HIPPOKRATIA 2009, 13, 2: 106-109

SPECIAL ARTICLE

The actual development of European Aviation Safety Requirements in Aviation Medicine: Prospects of Future EASA Requirements

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Common Rules for Aviation Safety had been developed under the aegis of the Joint Aviation Authorities in the 1990ies. In 2002 the Basic Regulation 1592/2002 was the founding document of a new entity, the European Aviation Safety Agency. Areas of activity were Certification and Maintenance of aircraft. On 18 March the new Basic Regulation 216/2008, repealing the original Basic Regulation was published and applicable from 08 April on. The included Essential Requirements extended the competencies of EASA inter alia to Pilot Licensing and Flight Operations. The future aeromedical requirements will be included as Annex II in another Implementing Regulation on Personnel Licensing. The detailed provisions will be published as guidance material. The proposals for these provisions have been published on 05 June 2008 as NPA 2008-17c. After public consultation, processing of comments and final adoption the new proposals may be applicable form the second half of 2009 on. A transition period of four year will apply. Whereas the provisions are based on Joint Awiation Requirement - Flight Crew Licensing (JAR-FCL) 3, a new Light Aircraft Pilot Licence (LAPL) project and the details of the associated medical certification regarding general practitioners will be something new in aviation medicine.

This paper consists of 6 sections. The introduction outlines the idea of international aviation safety. The second section describes the development of the Joint Aviation Authorities (JAA), the first step to common rules for aviation safety in Europe. The third section encompasses a major change as next step: the foundation of the European Aviation Safety Agency (EASA) and the development of its rules. In the following section provides an outline of the new medical requirements. Section five emphasizes the new concept of a Leisure Pilot Licence. The last section gives an outlook on ongoing rulemaking activities and the opportunities of the public to participate in them. Hippokratia 2009; 13 (2): 101-104

Key words: Aviation Safety Medical Requirements JAA EASA Basic Regulation Leisure Pilot Licence

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From its very beginning aviation and air transport were not limited to single countries but an international undertaking. Particularly in a geographical setting like Europe – a confined area with a diameter of about 4500 kilometres and about 500 million citizens - imminent difficulties are obvious: more than 300 billion kilometres are covered by airtransport annually and 41 different legal systems apply. As a consequence, there have been attempts to harmonise legal requirements for aviation from the beginning of aviation on. The International Civil Aviation Organisation (ICAO) was founded in 1944, based on the Chicago Convention. Standards and Recommended Practices are promulgated as Annexes to the convention and provide minimum standards for the ICAO member states. As a quasi European branch of ICAO the European Civil Aviation Conference (ECAC) was founded in 1955 with the scope of a safe, efficient and sustainable growth of European aviation and to harmonise the air traffic policy of the member states.

JAA requirements and their development

Economic needs required further harmonisation of safety procedures and standards in the beginning of the 1970ies. This applied to Certification of big transport aircraft first and extended to Maintenance next. The other regulatory areas of Flight Operation and Licensing – encompassing aeromedical regulations - had to be harmonised as well. The Joint Aviation Authorities (JAA) had been founded with the Cyprus Arrangement of 01. July 1990. The organisation had the legal status of a foundation under Dutch law and was based in Hoofddorp (Netherlands). The member states –membership was open to all ECAC members – committed themselves to develop Joint Aviation Requirements (JARs), adopt and implement them to replace the old national rules. The requirements for Licensing are published as JAR-FCL (Flight Crew Licensing)[4], those dealing with aero medical fitness as JAR-FCL 3 (Medical)[5]. The development of uniform provisions reflected the different national regulation system and health care systems of the member states. Centralised stood versus decentralized aeromedical certification systems, the very rigid, codified, Roman legal system of continental Europe ("If the law does not state you can, then you can't") versus a more flexible legal system based on the Anglo-Saxon common law ("If the law does not state you can't, then you can"), a more strict sys-

tem with a huge array of routine medical testing versus a more liberal system with only a small number of routine tests, based primarily on the medical history.

