Navigation System Database Standard, which is the international industry standard. When the IFP is loaded by each database supplier, numerous edit checks are performed to ensure the procedure will function as designed by the procedure designer when flown in airborne navigation units. These edit checks, however, do not check for information such as altitudes, compliance with PANS-OPS, or procedure design.

The database suppliers consider submitted path/terminators to be advisory when included with RNAV IFPs. Database suppliers enter both RNAV and conventional procedures into airborne databases to automatically fly the IFP in the manner in which they were intended to be flown. For new IFPs, or IFPs that have had significant modifications, it is recommended that the procedures be forwarded to the database suppliers significantly in advance of the AIRAC date to assist in providing time to exchange information regarding inconsistencies that may be found during the database loading process.

There are three significant layers of standards in the ARINC 424 document. The first is the standardization of the fields that contain various items of aeronautical information. The next level is the standardization of what attributes are assigned to each type of information, e.g. VORs include frequency, coordinates, class of navaid, etc. The next level is the standardization of each record of information, e.g. VOR records include in column one whether the navaid is standard or tailored, column two through four include the geographical area of the world.

6.4.2.4 *Data packing*

When the database supplier completes the loading of the database and the ARINC 424 compliant database is created for the next AIRAC cycle, the next step of the process is to create the airborne database for the specific avionics system, specific airline, specific geographical coverage, and various other parameters. This process of converting ARINC 424 data into airborne databases is typically known as the packing process. The packing process is sometimes performed by the avionics manufacturers and sometimes by the database supplier using software created and maintained by the avionics manufacturer.

There is typically an earlier information cut-off date for the database suppliers since the creation of the ARINC 424 compliant database must be followed by the packing process, and then sent to the airlines.

Most airlines need at least seven days to ensure that all their aeroplanes get to a location where the next data cycle can be loaded before the effective date.

Because avionics systems using databases have been in use since the early 1970s, there are many differences in the capability of the systems in operation today.

It is important to note that some of the packing processes will make modifications to the ARINC 424 compliant database to ensure it will work in the target avionics system.

7. STEP BY STEP DESCRIPTION OF ACTIVITIES WITHIN THE PROCESS

The following subsections reflect all the steps of the process flow showed above and provide additional comments and explanations. All of the steps relate to the same number of the process (e.g. 7.1 Initiation relates to process Step 1 – Initiation).

7.1 Initiation (Step 1)

The IFP process (origination or modification of an IFP) is generally initiated upon request from one of the stakeholders listed in 7.1.1 below. The development of the airspace concept for a particular airspace can also trigger this process.

Each State should describe the initiation and submission process valid within their State.

The necessity for a change can also result from the requirement to review existing procedures. Published procedures must be subjected to a periodic review to ensure that they continue to comply with changing criteria, and meet user requirements. The individual States will establish the interval for periodic review of instrument flight procedures according to the needs of the State and document their review intervals. The maximum interval for this review is five years.

The main reasons for the request must be stated, e.g. safety enhancement, efficiency of operations, environmental considerations. The request may be tied to a change in the aerodrome infrastructure or airspace structure.

Key objectives associated with the request must be identified. Examples of objectives include, but are not limited to, reduction of minima, improving the access to an aerodrome, implementation of a new procedure type corresponding to an overall programme or strategy, reorganization of the airspace, or response to flight calibration results.

As far as possible, indicators associated with the key objectives should be provided (e.g. reduction of the minima by xx ft).

7.1.1 Stakeholders

A request for initiation or modification of an IFP may be submitted by any of the IFP stakeholders including State aviation authorities, air navigation or air traffic service providers, air operators, airport authorities, aviation associations, municipal/civil/military authorities, environmental authorities and the procedure designer. Additionally, requests from other sources such as industry or environmental committees may be considered for submission by the aviation authority.

If the request for the initiation of an IFP is submitted with a predetermined solution that might not fit into the global picture, discussions with the involved stakeholders should take place. The final request should be an agreed consensus, as far as possible, between the stakeholders including the procedure designer.

7.1.2 Required information

The request should specify:

- the nature of the changed or new IFP;
- the reason for the change;
- the expected benefits;
- the expected users;

- required operational implementation date;
- consequences of not achieving the implementation date;
- additional external partners and activities needed (such as flight validation and checking);
- resource planning (human and financial, if possible with a funding plan);
- what co-ordination has been carried out with other stakeholders; and
- what responses have been received from other stakeholders.

7.1.3 Approval of request

The request should be submitted to a formal review by the organization responsible for approving the initiation of the IFP process. This approval process should consider the request in the light of all outstanding requests and should take account of the available resources, the expected benefits and the urgency of the requirement when making a decision.

The review process should also ensure that the proposed change:

- fulfils the expected operational requirements;
- meets the needs of the airspace users;
- complies with the requirements of relevant government departments, (e.g. transport and environment);
- is achieved within the proposed timescale;
- is adequately resourced; and
- does not conflict with any other airspace plans.

7.1.4 Documentation

The IFP request and the results of the formal review, including reasons for approval or rejection, should be fully documented. Copies of the document should be retained by the reviewing organization, the originator and within the IFP work file. An overall plan for all outstanding requests and ongoing IFP projects with assigned priorities should also be maintained and made available to all stakeholders.

7.2 COLLECT AND VALIDATE ALL DATA (STEP 2)

The procedure designer must ensure that specific ATS requirements related to local traffic patterns (altitude, direction, and airspeed), feeder/transitions, arrival/departures, preferred routes, ATS routes, communication facilities, time, restrictions and any ATS needs, restrictions or problems are available from the ATS provider.

The designer must collect the following data from recognized sources, validate for accuracy, resolution, integrity, reference geodetic datum and effective dates, and incorporate them into the design documentation:

- terrain data: electronic raster and/or vector data or paper cartographic maps;
- obstacle data: man made and natural with their coordinates and elevation;

- aerodrome/heliport data, e.g. ARP/HRP and runway(s) with their coordinates and elevation, lighting, magnetic variation and rate of change, weather statistics, altimeter source;
- aeronautical data: airspace structure, classifications (controlled, uncontrolled, Class A, B, C, D, E, F, G, name of controlling agency), airways/air routes, altimeter transition altitudes/flight levels, neighbouring instrument procedures, area(s) of magnetic unreliability;
- navaid data: coordinates, elevation, service volume, frequency, identifier, magnetic variation and
- existing significant points to local navigation.

7.2.1 User requirements

The IFP is the interface between all the stakeholders. It is important to have a common agreement on the requirements to change or to create an IFP. These may be addressed under the following headings:

7.2.1.1 ATC

- Compatibility of the IFP with existing ATS procedures, for the elected location and for the immediate surroundings if several aerodromes operate IFPs.

7.2.1.2 Users

- Need to shorten trajectories;
- Enhanced guidance;
- Availability of vertical guidance;
- Lower minima; and
- Enhanced flyability.

7.2.1.3 Airspace design

- Constraints given by existing airspaces;
- Requirements for additional / restructured airspace; and
- Danger / restricted and prohibited areas.

7.2.1.4 Environmental constraints

- Avoidance of populated areas;
- Avoidance of sensitive areas (such as chemical, nuclear or other facilities); and
- Noise abatement procedures, when applicable.

