

PURSUANT to Section 28 of the Civil Aviation Act 1990

I, HARRY JAMES DUYNHOVEN, Minister for Transport Safety,

HEREBY MAKE the following ordinary rules.

SIGNED AT Wellington March This 28 th 2006 day of by HARRY JAMES DUYNHOVEN Minister for Transport Safety

**Civil Aviation Rules** 

Part 67— Re-issue

## **Medical Standards and Certification**

Docket 4/CAR/1

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## Rule objective

The objective of the re-issue of Part 67 is to:

- Align medical standards and certification with the legal framework established by the Civil Aviation (Medical Certification) Amendment Act 2001 that came into effect on 1 April 2002;
- Incorporate the provisions of the Aviation Medical Transitional Criteria Notice 2002 issued by the Minister of Transport on 1 April 2002;
- Update the medical standards taking into account the recommendations of Bruce Corkill and Dr Simon Janvrin in "*Final Report of Review Team to Minister of Transport on Rule Part 67, Medical Standards and 1% Rule*" of November 2001 ("the Corkill-Janvrin report");
- Recognise the requirements of the International Civil Aviation Organization.

## Extent of consultation

On 11 December 2002, the Ministry of Transport, with the Civil Aviation Authority providing technical and medical advice, presented a draft Notice of Proposed Rulemaking (NPRM) for a new Part 67 with consequential amendments to Part 1 to the aviation medical consultation group.

The aviation medical consultation group is composed of representatives of the following: Aviation Industry Association of New Zealand, Aviation Medical Society of Australia and New Zealand, Combined New Zealand Aviation Medicine Forum, New Zealand Air Line Pilots' Association, Royal New Zealand Aero Club Inc, Aircraft Owners' and Pilots' Association (New Zealand) Inc, Sport Aviation Corporation Ltd, Sport Aircraft Association of New Zealand, New Zealand Warbirds Association Inc, Airways Corporation of New Zealand, Air New Zealand Limited, and the Guild of Air Pilots and Air Navigators.

The aviation medical consultation group reconvened on 14 February 2003 to provide feedback to the Ministry of Transport on the draft NPRM. Comments and issues raised at that meeting were addressed in a memorandum to the group on 9 July 2003 and in the subsequent NPRM.

On 10 July 2003, the NPRM was released for public consultation. The publication of this NPRM was notified in the *Gazette* and advertised in the daily newspapers of the five main provincial centres on 10 July 2003. The

NPRM was published on the Ministry of Transport website and distributed to identified stakeholders including representative organisations who were considered likely to have an interest in the proposal.

A period of 74 days was provided for comment on the proposed rule, with submissions closing on 22 September 2003. The Ministry received 20 written submissions on the NPRM.

On 9 August 2004, a re-drafted NPRM was released for public consultation, taking into account the submissions made in response to the first NPRM.

The publication of this NPRM was notified in the *Gazette* on 12 August 2004 and advertised in the daily newspapers of the five main provincial centres on 9 August 2004. The NPRM was published on the Ministry of Transport website and distributed to identified stakeholders including representative organisations who were considered likely to have an interest in the proposal.

A period of 60 days was provided for comment on the proposed rule, with submissions closing on 8 October 2004. The Ministry received 14 written submissions on the second NPRM.

The Ministry of Transport summarised the submissions received on both NPRMs and prepared responses to these.

On 28 January 2005, a revised draft of the rule was forwarded to the aviation medical consultation group for its information. On 11 March 2005, the Ministry met with members of the group, who reiterated some of the concerns raised in their submissions.

## Summary of submissions

The key issues raised during consultation, and the Ministry's responses to them, are summarised below.

• Adequacy of the general approach to describing the medical standards (the descriptive stem): Some submitters felt that this was too subjective and did not align closely enough to the standards in the Convention on International Civil Aviation.

The descriptive stem was based on the "safety relevant" concept in the Australian Civil Aviation Safety Regulations 1998. The Summary of Submissions dated 28 January 2005 expressed the view that this

concept gave effect to the standards in the Convention, albeit that they were expressed in a different way. There was also a concern to ensure the descriptive stem was compatible with the Act. Subsequently, further efforts to address submitters' concerns have been made, resulting in refinements to the descriptive stem to more closely align with the standards in the Convention;

- *Repetition of standards:* The approach used of prescribing a general standard followed by particular standards is commonly used in legislation. The lists of conditions are necessarily prescriptive reflecting international practice. It is also anticipated that expressing the standards in this way will assist medical examiners;
- *Function of general directions:* Some submitters believe that the general directions will be used to set medical standards when they only have an administrative function. Since general directions are issued by the Director, their content is a matter for the Director to consider. However, the Act expressly permits general directions to specify requirements of examinations or other clinical matters, including, but not limited to, "the significance of results of examinations for the purpose of determining whether or not an applicant is eligible for a medical certificate". This demonstrates that general directions have more than a purely administrative function;
- *Sufficiency of consultation:* The Ministry considers that the Minister's consultation obligations under section 34 of the Act have been fulfilled.

Following the publication of the Ministry's Summary of Submissions on 28 January 2005, it became clear that the provisions relating to the Convener review process should be omitted and minor drafting changes should be made. A summary of these changes is contained in the consultation details attached to these rules.

The rule as amended was then referred to Parliament's Regulations Review Committee before being signed by the Minister of Transport.

## Examination of submissions

Submissions may be examined by application to the Docket Clerk at the Civil Aviation Authority between 8.30 am and 4.30 pm on weekdays, except statutory holidays.

## **Re-issue**

The re-issue of this Part is reflected in the revocation of existing Part 67 and the insertion of a new Part 67.

## Effective date of rule

The re-issued Part 67 comes into force on 1 May 2006.

## Availability of rules

Civil Aviation Rules are available from-

CAA web site: <u>http://www.caa.govt.nz/</u>

Freephone: 0800 GET RULES (0800 438 785)

## Part 67 Re-issue

Part 67 is revoked and this new part 67 is inserted.

# Subpart A - General

## 67.1 Purpose

This Part prescribes rules concerning-

- (1) the issue and holding of medical certificates required by flight crew and air traffic controllers; and
- (2) the medical standards for a medical certificate; and
- (3) the certification and operating requirements of medical examiners; and
- (4) the requirements for determining suitably qualified medical examiners under section 27O of the Act.