The translation of the English original documents into the pertinent national languages opened some room for interpretation. There were even differences between the three German translations of Germany, Austria and Switzerland. The JAA member states had committed themselves to implement the harmonised requirements and use them as sole codes. However, this was often not interpreted as mandatory but as optional as the Cyprus Arrangement was seen as a "Gentleman's Agreement". JAA had the legal status of a foundation and no executive powers. Implementation and application of JARs could not be forced, deviations not be sanctioned. They were not binding per se, but by implementation into national law. Standardisation was achieved through audits – in the area of aviation medicine through MEST (Medical standardisation Team) visits)[9].

The development of EASA and its requirements

As the European Commission concluded that JARs had been implemented in different ways was or not at all, it stated that action on Commission level was necessary in the interest of aviation safety. EU Regulation 1592 / 02, the so-called Basic Regulation, tasked the EU – Commission to develop proposals for detailed, uniform and binding requirements by means of a new European Aviation Safety Agency (EASA)[1]. EASA started its activities in September 2003 in Brussels and soon moved to its permanent location in Cologne (Germany). Its basic idea is binding standards and requirements for all member states. The work started with Initial and Continuing Airworthiness (i.e. Certification and Maintenance) and soon it was envisaged to amend EU Regulation 1592/02 to allow for extension of the competencies to Flight Operations and Flight Crew Licensing. Aeromedical Certification is included in the latter. The legal procedures to amend the Basic Regulation – a co-Decision in a trialogue of EU Council, EU Parliament and EU Commission – took until the beginning of 2008. After final adoption by EU Parliament on 13 December 2007 and approval by the EU Council in the beginning of 2008 EU-Regulation 1592/092 was repealed by the new Basic Regulation 216/2008, which was published on 18 March 2008 and applicable from 08 April 2008 on[2].

After some delay and a long period of uncertainty, EASA reached full competency for Aviation Safety in April 2008. According to a road map outlined by the FUJA (Future of JA) report JAA´s major role had already ended in the end of 2006, from the beginning of 2007 it continued as JAA-T (JAA in Transition), providing for a liaison function for those JAA member states not or not yet being members of EU and EASA. However, as EASA did not possess the legal competencies for Rulemaking in the areas of Flight Crew Licensing and Flight Operations yet at that time, the working methods of JAA continued and EASA acted under a mandate of JAA in these areas.

The legal changes comprise – inter alia – in a new architecture and hierarchy of requirements, following the French three-tier system of rules: Basic Regulation with Essential Requirements – Implementing Rules – Acceptable Means of Compliance and Guidance Material. Essential Requirements (ER) outline the scope of the Regulation. The outlines for medical provisions are promulgated in the "ER for Pilot Proficiency". In the drafting process possible hazards had been identified – e.g. age of applicants or conditions limiting their physical or mental performance. The rules had to minimise potential risks but not to exceed this task and thus causing unnecessary restrictions of flying activities. All flight crew have to be mentally and physically fit and not to suffer from diseases or disabilities rendering them unable to safely operate an aircraft and fulfil the tasks of a pilot or their abilities to perceive. Some flexibility is granted as long as flight safety is not jeopardised. The rules for private and recreational aviation are less strict. The roles of Aeromedical Examiners (AMEs) and Aeromedical Centres (AeMCs) are described as well. „Implementing Rules" (IR) are the more detailed requirements and concretise how the Essential Requirements have to be satisfied. Acceptable Means of Compliance (AMC) describe in detail how compliance with the Implementing Rules can be achieved. Guidance Material comprises of detailed standards, numerical limits etc[9].

It was decided not to publish the new Essential Requirements as an addition to the existing EU Regulation 1592 / 02, but as the new Basic Regulation 216/2008 mentioned above. The Implementing Rules for the licensing and medical certification of pilots will be published as a separate Commission Regulation. The actual version of JAR-FCL 3 (Amendment 5) was the basis for drafting the medical requirements included in the Implementing Rules. The work of the pertinent working groups started in November 2006 and ended in autumn 2007. The new proposed provisions have been published as a proposal for a new Commission Regulation on 05 June 2008 for public consultation.