7.2.1.5 Schedule

- Timing of the foreseen implementation with regard to the complexity of existing airspace structure. Additional constraints might result from:
 - the need for training on the ANSP side for the integration of the new traffic flows;
 - the implementation schedule of new CNS/ATM systems; and
 - the requirements of the airline operators.

7.2.2 Data/metadata inputs to the procedure design process

The term metadata refers to information “about” the data rather than the data itself. For example, the quality characteristics associated with a data value is metadata. A specific example would be an accuracy definition of plus or minus one meter for runway length is metadata about the actual value of the runway length. The use of the term “data” below is used to address both actual data values **and** metadata.

7.2.3 Data quality requirements

Defined data quality requirements for inputs to the FPD process are key elements to ensure proper safety margins required by procedure design criteria. For example, appropriate obstacle clearance altitude/heights can only be determined if the accuracy of the input data is known.

Accuracy, resolution and integrity are the key quality requirements related to data inputs to the FPD process are defined in Annex 11 — *Air Traffic Services Annex 14 — Aerodromes* and Annex 15.

7.2.4 Procedure Design data acquisition

The acquisition of data for the FPD process must ensure that the acquired data’s quality characteristics are known and adequate, or that, in the case where the data’s quality characteristics are unknown or inadequate (invalid), that appropriate data verification (see verification section below) occurs prior to use.

7.2.5 Data sources and supplier status

All data sources must be identified. For the suppliers of critical and essential data elements, the status of the supplier should be established and reviewed on a regular basis.

Additionally, if a supplier does not have an approved quality management system, the supplied data must be considered to be of unknown quality characteristics (invalid against the data requirements) and must be verified as described below.

7.2.6 Incoming data verification and validation

All data received from a supplier that will be used in the FPD process must be validated against the data quality requirements. If the data is validated as having met the data quality requirements, then the data may be used without additional verification.

Where a supplier is unable to state data quality characteristics, or the quality characteristics are below the stated requirements, the data must be replaced with data of known and adequate quality characteristics, or be verified as adequate to the specifics of the procedure being designed. Data verification or mitigation for use in the FPD process can take many approaches including, but not limited to:

- analysis against other data of known quality characteristics such as control points;
- imposition of appropriate buffers based on the actual procedure;
- a determination of negligible effect on the actual procedure; or
- flight validation / checking

The validation of the data quality requirements must be documented and can serve in later studies.

7.2.7 Documentation

Required documentation to support the FPD process incoming data processing include incoming inspection of the data quality characteristics, disposition of the incoming data (valid or invalid), updating of the data source and supplier status documentation, and for non-verified data, clear documentation indicating the need for appropriate verification prior to use in the FPD process. All documentation needs to be clearly labelled as to the data it applies to, versioned and stored as necessary.

7.3 CREATE CONCEPTUAL DESIGN (STEP 3)

Once the collection of requirements and constraints has been completed and all necessary data has been acquired and verified, the designer can commence with the conceptual design.

An individual designer should be nominated as the designer responsible for the design concept and for the development of the actual design.

Coordination with interested / affected stakeholders should continue throughout the conceptual and the subsequent design phase of this process.

As an input for this activity, the procedure designer may draw on earlier designs if available and use the outputs of the previous steps such as presentation notes containing design objectives and indicators as well as the requirements and constraints and the verified data collated in the previous steps.

The intention would then be to develop a design strategy for the procedure based on ICAO Doc 8168 and/or other applicable criteria as well as the key inputs stated above.

In a more complex design environment it might be helpful or even necessary to develop one or more design alternatives in order to provide sufficient input for the review of the design concept.

7.4 REVIEW BY STAKEHOLDERS (STEP 4)

The conceptual design is reviewed by the stakeholders. It is important that the stakeholders, the designer and the designer's management agree on the conceptual design and on the planned implementation AIRAC date. This will allow a common understanding of the development stages of the design and will also increase the chances of a successful implementation.

7.5 APPLY CRITERIA (STEP 5)

Once the relevant data has been collected and the draft IFP has been approved, the design activity can commence. An individual designer should be nominated as the responsible designer. Continued coordination with interested/affected stakeholders should be maintained throughout the design phase.

7.5.1 Criteria

International procedure design criteria are detailed in PANS-OPS, Volume II (Doc 8168). ICAO regularly reviews and amends these criteria. It is important that the current applicable criteria be used by all personnel involved in the FPD process in order to ensure international harmonization.

Whenever changes to the criteria are published, the procedure design organization should review these to determine an appropriate implementation plan. If the change in the criteria is deemed to be a safety critical element, it should be carried out immediately.

Although the desirability of using the PANS-OPS criteria as a basis for achieving international harmonization is recognized, a State may elect to define or authorize the use of different sets of procedure design criteria.

A State may also elect to define national procedure design criteria for use with existing PANS-OPS criteria. Such additional or alternate design criteria should never be used together with PANS-OPS criteria unless they have been developed specifically for that purpose.

In both cases, such criteria should be fully documented, be regularly reviewed and be reflected in the State's AIP.

Under no circumstances may a mixture of different sets of criteria be used in the design of an instrument flight procedure.

7.5.2 Methods and tools

In order to make sure that a procedure design tool is appropriate for the FPD concept, it must be subject to both a validation process (for compliance with applicable criteria) and an assessment of compliance with user requirements (concerning available functions, human machine interface, and documentation).

The design methods employed during the FPD process should be thoroughly validated and clearly documented. Procedure designers should receive adequate training in applying the approved methods. Guidance on procedure design training is provided in Volume 2 – *Flight Procedure Designer Training*. Care should be taken that only the approved methods are applied during the FPD process.

Software tools should be used, where appropriate, to ensure design consistency. All software tools should be validated. Guidance on the validation of software tools is provided in Volume 3 – *Flight Procedure Design Software Validation*.

Calculation and construction techniques should comply with the guidelines contained in the relevant ICAO documentation or in the relevant national criteria. Guidance on design calculation standards and construction techniques will be provided in Volume 4 – *Flight Procedures Design Construction* (to be developed).

7.5.3 Design methods

Procedures may be designed using one or a combination of three possible methods:

- manual method. The manual method involves the use of paper charts, tracing paper, paper/plastic templates¹, pencils or drawing pens and calculators/spreadsheets. Photocopies or low grade reproductions of charts should not be used;

¹ Such as OAS templates, as detailed in PANS-OPS, Volume II and Holding, Reversal and Racetrack templates, as detailed in the *Template Manual for Holding, Reversal and Racetrack Procedures* (Doc 9371).

- COTS software method. The COTS method involves the use of commercial off-the-shelf software, such as CAD packages, and imported, or manually input, electronic topographic, aeronautical and obstacle data. Tool-specific macros and templates may be developed and used, after appropriate validation; and
- custom-made software method. The custom-made method involves the use of specialist software tools developed specifically for supporting the FPD process. These tools must have been validated in accordance with Volume 3 and must be used in accordance with the published user manual.

To enhance the integrity throughout the design process, the use of automated or semi-automated tools is recommended.

7.5.3.1 Documentation

On the basis of these activities, the actual FPD usually results in one or several draft procedure layouts, a textual description of the procedures as well as calculations and coordinates.

These documents are then used as a basis for the design verification and are the input for the determination of the level of safety impact of the design.

