European Aviation Safety Agency

NOTICE OF PROPOSED AMENDMENT (NPA) No 3/2004

DRAFT DECISION OF THE EXECUTIVE DIRECTOR OF THE AGENCY,

on guidance material for the certification of production organisations ("GM to Part 21")

Explanatory Note

I. General

1. The purpose of this Notice of Proposed Amendment (NPA) is to propose guidance material to the Annex (Part 21) to the Commission Regulation (EC) No 1702/2003[1]. The reason for this proposal is outlined further below. This measure is included in the Agency's 2004 Rulemaking programme. It is also foreseen that the related work will be executed with the help of a rulemaking group.

2. The text of this NPA was developed by the JAA Production Sub Certification Sectorial Team. It is the intention of the Agency to appoint this group as its rulemaking group to ease the transition and use the already existing expertise. In view of the urgency of the measure however, it has not been felt necessary to ask the group to adapt its text to the EASA regulatory context. That was done directly by the Agency. It is now submitted for consultation of all interested parties in accordance with Article 5(3) of the EASA rulemaking procedure ([2]). The review of comments will be made by that group, augmented as appropriate to fulfil the conditions of the EASA rulemaking procedure.

II. Consultation

4. To achieve optimal consultation, the Agency will rely on existing official channels and consultation practice currently applied by the JAA to disseminate the draft opinion to its widest audience and collect the related comments.

Comments on this proposal may be forwarded *(preferably by e-mail)*, using the attached comment form, to:

By e-mail: consultation.EASA-NPA@jaa.nl

By correspondence: Inge van Opzeeland
NPA Administrator
Joint Aviation Authorities
Box 3000
2130 KA Hoofddorp
Netherlands
Fax: +31 23 56 21714

before 27 August 2004

[1] OJ L 243, 27.9.2003, p. 6. Due to be re-published.
[2] Decision of the Management Board concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material ("rulemaking procedure"), EASA MB/7/03, 27.6.2003.

III. Comment response document

5. All comments received will be responded to and incorporated in a Comment Response Document (CRD). This will contain a list of all persons and/or organisations that have provided comments. The CRD will be widely available ultimately before the Agency adopts its final decision.

IV. Content of the draft Decision

6. At the 2003 FAA/JAA International Conference, it was agreed that improved control of data held in aircraft navigational databases was necessary to support the implementation of RNAV and RNP concepts.

7. Although the actual process of gathering and publishing navigational data within national Aeronautical Information Publications (AIP) does not fall within the scope of EASA, once the AIP data has been published the accuracy and integrity of that data must be preserved throughout any process of transcription and incorporation into airborne navigation equipment.

8. The proposed guidance material intents to confirm eligibility for Production Organisation Approval (POA) of organisations that transcribe, format and/or integrate information that originates from national Aeronautical Information Services (e.g. AIP) into electronic databases for airborne navigation systems. Links are required to the AIP provider and, where appropriate, the design holder responsible for the approval of the navigation equipment.

9. It identifies the paragraphs of Part 21 Subpart G that are of particular relevance to this activity. It also describes the conditions to be satisfied to ensure that databases are produced with the necessary quality characteristics, via appropriate supporting standards. It finally identifies appropriate release mechanisms for compliant databases.

10. The approach within this proposal is compatible with the FAA proposals in AC20-DB. However some areas addressed in the Advisory Circular (certification, change control and Operations and Maintenance) are subject to other requirements (Part 21 DOA, Part 145 and operational requirements) and are therefore outside of the scope of the proposed guidance material, which is only related to the production of data bases.

V. Discussion

11. The Agency acknowledges the importance of the envisaged measure for the safety of air navigation and air traffic management. It has however doubts about its ability to adopt it in the present state of its powers, as specified in the Basic Regulation. It invites therefore all stakeholders to comment on the following points of concern.

12. The first concern is related to the definition of parts and appliances.
The legal basis to approve organisations in the airworthiness domain is derived from article 5(2)(d) of the Basic Regulation. For production organisations the applicable implementing rule is Part 21 Subpart G. Both article 5(2)(d) of the Basic Regulation and paragraph 21A.131 are only applicable to organisations that produce products, part and appliances. In order to fit within the scope of the Basic regulation, navigation databases shall qualify as “parts and appliances’. Article 3(d) of the Basic Regulation defines “parts and appliances” as “any instrument, equipment, mechanism, part, apparatus, appurtenance or accessory, including

communications equipment, that is used or intended to be used in operating or controlling an aircraft in flight and is installed in or attached to the aircraft. It includes parts of an airframe, engine or propeller". The Agency has serious doubts whether navigation databases fall within the above definition of parts and appliances.