Outline of the future medical requirements

Whereas EU Directives are only applicable within the EU member states after implementation into national law, EU Regulations are directly applicable and supersede national law. EU Regulations have a standard structure: the clauses (starting with the term "Whereas …") describe what the regulation is about; the articles outline the scope of the regulation; the annexes contain the details and are therefore the really interesting part. The medical requirements will be Annex II Part Medical to the Implementing Regulation. It consists of four Subparts. The text is subdivided in paragraphs, numbered by the acronym "MED" for medical, a letter A, B or C for the pertinent Subpart, and a three-digit number. The general provisions for Class 1 (commercial pilots) and Class 2 applicants

are summarised as "Subpart A – General Requirements". "Subpart B – Requirements for Medical Certificates" consists of three sections. Section 1 contains a paragraph with general medical requirements, the specific requirements for Class 1 and Class 2 medical certificates are included in Section 2, Section 3 consists of one paragraph concerning the specific requirements for LPL medical certificates, which comprise of a short instruction for the medical examination of applicants for the future Leisure Pilot Licence (LPL) medical certificates (see below). Subpart C contains the requirements for Aero Medical Examiners (AMEs), Subpart D those for General Medical Practitioners (GMPs), who will be allowed to grant medical certificates for LPL applicants. Similar to Section 2 of JAR-FCL 3 there will be Guidance Material and Acceptable Means of Compliance (AMC). In JAR-FCL 3 Section 2 comprised mainly of syllabi for the training of aeromedical examiners, required forms, information sheets and explanations of applicable limitations. However, the Guidance Material of the proposed Commission Regulation includes the specific standards, numerical limits etc. for each, Class 1 and Class 2, separated. It follows the subdivision of the requirements and is further subdivided in several paragraphs, the headline consists of the title "AMC to …" followed by a letter – "A" indicating that the text relates to the Class 1 requirements and "B" indicating that the text relates to the Class 2 requirements, and finally a three digit number relating to the pertinent paragraph of the requirements. Detailed requirements, questionnaire and explanations for applicants and medical examiners for the future LPL are published as AMC to MED.A.040.

The JAA Manual of Civil Aviation Medicine[3], which encompasses all areas of Aviation Medicine covered by JAA medical requirements and related such as tropical medicine related to aircrews and reflects the "good medical standards" of European Aviation Medicine, is unfortunately not included in the Guidance Material. Furthermore, Guidance Material and Acceptable Means of Compliance may vary between the member states: if a member state or stakeholder can prove that an alternative procedure satisfies the Implementing Rules as well and achieves at least the same level of safety, then this alternative may be applied after EASA´s approval (soft law). The latter changes may result in a lesser level of harmonisation.

Even though the proposals for Authority Requirements will only be published in August 2008, it is foreseen that significant changes will apply to national Authorities. An AMS (Aeromedical Section) as final assessment and control body for aeromedical issues is no more envisaged. The term „ AMS "of JAR-FCL 3 has been replaced by the term "Licensing Authority". As reports of medical examinations will have to be forwarded to the "Licensing Authority" in the future, those medical data have not necessarily to be received and processed by medical personnel, but could potentially be received by non-medical personnel. There could be a collision with „medical confidentiality". Even though there is an EU Directive on "medical confidentiality", this term and the procedures safeguarding it are – different from the requirements and associated procedures of JAR-FCL 3 - not specifically described in the actual proposal. According to a senior representative of EASA, this conflict could probably be solved in the future in the way how it is dealt with in Germany, where there is are very strict legal requirements for medical confidentiality (detailed reports are kept in the medical files with AME or AeMC; only the result of the examination – fit or unfit – is transmitted to the Authority)[7, 9].

