Medical Examiners' - Medical Manual

Part 3 - Clinical Aviation Medicine

3.2 Respiratory System

ICAO Annex 1:	6.3.2, 6.4.2, 6.5.2
Civil Aviation Act:	s27B
CAR Part 67:	67.103 b, & e, 67.105 b, & e, 67.107 b, & e
GD:	Timing of Routine Examinations, Examination Procedures
ICAO medical Manual	Chapter 2

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3.2.1 Asthma

3.2.1.1 Considerations:

The 1992 International Consensus Report on Diagnosis and Treatment of Asthma proposed the following definition for Asthma:

"Asthma is a chronic inflammatory disorder, in which many cells and cellular elements play a role, in particular mast cells, macrophages, neutrophils, and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. The inflammation also causes an associated increase in the existing bronchial hyperresponsiveness to a variety of stimuli".

Persistent changes in lung function may occur over time as a result of sub-basement membrane fibrosis which can lead to airway remodelling.

Asthma represents a special problem for certification because it is a very common condition that has the potential to result in impairment or incapacitation.

Important factors in aeromedical decision making are:

- Adequacy of respiratory function;
- Severity of asthma;
- Stability of asthma;
- Medication requirements.

A history of asthma requires careful consideration, so does a history of symptoms or clinical signs, including impaired lung function, suggesting the possibility of asthma.

Symptoms & Signs suggestive of asthma

- Cough, worse at night, recurrent wheeze, recurrent breathlessness or chest tightness;
- Peak expiratory flow (PEF) variation of 20 % or more from PEF measured in the morning (prior to any bronchodilator) to PEF taking in the afternoon or evening (can be after bronchodilator). This is best documented by diary that includes exposure to symptoms precipitants.
- FEV1 variation of > 200 ml;
- FEV1 variation of 12%; or more;
- Hyperexpansion of the thorax (un-reliable on plain chest x-ray);
- Expiratory wheezing during normal breathing, noting that sounds during forced exhalation may originate in the glottis;
- Nasal symptoms or polyps;
- Allergic skin manifestations in the presence of the above symptoms.

Investigations

The GD "Examination Procedures" prescribes the standard for spirometry completion. A single PEFR or spirometry reading "within normal limits" **is not sufficient** to determine whether there is stability. PEFR diaries and serial spirometry may give some indication of asthma stability and an indirect measure of airways inflammation, but there are better tests available.

A spirometry before and after short acting bronchodilator should be performed at the time of examination on any one with a history of asthma, and anyone who has symptoms or clinical signs suggestive of asthma. The post bronchodilator spirometry should be performed even if the base line spirometry reading is entirely normal. This is because a normal spirometry (i.e. FEV1 100% of predicted) does not exclude significant reversibility. The normal values may also be optimistic.

The Global Lung Function Initiative (GLI), aims at establishing a mathematic formula (software) to predict normal values of spirometry for all ages and ethnic group. This is process in evolution. Ultimately it is expected that the GLI tool will become the universal tool for assessing spirometry results. See http://www.lungfunction.org/ . Until then the current NHANES 3 tables are acceptable, see:

http://www.cdc.gov/niosh/topics/spirometry/nhanes.html

People with a history of childhood asthma have a 40 % risk of recurrence in adulthood. Detailed inquiry and spirometry should also be performed in such applicants when they first apply and from time to time thereafter.

Interpretation of spirometry

Spirometry must be interpreted as prescribed in the GD "Examination Procedures" and with consideration to the following:

- Loop spirometry (showing inspiratory and expiratory flow volume loops) gives more information than measurement of FEV1 and FVC alone;
- Spirometric examination is best undertaken by an accredited Lung Function laboratory and reported by a Respiratory Physician, but may be undertaken by a competent ME, in accordance with the GD requirements;
- According to the American Thoracic Society a variability of 12 % or 200 ml in FEV1 is significant. An FEV1/FVC ratio of less than 70 % indicates obstruction;
- Lung function varies with age and ethnicity. The FEV1/ FVC ratio declines with age;
- A reduced FVC with maintenance of the FEV1/FVC ratio suggests a restrictive pattern. There are a number of causes for this, including a variety of lung diseases and obesity.

Bronchial challenge using Methacholine (or Histamine):

Methacholine used to provoke bronchoconstriction is a repeatable method of assessing bronchiolar hyperresponsiveness (BHR). The table below demonstrates the interpretation

of a Methacholine challenge. This test is however somewhat controversial and difficult to interpret.

Categorisation is based upon the concentration of Methacholine that results in a 20% reduction in FEV1. PC20 (mg/ml) - Bronchial Hyperresponsiveness (BHR)

> 16	Normal bronchial responsiveness
4.0 – 16	Borderline BHR
1.0 – 4.0	Mild BHR - positive test
< 1.0	Moderate to severe BHR

Before applying this interpretation, the following must be true: (1) baseline airway obstruction is absent; (2) spirometry quality is good; (3) there is substantial post-challenge FEV1 recovery. (Reference: American Thoracic Society Guidelines, categorisation of Methacholine Challenge Test Results).

Other options include Hypertonic Saline as an indirect test or Eucapnic Voluntary Hyperventilation (which dries airway – so might better mimic cabin conditions).

