



European Aviation Safety Agency

Standardisation Inspection Final Report

GERMANY

Luftfahrt Bundesamt (LBA)

Flight Crew Licensing and Medical

07 – 11 July 2014

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Foreword

Articles 24(1) and 54 of the Basic Regulation¹ require the European Aviation Safety Agency (EASA) to conduct standardisation inspections, in order to monitor the application by Competent Authorities of this Regulation and of its Implementing Rules, and to report to the Commission.

Articles 1(1) of the Standardisation Regulation² states that the Agency shall conduct standardisation inspections of Competent Authorities addressing each domain defined in Art. 9(1) of the same Regulation.

Article 4(2) of the Standardisation Regulation stipulates that inspections may include inspections of undertakings under the oversight of the Competent Authority inspected.

On this account, the Agency has the mandate to conduct of standardisation inspections in Member States and, if necessary, at undertakings.

Findings raised are classified in line with Article 18 of the Standardisation Regulation and are presented in Appendix 1 to this report.

Undertakings' non-compliances (UNCs) are presented in Appendix 2 to this Report. The Authority is reminded that it is responsible for taking action as appropriate.

¹ **REGULATION (EC) No 216/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC.

² **COMMISSION IMPLEMENTING REGULATION (EU) No 628/2013** of 28 June 2013 on working methods of the European Aviation Safety Agency for conducting standardisation inspections and for monitoring the application of the rules of Regulation (EC) No 216/2008.

Executive Summary

This Standardisation Inspection of the Luftfahrt Bundesamt (hereinafter referred to as LBA) covered the Implementation of European Regulations in the fields of Flight Crew Licensing and Medical. It was carried out by a Flight Crew Licensing (FCL) team of 3 inspectors, and a Medical (MED) team of 2 inspectors, from 7th to 11th July 2014.

In the course of the FCL inspection, 4 undertakings holding approvals as training organisations were visited to sample the oversight of approved organisations in the domain inspected. The MED team visited one aero-medical centre (AeMC) and one aero-medical examiner (AME). In addition, both teams reviewed the status of findings raised in previous inspections which were still open at the time of the visit.

A total of 5 non-compliance findings were raised during the FCL inspection and a further 7 Undertakings Non Compliance were noted at the organisations visited by the FCL team.

The MED team raised 13 non-compliance findings.

The inspection was characterised by the open and frank approach of the LBA staff which allowed the inspection to be conducted in an effective and constructive manner. All the staff met by the inspection teams were clearly well motivated, enthusiastic and competent.

The most significant deficiencies, as notified during the closing meeting, are related to:

- **Specific operating regulations (CE 2)**

Acceptable Means of Compliance developed by the Agency are not binding for AMEs and AeMCs. At the same time, alternative means of compliance are not developed and used. Therefore, the Competent Authority could not demonstrate how compliance with the rule is achieved.

- **State civil aviation system and safety oversight functions (CE 3)**

The LBA does not have the necessary powers to fulfil its responsibilities as the designated Competent Authority in the medical domain.

The Competent Authority has not yet established a management system, which includes a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process.

- **Technical personnel qualification and training (CE4)**

Examiner standardisation courses are not provided by the Competent Authority or by an ATO approved by the Competent Authority.

- **Technical guidance, tools and the provision of safety-critical information (CE5)**

The LBA did not have documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions which reflected the current regulations; specifically the audit checklist for ATO oversight.

The Competent Authority does not ensure that AMEs and AeMCs submit medical records, and does not include in its system of record-keeping, the details of aero-medical examinations and assessments submitted by AMEs or AeMCs. A Secondary review procedure is not established by LBA.

- **Surveillance obligations (CE 7)**

In the FCL Inspection report of November 2013, the following was reported: "In the current staff plan for the L1 section, which is responsible for the oversight of approximately 90 ATO and approximately 100 FSTD, the number of staff calculated as being required to accomplish the allocated tasks is 40; however, the actual number of staff allowed is 19." The current situation remains essentially unchanged.

This manpower plan is subject to a further review ordered by the Court of Auditors; the outcome of this review will not be known for some months. In addition, due to the nature of employment within the LBA (state officials), some categories of staff are difficult to recruit given the greater salaries on offer within the aviation industry.

This restriction on staff numbers is largely outside the control of the LBA but has the potential to affect safety critical areas of the work of the LBA.

This chronic shortage of staff is also reported in the LBA Annual report 2012/2013, p.63 by way of an interview with the Head of Division "Administration".