All aspects of the FPD process should be documented including:

- version of applicable design criteria;
- all data sources;
- service volume coverage analysis;
- all calculations including transformation parameters used;
- all parameters used (speeds, bank angles, wind velocity, temperature, descent gradient, climb gradient, timings, height loss margins, OAS coefficients, etc.);
- specific validation requirements (e.g. flyability, service volume coverage confirmation, etc.);
- flight inspection results (if required);
- full design rationale;
- design assumptions and constraints;
- alternative designs that were considered and the reasons for their rejection;
- stakeholder feedback during the design process;
- document version and date;
- draft elements for publication (when available), including coding advice (when applicable);
- any other pertinent points of interest resulting from the FPD process, e.g. software tools used for the design, advantages and drawbacks of the assessed scenarios, potential difficulties for the execution of certain phases of the procedure, environmental issues, financial aspects, etc.

The documentation should include a clear statement of compliance with the State-approved criteria together with detailed notes of any deviations and evidence of approval for each deviation. There should also be a record of each design review and sign-off.

7.6 DOCUMENT AND STORE (STEP 6)

Traceability is the key element in the design of a new IFP. All assumptions and methods taken or used in the implementation of a new or modified FPD should be documented in a uniform manner and kept available at least during the lifetime of the IFP.

All supporting documentation, such as spreadsheets, drawing files and other relevant files should, as far as practicable, remain in a common location, and for the lifetime of the procedures, be stored in an exploitable method.

After the withdrawal of a procedure, States should strive to archive the digital data that was used during the FPD process. As far as applicable, the archived data should remain available in a state permitting a repetition or validation of the process in a later stage.

It is the State's responsibility to define the minimum period of time during which this documentation must remain available after a full redocumentation following a review of the procedure or a withdrawal of the existing procedure.

The documentation should, when no longer needed and as far as practicable, be retained in an archive form for later consultation.

7.7 CONDUCT SAFETY ACTIVITIES (STEP 7)

This chapter provides a minimum of information on safety activities. For more detailed information please refer to *The Safety Management Manual* (Doc 9859).

7.7.1 Safety concepts

7.7.1.1 *Safety definition*

Safety is generally defined as "freedom from unacceptable risk ". From a formal point of view, a system can only be considered to be safe for operational use if its inherent risks have been identified, assessed and agreed to be below predefined limits. If such a commitment is reached, the system can be considered as acceptably safe.

7.7.1.2 *Safety assessment*

A safety assessment is a formal process by which an organization may ensure that risks associated with a system change have been properly identified and mitigated prior to going into operation. The results and conclusions of a safety assessment are usually described in a safety case. Broadly, the safety case is the documented assurance of the achievement and maintenance of safety.

7.7.1.3 *Demonstrating safety*

Primarily, the safety case is a matter of the organization assuring itself that its operations are safe. Only secondarily, it is a matter of demonstrating the safety of the operation to a regulatory body.

7.7.1.4 *Safety targets*

The aim should be to provide safety assurance based on an appropriate combination of the following general criteria:

- compliance with a target level of safety (TLS) – the so-called absolute approach;

- indication that the risk will be no higher than, or (where a safety improvement is required) substantially lower than, the pre-change situation – the relative approach; and
- that the risk will be reduced as far as reasonably practicable – the minimal approach.

7.7.1.5 *Safety system*

When considering the ATM system lying within the managerial control, it is important to understand the word system as the aggregation of human (H) making usage of supporting equipment (E) based on appropriate procedures (P) in order to deliver safe and efficient services in a particular operational environment. This kind of "system-thinking" approach is of utmost importance to guarantee consistency of safety assessments.

7.7.1.6 *Safety assessment of safety issues*

A "safety assessment of changes" must be systematically and formally conducted each time an element is changed or newly introduced in the ATM system lying within the Air Traffic Service Provider's managerial control. However, existing elements not being affected by modifications may also be questioned in respect to safety. In such cases, the trigger is different but a "safety assessment of safety issues" may be conducted based on the usage and application of similar tools and principles.

7.7.1.7 *Assessing the type of safety case needed*

To assess the impact on safety of the change, conduct a preliminary hazard analysis to determine the likely hazards that may arise from the change.

It is important to assess the level of the safety impact. Determining this may be accomplished by measuring the impact in various domains, such as:

- operational consequences of the change;
- operational consequences for external partners;
- level of new functionality introduced as opposed to the existing systems;
- amount of technical systems affected by the change;
- amount of training or amount of additional staffing needed; and
- complexity of the transition from the existing system.

7.7.2 Implication of safety in the flight procedure design process

It is impossible for an individual to have the entire background in the criteria contained in the relevant ICAO and/or State documentation. For this reason, it should be accepted that the criteria, as long as applied completely in accordance with the reference material, is safe.

Safety assessments for the FPD should therefore focus on two main elements. These are:

- application of methods for the design of a flight procedure. Looking at the methods from the reception of the requests, the application of the criteria, the handling of data throughout the process, the design aspects, including the cross-checking, the publication process, etc.; and
- the implementation of a procedure, looking at the interface with other procedures available in that location, the complexity and the workload imposed on ATC, cockpit workload, flyability, etc.

The overall aim should be to address the following five safety assurance goals:

- show that the underlying concept of the whole procedure is intrinsically safe – i.e. whether it is capable of satisfying the safety criteria, assuming that a suitable design could be produced – and what the key parameters are that make it so;
- show that everything necessary to achieve a safe implementation of the procedure – and related to equipment, people, and airspace design issues - has been specified,
- the design is correct – e.g. that:
 - the design is internally coherent – e.g. is consistent in functionality (in equipment, procedures and human tasks), and in use of data, throughout the system;
 - all reasonably foreseeable normal operational conditions have been identified, including such elements as adjacent procedures and airspace; and
 - the design is capable of meeting the safety criteria under all reasonably foreseeable normal operational conditions / range of inputs (in the absence of failure);
- show that the design is robust – i.e. that:
 - the system can react safely to all reasonably foreseeable external failures; and
 - the system can react safely to all other reasonably foreseeable abnormal conditions in its environment;
- show that the risks due to internal failure have been mitigated sufficiently such that, overall, the safety criteria are still satisfied – typically need to show that:
 - all reasonably foreseeable hazards, not directly linked to the safety case, but possibly impacting the safety case, have been identified (e.g. loss of communication, loss of navigational capabilities, etc.);
 - the severity of the effects from each hazard has been correctly assessed, taking account of any mitigations that may be available / could be provided external to the system;
 - safety objectives have been set for each hazard such that the corresponding aggregate risk is within the specified safety criteria;
 - all reasonably foreseeable causes of each hazard have been identified;
 - safety requirements have been specified (or assumptions stated) for the causes of each hazard, taking account of any mitigations that are / could be available internal to the system, such that the safety objectives are satisfied; and
 - those safety requirements are realistic – i.e. are capable of being satisfied in a typical implementation in aircraft and ground equipment, people and procedures.

7.7.3 Safety implications for new procedures

New instrument flight procedures may be designed in accordance to the reference documentation and be, as a stand alone procedure, fully acceptable with respect to the target level of safety. The publication of a new IFP and the implementation in the existing ATM environment might trigger safety issues. These safety issues should be considered and adequately mitigated prior to the operational use.

