

PROPOSAL FOR THE AMENDMENT OF DOCUMENT SA-CATS 67 ISSUED UNDER THE CIVIL AVIATION REGULATIONS, 2011

PROPOSER

SACAA

Private Bag X73

Halfway House

1685

PROPOSER'S INTEREST

The proposer has been established in terms of the Civil Aviation Act, 2009 (Act No. 13 of 2009), to control and regulate civil aviation in South Africa and to oversee the functioning and development of the civil aviation industry, and, particularly, to control, regulate and promote civil aviation safety and security.

GENERAL EXPLANATORY NOTE

1 PROPOSAL FOR AMENDMENT OF DOCUMENT SA CATS 67

1.1 Document SA CATS 67 is hereby amended by:

(a) the deletion in Schedule 31 of section 6 of the following section:

“[6. *Prostate Cancer*

A. General

- (i) **A diagnosis of prostate cancer is disqualifying and upon diagnosis, the applicant shall be deemed medically unfit to exercise the privileges of the class of the license they hold until proper treatment has been instigated, and the applicant is fully recovered and disease free.**
- (ii) **The outcome of prostate cancer varies greatly.**
- (iii) **It is mostly affected by whether the cancer has spread outside the prostate gland and how abnormal the cancer cells are (the Gleason score) upon diagnosis.**
- (iv) **Many patients with prostate cancer that has not spread can be cured, as well as some patients whose cancer has not spread very much outside the prostate gland.**
- (v) **Even for patients who cannot be cured, hormone treatment can extend their life by many years.**

B. Medical Requirements:

- (i) Cancer of the prostate has a generally good prognosis, and tends to metastasize locally or to bone.
- (ii) Once primary treatment has been completed, unrestricted certification will be possible where:
 - (1) There is no evidence of metastatic spread
 - (2) PSA has returned to acceptable limits
 - (3) There are no significant consequences of treatment, such as incontinence.
- (iii) The following examinations and procedure reports are required before the applicant's case can be considered with regard to medical certification/recertification:
 - (1) Specialist report, which must include clinical staging and/ or with Gleason score.
 - (2) Histology report.
 - (3) Blood test results: PSA (usually every 3 months to 1 year)
 - (4) Initial radiological reports, CXR/Bone scans/CT/MRI (done during diagnosis or staging)
 - (5) Should there be metastatic spread which has been controlled and PSA has returned to less than 10, a restricted certification may also be considered.
 - (6) Should the medical waiver be granted in cases of metastatic spread mentioned above, the follow up medical examinations and reports must be accompanied by a:
 - (a) Six (6) monthly progress reports from the treating specialist for at least 5 years (for cancer confined to the prostate) and 10 years (for metastatic cancer).
 - (b) Annual PSA level for at least 5 years (for cancer confined to the prostate) and 10 years (for metastatic cancer)

C. Restrictions in case of metastasis mentioned above:

- (i) License holders will be required to operate under a multi-crew environment, as or with co-pilot, or under-supervision (depending on their environment) etc., until the aeromedical risk has been assessed and deemed favourable for the restriction to be lifted.
- (ii) The cases of prostate cancer where the surgical operation is not performed will be dealt with on a case by case basis.]

(b) the insertion in after Schedule 31 of the following schedule :

“SCHEDULE 31A: PROTOCOL ON PROSTRATE CANCER

1. Applicability

- (1) This protocol is applicable to an applicant or a holder of Class 1, 2, and 3 medical certificate.

2.General

- (1) A diagnosis of prostate cancer is disqualifying and upon diagnosis, an applicant or a holder of a medical certificate shall be deemed medically unfit to exercise the privileges of the class of the license until such an applicant or a holder of a medical certificate undergoes appropriate treatment, the condition have been investigated , and an applicant or holder of medical certificate is fully recovered and disease free.
- (2) The outcome of prostate cancer varies greatly, it is mostly affected by whether the cancer has spread outside the prostate gland and how abnormal the cancer cells are (the Gleason score) upon diagnosis.
- (3) Many patients with prostate cancer that has not spread can be cured, as well as some patients whose cancer has not spread very much outside the prostate gland.
- (4) Even for patients who cannot be cured, hormone treatment can extend their life by many years.

