

EASA Workshop: From JARs to IRs

Cologne 09 – 10 October 2008



# Medical

**Dr. Virgilijus Valentukevicius**

**EASA Rulemaking Officer**

**Flight Standards Department**

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# Abbreviations

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**OR – Organisational Requirements**

**AR – Authority Requirements**

**AMC – Acceptable Means of Compliance**

**AeMC – Aeromedical Centre**

**AME – Aeromedical Examiner**

**MC – Medical Certificate**



# Organisation Requirements

**AEROMEDICAL CENTRES**

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# Organisation Requirements

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## Subpart AeMC – Aeromedical Centres

- Section 1 – General
- Section 2 – Organisation requirements

### AMC

- Section 1 – General
- Section 2 – Organisation requirements



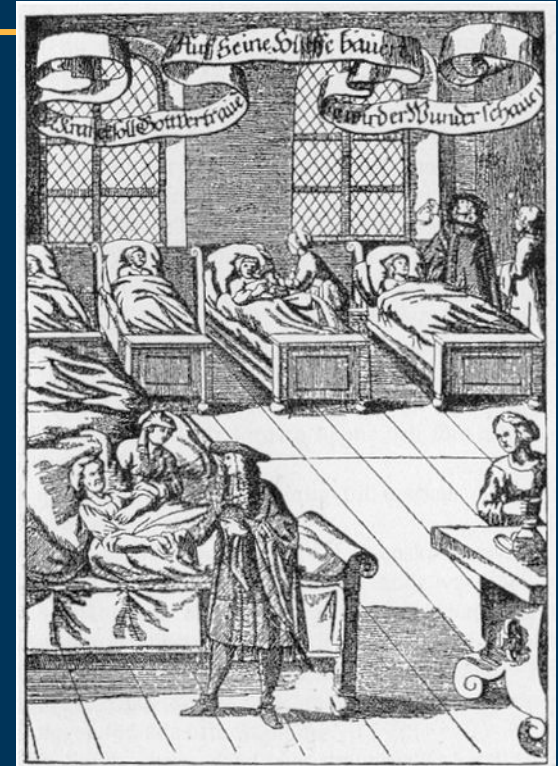
# Section 1 – General

## OR.AeMC.005 - Scope

- Additional requirements
- Approval as and AeMC
- Class 1 medical certificates

## OR.AeMC.015 - Application

- Compliance with Part Medical MED.C.005
- Clinical attachments to a designated hospital or medical institution





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# AMC to Subpart AeMC AMC to OR.AeMC.015

## Documentation for the approval of AeMC

Names and qualifications  
of all medical staff

List of medical and technical facilities  
for initial class 1 aeromedical exams

List of supporting specialist consultants



# Section 1 – General

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## OR.AeMC.030 – Continued validity

- Compliance with Part Medical MED.C.030:
  - ✦ Medical practice and Medical Register
  - ✦ Refresher training in a 3 years
  - ✦ Compliance with the terms of authorisation
  - ✦ Exercise privileges in accordance with Part Med
  
- 500 class 1 medical examinations/year



# Section 1 – General

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## OR.AeMC.030 – Findings (1)

- Head of AeMC not nominated
- Failure to ensure data protection
- Failure to provide Medical Assessor with the medical and statistical data for oversight purposes