Exhaled Nitric Oxide (FeNO) estimation is another indicator of airway inflammation. It has been shown to permit better control of asthma with reduced doses of corticosteroid inhalers but it does not predict well for exacerbations. Not all asthmatics have elevated FeNO.

Directing treatment at normalising the pulmonary eosinophilia has been shown to reduce exacerbations. Technically, however, it remains a labour intensive process and is not practical.

Classification of Asthma Severity

Severity is determined by the worst clinical features before treatment. This determination will give the ME an idea of how severe the condition may become if left untreated or if compliance is in question.

It is essential to document usual precipitants, frequency of asthma attacks, the rate of onset of asthma (precipitous asthma?), the need for acute therapy including nebulised bronchodilator, attendance to ED / GPs, hospitalisation including ICU admission and frequency of oral steroid use.

Generally speaking asthma control will be improved by preventative medications which usually include an inhaled cortico-steroid and LABA.

Ref: American Thoracic Society	Symptoms	Night time symptoms	Lung function
Mild Intermittent	Symptoms £ 2 times a week Asymptomatic and normal PEF between exacerbations Exacerbations brief (a few hours to a few days), variable intensity	£ 2 times a month	FEV1 of PEF >80 % predicted PEF variability < 20 %
Mild Persistent	Symptoms > twice weekly but less than once a day Exacerbation may affect activity	> 2 times a month	FEV1 of PEF >80 % predicted PEF variability 20 – 30 %
Moderate Persistent	Daily symptoms Daily use of inhaled short- acting beta agonist Exacerbation affect activity Exacerbation > twice weekly Exacerbation may last days	> 1 time a week	FEV1 of PEF > 60%-< 80 % PEF variability > 30 % predicted
Severe Persistent	Continual symptoms Limited physical activity Frequent exacerbation	Frequent	FEV1 of PEF < 60% or predicted

Indications of Control / Stability

	Excellent control	Good Control	Moderate control	Poor control
Prophylactic medication	May or not be used or needed	Yes	Yes	Yes
Night symptoms	No	No	More than 2 episodes per month	Occasional
Symptoms on exercise	No			Occasional
Symptoms affecting work	No			Occasional
Use of bronchodilator	No	No	Occasional	Frequent
Variation in FEV1 after Ventolin	No or less than 10%	No or less than 10%	10-15%	>15%
Nitric oxide (while taking inhaled steroid treatment)	Less than 35 ppb Only valid indicator in one who had elevated FeNO	Less than 35 ppb Only valid indicator in one who had elevated FeNO	35-50 ppb if symptomatic.	Greater than 50 ppb if symptomatic

3.2.1.2 Information to be provided

The ME should obtain sufficient information to assess the severity of the asthma and its stability.

Moderate and severe asthma require a high level or evidence that stability has been achieved to ensure a sufficiently low likelihood of incapacitation.

History of childhood asthma:

- Respiratory questionnaire at the first application;
- GP notes at the first application if the ME is uncertain about the history;
- Spirometry pre and post bronchodilator on first application;
- Inquiry at each subsequent examination about symptoms suggesting recurrence of asthma – if any positive answers, refer to 'current asthma' below. The consideration must be documented.

History of asthma in adulthood, or current asthma:

- Respiratory questionnaire at each examination;
- PEF series on first application, and consider at subsequent examinations;
- Spirometry pre and post bronchodilator at each examination, unless there is well established stability. In this case slightly less frequent spirometry testing is permissible;
- Copy of GP notes for the past 24 months at the first Class 1 application;
- Copy of GP notes for the past 24 months at the first Class 2, or 3 application if the asthma is suspected to be mild persistent or worse;
- Copy of GP notes for the past 12 months at subsequent Class 1, 2 and 3 if there is any doubt regarding the recent asthma history, i.e. if the asthma is known or suspected not to be under good control, or if an exacerbation has occurred;
- A respiratory physician report at the first Class 1 application if the asthma is suspected to be "mild persistent", or worse. Subsequent reports may be required on a case by case basis or if the control is suspected to be moderate or poor;
- A respiratory physician report at the first Class 2 or 3 application if the asthma appears to be moderately severe or worse, or if the control is moderate or poor. Subsequent reports may be required on a case by case basis;
- Other reports as the ME may find reasonably necessary.

3.2.1.3 Disposition

In case of doubt the ME should contact the CAA Aviation Medicine Team. The following guidance assumes correct assessment of the severity and stability of asthma. The ME should take a conservative approach to certification if unsure about the applicant's asthma severity and err in favour of public safety, particularly when assessing Class 1 applicants.

Reminder: Severity is determined by the worse clinical features before treatment, i.e. the worse asthma episode an applicant may have experienced.

