



## Notification of Alternative Means of Compliance

**Regulation Reference:** COMMISSION REGULATION (EU) No 1178/2011 Annex: IV Part MED

**Subject:** LAPL Diabetes

**Summary:** The protocol for the management of LAPL certificate applicants/holders with insulin-treated diabetes originally proposed by the UK requires updating following further specialist review panel meetings.

**Implementing Rule: MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates**

### SECTION 3

#### *Specific requirements for LAPL medical certificates*

#### **MED.B.095 Medical examination and/or assessment of applicants for LAPL medical certificates**

- (a) An applicant for an LAPL medical certificate shall be assessed based on aero-medical best practice.
- (b) Special attention shall be given to the applicant's complete medical history.
- (c) The initial assessment, all subsequent re-assessments after age 50 and assessments in cases where the medical history of the applicant is not available to the examiner shall include at least the following:
  - (1) clinical examination;
  - (2) blood pressure;
  - (3) urine test;
  - (4) vision;
  - (5) hearing ability.
- (d) After the initial assessment, subsequent re-assessments until age 50 shall include:
  - (1) an assessment of the LAPL holder's medical history; and
  - (2) the items under paragraph (c) as deemed necessary by the AeMC, AME or GMP in accordance with aero-medical best practice.

SUBPART C

**Existing Acceptable Means of Compliance:**  
**AMC5 MED.B.095 Metabolic and endocrine systems**

**AMC5 MED.B.095 Metabolic and endocrine systems**

- (a) Metabolic, nutritional or endocrine dysfunction  
Applicants with metabolic, nutritional or endocrine dysfunction may be assessed as fit subject to demonstrated stability of the condition and satisfactory aero-medical evaluation.
- (b) Obesity  
Obese applicants may be assessed as fit if the excess weight is not likely to interfere with the safe exercise of the licence.
- (c) Thyroid dysfunction  
Applicants with thyroid disease may be assessed as fit once a stable euthyroid state is attained.
- (d) Diabetes mellitus
- (1) The use of antidiabetic medications that are not likely to cause hypoglycaemia should be acceptable for a fit assessment.
  - (2) Applicants with diabetes mellitus Type 1 should be assessed as unfit.
  - (3) Applicants with diabetes mellitus Type 2 treated with insulin may be assessed as fit with limitations for revalidation if blood sugar control has been achieved and the process under (e) and (f) below is followed. An OSL limitation is required. A TML limitation for 12 months may be needed to ensure compliance with the follow-up requirements below. Licence privileges should be restricted to aeroplanes and sailplanes only.
- (e) Aero-medical assessment by, or under the guidance of, the licensing authority:
- (1) A diabetology review at yearly intervals, including:
    - (i) symptom review;
    - (ii) review of data logging of blood sugar;
    - (iii) cardiovascular status. Exercise ECG at age 40, at 5-yearly intervals thereafter and on clinical indication, including an accumulation of risk factors;
    - (iv) nephropathy/ nephropathy status.
  - (2) Ophthalmological review at yearly intervals, including:
    - (i) visual fields Humphrey-perimeter;
    - (ii) retinas full dilatation slit lamp and documentation;
    - (ii) cataract clinical screening.The development of retinopathy requires a full ophthalmological review.
  - (3) Blood testing at 6-monthly intervals:
    - (i) HbA1c; target is 7,5–8,5 %;
    - (ii) renal profile;
    - (iii) liver profile;
    - (iv) lipid profile.
  - (4) Applicants should be assessed as temporarily unfit after:
    - (i) changes of medication/insulin leading to a change to the testing regime until stable blood sugar control can be demonstrated;
    - (ii) a single unexplained episode of severe hypoglycaemia until stable blood sugar control can be demonstrated.
  - (5) Applicants should be assessed as unfit in the following cases:
    - (i) loss of hypoglycaemia awareness;
    - (ii) development of retinopathy with any visual field loss;
    - (iii) significant nephropathy;
    - (iv) any other complication of the disease where flight safety may be jeopardised.

(f) Pilot responsibility

Blood sugar testing is carried out during non-operational and operational periods. A whole blood glucose measuring device with memory should be carried and used. Equipment for continuous glucose monitoring (CGMS) should not be used. Pilots should prove to the AME or AeMC or licensing authority that testing has been performed as indicated below and with which results.

- (1) Testing during non-operational periods: normally 3–4 times/day or as recommended by the treating physician, and on any awareness of hypoglycaemia.
- (2) Testing frequency during operational periods:
  - (i) 120 minutes before departure;
  - (ii) <30 minutes before departure;
  - (iii) 60 minutes during flight;
  - (iv) 30 minutes before landing.
- (3) Actions following glucose testing:
  - (i) 120 minutes before departure: if the test result is >15 mmol/l, piloting should not be commenced.
  - (ii) 10–15g of carbohydrate should be ingested and a re-test performed within 30 minutes if:
    - (A) any test result is <4,5 mmol/l;
    - (B) the pre-landing test measurement is missed or a subsequent go-around/diversion is performed.