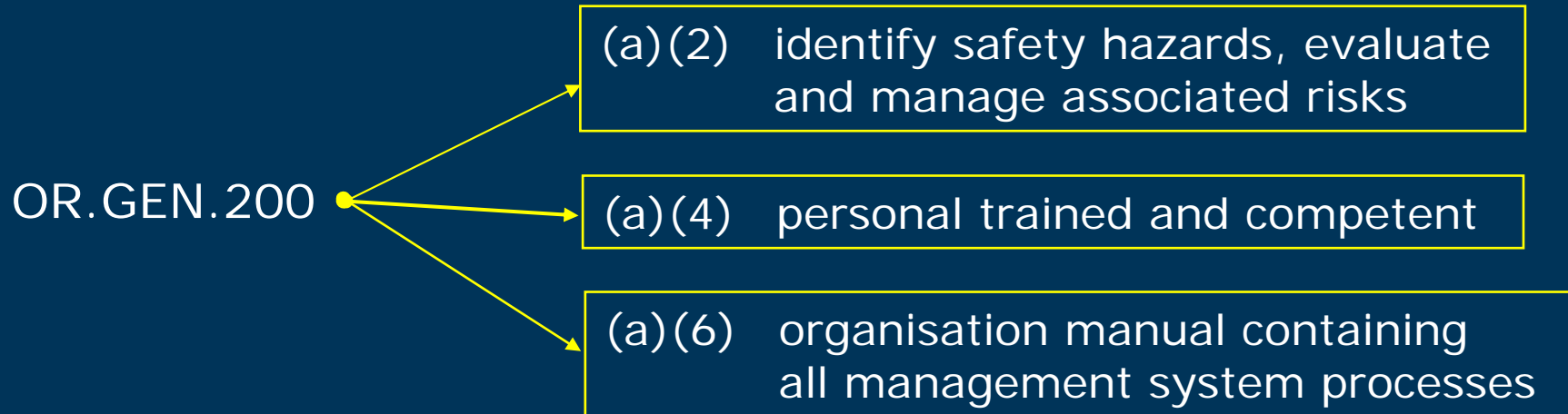




## Section 2 – Organisation requirements

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### OR.AeMC.200 – Management system



### **AeMC additionally shall establish processes:**

- for medical certification in compliance with Part Medical
- to conduct aeromedical research and publish the results
- to ensure medical confidentiality at all times



# Section 2 – Organisation requirements

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## OR.AeMC.210 – Personnel requirements

### ➤ Head of AeMC

- ✧ **Nomination**

- ✧ **Privileges to issue class 1 MC**

- ✧ **Sufficient experience in aviation medicine**

- ✧ **Responsible**

  - ➔ For coordinating the assessment

  - ➔ Sign reports and certificates

### ➤ Adequate number of fully qualified AME's



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# AMC to Subpart AeMC AMC to OR.AeMC.210

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Head of AeMC

Class 1 privileges  
At least 5 years

500 class 1  
examinations

AeMC may provide practical AME training



## Section 2 – Organisation requirements

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### OR.AeMC.215 – Facility requirements

- An AeMC shall be equipped with medico-technical facilities adequate to perform extensive aeromedical examinations necessary for the exercise of the privileges included in the scope of the approval.

AMC to OR.AeMC.215

List of medical-technical facilities





## Section 2 – Organisation requirements

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### OR.AeMC.220 – Record keeping

#### ➤ OR.GEN.220:

- ★ The organisation shall establish a system of record-keeping that allows adequate storage and traceability of all activities
- ★ The format of the records shall be specified in the organisation's procedures
- ★ Records shall be stored in a manner that ensures protection from damage, alteration and theft
- ★ Records shall be accessible to the competent authority

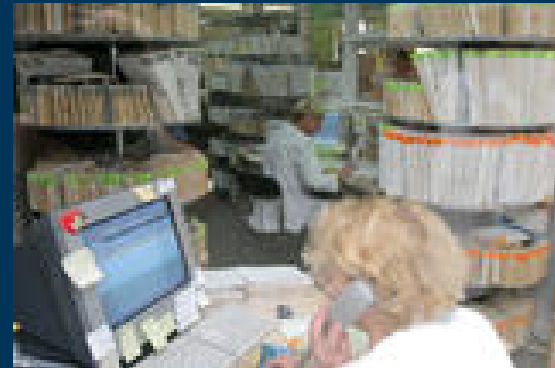


# Section 2 – Organisation requirements

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In addition to OR.GEN.220

- Maintain records with details in accordance with national rules
- Ensure medical confidentiality





# Authority Requirements

**Medical certification**

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# Subpart AeMC

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## Specific requirements related to aeromedical centres (AeMC's)

### Section 1

### General





# Subpart AeMC – AR.AeMC.005

## Certification procedure

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### AR.GEN.310 Certification procedure – organisations

- (a) Upon receiving an application for the issue of an approval or certificate for an organisation, the competent authority shall **verify** the organisation's compliance with the applicable requirements, and **conduct, where relevant, an inspection** of the organisation.
- (b) When satisfied that the organisation is in compliance with the applicable requirements, the competent authority shall **issue** the organisation approval certificate, as established in Appendix I to this Part. The certificate shall contain the privileges and the scope of the activities that the organisation is approved to conduct.
- (c) The competent authority shall **agree** with the organisations it certifies the scope of the changes to the organisation's procedures that require prior approval.



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# Subpart AeMC – AR.AeMC.005

## Certification procedure

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**Application**



**Inspection**



**Certificate**



# AR.AeMC.010 Continuing oversight and monitoring of activities

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## In accordance with AR.GEN.320

- (a) The competent authority shall establish a continuing **oversight and monitoring programme** of the organisations under its supervision, taking into account the complexity and the risks involved with the activity of those organisations. This programme shall include:
1. for each organisation, regular audits at intervals determined by the results of past surveillance activities. These intervals shall not exceed **24 months**.
  2. meetings convened with the accountable manager of each organisation at least once every **24 months** to ensure they remain informed of significant issues arising during audits.
- (b) The competent authority shall **keep and update** the continuing **oversight programme**, including a list of the approved organisations under its supervision, the dates when audit visits are due and when such visits were carried out.



