

# Federazione ATM-PP's comment and review proposal to NPA 2012-18 para 224 and "Diabetes protocol"

# *FOREWORD*

*Since the discover of insulin in Toronto in 1923 great progress has been made in the treatment of diabetes mellitus. In the last years control of this condition has improved dramatically with the development of patient operated computer chip glucose meters and patient education. Diabetic patients in Europe are followed and monitored by the diabetes care team and are normally educated about their condition and how to deal with any problems related to it. Blood test to assess long term control such as glicated hemoglobin (HbA1C), also have made it much easier to make alteration to diet, exercise, insulin or hypoglycemic medication dosage for optimum control.*

# *INTRODUCTIONS*

*The present situation for Air Traffic Controllers with Diabetes is that he can be assessed as fit if able to control blood sugar level only with diet or specific oral medications. ATCOs with insulin treated diabetes mellitus (ITDM) shall be assessed as unfit.*

*At present ICAO Annex 1 and "The EUROCONTROL Guidelines" specified that "applicants with diabetes requiring insulin or medication that can induce hypoglycemia shall be assessed as unfit". These documents also admit that "It was agreed that medical requirements would be regularly audited to ensure that they remain pertinent and necessary*
*and would be revised and updated as appropriate, in line with developments in aviation medicine and the Air Traffic Services (ATS) environment".*

*Medical knowledge and the experience in other countries such as USA and Canada, demonstrates that the risk of hypoglycemia in persons treated with insulin or oral medications can be reduced to an acceptable level by close monitoring, insulin analogues, subcutaneous insulin infusion, control of blood sugar level by that person and the ability of hypoglycemia awareness. Blood sugar test involves a small finger prick to produce a drop of blood that is then applied on a test strip. It takes between 20 and 60 seconds and does not affect the operational safety.*

*European laws recognize the right for diabetics of equal dignity and opportunity in the workplace and without doubt, for an ATCO being involved in operational tasks would increase the motivation to better control his condition with advantages in the medium and long terms. Diabetes is booming and it is estimated that in a short time will affect more than 6% of the population but we cannot overlook the fact that medicine has invested many resources to allow diabetics to lead an almost normal life.*

*EASA has proposed a protocol to mitigate the risk of incapacitation due to hypoglycemia. It is attached as APPENDIX I to the Explanatory Note of NPA 2012/18.*

*IN PARAGRAPH 224 OF THE ABOVE MENTIONED DOCUMENT STAKEHOLDERS ARE INVITED TO PROVIDE OPINIONS ABOUT MEDICAL CERTIFICATION OF ATCOs WITH INSULIN TREATED DIABETES OR USING MEDICATIONS THAN CAN INDUCE HYPOGLYCEMIA, INCLUDING PROPOSED MITIGATION MEASURES AND PROVIDING JUSTIFICATION ON THE POSSIBLE SAFETY, SOCIAL AND ECONOMIC IMPACT OF THE PROPOSAL, SUPPORTED BY MEDICAL EVIDENCE.*

***In this document the EASA proposal is in blue characters. Our proposed changes or integrations are in black characters.***

# *EASA "Diabetes Protocol"*

***I. Diabetes protocol***

*Referred to in paragraph 224 of this document.*

***ATCO.MED.B.025 Metabolic and endocrine systems***

*(a) …*

*(b) Diabetes mellitus*

*(1) Applicants with diabetes mellitus requiring medication for blood sugar control shall be referred to the licensing authority. A fit assessment may be considered in individual asymptomatic cases depending on the medication used and if it can be demonstrated that blood sugar control has been achieved and is stable.*

*(2) Limitation(s), including safe blood sugar testing whilst exercising license privileges, should be considered by the licensing authority.*

***AMC1 ATCO.MED.B.025 Metabolic and endocrine systems***

*(b) Diabetes mellitus*

*Subject to at least annual specialist assessment, absence of complications likely to interfere with license privileges, evidence of good control of blood sugar with no significant hypoglycaemic episodes, applicants with diabetes mellitus:*

*(1) not requiring medication may be assessed as fit by the AME or AeMC;*

*(2) requiring the use of antidiabetic medications other than insulin that are not likely to cause hypoglycemia may be assessed as fit by the licensing authority;*

