European
Commission

AV guidance

Session II - Compliance Forum Event
7th and 8th February 2012

Agenda presentation

- *Objectives guidance and project*
- *Deliverables to be developed*
- *Project approach*
- *Issues identified and approach to address those*
- *Prioritisation of issues*
- *Issues to be addressed in 2013 (after development guidance)*
- *Project planning – 4 TWG meetings – start March*

Objectives of the guidance

- *To provide relevant guidance materials and tools to support common understanding and implementation of the AV regulation*
- *To provide guidance material on:*
  - ✓ verification of installations & aircraft operators
  - ✓ accreditation & other issues

Deliverables of guidance package 1

User manual:

- *Overview responsibilities parties*
- *Relation between AVR, AR 765/2008, MRR, ISO standards, EA 6/03 and guidance*

Concise article by article guidance:

- *Explanation AV regulation article by article*
- *Explanation links between articles*
- *Concise and easy to read for all parties*

Deliverables of guidance package 2

Key guidance notes on specific issues

- *Specific notes on complex V&A issues in need for further elaboration (e.g. sampling, risk analysis)*
- *Update Verification Aviation Guidance*

Templates

- *Excel templates with build-in guidance*
- *Verification report and possibly other reports (e.g. reports mentioned in chapter VI)*

Deliverables of guidance package 3

Exemplars and examples

- *Exemplars meaning filled-in example templates*
- *Examples of verification plans, checklists or specific examples in guidance such as non-conformities*

Frequently asked questions

- *Update of existing FAQ published on COM website*
- *High level questions referring to other materials*

Criteria developing guidance

- *Existing documents adapted rather than started from scratch e.g. verification aviation guidance*

- *Account of MS best practices e.g. national verification guidances and templates*

- *Account of useful standards e.g. ISAE 3000, ISAE 3410 & relevant organization's guidance e.g. IAF*

- *Compatibility with third party guidance e.g. EA 6/03, IETA verification protocol*

- *Compatibility with MR regulation, AV regulation and other relevant legislation*

Consistency & Cost Efficiency

- *Compatibility and consistency with ISO 14065 and 17011*

- *Consistency with MR guidance where MR and AV issues are interconnected e.g. scope of verification, risk analysis/ risk assessment operator and data flow & control activities*

- *Cost efficient approaches e.g. simple verification processes for small & simple installations*

Project approach

Inception phase (January – February)

- *Identification of issues and best practices*
- *Indication in which deliverable an issue will be addressed*

Development phase (February – October)

- *Development of guidance package*
- *Discussion in TWG consisting of MS CA and EA*
- *TWG planned for March, May, July & September*

Identification of issues

General issues

Issues for which guidance is needed but which can be explained in main guidance or which are straightforward

Specific issues

Issues needing specific guidance in key notes

Other or remaining issues

Issues that need further guidance but that can be addressed in 2013

GENERAL ISSUES

General verification issues - main article guidance & examples 1

- *Principles of verification e.g. reasonable assurance*
- *Steps in verification process from pre-contract stage to issuing verification report*
- *Verification plan (examples)*
- *Dealing with misstatements and non-conformities*
- *Dealing with recommendations for improvement*
- *Materiality concept*
- *Internal verification documentation (example)*
- *How to check data gaps*

General verification issues - main article guidance & examples   2

- *How to check uncertainty assessment*

- *Independent review*

- *Competence process for verifiers*

- *Verification team requirements*

- *Use of technical experts*

- *Verifier's impartiality and independence*

- *Simplified verification requirements (Session III)*

General accreditation issues - main guidance & examples

- *Objectives of accreditation*

- *Steps in the accreditation process*

- *Witness e.g. who, frequency, what to check*

- *Surveillance & reassessment*

- *Extraordinary assessment & extension of scope e.g. when, what activities to be carried out*

- *Basic explanation mutual recognition verifiers*

Information exchange Chapter VI   4

Regulates:

- *Information exchange within MS with more than one CAs: one CA acting as focal point*
- *Information exchange from AB to CA of MS where the verifier accredited by that AB is operating – accreditation work programme & management report & info on adm. measures*
- *Information exchange requirements from CA to AB*
- *Information exchange resulting from AB's surveillance*
- *AB data base on verifier's details & notification from verifier to AB*