The project of a Leisure Pilot Licence

The publication of the proposals for the Essential Requirements for Pilot Licensing induced numerous comments regarding JAR-FCL 3 Class 2 requirements and procedures as too complicated and burdensome for recreational pilots. The EU Commission concluded that the provisions for General Aviation and the aeromedical provisions would be excessive and overly complicated and reacted with the idea to create a set of lighter requirements for General Aviation. The project was initially christened "Recreational PPL" (RPPL), then "Leisure Pilot License" (LPL), replaced by "Light Aircraft Pilot Licence" (LAPL) and finally again LPL. As the licence is sub ICAO it was intended to be applicable in the member states implementing it (implementation was not mandatory) for non-commercial air traffic on non-complex aircraft (< 5, 7 t, < 9 passenger seats, single pilot, no turbo jet engines). The subsequent NPA 14-2006 met a strong public interest; there was a response of more than 8000 comments. After heavy discussions in the public and in the appropriate Authorities the relevant working group MDM.032 changed some aspects: the name was changed, as well as the weight limit reduced to 2 t and the number of passengers to 3. The proposals relate to airworthiness, continued airworthiness and operation of a new group of aircraft – the European Light Aircraft as well. The administration can be delegated to qualified entities and assessment bodies such as national aero clubs[8]).

Many affirmative comments led to the proposal to allow General Medical Practitioners to conduct medical examinations and certify the medical fitness for the LPL. To do so specialisation in General Medical Practice or any relevant speciality relevant to aviation medicine, a training course in aviation medicine and either a one year experience in practicing a speciality relevant to aviation medicine (initially a one year practicing experience in aviation medicine was proposed) or holding a pilot licence are required. Some basic examinations like examination of vision, urine test, blood pressure, whispered voice test and examination of musculoskeletal system and an evaluation of the medical history have to be performed. An extensive questionnaire has to be completed by the examining physician. If all the questions can be

answered satisfactorily then the medical fitness can be certified right away, if not the applicant has to be referred to an AME or Aeromedical Centre (AeMC). The medical requirements and standards are less strict than those for Class 2 applicants. As AMS and Guidance material are subject to "soft law" member states may choose alternatives as long as these alternatives provide for the same level of safety. Furthermore, member states may choose not to implement the PLP at all.

The ongoing rulemaking activities and the role of the public in the development of the future requirements

In the JAA system the provisions have been drafted and amended by standing expert working groups (e.g. aeromedical specialists in the Licensing SubSectorial Team Medical (LSST(M)).The member states and associations of several groups involved in aviation as so-called "stakeholders" had been represented. Thus, the public and groups affected by the requirements participated already in the drafting process (consensus by participation). Where there are different positions and options in contentious issues a system of checks and balances creates more objective and better results according to the theory of cognition. This may be better achieved by bigger working groups representing all the different interests than in very small ones, where the chance of a bias by a one-sided position may be more significant. However, the Rulemaking of EASA involves only small expert working groups. The "stakeholders" can only produce non-binding proposals to the Executive Director of EASA, those affected by requirements can only influence proposals by delivering comments (consensus by consultation). Rulemaking involves some complicated mechanisms. As a consequence the provisions will be more static, a permanent amendment mechanism similar to the JAA Rulemaking system, reacting to experiences in the light of practical application of the rules, is not intended. The new proposals will direct aviation medicine for the years to come. Therefore, the only way to influence the future requirements is to participate in the public consultation[7].

The proposals mentioned above are included in the draft for the Implementing Rules for Pilot Licensing – Part Medical and have been published on 05 June 2008 as NPA 2008 – 17 c[6]. It was anticipated that the public consultation should last until 05 September 2008. However, the period was extended twice, finally until end of February 2009. During this phase the public was invited to deliver comments, proposals for changes and additions (for placing comments see: http://hub.easa.europa.eu/crt/). The comments will be processed in the subsequent three months and the publication of the final version as Opinion of EASA and Decision of the Executive Director of EASA is foreseen in the second half of 2009. After a transition period of four years the changes will be implemented in all EASA member states at latest.

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