3. Initial requirements following diagnosis.

- (1) An applicant or holder of a medical certificate shall be declared medically unfit on diagnosis pending receipt of satisfactory reports;
- (2) An applicant or holder of a medical certificate shall submit Urologist report;
- (3) Urologist report to include:
 - (a) The grading of the cancer using (Gleason score); Grade group score;
 - (b) The cancer must be staged using T and N staging and consideration should include mut not limited to :extracapsular extension, seminal vesical involvement or nodal disease if noted on MRI imaging;
 - (c) For localised disease indicate risk grouping as per recent (National Comprehensive Cancer Network) NCCN guidelines and the International prostate symptom score should be applied;
 - (d) For an assessment and exclusion of any distant spread, the following imaging reports must be submitted , Computerized Tomography Scan (CT) ,CAP(is this for prostate cancer or what does CAP stand for) , Bone scan, Prostate-Specific

Membrane Antigen Positron Emission Tomography (PSMA PET) and a Magnetic Resonance Imaging (MRI);

- (e) Pre and post treatment Prostate Specific Antigen (PSA) and baseline and follow up PSA dated;
- (f) Treatment, including dates and prognosis; and
- (g) A follow-up plan shall include clinical Urological reviews, Prostate Specific Antigen tests, imaging (is this not repetition, imaging and PSA is already mentioned above).

3. Requirements for Recertification:

- (a) An applicant or holder of medical certificate must not be on radiotherapy or systemic chemotherapy.
- (b) An applicant or holder of medical certificate shall submit a satisfactory treatment response, demonstrated by decrease in Prostate Specific Antigen (PSA).
- (c) An applicant or holder of medical certificate must be fully recovery from treatment and there must be no symptoms or complications that may affect flying.
- (d) The time for consideration of recertification of the applicant or holder will depends on treatment received and evidence that active surveillance requirements are through demonstration based on the following :
 - (i) a minimum 3 monthly specialist(urologist) reviews with PSA tests, multi-parametric Magnetic Resonance Imaging (MRI) results and repeat biopsy if undertaken;
 - (ii) follow-up reports to be submitted to the Medical Assessor for Class 1 and Class 2;
 - (iii) an applicant or holder of medical certificate with poor performance status, elderly with multiple co-morbidities and reduced life expectancy watchful waiting reserved.

4.Time to recertificate after treatment

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|-------------------------|--|---------------------|----------------------|----------------------------|
| <u>TREATMENT</u> | <u>Prostatectomy Transurethral resection of the prostate</u> | <u>Radiotherapy</u> | <u>Brachytherapy</u> | <u>Hormone Therapy</u> |
|-------------------------|--|---------------------|----------------------|----------------------------|

| | | | | |
|-----------------------------|--|--|---|---|
| | <u>(TURP/ Radical)</u> | | | |
| <u>REQUIREMENTS</u> | <u>Minimum 6 weeks after surgery</u> | <u>Minimum 4 weeks after last dose</u> | <u>Minimum 6 weeks after insertion of therapy</u> | <u>Minimum 4 weeks:On maintenance dose,stable,with no side effects reported</u> |
| <u>CERTIFICATION</u> | <u>Unrestricted</u> | <u>Unrestricted</u> | <u>Unrestricted</u> | <u>Unrestricted</u> |

5. Restrictions

(1) Class 1

- (a) An applicant or holder of medical certificate receiving curative treatment => Unrestricted medical certificate.
- (b) An applicant or holder receiving palliative treatment => Restricted Multicrew Certificate.

(2) Class 2 - unrestricted

6. Follow-Up Reports

- (1) Applicant or holder of medical certificate must submit an annual Urologist/ Oncologist report;
- (2) Applicant or holder of a medical certificate is unfit if there is evidence of local recurrence, metastatic disease or biochemical failure suggesting recurrent disease;
- (c) the substitution of Schedule 36 of the following schedule:

“SCHEDULE 36: PROTOCOL ON BENIGN PROSTATIC HYPERPLASIA (BPH)

1. Applicability

(1) This protocol is applicable to an applicant or a holder of Class 1, 2, and 3 medical certificate.