## 67.3 Definitions

(a) In this Part:

A medical condition is of **aeromedical significance** if, having regard to any relevant general direction, it interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which the relevant medical certificate relates.

**Aviation Medical Transitional Criteria Notice 2002** means the notice issued by the Minister under section 27Q of the Act, as amended by the Aviation Medical Transitional Criteria Amendment Notice 2006.

**Cardiac pacemaker** includes an automatic implantable cardiac defibrillator.

Licence holder means a person who-

(1) holds an aviation document or is a pilot; and

(2) holds, or is required under the rules to hold, a medical certificate.

**Medical assessment report** means the report of the Director under 67.59.

Medical condition includes:

- (1) any of the following (no matter how minor):
  - (i) any illness or injury;
  - (ii) any bodily infirmity, defect or incapacity;
  - (iii) any mental infirmity, defect or incapacity;
  - (iv) any sequela of an illness, injury, infirmity, defect or incapacity mentioned in (i), (ii) or (iii); and
- (2) any abnormal psychological state or behavioural or cognitive disorder; and
- (3) drug addiction and drug dependence; and
- (4) for a female pregnancy and the physiological and psychological consequences of pregnancy or of termination of pregnancy.

**Medical manual** means the medical manual issued by the Director and includes any incorporated general direction issued by the Director under section 27G(1) of the Act.

**Psychoactive substances** means alcohol, opioids, cannabinoids, sedatives and hypnotics, cocaine, other psychostimulants, hallucinogens, and volatile solvents, but excludes coffee and tobacco.

(b) To avoid doubt, a medical condition that causes or is likely to cause incapacitation, sudden or otherwise, is a medical condition of **aeromedical significance**.

## 67.4 Exemptions

(a) The Director may not grant an exemption from a requirement in Subpart C.

(b) To avoid doubt, paragraph (a) does not affect the power of the Director to rely on flexibility to issue a medical certificate to an applicant under section 27B(2) of the Act.

# Subpart B – Medical Certification

## 67.51 Purpose

This Subpart prescribes rules concerning-

- (a) the forms and information required when-
  - (1) applying for a medical certificate; and
  - (2) assessing an applicant for a medical certificate; and

(b) the classification, effective date and duration of a medical certificate; and

(c) the requirements and criteria for determining medical experts acceptable to the Director for the purpose of reaching an AMC.

## 67.53 Classification of medical certificates

The Director may issue the following classes of medical certificate under the Act:

- (1) class 1;
- (2) class 2;
- (3) class 3;
- (4) [Reserved].

## 67.55 Applications for medical certificates

An applicant for a medical certificate must-

- (1) complete the appropriate form specified by the Director and submit it to the Director with payment of the appropriate application fee prescribed by regulations made under the Act; and
- (2) produce one of the following documents as evidence of his or her identity:
  - (i) a current New Zealand passport;
  - (ii) a current New Zealand Driver Licence;
  - (iii) an equivalent form of photographic identification that is acceptable to the Director; and
- (3) where applicable, produce for inspection,-
  - (i) the licence that the applicant holds for which the medical certificate is required; and
  - (ii) the most recent medical certificate held by the applicant; and
  - (iii) the most recent medical assessment report; and
- (4) disclose or authorise the disclosure to the Director and the medical examiner of any information relating to the applicant's medical condition or history, including information concerning any conviction for an offence involving the possession or use of drugs or alcohol that the Director may reasonably require under section 27D(2) of the Act to determine whether the applicant satisfies the standards for a medical certificate.

## 67.57 Requirements for preparing an examination report

For the purposes of completing a report under section 27D(1) of the Act, a medical examiner-

- (1) must-
  - carry out a general medical examination of the applicant, having regard to the medical standards prescribed for the medical certificate applied for and any relevant general direction; and

- (ii) complete the appropriate form specified in the general directions; and
- (2) may not rely upon the results of any test, examination, or reexamination required under the Act for a period of more than 90 days from the date of the test, examination, or reexamination, unless any general direction provides otherwise.

### 67.59 Medical assessment reports

The Director must-

- (1) record an assessment of an application for a medical certificate, including details of the medical conditions considered and, if a medical certificate is issued, the surveillance requirements and endorsements imposed on the medical certificate, in an assessment report on the appropriate form specified in the general directions; and
- (2) provide a copy to the applicant.

### 67.61 Effective date and duration of medical certificates

- (a) Subject to paragraphs (c) and (e), the Director may issue-
  - (1) a class 1 medical certificate for a period of up to-
    - 6 months, if the applicant is 40 years of age or more on the date that the medical certificate is issued and is engaged in a single-crew air transport operation carrying passengers; or
    - (ii) 12 months, in all other cases;
  - (2) a class 2 medical certificate for a period of up to-
    - (i) 60 months, if the applicant is less than 40 years of age on the date that the medical certificate is issued; or
    - (ii) 24 months, if the applicant is 40 years of age or more on the date that the medical certificate is issued;
  - (3) a class 3 medical certificate for a period of up to-

- (i) 48 months, if the applicant is less than 40 years of age on the date that the medical certificate is issued; or
- (ii) 24 months, if the applicant is 40 years of age or more on the date that the medical certificate is issued;
- (4) [Reserved].
- (b) A medical certificate issued under paragraph (a)-
  - (1) takes effect on the date that it is issued; and
  - (2) remains in force for as long as it is current, unless-
    - (i) it is withdrawn under section 27H(2) of the Act; or
    - (ii) a subsequent or replacement medical certificate is issued to the holder.

(c) If, on the date of issue of a new medical certificate, the applicant holds a current medical certificate that expires in 30 days or less, the Director may issue the new medical certificate for a period that is longer than that specified in paragraph (a) with the expiry date that would have applied had the certificate been issued on the expiry date of the current medical certificate.

- (d) The provisions in paragraph (c) only apply, if-
  - (1) the Director concludes that the applicant is eligible for a new medical certificate issued for the maximum period permitted under paragraph (a); and
  - (2) the expiry date of the current certificate has not been extended under section 27E of the Act.

(e) The Director may issue a class 1 medical certificate under paragraph (a) to an applicant who is 40 years of age or more on the date that the medical certificate is issued that specifies one period of duration that applies under paragraph (a)(1)(i) and one period of duration that applies under paragraph (a)(1)(i).

## 67.63 Accredited medical conclusions

Before determining that a medical expert is acceptable for the purpose of reaching an AMC, the Director must be satisfied that–

- (1) the medical expert is a medical practitioner; and
- (2) the medical expert is suitably qualified and experienced in,-
  - (i) aviation medicine; or
  - (ii) if the Director considers it necessary in a particular case, a branch of medicine that is relevant to the AMC.