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# AR.AeMC.010 Continuing oversight and monitoring of activities

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In accordance with AR.GEN.320, except:

- Regular audits every **36 months**
- Meetings with the head of AeMC every **36 months**



# Subpart MED

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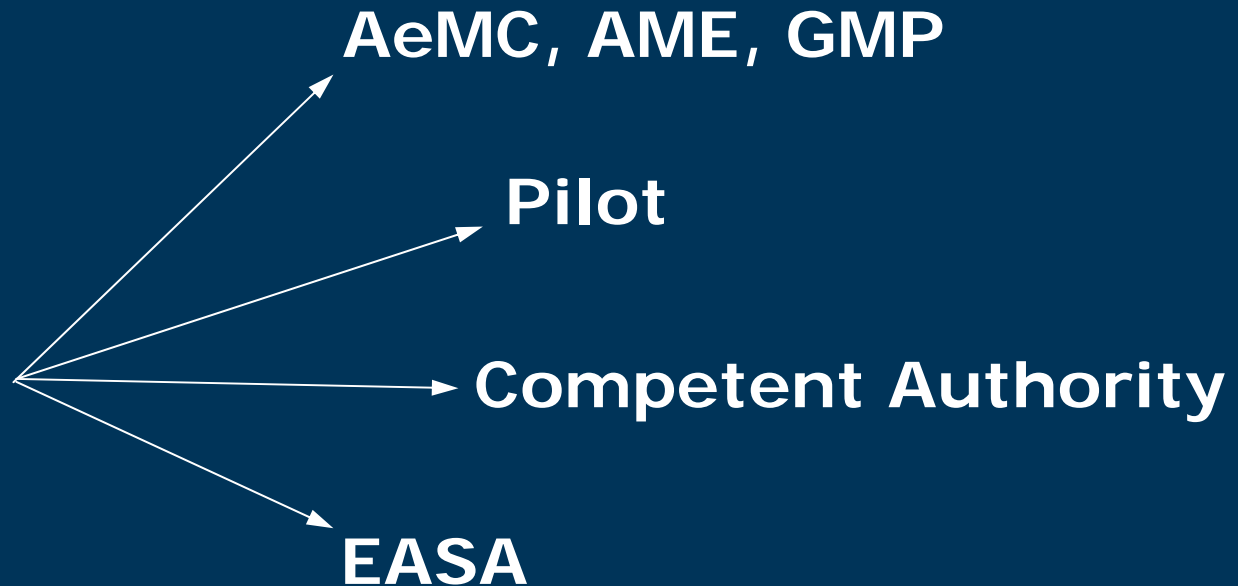
## Specific requirements related to aeromedical certification

- Section 1 – General
- Section 2 – Aeromedical Examiners (AME's)
- Section 3 – Medical certification



# AR.MED.015 Record keeping

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# AR.MED.020 Medical Assessor

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- One or more in the Authority
- Licensed and qualified in medicine
- Postgraduate training 5 years
- Specific knowledge and experience in aviation medicine
- Specific training in medical certification





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# AMC to AR.MED.020 Medical Assessor

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**Medical Assessor**

**Experience in aeromedical practice**

**200 class 1 aeromedical examinations**

**Maintain professional competence  
in aviation medicine**

**Refresher training courses**

**Audit of AeMCs**





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# AR.MED.025 Referral to the competent authority

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**MED.A.045 - Class 1 (limitations)**

**MED.A.050(c) – transfer of the documents**

**AMC to MED.A.045 - borderline cases,  
consultation with flight operations and/or  
other experts.**

**AMC to MED.A.050 – contents and form of the  
report, identification of the examiner**



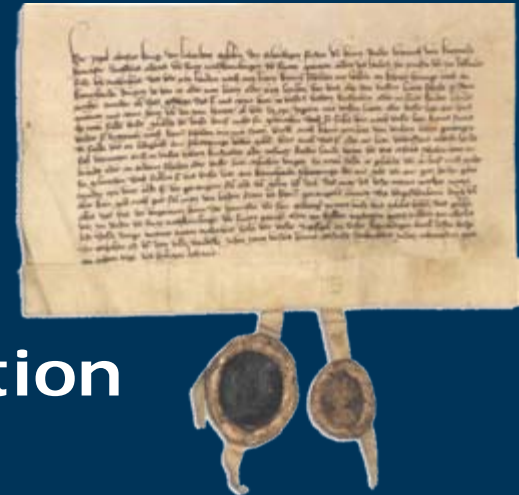
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# AR.MED.025 Referral to the competent authority

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Authority shall:

- Evaluate medical documentation
- Request further examinations, if needed
- Determine the applicant's fitness





# AMC to AR.MED.025 Referral to the competent authority

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- The competent authority should supply the AeMC or AME with all necessary information that lead to the decision on fitness or unfitness Class 1
- The competent authority should ensure that unusual or borderline cases are evaluated on a common basis



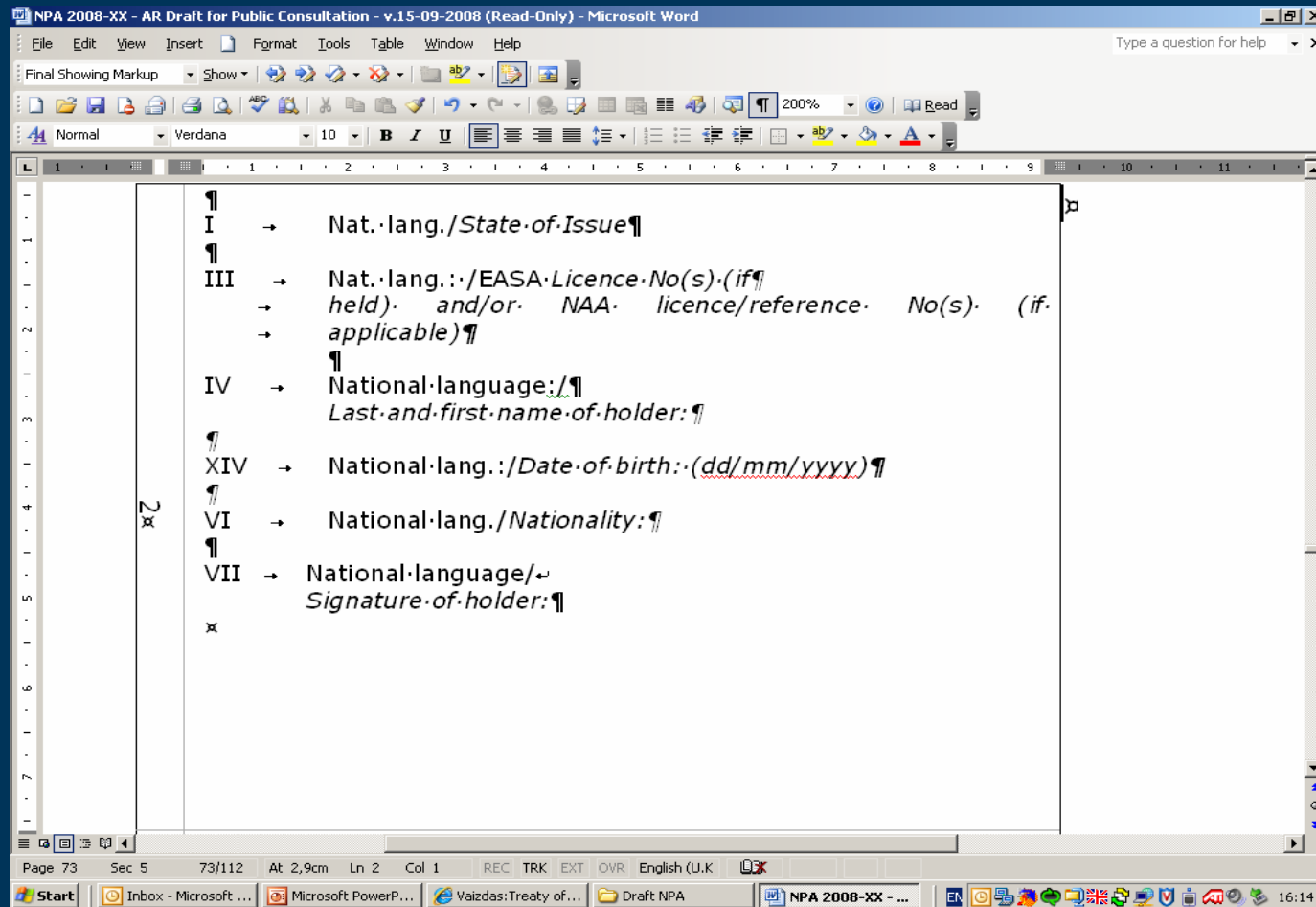
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# AR.MED.030 Medical certificate format (Appendix IV)