- **Moderate or poor control of asthma:** The applicant may not be assessed as meeting the Part 67 medical standards and should be assessed via the flexibility process;
- **Past childhood asthma - Class 1, 2 or 3** adult applicants with a history of childhood asthma but none since childhood: May be assessed as meeting the Part 67 medical standards if no current asthma is demonstrated;
- **Mild intermittent asthma - Class 1, 2, or 3** – Excellent or Good control achieved. The applicant may be assessed as meeting the Part 67 medical standards provided the certificate is endorsed with the requirement to have a short acting bronchodilator readily available at all time when flying and not to fly while experiencing symptoms of asthma. Applicant to comply with any prophylactic treatment.
- **Mild persistent asthma - Class 1:** Excellent or Good control achieved. The applicant may be assessed as meeting the Part 67 medical standards provided that the applicant is successfully treated with inhaled steroids, compliant with treatment, and stability has been reliably demonstrated following a respiratory physician report. The certificate should be endorsed with the requirement to have a short acting bronchodilator readily available at all time when flying and not to fly while having symptoms of asthma. The applicant should be informed to ground self and report to CAA in case of discontinuation of prophylactic medication;
- **Mild persistent asthma - Class 2 & 3**: Excellent or Good control achieved. The applicant may be assessed as meeting the Part 67 medical standards providing that the applicant is successfully treated with inhaled steroids, compliant, and stability has been reliably demonstrated. In doubt a respiratory physician report should be requested, but is not routinely required. The certificate should be endorsed with the requirement to have a short acting bronchodilator readily available at all time and not to fly or operate as an ATC while experiencing any symptoms of asthma. The applicant should be informed to ground self and report CAA in case of discontinuation of prophylactic medication.
- **Moderate asthma - Class 1**: The applicant may not be assessed as meeting the Part 67 medical standards and should be assessed via the flexibility process;
- **Moderate asthma - Class 2 & 3:** Excellent or Good control achieved. The applicant may be assessed as meeting the Part 67 medical standards provided that the applicant is successfully treated with inhaled steroids, compliant, and stability has been reliably demonstrated following a respiratory physician report. The certificate should be endorsed with the requirement to have a short acting bronchodilator readily available at all time when flying and not to fly or operate while experiencing any symptoms of asthma. The applicant should be informed to ground self and report to CAA in case of discontinuation of prophylactic medication;
- **Severe asthma – All classes:** The applicant may not be assessed as meeting the Part 67 medical standards and should be assessed via the flexibility process.

3.2.2 Chronic Obstructive Pulmonary Disease (COPD)

3.2.2.1 Considerations

The Global Initiative of Chronic Obstructive Lung Disease (GOLD) – a project initiated by the US National Heart, Lung, and Blood institute (NHLBI) and the World Health Organisation defines COPD as follows:

"Chronic obstructive pulmonary disease (COPD), a common preventable and treatable disease, is characterized by airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients".

COPD may be caused by chronic bronchitis, chronic asthma, emphysema, and alpha-1 antitrypsin deficiency. The most important risk factor for COPD is smoking. Around 80% of people affected by COPD have a history of smoking. In the absence of genetic / environmental predispositions, smoking less than 10 pack years is unlikely to result in COPD while smoking more than 40 pack years has a positive likelihood ratio of 12 [Confidence interval 2.7-50]. Thus inquiring about smoking habits is important.

Symptoms of COPD include chronic chough, sputum production and dyspnoea. Exertional dyspnoea is an early symptom.

Pulmonary functions tests are the cornerstone in the diagnosis of COPD. The most important values measured during spirometry are the forced expiratory volume in one second (FEV1) and the forced vital capacity (FVC). The post bronchodilator ratio FEV1/FVC determines the severity of irreversible airflow limitation. A ratio of less than 0.7 is considered abnormal however the normal value decreases with age. The force expiratory volume in six seconds (FEV6) obtained by stopping expiratory effort a 6 seconds is an acceptable surrogate for FVC. Spirometry reference values are available from: http://www.cdc.gov/niosh/topics/spirometry/nhanes. Please refer also to the asthma subchapter for spirometry normal values.

Staging of COPD

The Revised GOLD Classification looks at three things: Symptoms (Dyspnoea), FEV1 and history of Exacerbations.

Dyspnoea

Grade 0: "I only get breathless with strenuous exercise".

Grade 1: "I get short of breath when hurrying on level ground or walking up a slight hill".

Grade 2: "On level ground, I walk slower than people of the same age because of breathlessness, of have to stop for breath when walking at my own pace".

Grade 3: "I stop for breath after walking about 100 meters or after a few minutes on level ground";

Grade 4: "I am too breathless to leave the house or I am breathless when dressing".

FEV1

GOLD 1	Mild	FEV1>80% of predicted (but has other positive markers)
GOLD 2	Moderate	50% <FEV1<80%
GOLD 3	Severe	30% <FEV1<50%
GOLD 4	Very severe	FEV1 <30%

Exacerbations

Low risk: 1 or less exacerbations per year

High risk: 2 or more exacerbations per year.

3.2.2.2 Information to be provided

- Routine spirometry at the first application in accordance with the GD "timing of routine examination";
- Routine spirometry at age 46 and 56 if the applicant has ever smoked tobacco, in accordance with the GD "timing of routine examination";
- Spirometry at any application when an applicant presents with a history, signs or symptoms suggestive of lung disease;
- The spirometry is to include post bronchodilator recordings if the FEV1 is less than 80% of predicted or if the FEV1/FVC is less than 70%;
- Pulse Oximetry Oxygen Saturation result if COPD is suspected;
- Consider altitude simulation (FiO2 15%) oximetry at rest and with exercise if there is concern regarding abnormal gas exchange;
- GP notes for the past 24 months if the applicant reports attending for respiratory problems or the ME is uncertain about the history given;
- A respiratory physician report, on the first occasion that the FEV1/FVC is less < 60%, or SaO2 < 95%, or if the applicant has attended for respiratory problems or has signs or symptoms suggestive of more than mild COPD.