This lack of personnel could be seen to have an impact on the majority of the findings raised during this visit. (For example, the Competent Authority has not yet developed an oversight programme to monitor the conduct and performance of examiners. It should also be noted that currently there are 7 personnel with examiner qualifications available to oversee approximately 30000 events per annum). In particular, the Competent Authority was unable to verify continued compliance with the applicable requirements of organisations it has certified and, in addition, the inability of the team to close the existing open findings from previous inspections.

In the Medical domain, the medical personnel authorised by the Competent Authority to carry out oversight tasks of AMEs and AeMCs are prevented from examining the medical records, data, procedures and any other material, taking copies or extracts from such records and other material relevant to the execution of the oversight task.

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Appendix 1: Findings

Appendix 2: Undertakings' non-compliances

1. Objectives of the inspection

The purpose of this inspection was to monitor the application by the LBA of the aviation safety regulations in the fields of Flight Crew Licensing (FCL) and Medical (MED), and to report the results to the European Commission.

2. Key inspection data

2.1 Inspection summary

Competent Authority (CA)	Luftfahrt Bundesamt (LBA)
Inspection type	Comprehensive
Inspection scope	<ul style="list-style-type: none"> - REGULATION (EC) No 216/2008 as amended; and - COMMISSION REGULATION (EU) No 1178/2011 as amended, all Parts and Annexes, as applicable.
Inspection dates (start-end)	7 - 11 July 2014
Visited units / offices	Headquarters LBA - Braunschweig
Visited undertakings	FCL domain: <ul style="list-style-type: none"> - [REDACTED] - [REDACTED] - [REDACTED] MED domain: <ul style="list-style-type: none"> - [REDACTED] - [REDACTED]
Inspection team	FCL team: Team Leader: [REDACTED] EASA Team Member: [REDACTED] Team Member: [REDACTED] MED team: Team Leader: [REDACTED] EASA Team Member: [REDACTED] EASA
National Std Coordinator (NSC)	[REDACTED] BMVI
Sectorial Focal Point (SFP) FCL	[REDACTED] LBA
Sectorial Focal Point (SFP) MED	[REDACTED]

Other relevant information	<p>There is no implementation of a management system at the LBA, as required by the Aircrew Regulation.</p> <p>A number of current procedures are still in compliance of national or JAA requirements instead of Regulation (EC) No 216/2008 and the implementing rules.</p> <p>New procedures compliant with the Implementing rules are still either under development or waiting for the approval.</p> <p>Application of the national data protection law interferes with:</p> <ol style="list-style-type: none"> 1. <i>The implementation of the EU law and the standardisation of LBA in accordance with Regulation (EU) No 628/2013;</i> 2. <i>The oversight of AMEs and AeMCs.</i> <p>The LBA is often obliged to consult the Ministry and sometimes receives directives from the Ministry. This impacts on the ability of LBA to discharge its obligations as a Competent Authority.</p>
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2.2 Scale of activity

In the field of FCL, the LBA is responsible for the oversight of the following:

Training organisations approved by LBA	77
Total number of pilot licences issued by LBA	20.357
NOTE: in Germany the LBA is only responsible for professional pilot licences (aeroplane and helicopter) and licences with Instrument Ratings attached.	

In the field of MED, the LBA is responsible for the oversight of the following:

Approved aero-medical centres	7
Authorised aero-medical examiners:	
Class 1	219
Class 2	248
Occupational health medical practitioners	LBA has no data
General Medical Practitioners	None
Medical certificates and cabin crew medical reports:	
Class 1	LBA has no data
Class 2	LBA has no data
LAPL	0
Cabin Crew	LBA has no data

3. Inspection results

The key results of the Inspection are presented below, grouped in accordance with the eight Critical Elements (CE) of a Safety Oversight System as defined by ICAO³. They refer to the detailed findings that are listed in Appendix 1 to this report.

The team is thankful to the LBA management for its openness, its transparency and its professional attitude throughout the inspection. This contributed to the efficiency and effectiveness of the inspection, and resulted in the conclusions being agreed.

The team would like to thank in particular Mr Udo Dehning and Dr Andreas Kirkiles, as well as their teams, for their availability and support, and to commend their positive and constructive attitude at all stages of the process; this enabled the inspection to be performed as planned.