A screenshot of a Microsoft Word document titled "NPA 2008-XX - AR Draft for Public Consultation - v1.5-09-2008 (Read-Only) - Microsoft Word". The document is a medical certificate format, specifically AR.MED.030. It is a table with four rows and two columns. The first row is a header row with a large "X" in the first column and a large "X" in the second column. The second row contains the text "LOGO" in the first column and a large "X" in the second column. The third row contains the text "NAME" in the first column and a large "X" in the second column. The fourth row contains the text "OF" in the first column and a large "X" in the second column. The fifth row contains the text "COMPETENT AUTHORITY" in the first column and a large "X" in the second column. The sixth row contains the text "NATIONAL LANGUAGE" in the first column and a large "X" in the second column. The seventh row contains the text "MEDICAL CERTIFICATE" in the first column and a large "X" in the second column. The eighth row contains the text "PERTAINING TO A" in the first column and a large "X" in the second column. The ninth row contains the text "FLIGHT CREW LICENCE" in the first column and a large "X" in the second column. The document is displayed in a window with a standard Windows interface, including a taskbar at the bottom with icons for various applications and a system clock showing 16:10.



# AR.MED.030 Medical certificate format



# AR.MED.030 Medical certificate format

NPA 2008-XX - AR Draft for Public Consultation - v.15-09-2008 (Read-Only) - Microsoft Word

File Edit View Insert Format Tools Table Window Help

Final Showing Markup Show

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1 2 3 4 5 6 7 8 9 10 11

3x

XIII → National lang./Limitations: Code. Description:

X → Nat. lang./Date of issue: (dd/mm/yyyy)

XI → Signature of issuing AME/GMP: National lang./Stamp:

n/yyyy) No(s). (if.

Page 73 Sec 5 73/112 At 13,1cm Ln 29 Col 1 REC TRK EXT OVR English (U.K)

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## Section 2 – AME's and GMP

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### Part Medical – Subpart C and D

- Privileges
- Application
- The issue of an AME certificate
- Extension of privileges
- Training courses
- Changes to the AME certificate
- Validity of AME certificates





# AR.MED.200 Procedures for the issue of an AME certificate

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**AR.FCL.200** Procedure for issue and revalidation of a licence, rating or certificate

- (a) Upon receipt of an application for the issue, revalidation or change of a licence, rating or certificate and any supporting documentation, the competent authority shall **verify** whether the applicant meets the applicable requirements.
- (b) When satisfied that the applicant meets the requirements, the competent authority shall **issue** or **revalidate** the relevant licence, rating or certificate.



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# AR.MED.200 Procedures for the issue of an AME certificate

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Application



Inspection



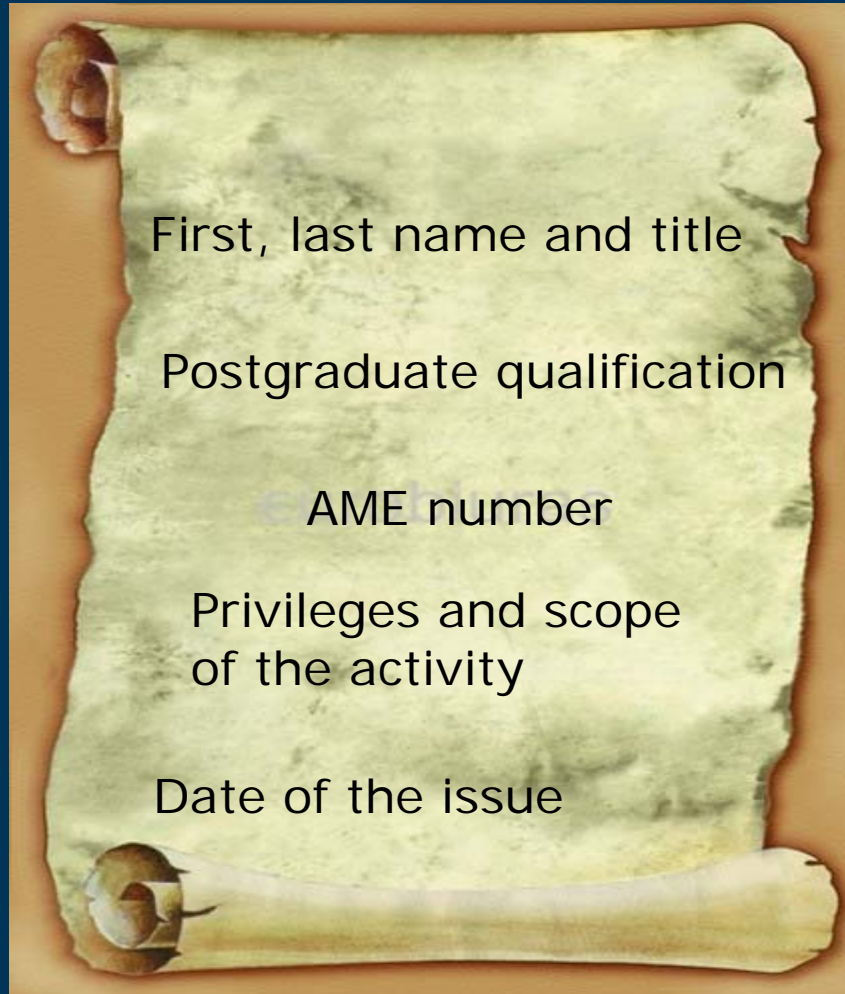
Certificate



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# AR.MED.200 Procedures for the issue of an AME certificate