**UK Alternative Means of Compliance:**

**UK AMC5 MED.B.095 Metabolic and endocrine systems**

(a) Metabolic, nutritional or endocrine dysfunction

Applicants with metabolic, nutritional or endocrine dysfunction may be assessed as fit subject to demonstrated stability of the condition and satisfactory aero-medical evaluation.

(b) Obesity

Obese applicants may be assessed as fit if the excess weight is not likely to interfere with the safe exercise of the licence.

(c) Thyroid dysfunction

Applicants with thyroid disease may be assessed as fit once a stable euthyroid state is attained.

(d) Diabetes mellitus

- (1) The use of antidiabetic medications that are not likely to cause hypoglycaemia should be acceptable for a fit assessment.
- (2) Applicants with diabetes mellitus treated with insulin or other medicines that may cause hypoglycaemia may be assessed by, or under the guidance of, the licensing authority as fit with limitations if blood sugar control has been achieved and the process under (3) and (6) below is followed. An OSL limitation is required, unless a medical flight test demonstrates good airmanship, briefing and safe testing procedures in flight for each class/group of aircraft flown. A TML limitation for 12 months may be needed to ensure compliance with the follow-up requirements below.
- (3) Aero-medical assessment in consultation with or on the basis of a report from a diabetology clinic at yearly intervals, including:

- (a) symptom review;
- (b) review of data logging of blood sugar and flying logbook;
- (c) cardiovascular status. To include Exercise ECG on clinical indication, or an accumulation of risk factors;
- (d) neuropathy status
- (e) nephropathy status.
- (f) Ophthalmological status, including:
  - (i) visual fields;
  - (ii) retinal screening; The development of retinopathy requires a full ophthalmological review.
  - (iii) cataract screening.
- (g) Blood test review:
  - (i) HbA1c; target is 7.5–8.5 %; (6-monthly for applicants using insulin)
  - (ii) renal profile;
  - (iii) liver profile;
  - (iv) lipid profile.

(4) Applicants should be assessed as temporarily unfit after:

- (i) changes of medication/insulin regime until stable blood sugar control can be demonstrated;
- (ii) a single unexplained episode of severe hypoglycaemia until stable blood sugar control can be demonstrated and after diabetes specialist review.

(5) Applicants should be assessed as unfit in the following cases:

- (i) loss of hypoglycaemia awareness;
- (ii) development of retinopathy with any visual field loss or reduction in visual acuity below standards;
- (iii) significant nephropathy;
- (iv) any other complication of the disease where flight safety may be jeopardised.

(6) Pilot responsibility

- (a) Applicants with diabetes who are not taking medications likely to cause hypoglycaemia should test their blood sugar prior to flight to ensure that their diabetes remains controlled.
- (b) Applicants with diabetes treated with insulin or other medicines that may cause hypoglycaemia are required to test their blood sugars in flight at times relevant to operations. A SSL MON (Monitoring of blood sugar required whilst exercising licence privileges) limitation is required. A blood glucose measuring device with memory should be used and a spare carried. Equipment for continuous glucose monitoring (CGMS) should not be used unless augmented with standard testing according to the protocol. Pilots should prove to the AME or AeMC or licensing authority that testing has been performed as indicated below and with which results.
  - (1) Testing during non-operational periods: as recommended by the treating physician, and on any awareness of hypoglycaemia.
  - (2) Testing frequency during times relevant to operational periods:

- (i) 120 minutes before departure;
- (ii) <30 minutes before departure;
- (iii) for pilots using any insulin, every 60 minutes during flight; for pilots taking oral potentially hypoglycaemic medications, every 120 minutes during flight
- (iv) within 30 minutes before landing
- (vi) If any diabetic symptoms are experienced

(3) Actions following glucose testing:

- (i) 120 minutes before departure: if the test result is >15 mmol/l, piloting should not be commenced.
- (ii) 10–15g of carbohydrate should be ingested and a re-test performed within 30 minutes if:
  - (A) any test result is <5.0 mmol/l;
  - (B) the pre-landing test measurement is missed or a subsequent go-around/diversion is performed.

**Assessment:**

**Assessed as meeting the Implementing Rule MED.B.095**

Since the UK CAA provided draft protocol material for use as Acceptable Means of Compliance (AMC) and guidance material, further meetings with diabetes specialist advisers have taken place to improve the protocol. In particular the following changes increase the margin of safety regarding risk of hypoglycaemia:

- A requirement to test if any symptoms are experienced
- A requirement to use a memory meter and carry a spare meter
- The lower limit at which pilots are required to ingest glucose tablets has been increased from 4.5 to 5.0 mmol/l

The proposed AMC allows pilots to fly unrestricted rather than OSL subject to a medical flight test to demonstrate safe testing procedures in flight.

Paragraph formatting and numbering have been changed to improve clarity

The minutes of the UK CAA diabetes specialist review panels are attached, together with the position paper of ESAM and UK CAA guidance material and information/briefing sheet.

Approved for submission to the Agency by: *Dr Sally Evans, Chief Medical Officer*

Signature:



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