3.1 Specific Operating Regulations (CE 2)

In the directive to LBA from the Federal Ministry of Transport and Digital Infrastructure (BMVI) dated 6th December 2013, it is stated that alternative means of compliance (AMCs) developed by the Agency are not binding for AMEs and AeMCs. At the same time, alternative means of compliance are not developed and used. Therefore, the Competent Authority could not demonstrate how compliance with the rules is achieved. It is not clear which medical standards are used for the aero-medical assessment of applicants (see finding #18352).

3.2 State civil aviation system and safety oversight functions (CE 3)

The LBA is established as the Competent Authority pursuant to the *Lufverkehrsgesetz* and the *Luffahrtbundesamtgesetz*. However, the evidence collected on-site indicate that the LBA does not have necessary powers to fulfil its responsibilities as the designated Competent Authority in the Medical domain (see finding #18350).

The Competent Authority has not yet established a management system, which includes a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process (see finding #18395).

3.3 Technical personnel qualification and training (CE 4)

Examiner standardisation courses are not provided by the Competent Authority or by an ATO approved by the Competent Authority (see finding #18393).

3.4 Technical guidance, tools and the provision of safety critical information (CE 5)

The Competent Authority developed a number of procedures to achieve compliance with implementing rules, but the majority of them are not legally adopted.

In the Medical domain, the Competent Authority does not include in its system of record-keeping, the details of aero-medical examinations and assessments submitted by AMEs or AeMCs (see finding #18353).

³ ICAO Doc 9734 AN/959 – Safety Oversight Manual.

At the same time, the Competent Authority does not ensure that AMEs and AeMCs submit to LBA, without delay, a signed or electronically authenticated report to include the assessment result (see finding #18358) or, in case of applicants from other Member States, to the competent authorities of these states. The LBA explained to the inspection team that sending of the medical records to the competent authorities is prevented by the national interpretation of the EU data protection rules. The inspection team expressed doubts whether the national interpretation of the EU data protection rules is correct.

The inspection team also noted that a number of German AMEs are also certified by the US Federal Aviation Administration (FAA) and they send medical records of applicants to this entity on a regular basis. This practice is accepted by the German data protection office. As a result of this situation, the LBA is not in a position to calculate the exact numbers of class 1 and class 2 medical certificates issued in the territory under its control.

The Competent Authority did not establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned, including on all findings raised and follow-up actions taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State, but certified by the competent authority of another Member State or the Agency (see finding #18355).

The Competent Authority has not established a procedure for the review of borderline and contentious cases with independent medical advisors experienced in the practice of aviation medicine, in order to consider and advise on an applicant's fitness for medical certification (see finding #18357).

In the case of the application for an AeMC certificate or an amendment to an existing certificate, there is no evidence that it is made in a form and manner established by the Competent Authority (see finding #18359).

The Competent Authority does not have a process to review medical certificates issued by non-compliant AeMCs and AMEs and render them invalid, where required, to ensure flight safety (see finding #18362).

The LBA did not have documentation specifically intended to provide its personnel responsible for safety oversight with guidance to perform their functions in accordance to the current regulations; specifically the audit checklist for ATO oversight (see finding #18397).

3.5 Licensing, certification, authorisation and approval obligations (CE 6)

In one of the undertakings visited, the distance learning courses were being provided by a number of external ATOs. The undertaking relied only on the existing approvals and failed to formally contract this activity with the external providers.

In one undertaking, the inspection team found that the distance learning and class room instruction arrangement of the course, and the integration of syllabi time with regard to the separate external training providers, was not documented.

3.6 Surveillance obligations (CE 7)

The Competent Authority was unable to verify continued compliance with the applicable requirements of organisations it has certified (see findings #18356 and #18396).

The Competent Authority has not yet developed an oversight programme to monitor the conduct and performance of examiners. It should also be noted that currently there are 7 personnel with examiner qualifications available for the oversight of approximately 30000 tests/checks per annum (see finding # 18394).

In the Medical domain, the Competent Authority did not establish and does not maintain an oversight programme for the AMEs and AeMCs (see finding #18354). The LBA explained that the program is developed but it is in a preliminary stage and will be active pending the agreement by the Ministry of Transport and Digital Infrastructure (BMVI) after the consultation process.

The medical personnel authorised by the Competent Authority to carry out oversight tasks of AMEs and AeMCs are prevented from examining the medical records, data, procedures and any other material, and taking copies or extracts from such records and other material relevant to the execution of the oversight task (see finding #18351).