7.7.4 Safety team

The safety assessment should not be performed by a sole individual, but should ideally be conducted by a team comprised of all relevant stakeholders. This allows consideration of the full implications of all interactions and possible hazards resulting from the operational use of a procedure. Normally, safety studies should not be lead by the designer. The designer is normally an active participant in the creation of the safety documentation.

7.7.5 Examples

To clarify the issues addressed above, two examples of safety applications are attached in Appendix B of this document. Furthermore, in Appendix C, the methodology as applied in Europe is also provided.

7.8 CONDUCT GROUND VALIDATION AND CRITERIA VERIFICATION (STEP 8)

Prior to the ground validation, a review of the procedure should be performed by a designer who was not involved in the original design. This review of the FPD may be done by sampling or by complete review based on complexity and downstream verification and validation processes. It should include a review of subjective logic employed by the procedure designer. The use of independent methods and tools adds to the verification effectiveness.

Validation is the necessary final quality assurance step in the procedure design process, prior to publication. The purpose of validation is the verification of all obstacle and navigation data, and assessment of flyability of the procedure. Validation normally consists of ground validation and flight validation. Ground validation must always be undertaken. When the State can verify, by ground validation, the accuracy and completeness of all obstacle and navigation data considered in the procedure design, and any other factors normally considered in the flight validation, then the flight validation requirement may be dispensed with.

Ground validation is a review of the entire instrument flight procedure package by a person(s) trained in procedure design and with appropriate knowledge of flight validation issues. It is meant to catch errors in criteria and documentation, and evaluate on the ground, to the extent possible, those elements that will be evaluated in a flight validation. Issues identified in the ground validation should be addressed prior to any flight validation. The ground validation will also determine if flight validation is needed for modifications and amendments to previously published procedures. The ground validation should also:

- compare the intended use of the instrument flight procedure with the initial stakeholder expectations and to the conceptual design; and
- consider the outcome of the safety activities in regards to correct application.

Ground validation may include the use of desktop simulation tools and/or require the use of flight simulators.

Note.— Data validation and the documentation of the validation methodology are normally documented and stored as a quality record.

The results of the validation can trigger changes to the initial design. The changes can be communicated to the original designer for review and incorporation, or, the verifier may make the changes and submit them to the designer for verification. It is important that any changes made are clearly documented and traceable.

7.9 CONDUCT FLIGHT VALIDATION AND DATA VERIFICATION (STEP 9)

7.9.1 Flight inspection and flight validation

For the purposes of quality assurance in the procedure design process, flight inspection and flight validation are separate activities that, if required, may or may not be accomplished by the same entity. Flight inspection is conducted with the purpose of confirming the ability of the navigation aid(s) upon which the procedure is based, to support the procedure, in accordance with the standards in Annex 10 — *Aeronautical Telecommunications* and guidance in the *Manual on the Testing of Radio Navigation Aids* (Doc 8071). Flight validation is concerned with factors other than the performance of the navigation aid that may affect the suitability of the procedure for publication, as detailed in PANS-OPS, Volume II, Part I, Section 2, Chapter 4, *Quality Assurance*.

The procedure design organization does not normally have the expertise necessary to determine under which conditions flight inspection and/or flight validation may be necessary. The State is responsible for the overall performance of the procedure, as well as the quality and suitability of the procedure for publication. For this reason it is recommended that a review of the procedure by the flight inspection and flight validation organizations be included in the State's procedure design process flow, following the ground validation. This function can also be accomplished during the ground validation, if the personnel performing the ground validation are suitably qualified to make determinations concerning flight inspection and/or flight validation requirements.

Personnel performing flight inspection duties should be qualified and certified in accordance with Doc 8071, Volume I, *Testing of Ground-Based Radio Navigation Systems*. PANS-OPS, Volume II, Part I, Section 2, Chapter 4, *Quality Assurance* requires the State to have a written policy requiring minimum qualifications and training for flight validation pilots, including those flight inspection pilots that perform flight validation of instrument flight procedures. This policy also must establish standards for the required competency level for flight validation pilots. Appendix B contains recommended qualifications and training, as well as guidance concerning the skills, knowledge and attitudes (SKA) to be addressed in training and evaluation of flight validation pilots.

7.9.2 Data verification

Where the FPD involves a complex new procedure or a significant change to existing procedures/routes in a complex airspace, the State is strongly advised to liaise with the major commercial navigation datahouses prior to promulgation. This liaison should provide the datahouses with additional advance notice of the proposed changes and should allow them to review the proposed procedures, clarify any outstanding questions and advise the State of any technical issues that may be identified.

Advanced notification of procedures should contain the following elements:

- graphical layout of the procedure;
- textual description of the procedure;
- coding advice, when applicable;
- coordinates of fixes used in the procedure.

7.10 CONSULT WITH STAKEHOLDERS (STEP 10)

At this stage of the development, all stakeholders should be consulted to get their opinion on the proposed procedure. Gathering their input at this stage allows having a statement on the fulfilment of the initially agreed requirements.

At this stage, those parts of specific competency that the design office do not possess should be validated by the stakeholders competent in that domain. A written statement from those entities will serve for the approval process of the IFP.

7.11 APPROVE IFP (STEP 11)

The IFP must be approved by the State or by an authority designated by the State, prior to the publication. This approval process must ensure that all the appropriate steps within the IFP process have been completed, documented and signed off by the competent authority.

7.12 CREATE DRAFT PUBLICATION (STEP 12)

At this stage of the process, all the elements for the draft publication are available. The AIS or charting group develops the chart taking into account all relevant requirements for the safe operation of the procedure.

The charting must comply with Annex 4. Additional requirements valid for the State in which the procedure is to be implemented should also be considered.

7.13 VERIFY DRAFT PUBLICATION (STEP 13)

Crosscheck the promulgated publication for completeness and consistency (it is recognized that this may be considered an AIS responsibility also).

The draft of the new chart should be submitted to all stakeholders, particularly the designer and the procedure owner.

The final draft of the instrument flight procedure chart must be verified on completeness and correctness.

7.14 PUBLISH IFP (STEP 14)

The publication of IFP and supporting data is normally a State responsibility. In some situations, it is possible that the publication may be delegated to another entity. The structure in which the State data is published can differ from one State to another.

It is important that the publication State's aviation authority receives the entire IFP, if possible supported by a graphical depiction for regulatory approval and for the initiation of the AIRAC publication process.

The stakeholders should also receive a copy of the draft State publication at this stage.

7.15 OBTAIN FEEDBACK FROM STAKEHOLDERS (STEP 15)

The State should implement a system to get the feedback from stakeholders about the operational implementation of the procedure. The advice of data houses, ATC and pilots actually using the procedure is particularly relevant. The system may be based upon regular meetings with stakeholders or on results (reports) from a consultation (questionnaire).

The procedure design office management should then analyse the feedback. Elements that generate positive feedback should be considered for other procedures. Negative feedback should be evaluated. Encountered problems or implementation issues should be carefully assessed with the procedure designers, so that corrective action can be initiated as appropriate. The corrective action can range from minor corrections to the publication to complete revision of the procedure.