Guidance on information exchange articles

Possibly templates or examples of accreditation work programmes, management report + information from CA

Specific Issues

Issues needing specific guidance

Scope of verification
Art. 7 (4) (5) & (6)   1

Regulates what a verifier has to assess:
- *Completeness emission report & compliance with Annex I MR*
- *Compliance with MP and permit (for installations)*
- *Whether data are free from material misstatements*
- *Whether information can be provided to improve the operator's or AO performance*

Key guidance note & examples :
- *how and to what extent a verifier should check elements*
- *when and how to report non-compliance with MR-R in VR*
- *What to do when MP or changes to MP are not approved*

LINK WITH MRR (ANNEX I MR-R and MP IN MR-R)

BP: *section 5 EA 6/03 & national guidances e.g. UK guidance*

Risk analysis and risk assessment Art 12, 13   2

Regulates risk analysis & impact inherent and control risk

Key guidance note and examples on:
- *Interpretation of inherent, control & detection risks and interconnection between those risks*
- *Example of verifier's risk analysis and explanation how this relates to operator's / AO risk assessment*
- *Explanation of impact of outcome risk analysis on verification plan and verification activities*

LINK WITH MR-R (risk assessment of operator/ AO)

BP: *EA 6/03, IETA verification protocol, ISAE 3410, national guidances*

What to check in process analysis Art 14, 15 + 16

Regulates activities during process analysis:
▪*Checking data flow, control activities and procedures*
▪*Substantive testing i.e. analytical procedures, data verification and checking monitoring methodology*

Key guidance note and examples on:
▪*Explanation different checking elements and examples*
▪*Examples on what to check during evaluation of the monitoring methodology*
▪*Explain link with verification plan and risk analysis*

Link with MR-R guidance issues *on data flow activities, control activities, procedures & monitoring methodology*

BP: *EA 6/03, ISAE 3410*

Sampling
Art 13 & 20 AVR   4

Regulates:
- *main principles of sampling & testing control activities*
- *requirement to set up data sampling plan and test plan as part of verification plan*

Key guidance note and examples on:
- *Explanation main methods used for sampling & testing*
- *Examples of sampling/ testing*
- *Explanation how certain factors impact sampling & testing*

Input: working paper for Draft Verification Guidance project in 2008 and discussed in TWG 2008

Criteria for site visits
Art 21 & 31

Regulates:

- *concept and definition of site visits for operators and AOs*
- *activities to be carried out during site visits*
- *waiver of site visits under conditions*

Short key guidance note and examples on:

- *further criteria for waiving site visits*
- *specific activities to be carried out during site visit*
- *adapting aviation guidance on site visits for AO*

BP: *Annex J EA 6/03 and UK annual verification guidance*

Verification report
Art 27 & 28

Regulates:

- *content verification report*
- *different verification opinion statements incl. limitation of scope*

Template with build-in guidance and exemplar

- *Excel template following similar format as aviation templates*
- *elaboration of different verification opinion statements and examples on formulating statements and situations in which they occur*

BP: *UK verification report template, German IT format*

Competence verifiers
Art 37, 38 & 39

Regulating competence requirements of (lead) auditors & technical experts and independent reviewers

Key guidance note:
 Elaborating on competence requirements in AV-R by taking section 6.2 EA 6/03 and ISO 14066 into account

Input: ISO 14066 & ISO 14065, section 6.2 EA 6/03

BP: Austrian guidance - UK guidance

Relation with ISO 14065
Art 4 and Chapter III   8

Contains requirements on *verifier's organization, procedures, competences, records & documentation, confidentiality, outsourcing & contracting etc.*

Key guidance note on:

▪*How to read the AV-R in relation to ISO 14065*

▪*Clarification on what is meant by presumption of conformity in article 4 AV-R*

▪*Explanation of elements in ISO 14065 in relation to AV-R*

▪*Clarification of difference between outsourcing & contracting*

▪*Explanation of how certain elements can be interpreted for single verifiers*

Relation with ISO 17011 & AR 765/2008 Art 5 and Chapter V

Contains requirements on

- *AB's structure, impartiality, competence, procedures, responsibilities, documentation, addressing complaints etc.*
- *Corrective action by MS & cross border accreditation*