*(3) requiring the use of potentially hypoglycemic medication(s), may be assessed as fit by the licensing authority with limitation(s), including documented testing whist exercising license privileges.*

***GM1 ATCO.MED.B.025 Diabetes mellitus***

*(a) Applicants with diabetes mellitus should have their condition under regular specialist follow-up that should include screening for complications of the disease. A fit assessment following diagnosis, or after any treatment change, may be considered once good blood sugar control is demonstrated. Applicants should use blood glucose testing devices that have memory and download capability. Overall stability of control is evidenced by the HBA1c level remaining in the appropriate therapeutic range. Individuals with ITDM or using medication that can induce hypoglycemic reactions, who have no other disqualifying condition, especially significant diabetes related complications such as arteriosclerotic coronary or cerebral disease, or retinal disease, will be eligible for a Special Consideration if they:*

1. *Have no complications of diabetes mellitus likely to interfere with their ability to safely control air traffic; or*

2. *Have had no hypoglycemic reaction resulting in impaired cognitive function, without warning symptoms, loss of consciousness, seizure or requiring intervention by another party during the last five years.*

*To provide an adequate basis for an individual medical determination, an individual using medications that can induce hypoglycemic reactions shall submit the following information to the AMC:*

1. *a copy of hospitalization records if admitted for any diabetes-related cause, including accidents and injuries;*

2. *complete reports explaining any aircraft, automobile or other incidents or accidents if diabetes related;*

3. *results of complete medical evaluation by an endocrinologist or diabetes specialist concerning the individual's medical history and current status. The report must include general physical examination and , at a minimum, the following information:*

    - *two readings of glycated hemoglobin during the last three months (three months prior and current);*
    - *confirmation by specialist of the absence of significant retinal disease;*
    - *examination and tests to detect any peripheral neuropathy or circulatory deficiencies of the extremities, when symptomatic;*
    - *a detail report of insulin dosages, types, and diet utilized for control*
    - *declaration by a specialist that the individual has been educated in diabetes and its control and has been informed of, and understand, the monitoring and management procedures for the condition and the actions that should be followed if complications, including hypoglycemia, arise.*

4. *when the individual is first started on insulin treatment, the ATCO must be reassigned to a non- safety related duties for three (3) months or until criteria for acceptable blood glucose regulations are met.*

*b. Screening for complications should occur at every specialist review or at least 6-monthly. In addition, where operational testing is required, evidence of compliance with the relevant protocol should be demonstrated to the AME or AeMC. The test meter memory will be periodically reviewed by an AMC or the Civil Aviation Authority to ensure the adherence with the measurement protocol. A failure to demonstrate the compliance with the schedule of testing will result in suspension of the medical certificate.*

*c. Certification of applicants with diabetes*

| *type of diabetes & treatment* | *limitations* | *operational blood test requirement* |
|---|---|---|
| *Type 1 or 2, insulin* | *SSL, ILA, MON, APC* | *Schedule ATCO A* |
| *Type 2, sulphonylureas (or any combination therapy that includes sulphonylureas)* | *SSL, MON, APC* | *Schedule ATCO B* |
| *Type 2, all non-sulphonylureas and non-insulin treatment* | | *Schedule ATCO C* |
| *Type 2, diet only* | | *none* |

*Abbreviations:*

- *SSL , special restrictions as specified;*
- *ILA, issued by the licensing authority in accordance with ATCO.MED.B.001;*
- *MON, monitoring of blood sugar required whilst exercising license privileges;*
- *APC, another qualified ATCO in close proximity to certificate holder able to take over duties without delay.*