7.16 CONDUCT CONTINUOUS MAINTENANCE (STEP 16)

On a continuous basis (as determined and notified by AIS) ensure that significant changes to obstacles, aerodrome, aeronautical and navaid data are assessed for their impact on the IFP. If action is required return to Step 1 to reinitiate the process. Criteria changes are assessed only if required or during the next periodic review. Criteria changes may also be considered in cases where there would be a significant advantage to the user.

In some organizations, it is possible that the Annex 14 surfaces in the close vicinity of an airport are maintained by an entity other than the flight procedure design office. In such cases, it is important to set up an agreement for relevant airport/obstacle data to be provided to the procedure designer. The airport takes responsibility for the protection of the Annex 14 surfaces. When these surfaces are infringed, close cooperation with the designer for obstacle assessment on the IFP is needed.

7.17 CONDUCT PERIODIC REVIEW (STEP 17)

On a periodic basis (periodicity determined by the State, but no greater than five years) the State must ensure that all changes to obstacles, aerodrome, aeronautical and navaid data are assessed. If action is required return to Step 1 to reinitiate the process.

On a periodic basis ensure that all changes to criteria, user requirements and depiction standards are assessed. If action is required return to Step 1 to reinitiate process.

It is important to note that the process, as such, does not have an "end" box. The quality process extends over the entire life cycle of the procedure. When the procedure is decommissioned, specific activities are needed to allow the withdrawal of an active procedure.

The quality assurance activities can be discontinued when the procedure has been removed from the publications and is no longer available for operation.

It is recommended to keep the quality assurance documentation for an adequate period of time to allow traceability for later purposes.

APPENDIX A

A.1. Quality process documentation

Process documentation is the foundation for consistent results and quality (ISO 9001:2000 "Quality management systems – Requirements", section 4.2 "Documentation Requirements"). A hierarchal documentation structure is shown in the triangle below. The top level of the triangle represents a high-level overview of the entire procedure design process. Each level below the overview level represents a consistent and more detailed view of the section above it.

The area of each section represents a relative measure of the volume of documentation at each level. For example; the overview may be a one page flowchart which breaks down into three procedures. Each of the procedures may be supported by two work instructions (six in total). The work instructions are supported by industry reference documents. The entire process is supported by checklists, logs and signoffs which provide an audit trail for traceability and problem resolution.

Maintaining the documentation to reflect current practices is essential to ensure consistency, broad dissemination of changing practices and up-to-date process training.

The hierarchy of quality process documentation is shown in the illustration below:

LEVEL DESCRIPTIONS	
DOCUMENT TYPE	PURPOSE
Overview	High level overview that describes the procedures within a process and their interactions / relationships.
Procedures	High level description of work at an operational level (what, when, where, why). (For the distinction between "procedure" and "flight procedure" see section 3 definitions).
Work Instructions	A subset of procedure level documents that describe procedural tasks in detail. "How" work is done at a task level.
Quality Records / Forms	Contain data (evidence) that work has been completed. Information is entered into these documents.
Reference Materials	Contain data that is referenced to support work tasks (Data that supports current practices).

A.1.1 Process objective and description

The process objective pinpoints the main objectives which are to be reached within the process area. The description consists of bullet points.

The process description attribute describes the main purpose of the process area. The description consists of input attribute, the description itself and output attribute. A process is an end to end description composed of an organized group of related tasks that work together to create a result of value:

- the input attribute describes the inputs required to start the process. The description consists of bullet points; and

- the output attribute describes the output delivered by the process. In other words, it is a list of deliverables. The description consists of bullet points.

Other elements of a process description are:

- Procedures;
Detailed process information where workflow procedures and responsibilities are defined.
- Performance indicator;
Quantifiable orders of all kinds for the measurement of the technical, managerial and staff performance in the business. Indicators can be used both within an area and for comparisons between the areas in terms of safety, performance, profitability or productivity;
- Measurement tool;
Determines the measurement resources to be used to measure the defined performance indicators;
- Performance measurement; and
Quantified measurement of processes on the basis of process goals and values. The performance measurement consists of the two attributes *performance indicator* and *measurement tool*.

A.1.2 Quality records

The International Standards Organisation, responsible for the ISO9000 and other standards defined the minimum list of required documents and mandatory procedures. A mandatory records procedure is required to specify:

- which records are kept;
- by whom;
- for how long; and
- and how they are disposed of.

The list of documentation that needs to be maintained and stored extends to:

- management review minutes;
- records of education, training, skills and experience;
- evidence that the realization processes and product fulfil requirements;
- records of sales activities;
- design and development inputs;
- design and development reviews and any related actions;
- design and development verification and any related actions;
- design and development validation and any related actions;
- design and development changes and any related actions;
- results of supplier evaluations and any arising actions;
- records to demonstrate the validation of special processes;

- where traceability is required, the unique identification of the product is recorded;
- customer property that is lost, damaged or otherwise found to be unsuitable;
- basis used for calibration of measuring equipment where no international or national standards exist;
- validity of the previous measuring results when measuring equipment is found to be out of calibration;
- results of calibration and verification of measuring equipment;
- internal audit results and follow-up actions;
- indication of the person(s) authorizing release of product;
- records of the product nonconformities and any subsequent actions;
- results of corrective action; and
- results of preventive action.

A.2 Key Performance Indicators

A.2.1 How an organization defines and measures progress toward its goals

Key Performance Indicators (KPI) help an organization define and measure progress toward organizational goals.

Once an organization has analysed its mission, identified all its stakeholders, and defined its goals, it needs a way to measure progress toward those goals, KPI are those measurements.

A.2.2 What Are Key Performance Indicators

Key Performance Indicators are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organization or of an entity. For the development of instrument flight procedures, such KPIs could reflect the overall performance of the IFP in regards to the stakeholders' expectations.

Whatever KPIs are selected, they must reflect the organization's goals, they must be key to its success, and they must be quantifiable (measurable). KPIs usually are long-term considerations. The definition of what they are and how they are measured do not change often. The goals for a particular KPI may change as the organization's goals change, or as it gets closer to achieving a goal.

A.2.3 Key Performance Indicators must be quantifiable

If a KPI is going to be of any value, there must be a way to accurately define and measure it.

It is also important to define the KPIs and stay with the same definition from year to year. For a KPI of "increase productivity", there is a need to address considerations like whether to measure by IFP implemented or by IFP developed.

There is a need to set targets for each Key Performance Indicator.

A.2.5 Key Performance Indicators must be key to organizational success

Many things are measurable. That does not make them key to the organization's success. In selecting KPIs, it is critical to limit them to those factors that are essential to the organization reaching its goals. It is also important to keep the number of KPIs small just to keep everyone's attention focused on achieving the same KPIs.

That is not to say, for instance, that a company will have only three or four KPIs in total. Rather, there will be three or four KPIs for the company and all the units within it will have three, four, or five KPIs that support the overall company goals and can be "rolled up" into them.

A.2.6 Key Performance Indicators in IFP

Objectives that could be set could be the reduction of safety errors during the design phase to 0 per cent and non-safety errors to less than 5 per cent during the initial review and to 0 per cent during the second quality review. The final objective should allow sending fault free publication elements to the external customers.

An additional element could be the provision of feedback to all comments and suggestions provided by entities outside of the FPD office.