3.2.2.3 Disposition

- **A Class 1 applicant** with mild COPD may be considered as having a condition that is not of aeromedical significance if: the FEV1 is 70 % of predicted or better, the Dyspnoea Grade 1 or less, the pulse oxymetry 95% or better, and there is no history of exacerbation;
- **A Class 2, or 3 applicant** with mild to moderate COPD may be considered as having a condition that is not of aeromedical significance if: the FEV1 is 60% of predicted or better, the Dyspnoea is Grade 1 or less, the pulse oxymetry 95% or better, and there is no more than one exacerbations per year.

3.2.3 Traumatic Pneumothorax

3.2.3.1 Considerations:

Traumatic pneumothorax is generally the result of a penetrating trauma to the chest resulting in perforation of the chest wall and the parietal and possibly visceral pleura. A blunt trauma may result in rib fracture with the broken rib then penetrating the visceral pleura. A blunt injury so severe as to open the chest wall or an excessive differential pressure between ambient and the respiratory tree may also be responsible for a pneumothorax (i.e. pulmonary barotrauma). The latter can occur while diving, at the time of ascending without exhaling fast enough (asthma may be a cause for this), or during sudden decompression at high altitude or in the decompression chamber. Surgery is another possible cause.

Flying duty can normally be resumed 6 weeks after resolution of the traumatic pneumothorax, provided full recovery from the trauma and the pneumothorax have occurred. However the ME should be confident that there is no underlying pathology that may have precipitated the event, i.e. asthma in a diver, bullous emphysema in an older pilot etc.

A chest X-ray confirming resolution of the intrapleural air and a spirometry is the minimum requirement. A respiratory physician opinion may at time be necessary. When in doubt the ME should seek advice from CAA.

3.2.3.2 Information to be provided:

- A detailed history of the trauma leading to the pneumothorax;
- Copy of all relevant medical notes and reports if the event has occurred in the past 12 months if the history is not clear, or if the ME suspect any underlying condition (i.e. Asthma, COPD);
- Copy of all chest radiology reports if the event has occurred in the past 12 months;
- At least one post event chest X-ray report;
- A respiratory physician report if the ME suspects that any underlying condition has contributed to the event or if there has been recurrence of the pneumothorax.

3.2.3.3 Disposition:

A Class 1, 2 or 3 applicant may be considered as having a condition that is not of aeromedical significance if:

- A clear history of trauma has been established and full recovery has occurred;
- The latest Chest X-ray report confirms resolution of the traumatic pneumothorax;
- At least 6 weeks have lapsed since complete radiological resolution of the traumatic pneumothorax;
- The ME has considered and excluded any underlying pathology.

3.2.4 Spontaneous (Primary) Pneumothorax

3.2.4.1 Considerations

A pneumothorax is said to be spontaneous if it occurs in the absence of trauma or underlying pathology. For instance an apparently spontaneous pneumothorax in someone with emphysema is to be considered as secondary rather than primary spontaneous for the purpose of this chapter.

The incidence of admissions for primary spontaneous pneumothorax in the UK has been found to be 16.7 / 100,000 / year in males and 5.8 / 100,000 / year in females. The condition typically occurs in tall thin men between 20 and 30 years of age. Approximately 75 % are current smokers.

A pneumothorax present before take-off or occurring during climb may result in a tension pneumothorax owing to the decreasing ambient pressure. This can lead to incapacitation and possibly death. At best, a pneumothorax would be distracting and could induce a degree of hypoxia.

Recurrence rate

Recurrence is common with 20 – 60 % events at 5 years. Risk factors for recurrences are:

- Previous spontaneous pneumothorax
- Gender: Women have a higher risk of recurrence, 71 % against 46 % for Men in one study;
- Smoking habits: According to one study, there is a higher recurrence rate in non-smokers. In smokers, smoking cessation decreases the likelihood of recurrence and is therefore important. It takes two years of smoking abstinence for the difference in the recurrence rate to become statistically significant;
- Bullae or blebs: The prognostic significance of pulmonary bullae of blebs remains controversial. However concern remains that the presence of bullae of blebs constitutes a risk factor.

In addition contralateral recurrences occur in 15 – 30 % of cases. Therefore patients who have undergone unilateral surgical intervention remain at increased risk of developing a pneumothorax on the contralateral side for some years. The likelihood of a recurrence decreases exponentially over time. Half the recurrences happen in the first year, a quarter in the second year, one eighth in the third year etc.

Current surgical techniques generally involve Video Assisted Thoracic Surgery (VATS) with apical resection (whether bullae are visible or not) or stapling of bullae, and (but not always done) pleurodesis by abrasion, using a sand paper type of material. This may be augmented by chemical pleurodesis or/and peeling of strips of pleura. The procedure may be unilateral or bilateral. Pleurectomy is now rarely performed as it is mostly unnecessary. It has a significant morbidity. Relapse is possible even after surgery.