2. Requirements

- (a) An applicant or holder of a medical certificate is required to submit an initial and a 6 months reports from a Urologist, which address the underlying cause of the Benign Prostatic Hyperplasia and the treatment if applicable;
- (b) If non-symptomatic or minimal symptoms can be managed by watchful waiting, therefore reports from a Urologist Report –Initially and then 6 Months shall be submitted;
- (c) A medical certificate with restrictions may be issued for Class 1 to an applicant or a holder of a medical certificate if symptoms are resolved and there are no adverse effects of treatment;
- (d) A medical certificate may be unrestricted after 6 months if an applicant or holder of a medical certificate is still symptom-free;
- (e) Before issuance of restricted or unrestricted medical certificate to an applicant or holder of a medical certificate, a Urologist Report must include including the following information :disease-specific history; uroflowmetry; post-void residual volume (PVR); renal function; frequency volume charts (FVC) and PSA;
- (f) The following medication may be used : Selective Alpha Blockers after 2 weeks grounding period (Tamsulosin);
- (g) Alfuzosin and 5 Alpha-Reductase Enzyme Inhibitors after 48 hours of grounding period and Dutasteride ;and
- (1) An applicant or holder of a medical certificate shall submit an annual Urologist report”.

(d) the substitution of Schedule 37 of the following schedule:

“SCHEDULE 37: PROTOCOL ON CHRONIC KIDNEY DISEASE

1. Applicability

(1) This protocol is applicable to an applicant or a holder of Class 1, 2, and 3 medical certificate.

2. Requirements

- (1) Chronic Kidney Disease applicant or holder of a medical certificate shall submit a Physician/Nephrologist report;
- (2) If Creatinine is <200 and symptomatic, applicant or holder of a medical certificate shall be declared medically unfit until he or she is treated and is stable;
- (3) An applicant or holder of a medical certificate with chronic kidney disease with Creatinine <200 may be considered for recertification if Physician/ Nephrologist Report provides the following:
 - (a) an applicant or holder of a medical certificate has been treated fully or has recovered with no current illness likely to cause instability.
 - (b) Renal function is stable with normal electrolytes; and
 - (c) underlying chronic medical conditions are controlled on current medication.
- (4) An applicant or holder of a medical certificate shall submit a 6 monthly Physician's/ Nephrologist report which shall include:
 - (a) Urea, Creatinine and Electrolytes;
 - (b) Haemoglobin; and Haematocrit;
 - (c) Urinalysis; and
 - (d) Underlying Condition must be compatible with flying/ on Protocol.
- (5) An applicant or holder of a medical certificate presented with chronic kidney disease, with Creatinine 200-500, shall be declared medically unfit if symptomatic, until he or she is treated and is stable.
- (6) An applicant or holder of a medical certificate with a diagnosis of chronic kidney disease, with Creatinine 200-500, medical fitness shall be considered on a case-by-case basis after recovery.
- (7) An applicant or holder of a medical certificate presented with chronic kidney disease, with Creatinine > 500 Micromole/L, shall be declared medically unfit.
- (8) An Applicant or holder of a medical certificate who requires dialysis shall be declared medically unfit.

3. Follow -Up Requirements

- (1) An Applicant or holder of a medical certificate for recertification, shall submit a 6 monthly Physician's/Nephrologist report which must include the following:

- (a) normal Electrolytes;
- (b) Haemoglobin is at least 10g/dL and Haematocrit 30%;
- (c) confirmation that underlying chronic medical conditions are controlled; and
- (d) confirmation that an applicant or holder of a medical certificate condition is asymptomatic and stable on current treatment”.

(e) the insertion in Technical Standard 67.00.2 after Schedule 47 of the following Schedules:

“SCHEDULE 48 PROTOCOL ON RENAL CALCULI

1. Applicability

(1) This protocol is applicable to an applicant or a holder of Class 1, 2, and 3. Medical certificate.

2. Restriction

- a) an applicant or a holder of Class 1, 2, and 3 who are stone free shall not be restricted ;
- b) an applicant or a holder of Class 1, 2, and 3 with residual stone and recurrent ureteric colic: Operational Multicrew Restriction /Operational Safety Pilot

2. General Medical Requirements

- (1) Based on the most recent event/ diagnosis >= 5 years ago;
- (2) An applicant or holder of a medical certificate must have no symptoms or current renal problems and the renal function must be normal.
- (3) An applicant or holder of a medical certificate must have no ongoing treatment or surveillance needed;
- (4) An applicant or holder of a medical certificate with a history of a single stone that passed <5 years ago, with no complications;
- (5) An applicant or holder of a medical certificate with a history of a single stone passed or is in the bladder with no further renal complications and imaging verifies no retained stones DAME-Issues;