13. The second concern is related to the definiton of applicable design data.
Paragraph 21A.131 applies to "… … showing conformity of products, parts and appliances with the applicable design data". Paragraph 21A.133 limits the eligibility for POA to organisations holding an approval for a specific design or having arrangements with the holder of that approval. So in order to fit within the scope of applicable implementing rule, there must be approved design data to which the supplier of navigation databases can show conformity. In the NPA the applicable design data is explained as being either ICAO Annex 15 or data formatting specifications and instructions given by the holder of the design approval for the navigation equipment, together with a definition of required data quality characteristics. The Agency agrees that the structure of a database can be understood as the design but doubts that this applies to the data itself, which in fact constitutes the database.

14. Both of the above concerns, if confirmed, lead to the conclusion that it would not be possible to adopt the envisaged measure as guidance material to Part 21 as there would be no legal basis to regulate this activity.

15. In such case, consideration should rather be given to recommending the use of the envisaged guidance material as a best practice for national aviation authorities that have the legal powers to regulate the production of data bases. That clearly excludes the Agency, which is the competent authority for foreign production organizations approvals, and would raise the question of the control of navigation data bases produced abroad.

16. Another option could be to consider some form of industry regulation. In principle the operator is responsible for the quality of the received navigation data. It should therefore perform quality checks to ensure safe operational practices. The Agency recognises that such burden may be unacceptable for some operators. However, this burden could be alleviated if the suppliers of databases have shown to comply with Eurocae ED-76 / RTCA DO-200A standards for processing aeronautical data. The question is whether compliance with this standard needs to be confirmed and controlled by the Aviation Authority by means of a formal organisation approval. It may be sufficient to rely on a statement of compliance with ED-76/DO-200A from the navigation database supplier itself, or an accredited third party.

VI. Regulatory Impact Assessment

17. Because of the limited time available and considering the urgency of the proposal, a full Regulatory Impact Assessment could not be established. What follows is the result of informed judgement.

18. Compliance with Part 21 Subpart G an existing organisation will obviously imply certain costs for an organisation producing navigation data bases that do not already hold a production organisation approval for other production activities, which is likely to be the general case. However it will depend on a range of variables what the exact costs will be: the size of the organisation, the scope of work, the level of current compliance and also the approving authority (due to their fees and charges). Therefore even a rough estimate of the

implementation costs cannot be made. In any case the number of organisations concerned is relatively small; in the order of in Community Member States and xxxin foreign countries. This means that the overall costs for the aviation community will be relatively small.

19. RNAV and RNP will make a significant contribution to increasing airspace capacity and therefore reduce the cost of air traffic congestion, which is currently evaluated at several tens of billions of Euros per years.. As the safe implementation of these concepts is only possible with high integrity navigational databases the envisaged measure will provide for a significant benefit at a cost, which is comparatively minor.

PROPOSALS

The following new GMs should be included in ED Decision No. 2003/1/RM of 17-10-2003:

GM 21A.133 Eligibility; Production Organisation Approval of Navigation Database Providers

Organisations that transcribe, format and/or integrate information that originates from State Aeronautical Information Services (e.g. AIP) into electronic databases for airborne navigation systems are eligible for a Production Organisation Approval. Links are required to the AIP provider and, where appropriate, the design holder responsible for the approval of the navigation equipment.

1. Terminology

1.1 Terms essential for the understanding of this guidance material are as follows:-

a) Navigation Database - Data (such as navigation information, flight planning waypoints, airways, navigation facilities, SID, STAR) that is stored electronically in a system that supports an airborne navigation application.

b) Data Service Provider – An organisation (not including the State AIP provider), which collects, originates or processes aeronautical data and provides a navigation database in a generic format (such as ARINC 424). Such organisations are eligible for a Type 1 POA under this GM (see Appendix 1 Para 8.1) showing that the generic database has been formatted under controlled conditions.

c) Data Application Integrator - An organisation that incorporates either State AIP data or a generic database into a format compatible with specific target airborne navigation equipment with a defined intended function (e.g. PRNAV). Such organisations require an interface with the design organisation responsible for the approval of the equipment, and are eligible for a Type 2 POA under this GM (see Appendix 1 Para 8.1). This provides a list of equipment models and part numbers where compatibility has been demonstrated to the Competent Authority, permitting the supply of navigation databases directly to end users/operators.