It must be understood that different combinations of techniques have different rates of relapse. MEs should therefore not assume that an applicant who underwent surgery is necessarily eligible for a Medical Certificate at a certain point in time.

The following table, compiled by CAA after meta-analysis of some 18 studies, gives an indication of the estimated recurrence rate depending on the procedure(s) performed if any.

Bilateral VATS + subtotal pleurodesis	Recurrence rate: no data. However it is safe to assume 3 % or less
Unilateral VATS + subtotal pleurodesis	Recurrence rate ~ 3 % Contralateral ~ 5 - 15 %
Unilateral VATS, no pleurodesis	Recurrence rate ~ 10 - 16 % Contralateral ~ 5 - 15 %
Conservative treatment	Recurrence rate ~ 20 - 60 % Contralateral ~ 5 - 15 %

Most recurrences following surgery occur in the first 12 – 18 months post intervention.

It is possible that an applicant who underwent bilateral Pleurectomy, or VATS with pleurodesis, could obtain a Medical Certificate 6 month post-surgery, perhaps restricted to multicrew operations for 6 – 12 months. In contrast someone who underwent unilateral bullectomy only may have to wait 18 to 24 months, while an applicant treated conservatively may have to wait up to a few years before becoming eligible for a Medical Certificate. An applicant with a history of recurrent spontaneous pneumothorax is unlikely to be issued a certificate unless surgery has been undertaken.

3.2.4.2 Information to be provided

The following information should be provided:

- Copies of any discharge summary and all specialist reports pertaining to the episode(s) of spontaneous pneumothorax;
- Copy of all radiology reports, to include any chest CT scan report;
- Copy of operating reports, showing details of the procedure(s) performed;
- A recent spirometry;
- A respiratory physician report and high resolution chest CT may be requested in some cases;
- The smoking status, before the episode(s) of spontaneous pneumothorax and after, including time elapsed since smoking cessation.

3.2.4.3 Disposition

No surgery undertaken

- **A Class 1 applicant** with a history of a single episode of spontaneous pneumothorax occurring less than 5 years prior should be considered as having a condition that is of aeromedical significance;
- **A Class 2 applicant** with a history of a single episode of spontaneous pneumothorax occurring less than 3 years prior should be considered as having a condition that is of aeromedical significance;
- **A Class 3 applicant** with a history of a single episode of spontaneous pneumothorax occurring less than 6 weeks prior should be considered as having a condition that is of aeromedical significance;
- **A Class 1, 2 or 3 applicant** with a history of more than one episode of spontaneous pneumothorax should be considered as having a condition that is of aeromedical significance.

Surgery undertaken

- **A Class 1or 2 applicant** with a history of spontaneous pneumothorax treated by surgery may be considered to have condition that is not of aeromedical significance following a period of observation;
- The period of observation depends on the surgery performed, whether the surgery was bilateral or unilateral, and the Class of licence applied for;
- The ME should inquire with CAA to seek advice about the period of observation applicable on a case by case basis;
- In case of doubt the ME should consider the applicant as having a condition that is of aeromedical significance;
- **A Class 3 applicant** with a history of spontaneous pneumothorax treated by surgery may be considered to have a condition that is not of aeromedical once recovery from surgery is complete, but nor earlier than six weeks post-surgery.

3.2.5 Non-Spontaneous (Secondary) Pneumothorax

3.2.5.1 Considerations

The term non-spontaneous or secondary pneumothorax is used to refer to a pneumothorax that is caused or contributed to by an underlying condition other than trauma, for instance asthma or bullous emphysema.

3.2.5.2 Information to be provided

- Copies of any discharge summary and all specialist reports relating to the episode(s) of spontaneous pneumothorax;
- Copy of all radiology reports;
- Copy of any operation report, showing details of the procedure(s) performed;
- Copy of the GP notes for the past two years, or longer if relevant;
- A recent spirometry;
- A respiratory physician report, on the first presentation following secondary pneumothorax;;
- The smoking status;
- A high resolution chest CT may be requested.

3.2.5.3 Disposition

- A Class 1, 2 or 3 applicant with a history of non-traumatic, non-spontaneous (secondary) pneumothorax should be assessed as having a condition that is of aeromedical significance.

3.2.6 Obstructive Sleep Apnoea

3.2.6.1 Considerations (reference ICAO medical manual):

Refer also to the bpac publication:

http://www.bpac.org.nz/BPJ/2012/november/docs/bpj_48_apnoea_pages_6-15.pdf

Obstructive sleep apnoea (OSA) is a condition characterised by loud snoring, episodes of sleep related upper airway obstruction and daytime sleepiness. The obstruction may be complete, leading to cessation of airflow (apnoea) or partial, leading to a markedly reduced inspiratory flow (hypopnoea).

OSA can be defined as the presence of five or more obstructive events (either apnoeas or hypopnoeas) per hour of sleep i.e. Apnoea-Hypopnoea Index (AHI) of 5 or more. Elevation in the AHI can occur (especially if mild) without daytime sleepiness.

The obstructive sleep apnoea syndrome is defined as the presence of OSA with daytime sleepiness. During apnoeas and hypopnoeas the difficulty in inspiration causes repeated arousals from sleep. Poor quality of sleep is then the cause of daytime sleepiness. OSA is both common and under-diagnosed.