## 67.65 Replacement of medical certificates

(a) A person who holds a medical certificate may apply in writing to the Director for a replacement certificate, if the certificate is-

- (1) lost, stolen, or destroyed; or
- (2) so damaged that the details on the certificate are no longer clearly legible.

(b) An applicant for a replacement certificate must submit to the Director payment of the appropriate application fee prescribed by regulations made under the Act with-

- (1) a statutory declaration that his or her medical certificate has been lost, stolen or destroyed; or
- (2) the damaged certificate.

## 67.67 Medical manual

The Director must issue a medical manual that incorporates any general direction issued under section 27G of the Act and that may include information relevant to the consideration of applications for medical certificates, including information and advisory material concerning clinical, administrative and legislative matters.

## 67.69 Medical confidentiality

To avoid doubt, nothing in this rule derogates from any provision of the Privacy Act 1993 or the Health Information Privacy Code 1994.

# Subpart C - Medical Standards

### 67.101 Purpose

This Subpart prescribes the standards for a medical certificate.

## 67.103 Class 1 medical certificate

(a) An applicant who satisfies the standards in paragraphs (b) to (m) meets the medical standards for a class 1 medical certificate.

## General

- (b) An applicant must-
  - (1) have no medical condition that is of aeromedical significance; and
  - (2) without limiting paragraph (b)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) an abnormality;
    - (ii) a disability or disease (active or latent);
    - (iii) a sequela of an accident, an injury, or a surgical procedure;
    - (iv) a physiological or pathological process;
    - (v) a malignant process;
    - (vi) a condition that induces fatigue;
    - (vii) an infection, unless adequate treatment or resolution or both is demonstrable;
  - (3) not be-
    - (i) taking any drug, medication, substance, or preparation nor undergoing any treatment; or
    - (ii) experiencing any side-effect from any drug, medication, substance, preparation or treatment-

that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 1 medical certificate relates.

#### Nervous system

- (c) An applicant must-
  - (1) have no history or diagnosis of any neurological, neurosurgical, psychiatric or psychological condition, or behavioural or cognitive disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (c)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) disease or disorder of any component of the nervous system;
    - (ii) migraine or other severe headaches;
    - (iii) disturbance of consciousness or function;
    - (iv) psychiatric condition;
    - (v) psychosis;
    - (vi) personality disorder;
    - (vii) mental abnormality or neurosis;
    - (viii) depression;
    - (ix) post-traumatic stress disorder;
    - (x) sequela of a head injury or neurosurgical procedure; and
  - (3) without limiting paragraph (c)(1), have no history or diagnosis of epilepsy or any other condition associated with an elevated risk of convulsions;

- (4) have no history or diagnosis of the use of any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 1 medical certificate relates; and
- (5) not be taking any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 1 medical certificate relates.

### Cardiovascular system

- (d) An applicant must-
  - (1) have no history or diagnosis of any condition of the heart or circulatory tree that is of aeromedical significance; and
  - (2) without limiting paragraph (d)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) coronary artery disease;
    - (ii) left bundle branch block;
    - (iii) right bundle branch block unless ischaemic causes have been excluded;
    - (iv) uncontrolled hypertension;
    - (v) abnormality of the muscle, valves, or conduction system of the heart;
    - (vi) abnormality of the rhythm of the heart; and
  - (3) without limiting paragraph (d)(1), have no disorder requiring a cardiac pacemaker; and
  - (4) have no excessive cardiovascular risk factors unless normal myocardial perfusion can be demonstrated.

### **Respiratory system**

- (e) An applicant must-
  - (1) have no history or diagnosis of any condition of the respiratory system that is of aeromedical significance; and
  - (2) without limiting paragraph (e)(1), have no history or diagnosis of asthma, to an extent that is of aeromedical significance, unless adequate control is obtained with the use of prophylactic inhaled corticosteroid therapy alone.

### Alimentary and endocrine systems

- (f) An applicant must-
  - (1) have no history or diagnosis of any condition of the alimentary or endocrine systems that is of aeromedical significance; and
  - (2) without limiting paragraph (f)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the digestive system or its adnexae;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the digestive system or its adnexae;
    - (iii) any metabolic, nutritional or endocrine disorder other than as specified in (3); and
  - (3) without limiting paragraph (f)(1), have no history or diagnosis of any form of diabetes mellitus or abnormal glucose metabolism unless:
    - (i) the condition is satisfactorily controlled without the use of any anti-diabetic drug; or
    - (ii) if an oral anti-diabetic drug is used to control the condition,-

- (iia) the condition is under on-going medical supervision and control; and
- (iib) insulin is not used; and
- (iic) having regard to any relevant general direction, the oral drugs used, individually and in combination, do not, and are not likely to, interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 1 medical certificate relates.

#### Reticulo-endothelial and immune systems

- (g) An applicant must-
  - (1) have no history or diagnosis of any condition of the reticuloendothelial or immune systems that is of aeromedical significance; and
  - (2) without limiting paragraph (g)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) enlargement of the spleen unless myeloproliferative and infective causes have been excluded;
    - (ii) localised or generalised enlargement of the lymphatic glands;
    - (iii) any disease or condition of the blood or its constituents;
    - (iv) a disorder or condition associated with immune deficiency or hyper-immunity.

#### Genito-urinary system

- (h) An applicant must-
  - (1) have no history or diagnosis of any condition of the genitourinary system that is of aeromedical significance; and

- (2) without limiting paragraph (h)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) abnormality or disease of the genito-urinary system;
  - (ii) sequela of disease or trauma of, or a surgical procedure on, the genito-urinary system;
  - (iii) obstruction, or elevated risk of obstruction, to the kidneys or urinary tract.

#### Reproductive system

- (i) An applicant must-
  - (1) have no history or diagnosis of any condition of the reproductive system that is of aeromedical significance; and
  - (2) without limiting paragraph (i)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) menstrual disturbance;
    - (ii) pregnancy.

#### Musculo-skeletal system

- (j) An applicant must-
  - (1) have no history or diagnosis of any condition of the musculoskeletal system or integument that is of aeromedical significance; and
  - (2) without limiting paragraph (j)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - abnormality, disease, or pathological process of the skin, connective tissues, bones, joints, muscles, ligaments, or tendons;

(ii) sequela of disease or trauma of, or a surgical procedure on, the skin, connective tissues, bones, joints, muscles, ligaments, or tendons.