APPENDIX B

B.1 Flight validation pilot training and evaluation

Where States apply flight validation, it must establish standards for the required competency level for flight validation pilots. The State must ensure that flight validation pilots have acquired and maintain this competency level through training and supervised on-the-job training (OJT). This is in order to achieve the safety and quality assurance objectives of the flight validation and to ensure that the quality assurance in the procedure design process and its output, including the quality of aeronautical information/data, meets the requirements of Annex 15.

Training for flight validation pilots should at least include initial training and recurrent training at periodic intervals.

Initial training must ensure that the flight validation pilot is able to demonstrate a basic level of competency that includes at least the following elements:

- knowledge of information of PANS-OPS, Volumes I and II and other related ICAO provisions relevant to the State; and
- knowledge and skills in ground and flight validation of procedures.

Recurrent training must ensure that the flight validation pilot is able to demonstrate a basic level of competency that includes at least the following elements:

- knowledge about updates in ICAO provisions and other provisions pertaining to procedure design and flight validation of procedures; and
- maintenance and enhancement of knowledge and skills on ground and flight validation of procedures.

The State must ensure that flight validation pilots have undergone an adequate supervised OJT.

Competency of the flight validation pilot must be evaluated by the State at regular intervals.

The following paragraphs address the skills, knowledge and attitude (SKA) that must be trained and evaluated for a flight validation pilot to be competent to perform flight validation of instrument flight procedures. In many States, flight inspection pilots perform the flight validation of procedures. The State must ensure that those flight inspection pilots authorized by the State to conduct flight validation of procedures also meet these requirements. These competencies are not exhaustive. They represent the minimum knowledge required to achieve the quality assurance objectives of the flight procedure design process.

B.2 Initial training**B.2.1 Knowledge of information in PANS-OPS, Volumes I and II and other related ICAO provisions**

- a. PANS-OPS, Volume I
- b. PANS OPS, Volume II
 - 1. General PANS-OPS subject areas
 - i. data quality requirements
 - ii. charting requirements
 - iii. environmental considerations
 - iv. quality assurance requirements
 - 2. Procedure design criteria for each type of procedure to be validated
 - i. obstacle protected areas
 - ii. required obstacle clearance for any given segment of a procedure
 - iii. climb and descent gradients
 - iv. ARINC coding
- c. Required Navigation Performance - Authorization Required Manual (if applicable)
- d. Quality Assurance Manual for Flight Procedure Design
- e. Annex 14

Note.— Substantial portions of the required knowledge in PANS-OPS can be obtained in a PANS-OPS procedure design course.

B.2.2 Knowledge and skills in ground and flight validation of procedures

- a. Ground training in flight and ground validation duties:
 - 1) *Manual on Testing of Radio Navigation Aids* (Doc 8071)
 - 2) flight inspection requirements
 - 3) procedure package contents
 - 4) procedure package review
 - 5) techniques and considerations for ground validation of obstacle data
 - 6) requirements, techniques and considerations for obstacle assessment in flight
 - 7) airport infrastructure assessment
 - 8) communications coverage
 - 9) flyability/Human Factors assessment
 - 10) charting considerations
 - 11) operational factors
 - 12) criteria to be met for waiving the requirement for a flight validation
- b. Flight training in flight validation duties:
 - 1) flight inspection requirements
 - 2) obstacle assessment requirements, techniques and considerations
 - 3) airport infrastructure assessment
 - 4) communications coverage
 - 5) flyability/Human Factors
 - 6) charting considerations
 - 7) operational factors

- c. Supervised on-the-job training adequate to achieve the required level of competency in flight and ground validation knowledge and skills.
- d. Initial ground and flight evaluation.

B.3. Recurrent training

The following are the minimum competencies to be addressed in a recurrent training programme for flight validation pilots, which should be accomplished at least every two years, or when major changes occur:

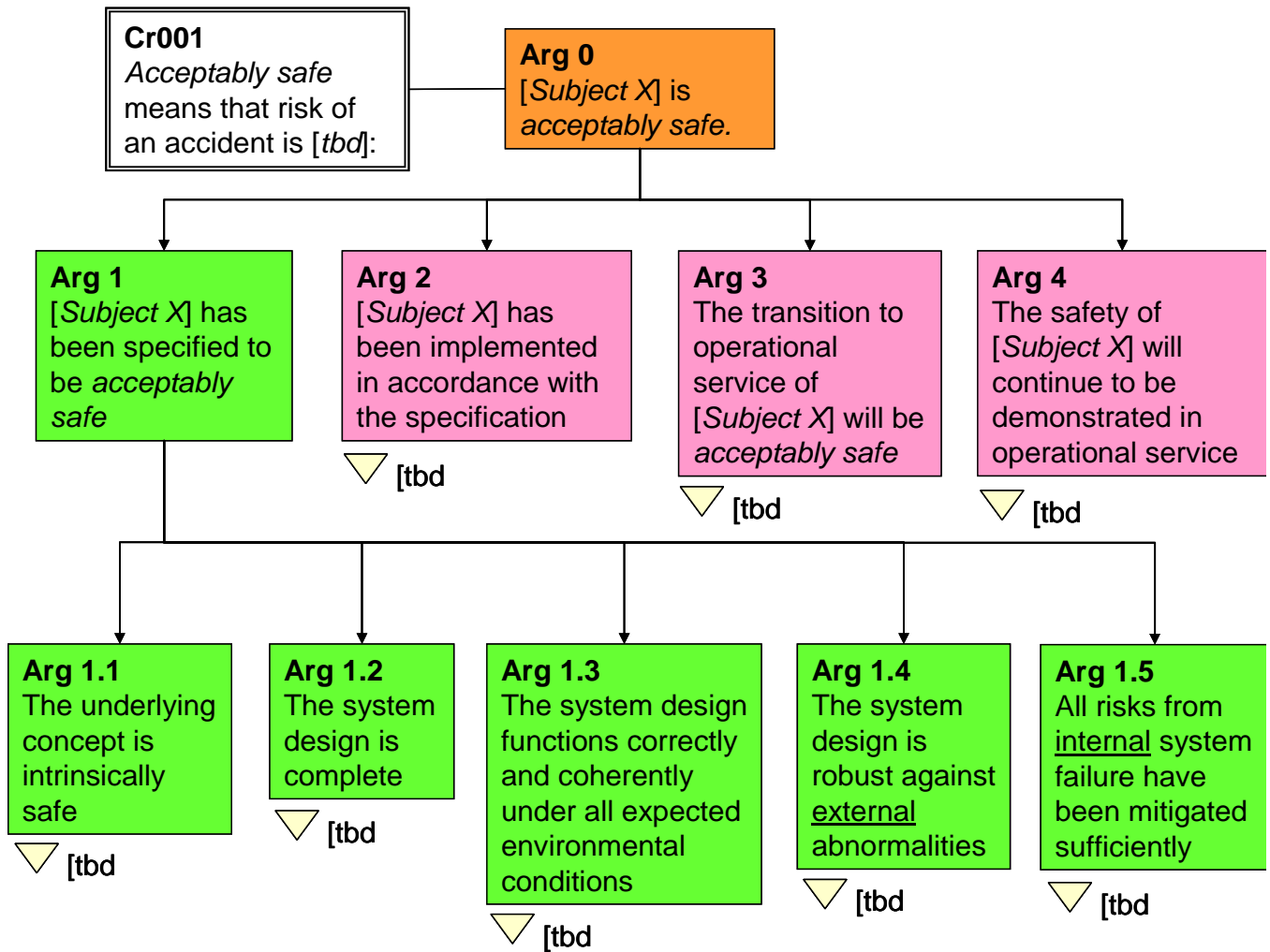
- a) update on changes in PANS-OPS criteria;
- b) review portions of PANS-OPS criteria most relevant to current or projected duties;
- c) review changes in airport infrastructure requirements; and
- d) knowledge and skills related to new developments in flight validation.