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# AR.MED.205 Changes – approved AME's

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- AR.GEN. 315 – for organisations
- Procedure restricted to the extent of the change
- Other changes – assessment of the documents provided to verify the compliance with the applicable requirements
- Non-compliance – notification of AME about non-approval



# AR.MED.210 GMP acting as AME's

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- Basic regulation Article 7
- Part Medical MED.A.030
- Notification
- List (disclosure)





# AR.MED.215 Monitoring of AME and GMP (AR.GEN.305)

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- (a) The competent authority shall establish and maintain an **oversight programme** to monitor persons and organisations exercising activities on the territory of the Member State or certified by the competent authority that is proportionate to the complexity of the activities and the risks involved. The programme shall be developed taking into account the size of the activities, local knowledge and past surveillance activities
- (b) The oversight programme shall include **sample inspections**, including unannounced inspections.
- (c) The oversight shall **focus** on a number of key risk elements and **identify** any finding.



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# AR.MED.215 Monitoring of AME and GMP

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The program shall take into account the number of AME and GMP within the territory where competent authority exercise oversight





# AR.MED.220 Limitation, suspension and revocation of AME certificate

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- The AME no longer complies with applicable requirements
- Failure to meet the criteria of certification or continuing certification
- Deficiency of aeromedical record keeping
- Submission of incorrect data or information
- Falsification of medical records, certificates or documentation
- Concealment of facts or false or fraudulent statements to the competent authority





# AR.MED.220 Limitation, suspension and revocation of AME certificate

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- Concealment of facts or false or fraudulent statements to the competent authority
- Failure to correct findings from audit of the AME office
- Unprofessional behaviour or ill health
- At the request of the certified aeromedical examiner

## AUTOMATIC REVOCATION

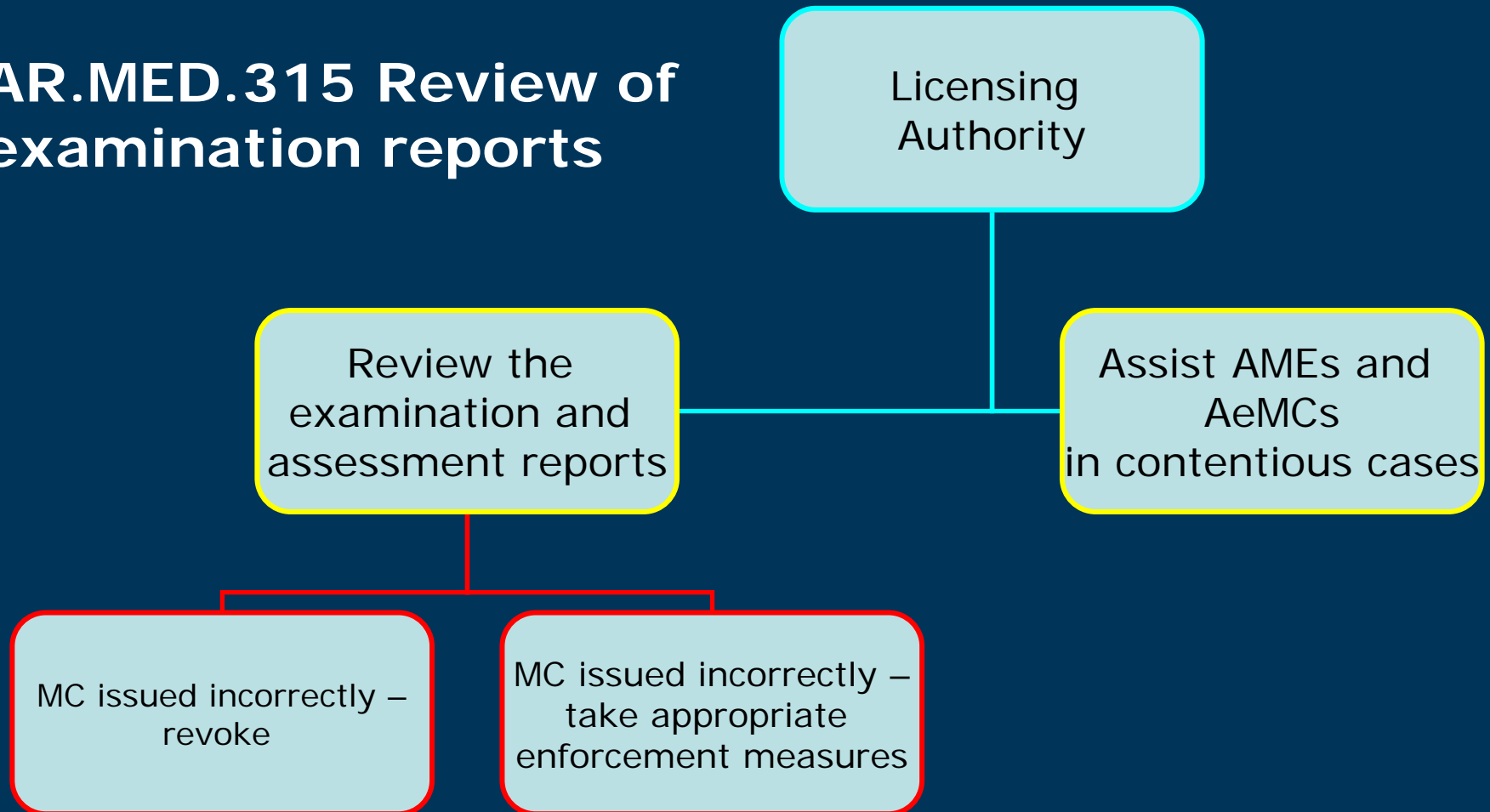
- Revocation of medical licence to practice
- Removal from Medical Register