#### Ear, nose and throat

- (k) An applicant must-
  - (1) have no history or diagnosis of any condition of the ears, nose, or throat that is of aeromedical significance; and
  - (2) without limiting paragraph (k)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the external, middle, or internal ear;
    - (ii) abnormality, disease, or pathological process of the mouth, teeth, or upper respiratory tract;
    - (iii) obstruction of the Eustachian tubes or abnormality of middle ear ventilation;
    - (iv) disturbance of the vestibular apparatus.

#### Hearing

- (l) An applicant must-
  - (1) have no history or diagnosis of any hearing disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (l)(1), have no history or diagnosis of hearing deficit in either ear of more than-
    - (i) 35 dB, at any of the frequencies of 500 Hz, 1000 Hz or 2000 Hz; or
    - (ii) 50 dB at the frequency of 3000 Hz,

to an extent that is of aeromedical significance.

### Vision

- (m) An applicant must-
  - (1) have no history or diagnosis of any vision disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (m)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the eyes or their adnexae;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the eyes or their adnexae;
    - (iii) abnormal fields of vision or binocular vision performance;
    - (iv) surgical procedure affecting the refractive status of either eye; and
  - (3) without limiting paragraph (m)(1), have distant visual acuity, with or without correcting lenses, of 6/9 or better in each eye separately and 6/6 or better binocularly; and
  - (4) without limiting paragraph (m)(1), have near visual acuity, with or without correcting lenses, of N5 or better binocularly at a distance of between 30 and 50 centimetres, and have intermediate visual acuity of N14 or better binocularly at a distance of 1 metre; and
  - (5) without limiting paragraph (m)(1), have no deficit of colour vision to an extent that is of aeromedical significance.

## 67.105 Class 2 medical certificate

(a) An applicant who satisfies the standards in paragraphs (b) to (m) meets the medical standards for a class 2 medical certificate.

### General

(b) An applicant must-

- (1) have no medical condition that is of aeromedical significance; and
- (2) without limiting paragraph (b)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) an abnormality;
  - (ii) a disability or disease (active or latent);
  - (iii) a sequela of an accident, an injury, or a surgical procedure;
  - (iv) a physiological or pathological process;
  - (v) a malignant process;
  - (vi) a condition that induces fatigue;
  - (vii) an infection, unless adequate treatment or resolution or both is demonstrable;
- (3) not be-
  - (i) taking any drug, medication, substance, or preparation nor undergoing any treatment; or
  - (ii) experiencing any side-effect from any drug, medication, substance, preparation or treatment-

that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 2 medical certificate relates.

#### Nervous system

- (c) An applicant must-
  - (1) have no history or diagnosis of any neurological, neurosurgical, psychiatric or psychological condition, or behavioural or cognitive disorder that is of aeromedical significance; and

- (2) without limiting paragraph (c)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) disease or disorder of any component of the nervous system;
  - (ii) migraine or other severe headaches;
  - (iii) disturbance of consciousness or function;
  - (iv) psychiatric condition;
  - (v) psychosis;
  - (vi) personality disorder;
  - (vii) mental abnormality or neurosis;
  - (viii) depression;
  - (ix) post-traumatic stress disorder;
  - (x) sequela of a head injury or neurosurgical procedure; and
- (3) without limiting paragraph (c)(1), have no history or diagnosis of epilepsy or any other condition associated with an elevated risk of convulsions;
- (4) have no history or diagnosis of the use of any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 2 medical certificate relates; and
- (5) not be taking any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 2 medical certificate relates.

### Cardiovascular system

(d) An applicant must-

- (1) have no history or diagnosis of any condition of the heart or circulatory tree that is of aeromedical significance; and
- (2) without limiting paragraph (d)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) coronary artery disease;
  - (ii) left bundle branch block;
  - (iii) right bundle branch block unless ischaemic causes have been excluded;
  - (iv) uncontrolled hypertension;
  - (v) abnormality of the muscle, valves, or conduction system of the heart;
  - (vi) abnormality of the rhythm of the heart; and
- (3) without limiting paragraph (d)(1), have no disorder requiring a cardiac pacemaker; and
- (4) have no excessive cardiovascular risk factors unless normal myocardial perfusion can be demonstrated.

#### **Respiratory system**

- (e) An applicant must-
  - (1) have no history or diagnosis of any condition of the respiratory system that is of aeromedical significance; and
  - (2) without limiting paragraph (e)(1), have no history or diagnosis of asthma, to an extent that is of aeromedical significance, unless adequate and reliable control is obtained.

### Alimentary and endocrine systems

(f) An applicant must-

- (1) have no history or diagnosis of any condition of the alimentary or endocrine systems that is of aeromedical significance; and
- (2) without limiting paragraph (f)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) abnormality, disease, or pathological process of the digestive system or its adnexae;
  - (ii) sequela of disease or trauma of, or a surgical procedure on, the digestive system or its adnexae;
  - (iii) any metabolic, nutritional or endocrine disorder other than as specified in (3); and
- (3) without limiting paragraph (f)(1), have no history or diagnosis of any form of diabetes mellitus or abnormal glucose metabolism unless:
  - (i) the condition is satisfactorily controlled without the use of any anti-diabetic drug; or
  - (ii) if an oral anti-diabetic drug is used to control the condition,-
    - (iia) the condition is under on-going medical supervision and control; and
    - (iib) insulin is not used; and
    - (iic) having regard to any relevant general direction, the oral drugs used, individually and in combination, do not, and are not likely to, interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 2 medical certificate relates.

### **Reticulo-endothelial system**

(g) An applicant must-

- (1) have no history or diagnosis of any condition of the reticuloendothelial or immune systems that is of aeromedical significance; and
- (2) without limiting paragraph (g)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) enlargement of the spleen unless myeloproliferative and infective causes have been excluded;
  - (ii) localised or generalised enlargement of the lymphatic glands;
  - (iii) any disease or condition of the blood or its constituents;
  - (iv) a disorder or condition associated with immune deficiency or hyper-immunity.

#### Genito-urinary system

- (h) An applicant must-
  - (1) have no history or diagnosis of any condition of the genitourinary system that is of aeromedical significance; and
  - (2) without limiting paragraph (h)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality or disease of the genito-urinary system;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the genito-urinary system;
    - (iii) obstruction, or elevated risk of obstruction, to the kidneys or urinary tract.

