

## AMENDMENT OF TECHNICAL STANDARDS

The Director of Civil Aviation hereby amends the technical standard relating to SA-CATS-MR. The Director is satisfied that the amendment of the technical standard as aforesaid is in the interests of aviation of safety. The stated amendment to the technical standard as contained in the Schedule shall come into operation on 01 October 2010.



**Capt. Colin Jordaan**  
**Director of Civil Aviation**

Date: 27/9/10

### SCHEDULE 1.

#### INSERTION OF PROTOCOL ON DIABETIS MELLITUS

The following protocol is hereby inserted in Document SA-CATS-MR:

##### “Diabetes Mellitus Protocol

###### 1. General

Aviation medical standards as laid down in Annex 1 of the convention on International Civil Aviation by the International Civil Aviation Organization to which South Africa is a contracting State, have identified broad medical conditions that, on the basis of expected risk of incapacitation, disqualify aviation personnel from flying.

South Africa is one of the countries that previously applied strict standards to applicants with a history of Diabetes Mellitus on Insulin. The previous protocol did not take into consideration new therapeutic interventions, risk factor modification or rehabilitation, all of which reduced the risk of sudden incapacitation

The SACAA has since reviewed this protocol, and is now making provision for aviation personnel with a history of Type II Diabetes Mellitus on Insulin to apply for the privileges of the license they wish to apply for. This consideration will be based on the individual medical condition of the applicant and risk factor involved.

###### 2. Background

Diabetes is defined as a metabolic disease with some genetic predisposition; it is characterized by an impaired ability to break down, store and utilize carbohydrates

effectively. This may be due to failure of production of insulin from the beta-cells in the islets of Langerhans in the pancreas or the presence of insulin resistance impeding the action of the endogenously produced hormone. Diabetes is divided into two categories; Type I Diabetes Mellitus, formerly "childhood, juvenile or insulin-dependent" diabetes islet cell failure (possibly autoimmune) destruction insulin-producing B cells pancreas, significant insulin deficiency; require Insulin. Type 2 (non insulin dependent diabetes) insulin resistance due to impaired insulin secretion ("burn out" b cells), insulin resistance (peripheral insulin receptors), and increased hepatic glucose production, may or may not require insulin. From a number of studies, the risk factors for severe hypoglycemia include previous hypoglycemia, long duration of diabetes and impaired hypoglycemic awareness. The risk to flight safety is greater in Type 1 Insulin-treated Diabetic patients than for Type 2; it is therefore recommended that Type 1 applicants should, with current treatment and level of knowledge, be precluded from obtaining a medical certificate.

The methods used to treat diabetic patients have improved over recent years, and individuals that require insulin to maintain satisfactory blood glucose levels may apply, or re-apply, for a license to fly or to undertake air traffic control work. The key areas of concern in certificating aircrew with insulin treated diabetes mellitus are hypoglycemia and the enhanced risks of micro- and macrovascular disease.

### **3. Estimated Incapacity Risk**

Using data from literature review, the rate of severe hypoglycemia using, i.e. hypoglycemia requiring the help of another in Type 2 treated Insulin, is of the order of 3% per annum. These data comes from a hospital population, and is not representative of the pilot population, who are highly selected, well motivated, and may be meticulous in managing their Diabetic.

### **4. General medical examination requirements applicable to all applicants**

All Initial applicants must submit their medical reports to the medical panel for assessment.

Applicants are required to monitor their blood glucose frequently, including daily fasting glucose measurements.

Extra snacks and glucagon should be readily available.

Applicants are required to test and record blood glucose levels before and during all flights and present the information to the SACAA on a six monthly basis.

### **5. Protocol for Diabetes Mellitus Type II controlled on Diet and Exercise**

A blood glucose test is not a routine part of the SACAA medical evaluation, however; the examination includes routine urine test. Applicants with a history of diabetes mellitus controlled on diet alone are considered medically fit for all the classes of medical certificates, provided that they have no evidence of associated disqualifying cardiovascular, neurological, renal, or ophthalmological disease. These applicants are required to submit an annual comprehensive endocrinologist/physician report.

## **6. Protocol for Diabetes Mellitus Type II Medication controlled-Except Insulin**

Applicants requiring oral hypoglycemic agents to control their blood glucose may be assessed as fit for all categories of license, provided they have no cardiovascular, neurological, ophthalmological or renal complications of diabetes, or any condition which could result in sudden or subtle incapacitation while exercising the privileges of their license.

## **7. Acceptable Oral Medication**

- Biguinoides
- Arcabose
- Thiozolidenediones

## **8. Initial follow up for medical certification**

Following initiation of medication, applicant's medical certificate will be withdrawn for a period of three (3) months; this is to ensure stabilization, adequate control, the absence of side effects, or complications from side effects. Should the applicant's medication be changed, a comprehensive endocrinologist report indicating the reason to change the medication and stating the name of the new information will be required.