Excessive daytime sleepiness, difficulty in concentration, an increased rate (2-5 times) of road traffic accidents and impairment of skilled motor tasks are consistently associated with moderate and severe OSA. Applicants often only recognize the extent of their performance decrement once it is successfully remedied with treatment. The diagnosis is made with evaluation in a sleep clinic.

OSA is also associated with an increased risk of coronary artery disease, hypertension, stroke and diabetes although there is some debate as to whether the association is causal or secondary to associated obesity, which is often present. Because of this association, it is appropriate to also conduct a cardiovascular risk assessment.

Risk factors for OSA include increasing age, obesity, hypothyroidism and a family history of OSA. Type 2 diabetes is found in association with OSA, probably secondary to the frequently present obesity. Most patients seen in a sleep clinic are significantly overweight, although not all with around 40% of OSA being attributable to maxillofacial factors (particularly retrognathia).

The majority with significant OSA snore to a level that is commented on by their bed partners, who typically report being alarmed by the apnoeic episodes. Specific questions addressed to the partner can be helpful if the medical examiner suspects that OSA may be an issue. Of note a few individuals with severe OSA move so little air before they obstruct that they do not snore as much as those with a less severe condition. However, they may have a history of severe snoring which has subsequently lessened. Severe snoring is a sensitive marker for OSA. Daytime sleepiness as a symptom is also reasonably sensitive, but may not be declared to a ME unless specific questions are asked.

There is also a group who despite having significant OSA state that they are not at all sleepy during the day and have very low Epworth scores, i.e. 0 – 3 (normal maximum

score is about 9). In this setting an objective measure of the individual's ability to maintain wakefulness may be helpful (Maintenance of wakefulness test).

There is a separate but related condition that is not uncommon. A patient may have a history of severe snoring. However, on sleep studies, there is no evidence of OSA but the patient is sleepy during the day and responds well to continuous positive airway pressure (CPAP). This condition is known as the "upper airway resistance syndrome."

CPAP is very effective in those who tolerate it. Most patients who are symptomatic, are accurately assessed and who have proper fitting of their interface (mask and headset), tolerate CPAP well. Technological advancements include: Humidification which reduced adverse upper airway side-effects; PAP devices that can auto-titrate (APAP) to maintain an open airway at the lowest effective pressure; expiratory pressure relief or C-Flex that lower pressure in the first part of expiration; downloadable compliance and AHI data.

In the one third of patients that do not tolerate CPAP, a mandibular advancement device (MAD) may be considered. Predictors of MAD success include: good dentition and nasal airflow; ability to protrude the mandible; lower BMI (< 35kg/m2) and positional OSA. Be aware that some changes in bite (occlusion) occur in most long term MAS treated patients so a dentist needs to be involved in follow-up. Upper airway surgery can be considered in selected patients if CPAP and MAS treatment unsuccessful. This usually requires a Respiratory / Sleep Specialist opinion.

The Epworth sleepiness scale is a subjective measure of daytime sleepiness that numerically scores the response to eight questions concerning an individual's likelihood of sleeping during different activities e.g. watching television, sitting and talking to someone. First published in 1991 and named after the Sleep Disorders Unit, Epworth Hospital, Melbourne, Australia. Copyright of Murray W. Johns, Australian physician, 1937.

It can be useful to get the spouse to participate in completion of this questionnaire. It is not flight task specific and is easily manipulated so low / normal values in the context of employment cannot be relied upon to exclude a diagnosis of aeromedically significant OSA. The Epworth questionnaire should be interpreted with caution.

ICAO recommends that the diagnosis of OSA should be considered in crew members who are overweight, have Type 2 diabetes, have a history of snoring or complain of excess daytime sleepiness. Any pilot who has fallen asleep on the flight deck, outside a planned rest period, may need investigation. Fatigue, shift work, sleep restriction and task monotony need to be considered as potential contributing factors.

Applicants who have hypertension and those with certain facial features, such as retrognatism, crowded pharynx, tonsil hypertrophy etc, should also be considered for this diagnosis. People with a BMI of 35 or more have a ~ 70-75 % likelihood of suffering from OSA and those with a BMI of 40 or above, a ~ 80% likelihood of having OSA.

The Mallampati score, initially used in anaesthesia to predict difficulties with intubation also predicts OSA. A Grade III or IV suggests the presence of OSA (AHI >5) but does not predict for severe OSA (AHI >30). However a high Mallampati score should incite the ME to inquire further about OSA.

