Protocol for Type 1 Diabetic Pilot Applicants

Requirements for first certification of Class 2 Type 1 diabetics (on insulin)

Exclusion criteria
- The applicant must have had no recurrent (two or more) episodes of hypoglycaemia (resulting in intervention by another party) in the past 5 years and none in the preceding 1 year
- Presence of significant complications such as:
  - Autonomic neuropathy
  - Significant Cardiovascular disease
  - Retinopathy
  - Renal Disease

Information to be provided
- The applicant will be required to provide copies of all medical records as well as aviation accident and incident records pertinent to their history of diabetes.
- A report of a complete medical examination by an Endocrinologist will be required. The report must include, as a minimum:
  - Two measurements of glycosylated haemoglobin (total A1 or A1c concentration and the laboratory reference range), the first at least 90 days prior to the current measurement.
  - Specific reference to the applicant's insulin dosages and diet.
  - Specific reference to the presence or absence of cerebrovascular, cardiovascular, peripheral vascular disease and neuropathy.
  - Confirmation by an ophthalmologist of the absence of clinically significant diabetic eye disease.
  - Verification that the applicant has been educated in diabetes and its control and understands the actions that should be taken if complications, especially hypoglycaemia, should arise.
  - The examining physician must also verify that the applicant has the ability and willingness to satisfactorily monitor and manage his or her diabetes.
  - If the applicant is age 40 or older, a report, with ECG tracings, of a maximal graded exercise stress test.
  - The applicant shall submit a statement from his/her treating physician, aviation medical examiner, or other knowledgeable person attesting to the applicant’s dexterity and ability to determine blood glucose levels using a recording glucometer).
Medical factors considered in CASA’s decision making

- Indicative criteria for blood sugar control that may be considered reasonable for consideration of entry into the following protocol are:
  - HbA1c between 6.5 and 8.0
  - Blood glucose analysis (over a three month period immediately prior to the time of application) indicating:
    - No more than 5% of readings below 4.0 mmol/L
    - 80% of readings must be between 5 and 15 mmol/L

- Other factors that can influence outcomes could include but are not limited to:
  - Excessive frequency of hypoglycaemia or hyperglycaemia
  - Documented hypoglycaemic unawareness
  - Poor treatment compliance

Implications of acceptance of meeting the criteria by CASA

- If applicants meet the above criteria they will be considered by CASA for entry into the protocol cohort on a case by case basis.

- If accepted into the cohort, the applicant will initially be issued a Class 2 certificate valid for flight with safety pilot only. To have the safety pilot requirement removed, the applicant must carry out the in-flight requirements in a two pilot situation for a minimum of 15 flights (details of types of flights and durations will be tailored by CASA to meet individual requirements) and provide the on-ground and in-flight data to CASA for assessment and consideration.

Monitoring and Actions Required During Flight Operations

- To ensure safe flight, the insulin-using diabetic aviator must carry:
  - two recording devices during flight, preferably a Continuous Glucose Monitoring System and a back up glucometer,
  - adequate supplies to obtain blood samples, and
  - amount of rapidly absorbable glucose, in 15 gm portions, appropriate to the planned duration of the flight.

- The aviator must discuss this protocol with his treating physician and obtain advice as to the best combination of food intake/medication that will optimise the glycaemic control without adversely affecting safety.

- The following actions shall be taken in connection with flight operations:
  1. Flight should not commence within 90 minutes of the administration of insulin (either short or long acting types), unless an insulin pump is used.
  2. One-half hour prior to flight, the aviator must measure the blood glucose concentration.
a. If the concentration is more than 15 mmols/l the flight must be cancelled.
b. If it is less than 5 mmol/l the individual must ingest an appropriate (not less than 15 gm) glucose snack and measure the glucose concentration one-half hour later. If the concentration is within 5-15 mmol/l, flight operations may be undertaken. If the blood glucose is less than 5 mmol/l, the process must be repeated; if over 15 mmol/l, the flight must be cancelled.

3. 30 minutes into the flight, and at each successive hour of flight, and within one-half hour prior to landing, the aviator must measure his or her blood glucose concentration.

a. If the concentration is less than 5 mmols/l, a 30 gm glucose snack must be ingested, and arrangements be made to land at the nearest suitable airport and may not resume flight until the glucose concentration can be maintained in the 5-15 mmols/l range.
b. If the concentration is 5-15 mmol/l, no action is required.
c. If the concentration is greater than 15 mmol/l, the aviator must land at the nearest suitable airport and may not resume flight until the glucose concentration can be maintained in the 5-15 mmols/l range (Note 1).

4. In respect to determining blood glucose concentrations during flight, the aviator must use judgment in deciding whether measuring concentrations or operational demands of the environment (e.g., adverse weather, etc.) should take priority. In cases where it is decided that operational demands take priority, the aviator must ingest a 15 gm glucose snack and measure his or her blood glucose level 1 hour later. If measurement is not practical at that time, the aviator must ingest a 30 gm glucose snack and land at the nearest suitable airport so that a determination of the blood glucose concentration may be made.

**Ongoing requirements for any subsequent Medical Certification**

1. For documentation of diabetes management, the applicant will be required to carry and use two whole blood glucose measuring devices with memory function and must report to the CASA immediately any hypoglycaemic incidents requiring external assistance, any involvement in accidents resulting in serious injury (whether or not related to hypoglycaemia), and any evidence of loss of control of diabetes, change in treatment regimen, or significant diabetic complications. With any of these occurrences, the individual must cease flying until cleared by the CASA.

2. At 3-month intervals, the aviator must be evaluated by the treating endocrinologist. This evaluation must include a general physical examination, review of the interval medical history, and the results of a
test for glycosylated haemoglobin concentration. The endocrinologist must
review the record of the aviator’s daily blood glucose measurements and
comment on the results (the blood glucose measurements must be done at
least 4 times every day). The results of these quarterly evaluations must be
accumulated and submitted annually unless there has been a change in the
treatment regime, or if the endocrinologist’s review is indicative of a
deterioration of control. The results must include a downloaded set of
blood sugar readings to be analysed to identify “high” and “low” readings
outside the physiological range (See indicative criteria above. If there has
been a change the individual must report the change(s) to the CASA and
wait for an eligibility letter before resuming flight duties).

3. On an annual basis, the reports from the examining endocrinologist must
include confirmation by an eye specialist of the absence of significant eye
disease.

4. At the first examination after age 40 and at 5-year intervals, the report,
with ECG tracings, of a maximal graded exercise stress test must be
included in consideration of continued medical certification.

5. The record of all in-flight measurements and log book entries for all flights
undertaken since the last certificate must be provided to CASA at the time
of all subsequent medical certifications.