The following conditions must be adhered to:

- An initial report from a treating physician, confirming no complications of diabetes including cardiovascular, neurological, ophthalmological or renal complications of diabetes;
- A statement regarding medication used dosage, presence or absence of side effects or complications, clinical significant episode of hypoglycemia and an indication of a satisfactory of the diabetes;
- Annual cardiovascular assessment such as symptom limited exercise ECG and clinical review by cardiologists.
- The applicant must not experience any adverse symptoms or effects from the oral hypoglycemic agent; or

- The applicant may not use any medication interacting with the oral hypoglycemic agent.
- Glucose: Fasting, Post-prandial peak < 6.7 mmol/L < 9.0 mmol/L
- HbA1c < 7.0% with risks, HbA1c <7.5% with no other risk factors
- Blood pressure 130/80 mmHg
- Total cholesterol < 4.8 mmol/L, LDL-C < 2.5 mmol/L, Triglycerides < 2.3 mmol/L and HDL-C > 1.0 mmol.

## **Protocol for Diabetes Mellitus Type II on Insulin treatment**

### **Applicability**

#### **Class I**

#### **Operational Restrictions**

#### **CLASS I**

ATP/Commercial with a Multicrew – As / or with a co-pilot only, restricted to fly in the SA airspace only.

#### **Class II**

Only applicable to Cabin Crew, this protocol is currently not applicable to Private Pilots and Students Pilots.

#### **Class III**

**ATC-**Required informing their supervisors of the medical condition.

#### **Class IV**

Protocol not applicable to Class IV applicants

### **Initial follow-up for medical certification**

The applicant must have been on insulin for a minimum of one year and the dosage should have been stable for at least six months, this is to ensure stabilization, adequate control, the absence of side effects, or complications from side effects.

An initial report from a treating physician, confirming no complications of diabetes including cardiovascular, neurological, ophthalmological or renal complications of diabetes should be submitted.

The following considerations must be adhered to:

- The applicant will be required to carry and use a blood glucose monitoring device with memory and report to the treating physician any hypoglycemic incidents.
- The applicant must not have a history of hypoglycemic episode requiring intervention of another party, during the previous one year.
- Applicant must have no history of recurrent (2 or more) hypoglycemic reactions resulting in a loss of consciousness or seizure within the past 5 years.
- Applicants must have no evidence of hypoglycemic unawareness, and a good diabetes education and understanding.
- Applicants are required to have a Stimulated C-Peptide levels > 25% of normal.
- Applicants are required to have a satisfactory HbA1c of 7-7.5% within the past 30 days.
- Positive attitude - monitoring and self-care.
- Applicants are required to have adequate blood glucose self-monitoring using a calibrated memory chip glucose meter.
- Applicants are required to maintain 90% of blood glucose measurements >5.5mmol/L

### **Annual follow-up for medical certification**

The applicant will be required to carry and use a blood glucose monitoring device with memory and report to the treating physician any hypoglycemic incidents.

Quarterly (3 monthly) interval evaluation reports by treating physician for-

- Physical examination
- HbA1c
- Review of daily blood glucose measurements.

Results of the quarterly evaluations must be accumulated and submitted annually to the medical panel.

Glucose: Fasting, Postprandial peak < 6.7mmol/l < 9.0mmol/l respectively

HbA1c <7.0% with risks, HbA1c < 7.5% with no other risk factors

Blood pressure 130/80 mmHg

Total cholesterol <4.8mmol/L, LDL-C < 2.5mmol/L, Triglycerides< 2.3mmol/L and HDL-C > 1.0mmol/L

Annual cardiovascular assessment such as symptom limited exercise ECG and clinical review by cardiologist.

Annual report from a treating physician to confirm no complications of diabetes including renal, neurological and visual complications.

### **Monitoring and Actions required during Flight Operations**

A regularly calibrated glucometer with a memory chip and 10 g portions of readily absorbable carbohydrate (cho) should be included on the treatment pack to cover duration of flight.

Applicants must measure blood glucose prior to flight, blood glucose must be  $> 6.0\text{mmol/L}$  .

During flight, the applicants blood glucose should be monitored every 30 – 60 minutes, if the blood glucose  $< 6.0\text{mmol/l}$ , then 10 g absorbable carbohydrate ingested.

The frequency of glucose monitoring on flight duty periods over two hours may be reduced depending on the individual circumstances, in consultation with the endocrinologist and the designated aeromedical committee.

Applicants involved in short haul operation, are required to monitor their blood glucose at midpoint of flight. Blood sugar will fluctuate slightly - over one - two hours.

Applicants presenting with blood glucose of  $>15\text{mmol/l}$ , appropriate corrective measures should be applied.

Blood glucose should be monitored 30-45 minutes prior to landing, should measurement reading fall  $<6.0\text{mmol/l}$ , 10 g of cho consumed.

The crew members would need to be made aware of the potential for hypoglycemic events because of his insulin use and should be trained on management strategies.

Applicants are required to test and record blood glucose levels before and during all flights and present the information to the SACAA on a six monthly basis.

### **Acceptable Insulin**

Basal Insulin

Bolus Insulin