# Section 3 – Medical certification

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## AR.MED.315 Review of examination reports





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# AR.MED.320 Issuance and removal of limitation(s) to MC

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**Licensing authority**

**Impose in accordance with MED.A.045**

**Remove in accordance with MED.A.045**

**If more than one limitation – consider additive and interactive effects on flight safety**

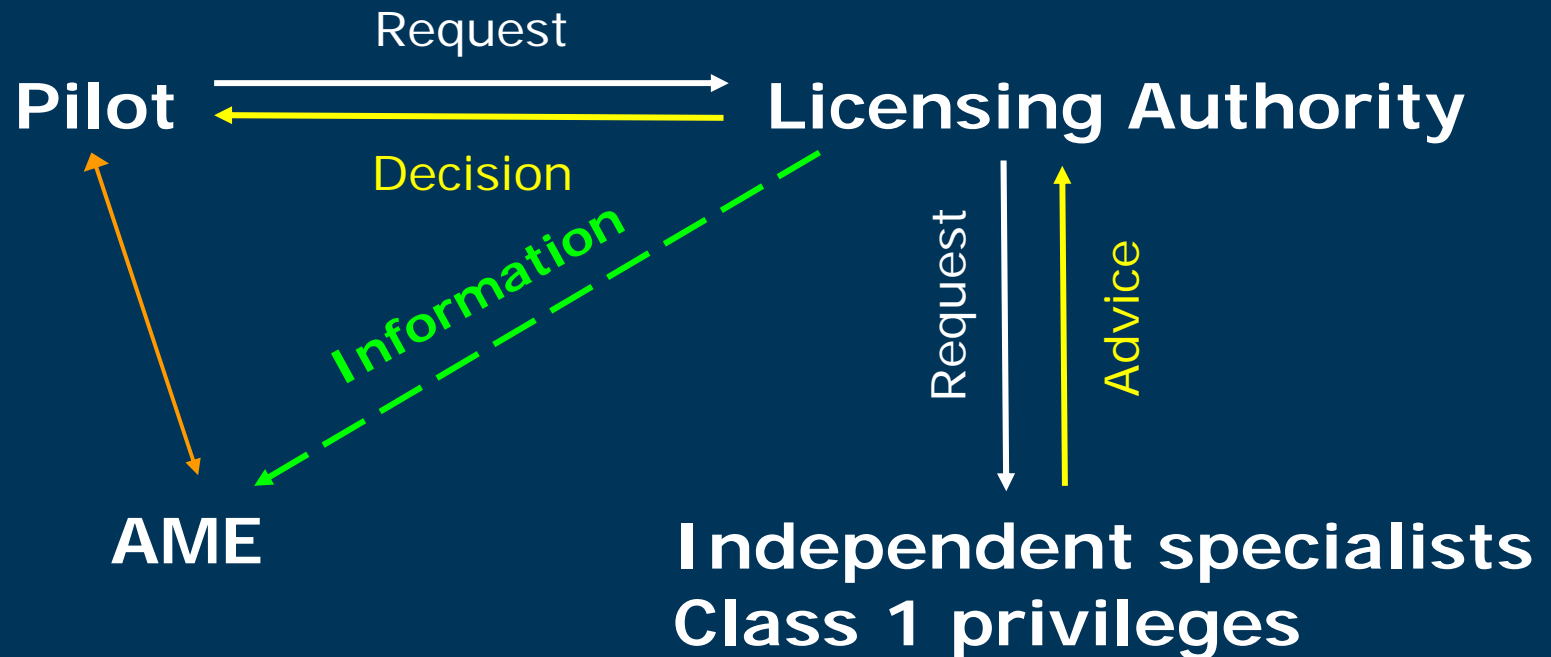


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# AR.MED.325 Secondary review procedure