#### Reproductive system

(i) An applicant must-

- (1) have no history or diagnosis of any condition of the reproductive system that is of aeromedical significance; and
- (2) without limiting paragraph (i)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
  - (i) menstrual disturbance;
  - (ii) pregnancy.

#### Musculo-skeletal system

- (j) An applicant must-
  - (1) have no history or diagnosis of any condition of the musculoskeletal system or integument that is of aeromedical significance; and
  - (2) without limiting paragraph (j)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - abnormality, disease, or pathological process of the skin, connective tissues, bones, joints, muscles, ligaments, or tendons;
    - sequela of disease or trauma of, or a surgical procedure on, the skin, connective tissues, bones, joints, muscles, ligaments, or tendons.

#### Ear, nose and throat

- (k) An applicant must-
  - (1) have no history or diagnosis of any condition of the ears, nose, or throat that is of aeromedical significance; and
  - (2) without limiting paragraph (k)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:

- (i) abnormality, disease, or pathological process of the external, middle, or internal ear;
- (ii) abnormality, disease, or pathological process of the mouth, teeth, or upper respiratory tract;
- (iii) obstruction of the Eustachian tubes or abnormality of middle ear ventilation;
- (iv) disturbance of the vestibular apparatus;

### Hearing

- (l) An applicant must-
  - (1) have no history or diagnosis of any hearing disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (l)(1), have no hearing deficit in either ear detectable on conversational voice test or of more than-
    - (i) 35 dB, at any of the frequencies of 500 Hz, 1000 Hz or 2000 Hz; or
    - (ii) 50 dB at the frequency of 3000 Hz,

to an extent that is of aeromedical significance.

### Vision

- (m) An applicant must-
  - (1) have no history or diagnosis of any vision disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (m)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the eyes or their adnexae;

- (ii) sequela of disease or trauma of, or a surgical procedure on, the eyes or their adnexae;
- (iii) abnormal fields of vision or binocular vision performance;
- (iv) surgical procedure affecting the refractive status of either eye; and
- (3) without limiting paragraph (m)(1), have distant visual acuity, with or without correcting lenses, of 6/12 or better in each eye separately and 6/9 or better binocularly; and
- (4) without limiting paragraph (m)(1), have near visual acuity, with or without correcting lenses, of N5 or better binocularly at a distance of between 30 and 50 centimetres; and
- (5) without limiting paragraph (m)(1), have no deficit of colour vision to an extent that is of aeromedical significance.

### 67.107 Class 3 medical certificate

(a) An applicant who satisfies the standards in paragraphs (b) to (m) meets the medical standards for a class 3 medical certificate.

### General

- (b) An applicant must-
  - (1) have no medical condition that is of aeromedical significance; and
  - (2) without limiting paragraph (b)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) an abnormality;
    - (ii) a disability or disease (active or latent);
    - (iii) a sequela of an accident, an injury, or a surgical procedure;
    - (iv) a physiological or pathological process;

- (v) a malignant process;
- (vi) a condition that induces fatigue;
- (vii) an infection, unless adequate treatment or resolution or both is demonstrable;
- (3) not be-
  - (i) taking any drug, medication, substance, or preparation nor undergoing any treatment; or
  - (ii) experiencing any side-effect from any drug, medication, substance, preparation or treatment-

that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 3 medical certificate relates.

#### Nervous system

- (c) An applicant must-
  - have no history or diagnosis of any neurological, neurosurgical, psychiatric or psychological condition, or behavioural or cognitive disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (c)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) disease or disorder of any component of the nervous system;
    - (ii) migraine or other severe headaches;
    - (iii) disturbance of consciousness or function;
    - (iv) psychiatric condition;
    - (v) psychosis;

- (vi) personality disorder;
- (vii) mental abnormality or neurosis;
- (viii) depression;
- (ix) post-traumatic stress disorder;
- (x) sequela of a head injury or neurosurgical procedure; and
- (3) without limiting paragraph (c)(1), have no history or diagnosis of epilepsy or any other condition associated with an elevated risk of convulsions;
- (4) have no history or diagnosis of the use of any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 3 medical certificate relates; and
- (5) not be taking any psychoactive substance that, having regard to any relevant general direction, interferes or is likely to interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 3 medical certificate relates.

### Cardiovascular system

- (d) An applicant must-
  - (1) have no history or diagnosis of any condition of the heart or circulatory tree that is of aeromedical significance; and
  - (2) without limiting paragraph (d)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) coronary artery disease;
    - (ii) left bundle branch block;
    - (iii) right bundle branch block unless ischaemic causes have been excluded;

- (iv) uncontrolled hypertension;
- (v) abnormality of the muscle, valves, or conduction system of the heart
- (vi) abnormality of the rhythm of the heart; and
- (3) without limiting paragraph (d)(1), have no disorder requiring a cardiac pacemaker; and
- (4) have no excessive cardiovascular risk factors unless normal myocardial perfusion can be demonstrated.

#### **Respiratory system**

- (e) An applicant must-
  - (1) have no history or diagnosis of any condition of the respiratory system that is of aeromedical significance; and
  - (2) without limiting paragraph (e)(1), have no history or diagnosis of asthma, to an extent that is of aeromedical significance, unless adequate control is obtained with the use of prophylactic inhaled corticosteroid therapy alone.

#### Alimentary and endocrine systems

- (f) An applicant must-
  - (1) have no history or diagnosis of any condition of the alimentary or endocrine systems that is of aeromedical significance; and
  - (2) without limiting paragraph (f)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the digestive system or its adnexae;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the digestive system or its adnexae;

- (iii) any metabolic, nutritional or endocrine disorder other than as specified in (3); and
- (3) without limiting paragraph (f)(1), have no history or diagnosis of any form of diabetes mellitus or abnormal glucose metabolism unless:
  - (i) the condition is satisfactorily controlled without the use of any anti-diabetic drug; or
  - (ii) if an oral anti-diabetic drug is used to control the condition,-
    - (iia) the condition is under on-going medical supervision and control; and
    - (iib) insulin is not used; and
    - (iic) having regard to any relevant general direction, the oral drugs used, individually and in combination, do not, and are not likely to, interfere with the safe exercise of the privileges or the safe performance of the duties to which a class 3 medical certificate relates.