d) Data Quality Requirements - A specification of the characteristics of data to ensure that data is compatible with its intended use.

e) PRNAV – Precision Area Navigation

f) Type 1 POA – Approval granted where a Navigation Database supplier complies with ED-76 with no identified compatibility with an aircraft system. A Type 1 POA confirms that the processes for producing navigation data comply with this GM and the documented Data Quality Requirements. A Type 1 POA may not release navigation databases directly to end users.

g) Type 2 POA – Approval granted where a Navigation Database supplier complies with ED-76 and provides data compatible with specified avionics system(s). A Type 2 POA confirms that the processes for producing navigation data comply with this GM and the documented Data Quality Requirements for the avionics systems specified. The Data Quality Requirements must be provided by or agreed with the design holder for the specified equipment in accordance with a formal arrangement. A Type 2 POA may release navigation databases directly to end users. Such releases may also include data packing tools, where the use of such tools has been demonstrated to be ED-76 compliant.

2. Applicability

This guidance material applies to the production activities associated with receiving, assembling, translating, selecting, formatting, integrating and distributing navigation data in electronic format for subsequent loading into aircraft navigation or flight management systems. It does not apply to the origination of data for publication into a national AIP.

Notes: 1. Production activities specific to aeronautical Data are elaborated in the standard referenced in 3.3.
2. The primary objective of this guidance is to support regulatory oversight of navigation database providers. However, it is recognised that the underlying principles may be applicable to the production of airborne databases used for other purposes.

3. Reference Documents

3.1	ICAO	Annex 15	Aeronautical Information
3.2	ICAO	Doc 8126	Aeronautical Information Services Manual
3.3	EUROCAE & RTCA	ED-76 & DO-200A	Standards for Processing Aeronautical Data
3.4	EUROCAE & RTCA	ED-77 & DO-201A	Standards for Aeronautical Information
3.5	Aeronautical Radio Inc.	ARINC 424	Navigation System Data Base
3.6	FAA	AC20-DB	Acceptance of Data Processes and Associated Navigation Databases

4. Related Paragraphs of Part 21

Part 21A.3 & AMC 21A.3(b)(2); Part 21A.4 & AMC 21A.4; Part 21A.133(b)&(c) & AMC No. 1 and 2 to 21A.133(b)&(c); Part 21A.139 & GM 21A.139(b)(1); Part 21A.143; Part 21A.145(b) & GM 21A.145(b)(2).

5. Eligibility of organisations producing Navigation Databases for Production Organisation Approval under Part 21 Subpart G

5.1 The Agency has determined that a Production Organisation Approval is appropriate to control the integrity of aircraft navigation databases. Therefore, in accordance with the criteria of Part 21A.133(b), an organisation having suitable arrangements to the AIP provider and, where appropriate, the design holder responsible for the approval of the navigation equipment is eligible to apply for POA.

5.2 The arrangements and supporting procedures documented in the applicant's Production Organisation Exposition (POE) will form the basis of the investigation for POA.

6. Guidance

6.1 ICAO Annex 15 defines the State's obligations and requirements for data published in the AIP, which forms applicable design data to which conformity of navigation databases must be demonstrated. Data Service Providers will need to demonstrate the means by which correct and up to date data is received from the original AIP source, together with a mechanism for reporting errors detected within the AIP data.

Note: It is accepted that a formal arrangement between the applicant and the national authorities meeting the exact requirements of Part 21A.4 and 21A.133(b) may not currently be possible with respect to the provision of AIP data. The interface must ensure the receipt of up-to-date data and a feedback mechanism for reporting errors as a minimum.

6.2 Where data is to be formatted in accordance with data formatting specifications (such as ARINC 424), or instructions given by the holder of the design approval for navigation equipment, such specifications and instructions, together with a definition of required data quality characteristics, will need to be identified as applicable design data to which the POA applicant will show database conformity.

6.3 To satisfy Part 21A.133(b), Data Application Integrators will need to have a documented arrangement that defines at least the following:-

(a) The responsibilities of the holder of the approval for an equipment design to ensure correct and timely transfer of up-to-date airworthiness data and instructions that concern compatibility of data with the target equipment.