*d. TESTING PROTOCOL*

| *Testing protocol* | *Minimum frequency of testing – operational period* | *actions* |
|---|---|---|
| *ATCO - A* | • *120 minutes before shift*<br>• *< 30 minutes before shift*<br>• *Every 60 minutes (120 minutes) during shift*<br>*(30 minutes if BG< 4 mmol/l – 72 mg/dl)*<br><br>*If diabetic symptoms are experienced.* | *If > 16 mmol/l – 290 mg/dl not commence duty.*<br>*If BG is < 5 mmol/l – 90 mg/dl ingest 10-15 g of rapidly absorbable glucose. Retest after 30 minutes.*<br>*If a measurement is missed for operational reasons, 10-15 g of carbohydrates should be ingested.* |

| | | |
|---|---|---|
| | | *Retest after 30 minutes.*<br>*No two consecutive test may be replaced by ingestion of glucose.* |
| *ATCO - B* | *See ATCO - A* | *See ATCO - A* |
| *ATCO - C* | *2 hours before shift* | *If > 16 mmol/l – 290 mg/dl not commence shift or cease carbohydrate ingestion until BG reduces.*<br>*If < 6 mmol/l – 90 mg/dl ingest 10-15 g of glucose or carbohydrate. Retest after 30 minutes* |

*Controllers have to declare that taking of medication and testing during duty period do not affect operational safety. These activities could be carried out during scheduled breaks within the shift.*

***d. guidelines for Individuals who have been granted special consideration for air traffic control duties.***

*Diabetic ATCOs must carry and use:*

- *a digital, whole blood glucose monitoring device with memory and associated supplies;*
- *a source of rapidly absorbable glucose;*
- *insulin and syringes or pump as appropriate and associated supplies.*

*Records of blood glucose measurements must be provided to a specialist or to a Civil Aviation Authority Inspector when requested. All materials must be in their expiration dates. Material is realized in order to be disposed of in the normal unsorted municipal waste.*

***e. Guidelines for Supervisor/colleague of Diabetic ATCOs***

*At the beginning of the shift, Air Traffic Controllers with diabetes are required to identify themselves to the Supervisors/colleagues. Colleagues should be informed about symptoms of diabetes.*

*The symptoms of low blood sugar (hypoglycemia) includes:*

- *sweaty, pale skin;*
- *mood changes;*
- *poor concentration, distraction;*
- *confusion.*

*The symptoms of high blood sugar (if level greater than 20 mmol/l – 360 mg/dl) includes:*

- *thirst;*

- *excess urine output;*
- *dehydration;*
- *mood changes;*
- *excessive tiredness/sleepy;*
- *blurred vision.*

*Symptoms or behavior of diabetes should be dealt with in the same way as any other presenting acute medical condition in a crew member.*

*f. Medical assessment and surveillance requirements.*

| | ***Diet only or non-hypoglycemic medication*** | ***Potentially hypoglycemic medication*** |
|---|---|---|
| *Review of clinical repors, data logging of operational blood sugars and review of duty log.* | ***6 monthly*** | ***6 monthly*** |
| *Reporting of symptoms* | *mandatory* | *mandatory* |
| *1c*<br>*Renal and liver profiles*<br>*Lipids* | *6/12* | *3/12* |
| *Specialist diabetology review including:*<br>• *symptoms review;*<br>• *cardiovascular status/risk;*<br>• *nephropaty status;*<br>• *neuropathy status;*<br>• *ophthalmic screening* | *12/12* | *6/12* |
| *Exercice test* | *iagnosis*<br>*ıal over 40* | *iagnosis*<br>*ıal over 40* |

*g. Target range of clinical variables*

| *Variable* | *target* | *unfit* |
|---|---|---|
| *HbA1c* | *7.5%(see note below)-8.5%* | *10 %* |
| *Systolic BP* | *< 140* | *>160 mmHg* |

| | | |
|---|---|---|
| | *mmHg* | |
| *Diastolic BP* | *< 90 mmHg* | *>95 mmHg* |
| *Cholesterol* | *4.0 – 4.5 mmol/l* | *n/a* |

***Note: this value of HbA1c is considered to correlate with average estimated glucose level of 9.2 mmol/l (165 mg/dl). Lower levels of HbA1c should not be considered disqualifying if adherence to the testing protocol is demonstrated particularly with regard to hypoglycemic events.***