#### **Reticulo-endothelial system**

- (g) An applicant must-
  - (1) have no history or diagnosis of any condition of the reticuloendothelial or immune systems that is of aeromedical significance; and
  - (2) without limiting paragraph (g)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) enlargement of the spleen unless myeloproliferative and infective causes have been excluded;
    - (ii) localised or generalised enlargement of the lymphatic glands;

- (iii) any disease or condition of the blood or its constituents;
- (iv) a disorder or condition associated with immune deficiency or hyper-immunity.

#### **Genito-urinary system**

- (h) An applicant must-
  - (1) have no history or diagnosis of any condition of the genitourinary system that is of aeromedical significance; and
  - (2) without limiting paragraph (h)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality or disease of the genito-urinary system;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the genito-urinary system;
    - (iii) obstruction, or elevated risk of obstruction, to the kidneys or urinary tract.

#### **Reproductive system**

- (i) An applicant must-
  - (1) have no history or diagnosis of any condition of the reproductive system that of aeromedical significance; and
  - (2) without limiting paragraph (i)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) menstrual disturbance;
    - (ii) pregnancy.

#### Musculo-skeletal system

- (j) An applicant must-
  - have no history or diagnosis of any condition of the musculoskeletal system or integument that is of aeromedical significance; and
  - (2) without limiting paragraph (j)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - abnormality, disease, or pathological process of the skin, connective tissues, bones, joints, muscles, ligaments, or tendons;
    - sequela of disease or trauma of, or a surgical procedure on, the skin, connective tissues, bones, joints, muscles, ligaments, or tendons.

#### Ear, nose and throat

- (k) An applicant must-
  - (1) have no history or diagnosis of any condition of the ears, nose, or throat that is of aeromedical significance; and
  - (2) without limiting paragraph (k)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the external, middle, or internal ear;
    - (ii) abnormality, disease, or pathological process of the mouth, teeth, or upper respiratory tract;
    - (iii) disturbance of the vestibular apparatus;

### Hearing

(l) An applicant must-

- (1) have no history or diagnosis of any hearing disorder that is of aeromedical significance; and
- (2) without limiting paragraph (l)(1), have no history or diagnosis of hearing deficit in either ear of more than-
  - (i) 35 dB, at any of the frequencies of 500 Hz, 1000 Hz or 2000 Hz; or
  - (ii) 50 dB at the frequency of 3000 Hz,

to an extent that is of aeromedical significance.

#### Vision

- (m) An applicant must-
  - (1) have no history or diagnosis of any vision disorder that is of aeromedical significance; and
  - (2) without limiting paragraph (m)(1), have no history or diagnosis of any of the following specific medical conditions, to an extent that is of aeromedical significance:
    - (i) abnormality, disease, or pathological process of the eyes or their adnexae;
    - (ii) sequela of disease or trauma of, or a surgical procedure on, the eyes or their adnexae;
    - (iii) abnormal fields of vision or binocular vision performance;
    - (iv) surgical procedure affecting the refractive status of either eye; and
  - (3) without limiting paragraph (m)(1), have distant visual acuity, with or without correcting lenses, of 6/9 or better in each eye separately and 6/6 or better binocularly; and
  - (4) without limiting paragraph (m)(1), have near visual acuity, with or without correcting lenses, of N5 or better binocularly at a distance of between 30 and 50 centimetres, and have

intermediate visual acuity of N14 or better binocularly at a distance of 1 metre; and

(5) without limiting paragraph (m)(1), have no deficit of colour vision to an extent that is of aeromedical significance.

#### 67.109 Reserved

### Subpart D – Medical Examiners

#### 67.151 Purpose

This Subpart prescribes rules relating to-

- (1) the designation of medical examiners; and
- (2) the determination of suitably qualified medical examiners under section 27O(2) of the Act.

#### 67.153 Medical examiner certificates

The Director may issue the following medical examiner certificates under the Act:

- (1) Medical Examiner 1 Certificate;
- (2) Medical Examiner 2 Certificate;
- (3) Special Medical Examiner Certificate.

#### 67.155 Applications for certificates

(a) A person applying for a medical examiner certificate must complete the appropriate form specified by the Director and submit it to the Director with-

- (1) the exposition required by 67.163; and
- (2) payment of the appropriate application fee prescribed by regulations made under the Act.

(b) A person applying for the renewal of a medical examiner certificate must complete the appropriate form specified by the Director and submit it to the Director-

- (1) with payment of the appropriate fee prescribed by regulations made under the Act;
- (2) not less than 30 working days before the renewal date specified in the certificate or, if no such date is specified, not less than 30 working days before the certificate expires.

#### 67.157 Issue of medical examiner certificates

(a) Subject to section 9 of the Act, the Director must issue a medical examiner certificate to a person who has applied under 67.155, if the Director is satisfied that he or she meets the certification requirements prescribed in 67.161.

(b) Despite paragraph (a), and subject to section 9(1)(b)(ii) of the Act, the Director may, subject to any conditions that the Director considers necessary, issue a Special Medical Examiner Certificate to a person who does not meet the certification requirements prescribed in 67.161, if-

- (1) the person is a medical practitioner; and
- (2) the Director is satisfied that there are emergency or special geographical or special operational circumstances that justify the issue of a Special Medical Examiner Certificate to the person.

#### 67.159 Privileges of medical examiner certificate holders

A person who holds a current-

- (1) Medical Examiner 1 Certificate may conduct medical examinations for the purpose of issuing any class of medical certificate;
- (2) Medical Examiner 2 Certificate may conduct medical examinations for the purpose of issuing a class 2 medical certificate;
- (3) Special Medical Examiner Certificate may conduct medical examinations as specified in writing by the Director.

#### 67.161 Medical examiner certification requirements

A person applying for a medical examiner certificate meets the certification requirements for that certificate, if the person-

- (1) is a medical practitioner; and
- (2) has-
  - (i) successfully completed aviation medicine training acceptable to the Director; and
  - (ii) successfully completed aviation regulatory medicine training acceptable to the Director; and
  - (iii) demonstrated to the Director that he or she meets the relevant competencies set out in Appendix A; and
- (3) has access to clinical, administrative and communication facilities adequate for the purpose of carrying out medical examinations to the required standard in accordance with the medical manual; and
- (4) has a reasonable ability to communicate effectively in English; and
- (5) meets the exposition requirements in 67.163.