Where States apply flight validation, the competency of the flight validation pilot must be evaluated by the State at regular intervals. The skills, knowledge and attitude to be addressed in this evaluation should at least include those areas that pose the greatest risk to the overall quality of the State's procedure design process if not accomplished correctly.

APPENDIX C

C.1. Generic safety argument for ATM safety assessment

In this appendix an example of how an ATM safety assessment could be laid out is given. This example outlines a method that has been implemented in the European (EUR) Region.



Note.—The term "tbd" in the illustration above indicates that the subarguments would still need to be developed during the application of such a safety case method.

The top-level claim (Argument 0) states that the subject (i.e. on-going service or change) is *acceptably safe*. Strictly speaking, in the case of a change, this would be an abbreviated way of saying that the ATM service, following the introduction of the change, is acceptably safe.

What is meant by acceptably safe in Argument 0 is defined by the safety criteria in Cr001 – these may be defined:

- absolutely - e.g. compliance with a target level of safety (TLS), and/or
- relatively - e.g. risk to be no higher than, or (where a safety improvement is required) substantially lower than, the pre-change situation; and/or
- minimally – e.g. risk to be reduced as far as reasonably practicable.

The claim is then decomposed into four principal safety arguments, using the goal structuring notation convention that an argument can be considered to be true, if (and only if) each of its immediate ‘offspring’ can be shown to be true².

Arguments 2 to 4 reflect normal ATM safety practice and are not expanded herein – for further guidance see EUROCONTROL *Safety Case Development Manual*. However, it is important to note that argument 1 applies to the concept as a whole; therefore, where such concepts are implemented in stages, the term “transition” in Argument 3 should be interpreted as including the safety of each stage of a phased deployment of the end system.

It is the decomposition of Argument 1 which reflects the success approach (Argument 1.1 to Argument 1.3) and failure approach (Argument 1.4 and Argument 1.5)³. Typical issues to be addressed under each argument are discussed in the rest of this section – in each case, the human, procedure, equipment and airspace elements of the system must be considered.

C.1.1 Intrinsic safety of the concept (Argument 1.1)

Need to show, inter alia, that:

- the operational context and scope of the concept has been clearly described;
- differences from existing operations have been described, understood and reconciled;
- the impact of the concept on the operational environment has been assessed and shown to be consistent with the safety criteria; and
- the key functionality and performance parameters have been defined and shown to be consistent with the safety criteria.

The issues here are whether the basic idea is intrinsically safe – i.e. whether the concept is capable of satisfying the safety criteria, assuming that a suitable system design could be produced – and what the key parameters are that make it so.

C.1.2 Design completeness (Argument 1.2)

Need to show that:

- the boundaries of the system are clearly defined;
- the concept of operations fully describes how the system is intended to operate;

² At the lowest eventual level of decomposition, of course, an Argument can be considered to be true if there is adequate Evidence to show that it is.

³ It is a moot point whether Argument 1.4 should be in the success approach or the failure approach. In practice, the distinction between the *success* and *failure* approaches is unimportant compared with ensuring overall that everything required by Argument 1.1 to 1.5 is covered

- everything necessary to achieve a safe implementation of the concept – related to equipment, people, procedures and airspace design - has been specified (as safety requirements);
- all safety requirements on, and assumptions about, external⁴ elements of the end-to-end system have been captured; and
- safety requirements are realistic – i.e. are capable of being satisfied in a typical implementation in hardware, software, people and procedures.

The main question here is whether we have thought of everything, in terms of the design, that is necessary to fully implement the concept.

C.1.3 Design correctness (Argument 1.3)

Need to show that:

- the design is internally coherent – e.g. is consistent in functionality (in equipment, procedures and human tasks), and in use of data, throughout the system;
- all reasonably foreseeable normal operational conditions / range of inputs from adjacent systems have been identified;
- the design is capable of delivering the required risk reduction under all reasonably foreseeable normal operational conditions / range of inputs; and
- the design functions correctly in a dynamic sense, under all reasonably foreseeable normal operational conditions / range of inputs.

The main question here is whether we have maximised the opportunity to reduce risk, over the full range of conditions that the system is likely to be subjected to in its operational environment.

C.1.4 Design robustness (Argument 1.4)

Need to show that:

- the system can react safely to all reasonably foreseeable external failures – i.e. any failures in its environment / adjacent systems that are not covered under Argument 1.3; and
- the system can react safely to all other reasonably foreseeable abnormal conditions in its environment / adjacent systems.

Here we are concerned with abnormal conditions in the operational environment, from two perspectives: can the system continue to operate effectively – i.e. **reduce** risk; and could such conditions cause the system to behave in a way that could actually **induce** a risk that would otherwise not have arisen?

C.1.5 Mitigation of internal failures (Argument 1.5)

This relates to the more ‘traditional’ failure-based approach to ATM safety assessment. Unlike Arguments 1.1 to 1.4, which lead to a specification of the risk-reducing properties of the system (i.e.

⁴ The term ‘external’ here usually refers to those elements that lie outside the managerial control of the organisation accountable for the safety assessment.

safety requirements for the functionality and performance of the system), Argument 1.5 leads mainly to a specification of safety objectives⁵ and safety requirements for the integrity of the system.

Typically, need to show that:

- all reasonably foreseeable hazards, at the boundary of the system, have been identified;
- the severity of the effects from each hazard has been correctly assessed, taking account of any mitigations that may be available / could be provided external to the system;
- safety objectives have been set for each hazard such that the corresponding aggregate risk is within the specified safety criteria;
- all reasonably foreseeable causes of each hazard have been identified;
- safety requirements have been specified (or assumptions stated) for the causes of each hazard, taking account of any mitigations that are / could be available internal to the system, such that the safety objectives are satisfied; and
- those safety requirements are capable of being satisfied in a typical implementation in hardware, software, people and procedures.

Here we are concerned with the internal behaviour of the system, from two perspectives: how loss of functionality could reduce the effectiveness of the system in reducing risk; and how anomalous behaviour of the system could induce a risk that would otherwise not have arisen.

⁵ Safety objectives is a term used in ESARR 4 and the EUROCONTROL Safety Assessment Methodology to describe the maximum tolerable occurrence rate of hazards.

APPENDIX D

EXAMPLES OF APPLICATIONS OF SAFETY ASSESSMENT FRAMEWORKS

This section gives a brief outline of how the above safety assessment framework has been (or could be) applied to two current European safety assessments.

In each case, a short introduction is followed by the specified safety criteria and a description of what work is involved in addressing each of the five main branches of the safety argument.

D.1 Example of a safety application (EUR RVSM)

The introduction of RVSM, between FL290 and FL410, in January 2002 was heralded as the biggest change in EUR airspace for more than fifty years. It required all forty-one States involved to implement the change at precisely the same time, having first obtained the approval of their respective safety regulatory authorities.