In this regard the LBA explained as follows:

"The oversight tasks of the LBA are defined and limited by the German legislation. EU legislation is considered neither precise enough nor in harmonization with German data protection requirements to permit the regular transfer of detailed medical data to an authority as expected by EASA. The term "report" in MED.A.025b4 is considered not distinct enough to oblige the AME to transfer all aeromedical data, which led to the result of an assessment or examination. However, the article 11(b)(6) of the Regulation EU No 1178/2011 only allows the authority to execute the tasks mentioned in article 11(b)(5) according to the national legislation. According to the needs of the German data protection requirements, the transfer of medical data to the authority is limited and has to be transmitted in an anonymous way. The disclosure of the information to whom aeromedical data will refer for auditing purposes, in general, is not allowed and only acceptable in rare cases where there is an immediate safety risk."

For oversight of the AeMCs and AMEs, the Competent Authority does not have a system to raise findings and analyse them for their safety significance, keep records and communicate them to the certificate holder (see finding #18361).

In the case of the medical assessment of the cabin crew members, the Competent Authority does not ensure that occupational health medical practitioners (OHMP) comply with the applicable rules (see finding #18360).

3.7 Immediate Safety Concerns⁴

None observed.

⁴ Art. 19 of the Standardisation Regulation.

3.8 Additional relevant information

Verification of initial and recurrent training plans.

The LBA has a difficulty in allowing the inspection teams access to the relevant documents to verify initial and recurrent training plans; this is due to a directive from the BMVI regarding data protection. This directive dated 28 August 2013 also refers to previous directives from 11 November 2009 and 1 February 2010 which prohibits the LBA from allowing the team any access to documents containing personal data. This applies equally to any other domain. (See also finding #18351).

Current National Legislation.

During the inspection it was noted that the current national legislation is, in some areas, in conflict with the European legislation. It was also noted that the current rules are being amended. It is strongly recommended that this amendment is reviewed in order to ensure that the new national regulation no longer conflicts with that of the EU.

Staff resources.

In the FCL final report stemming from the inspection of November 2013, the following was reported: "In the current staff plan for the L1 section, which is responsible for the oversight of approximately 90 ATO and approximately 100 FSTD, the number of staff calculated as being required to accomplish the allocated tasks is 40; however, the actual number of staff allowed is 19." The current situation remains essentially unchanged.

This manpower plan is subject to a further review ordered by the Court of Auditors; the outcome of this review will not be known for some months. In addition, due to the nature of employment within the LBA (state officials), some categories of staff are difficult to recruit due to the greater salaries on offer within the aviation industry.

This restriction on staff numbers is largely outside the control of the LBA but has the potential to affect safety critical areas of the work of the LBA.

Staff motivation and competence.

All the staff met by the inspection teams are clearly well motivated, enthusiastic and competent. The greatest barrier to the LBA achieving its goals appears to be a chronic shortage of staff; this is previously documented in other inspection domains. The second significant challenge for LBA is that there is evidence that two different entities – LBA and BMVI – are acting as a "competent authority". (See also finding #18350).

Initial certification and continuous oversight of the aero-medical centres.

For the purposes of the initial certification and continuous oversight of the aero-medical centres, the Federal Ministry of Transport and Digital Infrastructure (BMVI), in a letter to LBA No 6174.5/0 dated 14.11.2013, recommended to accept ISO 9001 certificate as a safety management system. As ISO 9001 certificate does not necessarily reflect to the requirements of Regulation EU No 1178/2011, it is strongly recommended to evaluate the aero-medical centres safety management system in accordance with these requirements.

3.9 Conclusions

During this Standardisation Inspection, 5 findings of non-conformity were raised in the FCL domain and 13 findings of non-conformity were raised in the MED domain. The final classified findings can be found in Appendix 1 to this report. There were no indications of any immediate safety concern.

Some findings are based upon undertakings' non-compliances (UNCs) detected in the course of the inspection and notified to the LBA at the closing session. Such UNCs can be found in Appendix 2 to this report.

The most significant deficiencies in FCL domain, as notified during the closing meeting, are:

- **State civil aviation system and safety oversight functions (CE3)**
 - o The Competent Authority has not yet established a management system, which includes a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures including the establishment of an internal audit process and a safety risk management process.
- **Technical personnel qualification and training (CE4)**
 - o Examiner standardisation courses are not provided by the Competent Authority or by an ATO approved by the Competent Authority.
- **Technical guidance, tools and the provision of safety-critical information (CE5)**
 - o The LBA did not have documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions which reflected the current regulations; specifically the audit checklist for ATO oversight.
- **Surveillance obligations (CE7)**
 - o The Competent Authority has not yet developed an oversight programme to monitor the conduct and performance of examiners. It should also be noted that currently there are 7 personnel with examiner qualifications available to oversee approximately 30000 events per annum.
 - o The Competent Authority was unable to verify continued compliance with the applicable requirements of organisations it has certified.