*h. fitness/unfitness status*

- *medication type or regime change (where change necessitates a change to the testing regime – 2 months unfit) (three months unfit or until criteria for acceptable blood glucose regulations are met);*
- *episodes of severe hypoglycemia (requiring intervention of another party or without warning symptoms). Specialist review required. Further operational restriction likely to be appropriate;*
- *development of retinopathy requires full ophthalmological assessment and is likely to result in further restriction or unfitness especially if there is any field loss;*
- *presence of significant nephropathy significantly increases cardiovascular risk is likely to entail unfitness.*

***CONCLUSIONS***

*It has long been a controversial issue whether or not to provide medical certification to diabetic ATCOs and Pilots. Civil Aviation Authority in USA and Canada permit to ATCOs with diabetes mellitus to work on a case by case basis and under strict control.*

*The aero-medical discussion concerning Air Traffic Controller treated with potentially hypoglycemic medication are focused on the possible conflict between the requirement of sufficiently high blood glucose levels to prevent on-shift hypoglycemia as opposed to intensive glucose lowering treatment aimed at prevention of micro and macrovascular complications of disease but the risk of hypoglycemia can also be reduced with insulin analogues, continuous subcutaneous insulin infusion, frequent blood glucose monitoring and the ability of hypoglycemia awareness. We are talking of medications and practices accessible to everybody in Europe.*

*We can say for sure that in Europe diabetic patients are usually properly followed and informed about what actions to take to deal with any problems related to diabetes. The blood glucose measurement electronic device with memory allow, if necessary, simply having a computer with internet connection, to transfer via email the latest measurements made at the AMC to verify the adherence to the "protocol".*

*Is now diffused opinion that the difficulties of people with diabetes in the workplace and by extension in the aeronautic field, is a cultural problem more than medical. That's why the medical knowledge permits to well balanced diabetic patients to lead an almost normal life.*

*There is no doubt that the obligation of adherence to the protocol by the diabetic operator raises the motivation to take care of his condition with advantages in the medium/long term.*

*On social level the benefit of using the full capabilities of the worker with the operational tasks for which it was formed is evident.*

*In a transitional experimental phase, controllers with diabetes, on voluntary basis, could be used in "double-control" with ATCOs Instructor, at no cost for the providers and under strict medical supervision, in order to demonstrate that there is no impact of their condition on operational safety.*

***Our opinion is that following the "Diabetes Protocol" and with the appropriate level of monitoring to ensure safety standards are met, it is right that ATCOs with diabetes are allowed to contribute their valuable skills and knowledge in their chosen field.***

# *REFERENCES*


- *European Aviation Safety Agency – Notice of Proposed Amendment NPA 2012/18 "Licensing and medical certification of traffic controllers";*
- *European Aviation Safety Agency – explanatory note to NPA 2012/18 – appendix I "DIABETES PROTOCOLS";*
- *"Certificatory Assessment and Surveillance – consideration for applicants with diabetes" – the UK draft protocol (dr.Stuart Mitchell, Head of Authority Medical Section, CAA UK);*
- *CAA UK - "UK CAA Briefing sheet: certificate holders with diabetes treated with potentially hypoglycemic medication";*
- *U.S. Department of Transportation – Federal Aviation Administration – order 3930.3b 20/07/2012 – Appendix B – Insulin treated diabetes mellitus, guidelines for initial evaluation of Air Traffic Controllers with Insulin Treated Diabetes Mellitus (ITDM);*
- *Handbook for Civil Aviation Medical Examiner – "Canadian guidelines for the assessment of medical fitness in pilots, flight engineers and air traffic controllers with diabetes mellitus" – 03/2004;*
- *ESAM – European Society of Aerospace Medicine – "Insulin treated diabetic pilot applicants: recommendation. Position Paper of the European Society of Aerospace Medicine", Ries Simons on behalf of the ESAM Advisory Board – 11 march 2012*
- *Flight Safety Foundation, Human Factors & Aviation Medicine "U.S. considers authorizing pilot medical certification for insulin taking diabetics. Pag. 1 "Air Traffic Controllers Certification" – nov-dec 1995;*
- *EUROCONTROL – "Requirements for European Class 3 Medical Certification of Air Traffic Controllers";*
- *International Civil Aviation Organization – "ICAO annex I".*


**Federazione ATM-PP**