#### 67.163 Exposition

(a) A person applying for a medical examiner certificate must provide the Director with an exposition containing-

- (1) a statement signed by the person confirming that the exposition-
  - (i) accurately describes the person's aviation medical practice and demonstrates the person's means and methods of ensuring ongoing compliance with 67.161; and
  - (ii) will be complied with by the person and any personnel involved in the person's aviation medical practice, at all times; and
- (2) a description of the scope of the person's aviation medical practice; and

- (3) the titles and names of any of the personnel involved in the person's aviation medical practice; and
- (4) the duties and responsibilities of personnel referred to in paragraph (a)(3); and
- (5) a list of the locations at which the person will practise aviation medicine; and
- (6) details demonstrating that the person has access to clinical, administrative and communication facilities that are adequate for the purposes of carrying out aviation medical examinations to the required standard in accordance with the medical manual; and
- (7) procedures for communicating with the Director, including-
  - (i) the referral of applications for medical certificates to the Director for assessment; and
  - (ii) where applicable, the reporting of changes in the medical condition of a person who holds a medical certificate, or the existence of any previously undetected medical condition in a person who holds a medical certificate, that may interfere with the safe exercise of the privileges to which that person's medical certificate relates; and
  - (iii) the prior notification of every proposed change to any of the details specified in paragraphs (a)(2), (a)(3), (a)(4), or (a)(5); and
- (8) details of the person's means of ensuring that the continued compliance requirements specified in 67.203 will be met; and
- (9) details of systems and procedures to ensure the adequate-
  - (i) control, inspection, testing, and calibration of medical equipment; and
  - (ii) control and amendment of documentation relevant to the person's aviation medical practice; and

- (iii) identification, collection, indexing, storage, maintenance and disposal of records; and
- (iv) training, assessment and authorisation of any personnel to carry out the functions in (9)(i), (9)(ii) and (9)(iii); and
- (10) details of procedures for identifying and managing any conflict of interest arising out of the person's professional obligations; and
- (11) details of an annual internal quality assurance audit programme to ensure the conformity of the person's aviation medical practice with the procedures in the exposition; and
- (12) details of procedures to-
  - (i) control and amend the exposition; and
  - (ii) ensure that it meets the applicable requirements of this Part; and
  - (iii) ensure that the Director is provided with a copy of every amendment to the exposition as soon as practicable after its incorporation into the exposition; and
  - (iv) distribute the exposition to personnel.
- (b) The person's exposition must be acceptable to the Director.

# Subpart E – Operating Requirements for Medical Examiners

#### 67.201 Purpose

This Subpart prescribes rules relating to the operating requirements of medical examiners.

#### 67.203 Continued compliance

(a) A person who holds a medical examiner certificate must-

- (1) hold at least one complete and current copy of the certificate holder's exposition at each location of the practice specified in the exposition; and
- (2) comply with all procedures, systems and programmes detailed in the certificate holder's exposition, including those relating to conflicts of interest; and
- (3) make every applicable part of the exposition available to personnel who require it to carry out their duties; and
- (4) continue to meet and comply with the requirements prescribed for medical examiner certification under Subpart D; and
- (5) attend ongoing training courses in aviation medicine and aviation regulation, as may reasonably be required by the Director; and
- (6) comply with general directions and emergency directives issued under section 27G of the Act; and
- (7) hold an up-to-date copy of the medical manual; and
- (8) ensure that an accurate record is kept of every examination of every applicant for a medical certificate; and
- (9) notify the Director of any change of address for service, telephone number, or facsimile number within 28 days of the change.

(b) The Director may prescribe conditions under which a person who holds a medical examiner certificate may operate during or following any of the changes specified in 67.163(a)(7)(iii).

- (c) A person who holds a medical examiner certificate must-
  - (1) comply with any conditions prescribed under paragraph (b); and
  - (2) where any of the changes referred to in paragraph (b) require an amendment to the certificate holder's medical examiner certificate, forward the certificate to the Director as soon as practicable; and

(3) make such amendments to the certificate holder's exposition as the Director considers necessary in the interests of aviation safety.

# Subpart F – Requirements for Delegations by the Director

#### 67.251 Determining suitably qualified medical examiners

For the purposes of a delegation under section 27O(2) of the Act, a person is a suitably qualified medical examiner, if–

- (1) the person holds-
  - (i) for any class of medical certificate, a Medical Examiner 1 Certificate; or
  - (ii) for class 2 medical certificates, a Medical Examiner 2 Certificate; and
- (2) the Director is satisfied that the person-
  - (i) has the necessary skill and experience; and
  - (ii) comprehends aviation medical certification policy and procedures; and
- (3) the person undertakes to attend ongoing training courses in aviation medicine and aviation regulation, as may reasonably be required by the Director; and
- (4) the Director is satisfied that the person has adopted and applies suitable procedures for the identification of conflicts of interest.

# Subpart G – Aviation Examiners – reserved

#### 67.301 Reserved

# Subpart H – Transitional Arrangements

#### 67.351 Transitional provisions

(a) Subject to paragraphs (b) and (c), if an application for the issue or renewal of a Medical Examiner 1 Certificate or a Medical Examiner 2

Certificate is received by the Director but not determined before this rule comes into force, the Director may issue or renew the certificate, as if the Aviation Medical Transitional Criteria Notice 2002 were still in force.

(b) If (a) applies, an application for the issue or renewal of a Medical Examiner 2 Certificate may not be granted unless the applicant meets the relevant competencies set out in Schedule 1 of the Aviation Medical Transitional Criteria Notice 2002, except if the Director issues or renews the certificate on a special case basis because of a particular need for geographical coverage.

(c) A person who holds a medical examiner certificate issued in accordance with the Aviation Medical Transitional Criteria Notice 2002 must provide the Director with an exposition that meets the requirements of 67.163 no later than 6 months after the date that this rule comes into force.

(d) A person who holds a medical examiner certificate issued in accordance with the Aviation Medical Transitional Criteria Notice 2002 is not required to comply with the operating requirements in Subpart E relating to expositions until the date that he or she is required to provide the Director with an exposition.

(e) If an application for the issue of a medical certificate is received by the Director but not determined before this rule comes into force, the Director must determine the application, as if the rules applying at the time the application was received were still in force.

### Appendix A – Medical Examiner Competencies

# Competencies required to be demonstrated for issue of medical examiner certificate

To be eligible for the issue of a medical examiner certificate, an applicant must, in addition to satisfying other general requirements, demonstrate competence in performing the functions of a medical examiner. The functions are established in the Civil Aviation Act 1990. There are four generic competence categories: identification, assessment, management, and audit/review.