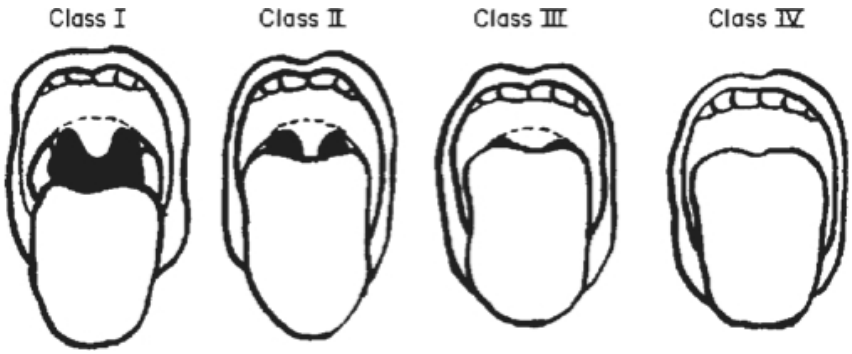
Mallampati score

Grade I: Entire tonsil clearly visible

Grade II: Upper half of tonsil fossa visible

Grade IV: Soft and Hard Palate clearly visible

Grade V: Only Hard Palate visible



Obstructive sleep apnoea is not the only cause of daytime hypersomnolence. Shift work related sleep restriction, periodic leg movement disorder, narcolepsy, idiopathic hypersomnolence, sleep phase reversal, poor sleep hygiene and sleep disturbance due to depression or pain should be considered in patients who have hypersomnolence but normal respiratory sleep studies. Sleepy individuals require evaluation, even in the absence of OSA risk factors.

Process for identifying obstructive sleep apnoea

The ME should inquire about snoring at a level that disturbs someone sleeping in the same room, tendency to fall asleep or doze at inappropriate times and traffic accidents.

The ME should consider the BMI, neck circumference, blood pressure, glucose metabolism status and facial and throat morphologic features of the applicant. The ME should also inquire about alcohol consumption.

An Epworth Sleepiness questionnaire should be completed in case of any suspicion of OSA. It is however worth noting that, in the context of employment medical examinations and the regulatory environment, the Epworth Sleepiness questionnaire has a poor negative predictive value. A score of 10 or above has however a high predictive value for OSA.

bpac advises: Flemmons' score (adapted from Skjodt, 2008)

Measured Neck circumference + Addition as below = **Adjusted neck circumference**

Neck circumference in cm + Add:

3 cm for snoring history:

3 cm for history of witnessed apnoea

4 cm for a history of hypertension

Result:	OSA Risk
< 43 cm	low risk (17% probability)
43 – 47.9	intermediate risk
48 cm and above	high risk (> 80 %)

Types of sleep studies:

Level 1 study: This is a Polysomnography conducted in a laboratory with a technician present and under the supervision of a respiratory physician involved in sleep medicine. This is the gold standard.

Level 2 study: This is an unattended sleep study, recording the same parameters. The patient is pre-wired in the lab or a technician may attend the patient at home to conduct the study there. This has the advantage of a more natural environment, but the study is not witnessed.

Level 3 study: Records airflow, respiratory effort, SatO2 and heart rate. It is inadequate for certification purpose.

Level 4 study: typically only records SatO2 and heart rate. It is inadequate for certification purpose.

3.2.6.2 Information to be provided

- An Epworth Sleepiness questionnaire should be completed if the response to any sleep or fatigue related question asked by the ME is positive or if the ME has reasons to believe that OSA may be present;
- An Epworth sleepiness questionnaire should be completed if the applicant has morphologic features suggestive of OSA, such as an adjusted neck circumference of 43 cm or above, a Body Mass Index greater than 35 or a Grade III or IV Mallampati score;
- A respiratory physician report, to include a Level 1 or 2 sleep study, on the first occasion that OSA is thought to be likely by the ME;
- In the case of diagnosis of OSA, a follow up respiratory physician report indicating successful treatment by CPAP/APAP or MAD; and
- A CPAP / APAP usage data log.

Once satisfactory CPAP/APAP treatment is established, demonstrated by CPAP Log, reduced daytime sleepiness and absence of snoring on treatment, a return to flying should normally be allowed. Unless major weight loss occurs, CPAP/APAP or MAD treatment is likely to be needed lifelong. Follow-up at a sleep clinic may be required to ensure the ongoing adequacy of treatment and compliance.

3.2.6.3 Disposition

An applicant with demonstrated Obstructive Sleep Apnoea should be considered as having a condition of aeromedical significance unless:

- The applicant is treated by CPAP/APAP, MAD or surgery; and
- The applicant is compliant with the treatment as demonstrated by a machine log if using CPAP/APAP;
- The treatment is successful as indicated by a respiratory physician report; and
- The applicant does not suffer from aeromedically significant complications from OSA; and
- The applicant does not suffer from on-going excessive fatigue or sleepiness; and
- The applicant is informed that cessation or noncompliance with the prescribed treatment will constitute a change in medical condition under section 27C, requiring the applicant to ground self and report to the director.

An applicant treated by other means or not fulfilling the above criteria should be considered has having a condition that is of aeromedical significance and be assessed via the flexibility process.

In doubt the Medical Examiner should consult with CAA.

3.2.7 Sarcoidosis

3.2.7.1 Considerations

Sarcoidosis is a systemic disease of unknown origin. It causes widespread non-caseating granulomas that may affect not only the lung but also the myocardium, eyes, skin, liver, spleen, lymph nodes, bones, joints, nervous system, endocrine system and digestive tract. The peak incidence is in patients between the ages of 20-40 years and up to 50% of patients are asymptomatic. The overall mortality rate varies between 5 and 10%.

The symptoms usually consist of cough that may be paroxysmal in the acute phase and may cause incapacitation. The non-respiratory symptoms may consist of anorexia, malaise, lassitude, joint pains (arthralgia) and the almost pathognomonic occurrence erythema nodosum.