Key guidance note on:

- *How to read AV-R in relation to ISO 17011 & AR 765/2008*

- *Clarification of article 5 AV-R i.e. general framework for accreditation & clarification cross border accreditation*

- *Explanation of elements of AR 765/ 2008 and ISO 17011 that are relevant for understanding AVR requirements*

Certification of verifiers
Art 54, 64 and 66   10

- Certification of only natural persons is allowed
- Certified verifiers to meet same requirements as accredited verifiers
- National certifying authorities to meet the requirements of the AV-R, including information exchange requirements
- National authorities to provide the necessary documentary evidence to the Commission & MS to allow an assessment of the certified bodies' competence
- National authorities to meet a level of credibility equivalent to AB having undergone successful peer evaluation
- MS to provide all necessary documentary evidence to that
- MS to periodically review the functioning of national authority

Certification of verifiers
Art 54, 64 and 66

Key guidance note

▪*Clarification on what certification must entail & that only natural persons and not companies may be certified*

▪*Clarification that the same AV-R requirements shall apply to certified verifiers & national authorities*

▪*Clarification how to interpret the requirement that national authority has to meet equivalent credibility level*

▪*Explanation on how and what documentary evidence should be given by MS to Commission & other MS*

▪*Guidance on mutual recognition of certified verifiers*

▪*Explanation on certification in relation to EMAS verifiers*

Issues to be addressed in 2013   1

- *Man day table - verifier's time allocation tool for AB*
- *Guidance on peer evaluation criteria set by EA*
- *Examination and training of (lead) auditors*
- *Electronic data exchange and use of automated systems in relation to Verification and Accreditation*
- *EA's Database of verifier's information*
- *Checklists to be used during process analysis*

Issues to be addressed in 2013

- *Verification related to Article 24 (1) Allocation Decision 2011/278 i.e. information on planned or actual changes to capacity, activity level & operation*

- *Guidance on administrative measures to be imposed by AB to verifier's (examples)*

- *Access to information and confidentiality issues*

- *Possibilities of CA to monitor the performance of a foreign verifier according to Services Directive*

- *Issues resulting from this project that need further explanation*

Deliverables for TWG-I March

Introduction and approach for addressing issues

Structure of guidance package including
responsibilities of parties & overview relation guidance to AV-R

General Issues:
principles of verification, part verification process, materiality

Specific issues:
scope of verification, risk analysis and operator's - AO risk assessment, preliminary approaches to deal with certification

Deliverables for TWG-II May

General issues:

- *objectives of accreditation, accreditation process & witness*
- *dealing with misstatements and non-conformities*
- *dealing with recommendations on improvements*
- *simplified verification requirements*
- *Examples of verification plan*

Specific issues:

- *verification report*
- *what to check during process analysis*
- *Certification of verifiers in relation to EMAS & AV-R req.*
- *Ideas on how to approach site visits*

Deliverables for TWG-III July

General issues

- *competence process and verification team requirements*
- *use of technical experts*
- *information exchange*
- *impartiality and independence verifiers*
- *Update of aviation ETS verification guidance*
- *Surveillance, reassessment, extension of scope, extraordinary assessments*

Specific issues

- *competence requirements & sampling*
- *relation with ISO 14065 and relation with ISO 17011*
- *Mutual recognition of verifiers*

Deliverables for TWG-IV September

- *Remaining issues from TWG discussions – wrapping up*
- *Example internal verification documentation*
- *data gaps and checking uncertainty assessments*

Whole package except for user manual & FAQ needs to be ready

Final drafts deliverables for October

- *User manual*
- *Main article by article guidance*
- *Update verification aviation guidance*
- *Key guidance notes on verification & accreditation*
- *Templates*
- *Exemplars and examples*
- *Frequently asked questions*

Suggestions for endorsement of documents by CCC meeting

- *Main article by article guidance*
- *Key guidance notes on verification & accreditation*
- *Templates*