Furthermore, during this inspection the team reviewed the status of 2 open findings stemming from the FCL.DE.02.2010 inspection. After review of the evidence provided, none of these findings could be closed. It should be noted that these findings relate to oversight/surveillance of organisations and are essentially the same as finding #18396 above.

The most significant deficiencies in MED domain, as notified during the closing meeting, are:

- **Specific operating regulations (CE 2)**
 - o Acceptable Means of Compliance developed by the Agency are not binding for AMEs and AeMCs. At the same time, alternative means of compliance are not developed and used. Therefore, the Competent Authority could not demonstrate how compliance with the rule is achieved. It is not clear which medical standards are used for the aero-medical assessment of applicants.
- **State civil aviation system and safety oversight functions (CE 3)**
 - o The LBA does not have necessary powers to fulfil its responsibilities as the designated Competent Authority in the medical domain.

- **Technical guidance, tools and the provision of safety-critical information (CE 5)**
 - o The Competent Authority does not ensure that AMEs and AeMCs submit medical records, and does not include in its system of record-keeping the details of aero-medical examinations and assessments submitted by AMEs or AeMCs.
 - o Secondary review procedure is not established by the LBA.
- **Surveillance obligations (CE 7)**
 - o In the case of the AME and AeMC oversight, medical records are not available to the authorised personnel.
 - o The Competent Authority did not establish and does not maintain an oversight programme for the AMEs and AeMCs, and there is no evidence that the Competent Authority verifies continued compliance with the applicable requirements of AeMCs and AMEs it has certified.

Furthermore, during this inspection the medical team reviewed the status of **9** open findings stemming from the **FCL.DE.02.2010** inspection. After review of the evidence provided, it was not possible to close any of these findings.

4. Comments of the Competent Authority⁵

The LBA provided comments to findings which can be found in the Appendix 1 to this report, together with the Agency's response.

There were no further comments of LBA to the draft final report.

5. Follow-up actions

In the follow-up and closure phase, which starts at the date of receipt of the draft Report, the Agency and the Competent Authority inspected shall agree on corrections and corrective actions addressing each finding raised.

The maximum timeframe for achieving full agreement on all findings is **16 weeks** from the date of receipt of the draft Report. Furthermore, the Authority shall submit its proposed actions as follows, as stipulated by Articles 17(1) and 17(2) of the Standardisation Regulation:

- Within **4 weeks** from the date of receipt of the draft Report, for class D and G findings, and
- Within **10 weeks** from the date of receipt of the draft Report, for class C findings.

The Agency expects the proposed corrections / corrective actions to include, for each finding, the outcome of a thorough root-cause analysis and an indication of whether the issue was found to be an isolated case or a systematic issue. Each correction / corrective action shall include a defined timeframe for completion.

Furthermore, whenever a finding is linked to one or more undertakings' non-compliances (UNCs), the Authority shall also include in its proposed action(s) all aspects related to the further investigation of UNCs at the undertakings' level (i.e. at the visited undertaking, but also at any other undertaking which may be affected, as deemed appropriate).

Failure to do so will prevent the Agency from giving its agreement on the proposed action(s).

If no agreement can be reached on one or more proposed actions within the abovementioned timeframes, the Agency shall request the Competent Authority to provide clarifications and to submit supplementary actions, and may ultimately issue a **supplementary report⁶** to the Competent Authority and to the European Commission.

⁵ Art. 16(4) of the Standardisation Regulation.

⁶ Art. 22(3)(b) of the Standardisation Regulation.



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Appendix 1: Findings

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Finding ID	DE #18393	Date	11/07/2014
Class	D	ICAO CE 4	
Requirement(s)	FCL.1015(a)		
Status	Open		

Description	Examiner standardisation courses are not fully provided by the competent authority or by an ATO approved by the competent authority.
Related UNC(s)	None
Comments	Competent Authority comment to final finding: The LBA currently provides part of the standardisation course, namely in accordance with FCL.1015 (b) (2, 3, 4 & 5). EASA position: Classified as "D" because the assessment of competence or proficiency check is not conducted.