D.1.1 RVSM safety criteria

Overall, EUR RVSM is required to satisfy three safety criteria:

- the ICAO TLS of $\leq 5 \times 10^{-9}$ accidents per flight hour (pfh), including a failure-free component, due to aircraft technical height keeping error, of $\leq 2.5 \times 10^{-9}$ accidents pfh;
- the post-RVSM accident rate to be no greater than the pre-RVSM rate; and
- the risks associated with RVSM to be reduced as far as reasonably practicable.

D.1.2 Intrinsic safety of RVSM concept

The decision, in the 1960s, to set vertical separation above FL 290 at 2000 ft was based on the concerns about baro-altimetry accuracy at these higher altitudes. Clearly, the fundamental (intrinsic) safety of RVSM necessarily depends on modern altimetry and autopilot systems being able to maintain aircraft at their assigned altitude to an accuracy commensurate with 1000 ft vertical separation.

Key functional safety requirements for the aircraft equipment are specified in RVSM minimum aircraft system performance specification (MASPS). Ongoing proof of compliance with these requirements in the EUR Region is the subject of a major height-monitoring programme (and associated collision-risk modelling exercise) involving five height monitoring units positioned at key points around Europe.

In terms of the possible effects of RVSM on the safety of the operational environment, a number of issues were considered, including the effect on:

- the pre-existing risk associated with “level busts”;
- RVSM-incompatible versions of TCAS (V6.04a);
- RVSM-compatible versions of TCAS (V7.0) in terms of rate of nuisance alerts; and
- the severity of wake vortex and mountain wave encounters.

D.1.3 RVSM design completeness

The design of the system to support RVSM covered the following main areas, for which functional safety requirements were specified:

- airspace design – e.g. FL orientation, RVSM / CVSM transition areas, and resectorisation;
- flight crew procedures and training – e.g. aircraft operational procedures, RT phraseology’;
- aircraft equipment – see above;
- ATC procedures and training - e.g. ATC operational procedures, RT phraseology;
- ATC equipment – e.g. display of RVSM status, modification of STCA parameters;
- flight planning – including aircraft operators and integrated flight planning system; and

- system monitoring – e.g. MASPS compliance, operational errors, collision-risk assessment.

D.1.4 RVSM design correctness

Proving the correctness and coherency of the design of the EUR RVSM system was based on:

- about four years prior operational experience of RVSM in the NAT Region; and
- a five-year programme of fast- and real-time simulations, in eleven key areas of EUR airspace.

D.1.5 RVSM design robustness

Assessment of the robustness of the design of the EUR RVSM led to the development of additional flight crew and ATC procedures (and associated training) for, inter alia: reporting and handling of aircraft emergencies, lost communications and loss of RVSM capability.

D.1.6 Mitigation of RVSM internal failures

This followed a ‘conventional’ safety assessment approach, and included analysis of, inter alia: initial flight-planning errors, flight crew operational errors, ATC operational errors, aircraft equipment failures, ATC equipment failures.

D.2 Time-based separation

Time-based separation (TBS) is a new concept of using aircraft separation based on time intervals for landing in strong headwind conditions. The problem with the currently used distance-base separation (DBS) is that the time taken to cover the distance intervals between aircraft increases as aircraft ground speed decreases, resulting in decreased runway capacity during periods of strong headwinds. The objective of the on-going EUROCONTROL TBS project is to investigate the possibility of recovering any such loss of runway arrival capacity, at busy airports, while maintaining required levels of safety.

D.2.1 TBS safety criterion

A relative approach is being taken in the safety assessment of the TBS concept. TBS will be considered to be acceptably safe if it can be shown that the risk associated with TBS scenarios is no higher (and preferably lower) than for the equivalent DBS scenarios.

D.2.2 Intrinsic safety of TBS concept

In order to avoid loss of runway arrival capacity, TBS (time) minima have to be no greater than the time interval that would exist if DBS minima were applied in zero-wind conditions – i.e. the minimum distance between aircraft under TBS are reduced, in comparison to DBS distances, in proportion to the strength of the headwind.

However, the DBS (distance) minima themselves have to take account of two key safety considerations:

- the wake vortex encounter (WVE) risks during normal operations - i.e. separations and operating conditions are as designed, and there have been no system failures; and
- the mid-air collision (MAC) risks due to limitations in surveillance radar performance – particularly accuracy and resolution.

Therefore, we need to be sure that the reduction in separation distances between aircraft, which results from TBS, does not increase either of the above risks.

The WVE issue is complex since wake vortex effects generally decay with time, reduce with distance from the generator aircraft, and dissipate more quickly in rougher air conditions. It will be necessary, therefore, to carry out wake vortex encounter modelling in order to assess the relative risks (TBS c.f. DBS) and set the TBS separation minima to meet the safety criterion – i.e. such that TBS risks of encountering a vortex of a certain circulation speed are no higher than for DBS.

If TBS leads to separation minima below the current radar-defined minima, new (safety) requirements for radar surveillance will be specified such that the current risk of MAC is not exceeded.

The effect of TBS on the operation of safety nets – particularly STCA - will also need to be considered. The smaller average aircraft distance separations under TBS may limit the effectiveness of STCA, unless STCA is suitably modified.

D.2.3 TBS design completeness

Issues to be considered in this context include:

- procedures for determining when and how to apply TBS rather than DBS⁶;

⁶ In principle, application of minimum time-based separation intervals on final approach, as opposed to minimum distance-based radar separation minima, could also be applied consistently across all wind conditions.

- procedures for applying TBS for specific WVE cases – e.g. light aircraft following heavy aircraft;
- requirements for ATC support tools to calculate the aircraft spacing necessary to achieve the minimum time separations accurately;
- ATC display requirements; and
- ATCO training in TBS procedures.

D.2.4 TBS design correctness

Issues that will need to be considered include:

- effect on ATCO workload and effectiveness;
- the effects of changeover from DBS to TBS and vice versa;
- interfacing / coordination between TBS and DBS airspace - conceptually, DBS may continue to be applied in a TBS environment for all flight phases prior to final approach intercept (or to a limited area in the vicinity of the intercept); and
- interactions between TBS and other APP / TWR procedures, including the need to protect the OFZ and (where applicable) ILS localiser sensitive area.

Real-time simulations will be an important part of assessing the dynamic behaviour of TBS.

D.2.5 TBS design robustness

There are at least three key issues here:

- the possibility of sudden changes in wind conditions. In the required WVE risk modelling, the resulting WVE probability/ severity curves will be factored by the estimated occurrence frequency of this event;
- the increased interdependencies between the arrival manager (AMAN) and TBS - the former is the source of the information for Trailing Target Positions (TTP) - a support tool which displays the minimum time separation between aircraft; and
- the effects of variation in actual aircraft groundspeed, due to TBS being based upon nominal groundspeed values.

D.2.6 Mitigation of TBS internal failures

The failure-risk assessment has not yet been completed. Potential failures that need to be considered and addressed in the design of the controller support tool(s) include:

- incorrect calculation of TBS minima, by ATC support tools;
- incorrect application of TBS minima by ATC; and
- pilot non-compliance with ATC instructions. This refers to the effect of TBS on pilot situational awareness, as a result of which pilots may disbelieve ATC due to the resulting unfamiliarly close separation.