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## Borderline and contentious cases





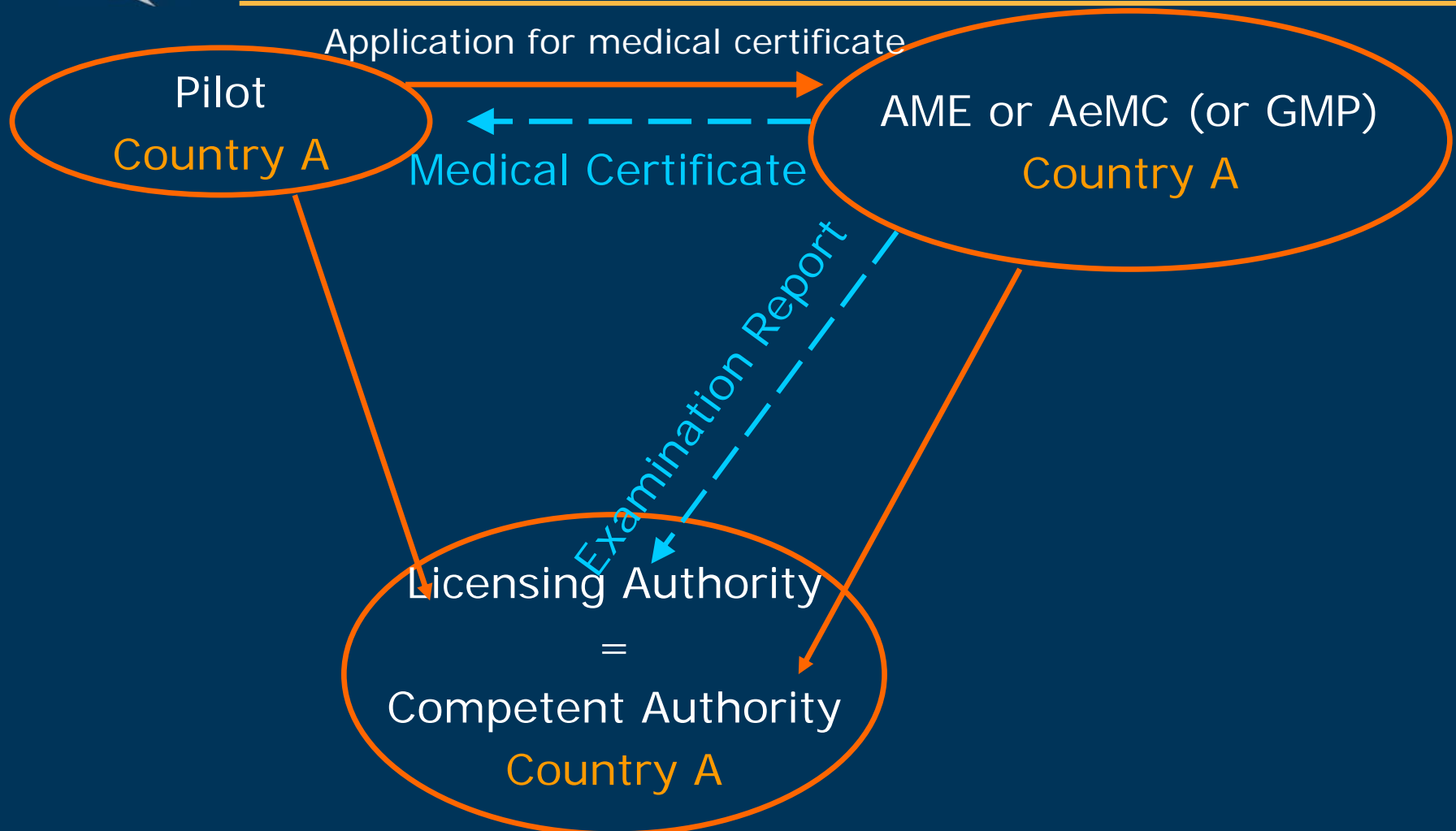
**Thank you**

**Dr. Virgilijus Valentukevicius**

**virgilijus.valentukevicius@easa.europa.eu**



# Medical certification procedure





# Medical certification procedure