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Finding ID	DE #18394	Date	11/07/2014
Class	D	ICAO CE 7	
Requirement(s)	ARA.FCL.205(a)		
Status	Open		

Description The competent authority has not yet developed an oversight programme to monitor the conduct and performance of examiners. It should also be noted that currently there are 7 personnel with examiner qualifications available to oversight approximately 30000 events per annum.

Related UNC(s) None

Comments Competent Authority comment to final finding:
There is a draft plan under development which requires further refinement in consultation with the Ministry and the Federal States before it can be executed. In addition we intend to incorporate the outcome of the review by EASA of the Sub-parts J & K of the "Aircrew Regulation" when this is finalised.

EASA position:
Standardisation inspections are performed based on the regulation in force. It is not acceptable to wait until new rules are applicable, especially since Subparts J and K do not address this issue.

Finding ID	DE #18395	Date	11/07/2014
Class	C	ICAO CE 3	
Requirement(s)	ARA.GEN.200(a)(4)		
Status	Open		

Description The competent authority has not yet established a management system, which includes a function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures including the establishment of an internal audit process and a safety risk management process.

Related UNC(s) None

Comments Competent Authority comment to final finding:
Nil



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Finding ID	DE #18396	Date	11/07/2014
Class	D	ICAO CE 7	
Requirement(s)	ARA.GEN.220(a)(2) ARA.GEN.300(a)(2)		
Status	Open		

Description The competent authority was unable to verify continued compliance with the applicable requirements of organisations it has certified.

Related UNC(s)	[REDACTED]	DE UNC#18331
	[REDACTED] GmbH	DE UNC#18333
	[REDACTED]	DE UNC#18334
	[REDACTED] GmbH	DE UNC#18332
	[REDACTED]	DE UNC#18328
		DE UNC#18329
		DE UNC#18330

Comments None

Finding ID	DE #18397	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ARA.GEN.300(b)(1)		
Status	Open		

Description The LBA did not have documentation specifically intended to provide personnel responsible for safety oversight with guidance to perform their functions which reflected the current regulations. Specifically the audit checklist for ATO oversight.

Related UNC(s) None

Comments None



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Appendix 1: Findings

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Finding ID	DE #18350	Date	11/07/2014
Class	D	ICAO CE 3	
Requirement(s)	Reg.(EU) 1178/2011 - Art.11b(1) Reg.(EU) 1178/2011 - Art.11b(3)		
Status	Open		

Description Based on the evidence received the LBA is the CA in the aero-medical domain. However, the evidence collected on-site indicate that the LBA does not have necessary powers to fulfil its responsibilities as the designated CA in the medical domain.
The person in the Federal Ministry of Transport and Digital Infrastructure responsible for the oversight and supervision of the LBA in the aero-medical domain is an AME certified and supervised by LBA.

Related UNC(s) None

Comments Competent Authority comment to final finding:
None



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Appendix 1: Findings

Finding ID	DE #18351	Date	11/07/2014
Class	D	ICAO CE 7	
Requirement(s)	Reg.(EU) 1178/2011 - Art.11b(5) MED.A.025(d)		
Status	Open		

Description Medical personnel authorised by the competent authority to carry out oversight tasks of AMEs and AeMCs are actively prevented from examining the medical records, data, procedures and any other material and taking copies or extracts from such records and other material relevant to the execution of the oversight task.

Related UNC(s) None

Comments Competent Authority comment to final finding:
The oversight tasks of the LBA are defined and limited by the German legislation. EU legislation is considered neither precise enough nor in harmonization with German data protection requirements to permit the regular transfer of detailed medical data to an authority as expected by EASA. The term "report" in MED.A.025b4 is considered not distinct enough to oblige the AME to transfer all aeromedical data, which led to the result of an assessment or examination. However the article 11b6 of the regulation EU 1178/2011 only allows the authority to execute the tasks mentioned in article 11b5 according to the national legislation. According to the needs of the German data protection requirements the transfer of medical data to the authority is limited and has to be transmitted in an anonymous way. The disclosure of the information to whom aeromedical data will refer for auditing purposes in general is not allowed and only acceptable in rare cases where there is an immediate safety risk.

EASA position:

The comment is not accepted. 11b(6) may not prevent the implementation of 11b(5).