The presence of Lofgrens Syndrome with erythema nodosum (nodular skin lesions), bilateral hilar lymphadenopathy, and a low-grade fever, imply a favourable prognosis.

Lung function is often normal despite some chest X-ray changes. Of those presenting with interstitial pulmonary disease alone, only one quarter show complete resolution. The remainder may progress to pulmonary fibrosis with impaired lung function, and then, cor pulmonale.

Acute sarcoidosis:

Acute sarcoidosis normally resolves within 2 months to 2 years. There are risks of sudden disabling symptoms in acute sarcoid.

The risk of chronicity is reduced if the acute illness is of short duration (less than a year), the onset occurs at a young age, there is presence of erythema nodosum, (a good prognostic factor), there is minimum lung involvement i.e. any interstitial shadowing should be mild and short lived, there is no cardiac involvement and no steroids are required.

Hyperalcaemia or hypercalciuria may occur as non caseating granulomas secrete 1,25 vitamin D. This occurs in about 10-13% of patients. The presence of elevated vitamin D levels are associated with protracted treatment in sarcoidosis. The Angiotensin Converting Enzyme (ACE) may be elevated.

Cardiac Sarcoidosis

One of the main concerns with sarcoidosis is the possibility of cardiac sarcoidosis. Thallium myocardial scans suggest granulomatous involvement of the heart in 30% of cases of sarcoid.

There is clinical evidence that tachy-arrhythmias, heart blocks, cardiomyopathy, congestive cardiac failure and sudden death may occur. The instances of sudden death in patients known clinically to have myocardial involvement are almost 50%, with 65% of these being due to arrhythmia. Unfortunately the risk of sudden death and cardiac dysfunction persists for up to 15 years, perhaps more, after the onset of symptoms, even once the sarcoid symptoms have resolved.

Chronic sarcoidosis

Chronic disease causes a wider and more severe complex of symptoms than the acute disease, and tends to occur in patients in middle age or older. The condition may evolve to progressive pulmonary fibrosis. Advanced disease will cause breathlessness, cough, reduced lung function and exercise intolerance. Any suggestion that the disease is becoming chronic and progressive usually implies that the condition is incompatible with flying status.

3.2.7.2 Information to be provided

- A detailed history of the illness together with a copy of all relevant specialists reports;
- A copy of all investigations reports;
- A copy of any Transbronchial Biopsy (TBBX) or Endobronchial Biopsy of Mediastinal Lymph Nodes biopsy (EBUS) results;
- A recent Chest X-ray (PA and Lateral);
- Pulmonary Function Tests (Spirometry);
- Gas Transfer if the spirometry result is not normal;
- An ECG;
- A special eye report;
- Serum Calcium, Angiotensin-Converting Enzyme (ACE) and liver function tests, unless the disease is considered to have long resolved by the treating specialist;
- A Holter monitoring report, an MRI of the heart, a CT of the chest and other investigations may be required as part of an AMC process.

3.2.7.3 Disposition

A Class 1 applicant who first present with a history of Sarcoidosis should be considered as having a condition that is of aeromedical significance.

A Class 2 or 3 applicant who first present with a history of Sarcoidosis should be considered as having a condition that is of aeromedical significance unless:

- The sarcoidosis was acute and of less than two year duration; and
- The sarcoidosis was mild and did not require steroids or immunosuppressant treatment; and
- A recent respiratory physician report indicates absence of chronicity or any abnormal findings;
- An ECG is normal, showing nor block or arrhythmia;
- The acute episode occurred more than 15 years ago.

3.2.8 Tuberculosis

3.2.8.1 Considerations

Tuberculosis (TB) remains an important communicable disease in New Zealand.

There are 350 – 400 new reported cases per year for an incidence of 6.6 per 100'000. In recent years the incidence rate has been higher than those in Australia, the United States, and Canada, and slightly lower than the rate in the United Kingdom.

Student pilots from regions where tuberculosis is endemic are commonly training at New Zealand flying schools and MEs should remain alert to this condition when examining applicants. The GD "Timing of Routine examinations" stipulates when a routine chest X-ray should be undertaken.

The Civil Aviation rules Part 67 stipulate that an applicant must not have, to an extent that is aeromedical significance: "an infection, unless adequate treatment or resolution or both is demonstrable".

ICAO specifies that Applicants with active pulmonary tuberculosis shall be assessed as unfit; and

Applicants with quiescent (no evidence of active disease) or healed lesions which are known to be tuberculous, or are presumably tuberculous in origin, may be assessed as fit.

3.2.8.2 Information to be provided

- A chest X-ray on the first occasion that an applicant presents with a history of treated tuberculosis;
- Copy of any treating physicians reports relating to the history of tuberculosis;
- In case of doubt regarding resolution of the infection, a recent respiratory physician report;
- In the case of tuberculosis undergoing treatment, a recent respiratory physician report.

3.2.8.3 Disposition

- An applicant with a history of past tuberculosis that has been successfully treated and who is suffering no sequelae may be assessed as having a condition that is not of aeromedical significance;
- An applicant with active disease or currently undergoing treatment should be assessed as having a condition that is of aeromedical significance.