(b) The responsibilities of a POA applicant to assist the holder of an approval for an equipment design in dealing with continuing airworthiness matters and for any required actions, such as traceability of databases shipped directly to users, data modifications, traceability of process outputs, approval of deviations, provision of technical information and assistance).

6.4 The applicant will need to provide an Exposition in accordance with Part 21A.143.

6.5 The applicant will need to demonstrate a documented quality system (Part 21A.139) and equipment and facilities (Part 21A.145) to ensure that databases produced conform to the applicable design data. Procedures will be required to ensure correct transcription of AIP/equipment design data and to demonstrate the conformity and traceability of produced databases.

6.6 When EUROCAE document ED-76, *Standards for Processing Aeronautical Data* is used by the applicant to demonstrate compliance, the additional topics listed in Part 21 GM 21A.139(b)(1), as appropriate, will need to be included to show compliance with Subpart G. The Competent Authority will need to be satisfied that overall compliance to Subpart G has been established.

7. Release of Navigation Databases

7.1 It is proposed that a POA granted as a result of a successful assessment by the Competent Authority acts in a similar manner to an FAA Letter of Acceptance (LOA) under the FAA Advisory Circular, in that it provides evidence to an end user that the database has been produced in accordance with agreed standards, and in the case of Type 2 POAs supports specific models of navigation equipment for which compatibility has been assessed, without the need for an Authorised Release Certificate (EASA Form One or FAA 8130-3) to accompany each database.

7.2 The POA holder will need to establish mechanisms to advise customers/end users of the status of their POA and any changes to that status in a timely manner.

7.3 Although an EASA Form One does not have to be provided with each navigation database, the POA holder will still need to demonstrate that such databases are in conformity to the applicable design data prior to release into the field. An internal conformity statement / certification will need to be made confirming that the database configuration to be supplied meets the applicable design data and has been subjected to full configuration control. This statement / certification may be a company-defined document agreed with the Competent Authority and identified in the Exposition. All associated controls (signatories, retention times etc.) normally associated with EASA Form One completion and defined in Part 21A.163 and 165 are considered applicable.

7.4 The authority to release databases to the field will only be held by certain qualified individuals within the organisation. These persons are considered as certifying staff under Part 21 and the requirements of Part 21A.145(d) are therefore applicable.

7.5 Where a database release also includes software tools permitting duplication of the database by the end user/installer, such tools shall form part of the POA scope of approval (for Type 2 POAs) and shall be subject to the similar configuration and release controls as the database itself.

7.6 Release certification under this GM is intended to certify the databases themselves, not the disposable media by which they are distributed (disks, CD-Roms etc).

8. Availability of documents

EUROCAE documents may be purchased from EUROCAE, 17 rue Hamelin, 75783 Paris Cedex 16, France, (Fax: 33 1 45 05 72 30). Web site: www.eurocae.org.

ICAO documents may be purchased from Document Sales Unit, International Civil Aviation Organisation, 999 University Street, Montreal, Quebec, Canada H3C 5H7, (Fax: 1 514 954 6769, e-mail: sales_unit@icao.org) or through national agencies.

RTCA documents may be obtained from RTCA Inc, 1828 L Street, NW., Suite 805, Washington, DC 20036, USA., (Tel: 1 202 833 9339; Fax 1 202 833 9434). Web site: www.rtca.org.

FAA Advisory Circulars may be obtained from the Department of Transportation, Subsequent Distribution Office, SVC-121.23, Ardmore East Business Center, 3341 Q 75th Ave, Landover, MD 20785. Web site: www.faa.gov/aba

GM 21B.220 The Conduct of POA Assessment for Navigational Database Providers

1 General

The Competent Authority should use its procedures for receipt of POA applications, establishment of eligibility, demonstration of compliance, and general planning and conduct of assessments, as modified by the provisions below.

2 Exposition Contents

The applicant will need to submit a Production Organisation Exposition to the Competent Authority to comply with Part 21A.143. In addition to the usual Part 21 Subpart G requirements, the exposition will also need to take account of EUROCAE document ED-76.

3 Demonstration of Required Interfaces

3.1 Interface with the Data Originators (State AIP Providers)

3.1.1 The applicant will need to demonstrate that a robust and effective interface exists with the data originators. Procedures will need to be established to communicate instances of erroneous or inconsistent data to the Originator and that timely and effective responses are received and remedial action undertaken by the applicant. These processes will be subject to audit during the assessment.