Finding ID	DE #18352	Date	11/07/2014
Class	D	ICAO CE 2	
Requirement(s)	ARA.GEN.120		
Status	Open		

Description In the directive to LBA from the Federal Ministry of Transport and Digital Infrastructure dated 6th December 2013 it is stated that AMC's developed by the Agency are not binding for AMEs and AeMCs. At the same time, alternative means of compliance are not developed and used. Therefore, the CA could not demonstrate how compliance with the rule is achieved. There is no evidence of the medical standards used for the aero-medical assessment of applicants.

Related UNC(s) None

Comments Competent Authority comment to final finding:
None



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Finding ID	DE #18353	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ARA.MED.150(a)		
Status	Open		

Description The competent authority does not include in its system of record-keeping details of aeromedical examinations and assessments submitted by AMEs or AeMCs.

Related UNC(s) None

Comments Competent Authority comment to final finding:
See other comments. In addition to EU rules the LBA is bound to the scope of national regulations. Therefore we cannot have a record keeping system containing details of aeromedical examinations.

EASA position:
National regulations shall not prevent compliance with the EU law.

Finding ID	DE #18354	Date	11/07/2014
Class	C	ICAO CE 7	
Requirement(s)	ARA.GEN.305(a)		
Status	Open		

Description The competent authority did not establish and does not maintain an oversight programme for the AMEs and AeMCs.

Related UNC(s) None

Comments Competent Authority comment to final finding:
The LBA developed already an oversight program. It is described in the procedure "Verfahrensanweisung L5-3 Aufsicht des Referats L5". This procedure is in a preliminary stage and will be active pending on the agreement by the Ministry of Transport and Digital Infrastructure after the consultation process.

EASA position:
The finding is related to the finding #18350



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Finding ID	DE.#18355	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ARA.GEN.200(c)		
Status	Open		

Description The competent authority did not establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned including on all findings raised and follow-up actions taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State, but certified by the competent authority of another Member State or the Agency.

Related UNC(s) None

Comments Competent Authority comment to final finding:
Due to the limited access of the LBA to the aeromedical details of the examinations/assessments done by German AME's and AeMC's (as specified above) and with restraints caused by data protection requirements the LBA can not exchange all requested information. It will be self-evident that the LBA will follow the obligations resulting from ARA.GEN.200c, if it gets any information with importance for other authorities and confirmation that this procedure will be in compliance with the data protection requirements. This obligation is defined in the sections 2 and 3 of the administrative procedures act (Verwaltungsverfahrensgesetz).

EASA position:

The requirement to have a procedure is nevertheless applicable.

Finding ID	DE #18356	Date	11/07/2014
Class	C	ICAO CE 7	
Requirement(s)	ARA.GEN.300(a)(2)		
Status	Open		

Description There is no evidence that the competent authority verifies continued compliance with the applicable requirements of AeMCs and AMEs it has certified.

Related UNC(s) None

Comments Competent Authority comment to final finding:
The approval certificates issued by the LBA for all German AME's and AeMC's contain obligations for the holder of the certificate in order that he is fully aware of the applicable requirements he has to comply with. For the initial applications the LBA verifies the compliance. Continued compliance is subject to the oversight program.

EASA position:

Comment partly accepted. Text and reference change. The finding is linked with finding #18354.



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Finding ID	DE #18357	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ARA.MED.325		
Status	Open		

Description The competent authority did not establish a procedure for the review of borderline and contentious cases with independent medical advisors, experienced in the practice of aviation medicine, to consider and advise on an applicant's fitness for medical certification.

Related UNC(s) None

Comments Competent Authority comment to final finding:
It is foreseen in the draft amendment of the German "Regulation on Personnel Licensing" (LuftPersV) to establish a review board, called "Fliegerärztlicher Ausschuss" to deal with all contentious and borderline cases accordant to the requirements of the secondary review mentioned in ARA.MED.325. The board members will be designated by the Ministry of Transport and Digital Infrastructure. The LBA has to execute the decisions from the board.

EASA position:

The procedure is still in the draft phase. In addition, the draft procedure as described in the comment does not fulfill the requirements of ARA.MED.325.

Finding ID	DE #18358	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	MED.A.025(b)(4)		
Status	Open		

Description In the case of applicants for a medical certificate, the competent authority doesn't ensure that AMEs and AeMCs submit without delay a signed, or electronically authenticated, report to include the assessment result to the licensing authority.