- (6) An applicant or holder of a medical certificate with multiple or retained asymptomatic stone(s) <5 years ago with no complications;
- (7) A urologist report submitted shall confirm the following current medical status of an applicant or a holder of a medical certificate as being:
- (a) asymptomatic;
 - (b) stable (no increase in number or size of stones); and
 - (c) unlikely to cause a sudden incapacitating event.
- (8) An applicant or holder of a medical certificate who have undergone surgery, the following medical information shall be provide :
- (a) An applicant or holder is off pain medication(s);
 - (b) have fully recovered;
 - (c) fully released from the surgeon; and
 - (d) has no history of complications.
- (9) Supportive treatments such as hydration or medications (thiazides, allopurinol, or potassium citrate) to decrease recurrence (with no side effects) are allowed.
- (10) An applicant of holder of medical certificate shall be assessed on a case-by-case basis and presented by the Medical Assessor to ensure Accredited Medical Conclusion prior to reconsideration certification if such an applicant or a holder of a medical certificate present with the following complications:
- (a) Hydronephrosis (chronic);
 - (b) Metabolic/ underlying condition requiring treatment/surveillance/monitoring;
 - (c) Procedures (3 or more for kidney stones within the last 5 years);
 - (d) Renal failure or obstruction (acute or chronic);
 - (e) Sepsis or recurrent urinary tract infections due to stones;
 - (f) Symptomatic; and
 - (g) Underlying cause for recurrent stones.

4. FOLLOW-UP

4.1 An applicant or holder of a medical certificate shall submit the following reports to the Medical Assessor:

- (a) Xray;
- (b) Ultrasound;
- (c) Urogram; and
- (d) Urologist Reports”.”

- a) An applicant or holder of medical certificate on this technical standards will be followed up for a period of seven (7) Years pending submission of favourable reports .After a period of seven (7) follow-up period ,the Medical Assessor based on the holder/applicants favourable reports may consider to discontinue compliance to the technical standard .

“SCHEDULE 49: PROTOCOL ON RENAL TRANSPLANT

1. Applicability

(1) This protocol is applicable to an applicant or a holder of Class 1, 2, 3 and 4 medical certificate.

2. Restrictions

(1) The following restrictions may be imposed:

- (a) Class I – Multicrew;
- (b) Class II – Need Safety-pilot restriction;
- (c) Air Traffic Controller = Operate Under Supervision; and
- (d) Cabin Crew and Recreational Pilots – (Restriction may be imposed on case by case basis).

3. Initial requirements following diagnosis

(1) An applicant or holder of a medical certificate shall be temporary declared medically unfit after renal transplant;

- (2) An applicant or holder of a medical certificate shall submit Physician/ Nephrologist Report discussing aetiology of primary renal disease.
- (3) An applicant or holder of a medical certificate shall submit Hospital admission notes, operative notes, and discharge summary report.
- (4) An applicant or holder of a medical certificate shall disclose any history of Hypertension or cardiac dysfunction and Blood Pressure is within normal limits on approved antihypertensive.
- (5) An applicant or holder of a medical certificate shall submit Sequela prior to transplant.
- (6) Renal function shall be stable, with no underlying systemic disorder likely to cause sudden change.
- (7) Cardiovascular risk shall be assessed as minimal by a Cardiologist/ Physician, including exercise ECG.
- (8) An applicant or holder of a medical certificate shall submit Immunosuppressive Therapy they are taking and side effects, if any.
- (9) An applicant or holder of a medical certificate must submit the following Laboratory results; Full Blood Count; Blood Urea and Nitrogen, Creatinine and electrolytes.
- (10) The Levels of anti-rejection drugs shall be within therapeutic range to minimize side effects.
- (11) Steroid dosage shall be below 10mg per day.

4.Follow-Up Reports

- (1) An applicant or holder of a medical certificate shall submit :
 - (a) an annual Physician/Nephrologist report;
 - (b) an annual cardiology review, including exercise ECG; and
 - (c) other requirements test (Full Blood Count; U&E)".

MOTIVATION

The purpose of this submission is to insert new technical standards which were previously not included under Part 67 CATS (Renal Stones and Renal Transplant

.The other technical standards were due to amended based on the latest research and technological developments