3.1.2 Where resolution cannot be obtained for data that has been queried, the applicant's procedures for dealing with this situation will be audited to confirm that effective controls are

in place to ensure that an unsafe product is not released and that communicate the concern to end-users taking account of Part 21A.165 (e).

3.2 Interface with the Type Design holders of Navigation Equipment

The applicant will need to demonstrate that a robust and effective interface exists with the equipment Type Design holders. In particular, procedures will be audited to confirm that the equipment Type Design holders communicate issues and constraints concerning compatibility/ eligibility for installation between their equipment and the databases to the applicant in a timely manner.

3.3 Interface with Aircraft Operators

Where the applicant has an interface with an aircraft operator as its direct customer, the audit will verify that a robust and effective interface is in place to ensure that operators' requests are clearly defined and subject to technical review (to ensure compatibility with State AIP data and the constraints of the Type Approved Equipment) by the applicant. Further, the applicant's procedures will be audited to ensure that the aircraft operator's instructions for tailored data are confirmed as originating from a person with written authority within the operator's organisation.

4 Demonstration of required Facilities, Resources, Skills and Competencies

4.1 The applicant will need to demonstrate compliance with the requirements of Part 21A.145 with specific emphasis on the essential needs of a Data Service Provider organisation. POA assessment of this area will need to be undertaken by appropriate Specialist Authority personnel.

4.2 To promote standardisation the initial POA Assessment Team should consist of a Production Approval Specialist from the Competent Authority acting as Team Leader supported by the Specialists nominated as the "Core Team". Once approval is granted, continued surveillance should be carried out by the Competent Authority supported by appropriate specialists as required.

5 Implementation of Part 21 Subpart G

5.1 The applicant will need to submit a completed compliance checklist to the Competent Authority.

5.2 The assessment will review all applicable areas of Part 21 Subpart G in accordance with procedures of the Competent Authority. The compliance checklist will be used both as a compliance statement for the applicant and as an audit checklist where the competent authority personnel can record areas reviewed and information gathered during the assessment.

6 Implementation of EUROCAE Document ED-76 *

6.1 The applicant will need to produce a Compliance Matrix detailing how his data production processes relate to EUROCAE ED-76.

6.2 In addition to the standard Part 21 Subpart G elements, the audit will assess the standards and processes applied by the applicant to determine the characteristics of the delivered database. The following paragraphs identify specific areas that will be audited against EUROCAE ED-76.

- Plans and procedures.
- Internal Standards and Data Quality Requirements Definition.

- Concession procedures (i.e. those procedures that control and agree deviations from the approved design data).
- Data validation.
- Data traceability.
- Data processing.
- Data formatting.
- Data configuration management.
- Data timeliness.
- Software tool qualification.
- Internal audit checks and response mechanisms.
- Error tracking and corrective action procedures.
- Safety reporting procedures (including Mandatory Occurrence Reporting).
- Data distribution and transmission practices.

* For the purposes of this guidance material, RTCA DO-200A is accepted as equivalent to EUROCAE ED-76.

7 Audit Reporting and Follow-Up Action

7.1 The Assessment Team will conduct a closing meeting with the applicant and report audit findings in accordance with the procedures of the Competent Authority.

7.2 The Team Leader may require additional verification visits where it is necessary to close audit findings.

7.3 Once the Competent Authority is satisfied that compliance has been generated to Part 21 Subpart G and the contents of this GM, a Part 21 Subpart G approval shall be issued.

8 Format of the POA Approval

8.1 The approval will be consistent with GM 21A.151 and will be worded as follows:-

Scope Products/Categories

Parts Airborne Navigational Databases – Type 1

The [*Insert Competent Authority here*] has assessed [*Insert Approval Holder here*] to the procedures defined in [*Insert POE reference here*], which have been found to comply with the requirements of Part 21 Subpart G with regards to the processing of navigational data. This Type 1 POA does not authorise the supply of navigation databases directly to end users/operators.

and/or

Parts Airborne Navigational Databases – Type 2

The [*Insert Competent Authority here*] has assessed [*Insert Approval Holder here*] to the procedures defined in [*Insert POE reference here*], which have been found to comply with the requirements of Part 21 Subpart G with regards to the processing of navigational data. This Type 2 POA authorises the supply of navigation databases to end users/operators for the following system, for which compatibility has been demonstrated:-

[*Manufacturer*] Flight Management System Model [*XXX*], Part No [*YYY*]

Database Duplication Tool [*ZZZ*]

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