Related UNC(s) None

Comments Competent Authority comment to final finding:
As stated above, the LBA is not allowed to get all aeromedical information on a general basis. However the LBA gets the medical certificates and the information of a denial in every case a German license holder is affected. For that reason the LBA can only ensure that it will get these documents.

EASA position:

The requirement is to submit a report to include the assessment result and a copy of a medical certificate.



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Finding ID	DE #18359	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ORA.GEN.115(a)		
Status	Open		

Description In the case of the application for an AeMC certificate or an amendment to an existing certificate, there is no evidence that it is made in a form and manner established by the competent authority.

Related UNC(s) None

Comments Competent Authority comment to final finding:
The manner as well as the form of an application is defined by part 2, section 1 of the administrative procedures act (Verwaltungsverfahrensgesetz).

EASA position:
When the evidence will be produced, finding will be re-assessed.

Finding ID	DE #18360	Date	11/07/2014
Class	C	ICAO CE 7	
Requirement(s)	MED.D.040		
Status	Open		

Description The competent authority doesn't ensure that OHMPs comply with the applicable rules.

Related UNC(s) None

Comments Competent Authority comment to final finding:
None



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Finding ID	DE #18361	Date	11/07/2014
Class	C	ICAO CE 7	
Requirement(s)	ARA.GEN.350 ARA.GEN.355		
Status	Open		

Description For oversight of the AeMCs and AMEs, the competent authority does not have a system to raise findings and analyse them for their safety significance, keep records and communicate them to the certificate holder.

Related UNC(s) None

Comments Competent Authority comment to final finding:
This is subject to an appropriate oversight program which is already mentioned under #6. In addition, the German "Regulation on Certification and Licensing in Aviation" (LuftVZO) contains provisions that the LBA is obliged to prosecute certificate holders who do not comply with the regulations.

EASA position:
Noted

Finding ID	DE #18362	Date	11/07/2014
Class	C	ICAO CE 5	
Requirement(s)	ARA.MED.255		
Status	Open		

Description The competent authority does not have a process to review medical certificates issued by non-compliant AeMCs and AMEs and render them invalid where required to ensure flight safety.

Related UNC(s) None

Comments Competent Authority comment to final finding:
According to §24d4 of the German "Regulation on Certification and Licensing in Aviation" (LuftVZO) each German medical certificate is declared to be invalid, if the certificate holder does not comply with the regulations. According to the §24e9 of this regulation the approval of an AME has to be declared invalid and has to be revoked, if the holder of the approval does not comply with the requirements or regulations.

EASA position:
Comment noted. However, it does not address the finding. Change of a legal reference to ARA.MED.255.



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Appendix 2: Undertakings Non Compliances

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Undertaking: [REDACTED] GmbH

UNC ID **DE UNC#18331**

Date 11/07/2014

Requirement(s) ORA.GEN.200(a)(3)

Description The organisation had not established a system for the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness.

Related finding(s) DE# 18396



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Undertaking: [REDACTED] GmbH

UNC ID DE UNC#18333 **Date** 11/07/2014

Requirement(s) ORA.GEN.200(a)(3)

Description The organisation had not established a system for the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness.

Related finding(s) DE# 18396

UNC ID DE UNC#18334 **Date** 11/07/2014

Requirement(s) ARA.GEN.205(a)

Description Distance learning courses were being provided by a number of external ATO, the undertaking relied only on the existing approvals and failed to formally contract this activity with the external providers. In addition the integration of syllabi time with regard to the separate external training providers was not documented.

Related finding(s) DE# 18396



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Undertaking: [REDACTED] GmbH

UNC ID DE UNC#18332 **Date** 11/07/2014

Requirement(s) ORA.GEN.200(a)(3)

Description The organisation had not established a system for the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness.

Related finding(s) DE# 18396



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Undertaking: [REDACTED]

UNC ID DE UNC#18328 **Date** 11/07/2014

Requirement(s) ARA.GEN.300(a)(2)

Description The last documented external audit of this organisation by LBA was conducted 25th September 2008.

Related finding(s) DE# 18396

UNC ID DE UNC#18329 **Date** 11/07/2014

Requirement(s) ORA.GEN.200(a)(6)

Description The organisation had not established a function to monitor compliance of itself with the relevant requirements. The last documented internal audit was dated 22 April 2010.

Related finding(s) DE# 18396

UNC ID DE UNC#18330 **Date** 11/07/2014

Requirement(s) ORA.GEN.200(a)(3)

Description The organisation had not established a system for the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness.

Related finding(s) DE# 18396