#### Notes:

- For the holders of Medical Examiner 2 Certificates, the competencies relate to the conduct of examinations for the purpose of issuing a Class 2 medical certificate.
- For the holders of Medical Examiner 1 Certificates, the competencies relate to the conduct of examinations for the purpose of issuing a Class 1, 2 or 3 medical certificate.
- The competencies are set at 3 levels as follows:

expert	the person can operate without supervision and could supervise others.
practised	actual practical experience such that the person could operate under supervision
awareness	theoretical knowledge of the subject only

The table below describes each competency and lists the competency level required of the holders of Medical Examiner 1 Certificates and Medical Examiner 2 Certificates.

Description of competencies required		Level of competency for	
Identi	ification	ME 1	ME 2
1	<ul> <li>Apply clinical skills to accurately diagnose and evaluate conditions and situations that have the potential to interact adversely with the aviation environment by utilising:</li> <li>Clinical history taking:</li> <li>Physical and mental examination:</li> <li>Further investigations or consultant reviews (whether performed or arranged by medical examiner):</li> <li>Diagnostic skills:</li> <li>Liaison with colleagues, other health professionals, and other organisations.</li> </ul>	expert	expert
2	Identify aspects of an applicant's medical condition or situation that may cause the applicant to interact adversely with the aviation environment.	expert	practised

Description of competencies required		Level of competency for	Level of competency for:
3	Identify the competing or conflicting interests inherent in regulatory medical practice.	practised	practised
4	Access additional information, such as journals, scientific research, internet resources, colleagues, and specialist advisors, to support the assessment of an applicant's suitability and safety to operate in an aviation environment.	practised	practised
Asses	sment		
5	Employ evidence-based medical principles and processes in determining and analysing the suitability and safety of an applicant to operate within the aviation environment.	expert	practised
6	Determine and analyse the legislation, regulations, and medico-legal considerations relating to the safety and suitability of an applicant to operate within the aviation environment.	practised	practised
7	Critically analyse and utilise additional information, such as journals, scientific research, internet resources, colleagues, and specialist advisors, to support the assessment of an applicant's suitability and safety to operate in an aviation environment.	practised	practised
Mana	agement		

Descr	ription of competencies required	Level of competency for	Level of competency for:
8	Assessing the risk related to an applicant operating in the aviation environment by applying the necessary standards, methodologies, and processes.	expert	expert
9	Manage conflicting or competing interests in a manner that does not compromise aviation safety or the quality of clinical decision- making.	expert	practised
10	<ul> <li>Effectively communicate:</li> <li>Risk assessment determinations and considerations to applicants, the CAA, colleagues, and other organisations</li> <li>Information concerning the relevant legislation and regulations to applicants</li> <li>With colleagues, consultants, and others as necessary for the purposes of obtaining additional information, advice, and guidance concerning regulatory risk management decisions.</li> </ul>	expert	expert
11	<ul> <li>Manage practice administration and record keeping systems so that:</li> <li>Regulatory risk assessment and risk management decisions</li> </ul>	expert	expert

Description of competencies required		Level of competency for	Level of competency for:	
		and actions are reliably and thoroughly documented		
	•	Regulatory risk assessment and risk management decisions can be effectively and unambiguously communicated		
	•	Regulatory risk assessment and risk management decisions and actions are easily retrievable over time.		
Review	w/audit			
12	Be a constructive participant in monitoring, review, and audit activities through:		practised	practised
	•	Taking an active involvement in review processes		
	•	Appreciating and accepting review findings and outcomes		
	•	Implementing review recommendations.		



Appendix B – Concrete and Concr

# **Consultation Details**

(This statement does not form part of the rules contained in Part 67. It provides details of the consultation undertaken in making the rules.)

#### Notice of Proposed Rule Making July 2003

An NPRM for the re-issue of Part 67 was published on 10 July 2003. The purpose of the NPRM was to seek comments on the re-issue, which was intended to:

- Align medical standards and certification with the legal framework established by the Civil Aviation (Medical Certification) Amendment Act 2001 that came into effect on 1 April 2002;
- Incorporate the provisions of the Aviation Medical Transitional Criteria Notice 2002 issued by the Minister of Transport on 1 April 2002;
- Update the medical standards taking into account the recommendations of Bruce Corkill and Dr Simon Janvrin in *"Final Report of Review Team to Minister of Transport on Rule Part 67, Medical Standards and 1% Rule"* of November 2001 ("the Corkill-Janvrin report");
- Recognise the requirements of the International Civil Aviation Organization (ICAO).

This proposal also included consequential amendments to Part 1 of the rules.

20 submissions were received on this NPRM.

#### Summary of submissions on NPRM dated 10 July 2003

General comments on the NPRM

A number of **submitters** expressed concern at the general approach taken to describing standards. Many believe that the stem is too vague and does not set specific medical standards. The meaning of terms such as "likely", "significant", "elevated risk of incapacitation" and "unsafe behaviour" is unclear. The standards are therefore at risk of being interpreted so liberally that–

• too many medical certificates are issued under section 27B(1) of the Civil Aviation Act 1990 (the Act);

• section 27B(2) is undermined because the flexibility permitted by that section is instead effectively exercised in assessing compliance with the standards.

The descriptive stem would also increase the likelihood of the standards and the decisions of aviation medical examiners being open to legal challenge

Ministry of Transport (MOT) comment: The descriptive stem was consciously developed to give aviation medical examiners the flexibility to exercise medical judgement in determining whether, by having regard to the general directions (GDs), the prescribed medical standards were met rather than being so prescriptive that in most cases eligibility had to be determined under section 27B(2) of the Act. It was also intended to plainly state the aspects of any medical condition that engendered safety concerns. The concept of "unsafe behaviour" was developed to address conditions of medical interest that make aviation unsafe but that do not produce any functional incapacity or impairment of functional capacity. An example is risk taking associated with psychiatric disorders. However, the Ministry appreciates the concern that the descriptive stem may create interpretation difficulties and produce inconsistent outcomes. Accordingly, other options for expressing the standards will be explored.

The New Zealand Agriculture Aviation Association (NZAAA) believes the standards are too strict. This will affect the sector's ability to retain experienced pilots.

**MOT comment:** NZAAA does not specify any particular standard as being too strict so presumably their comments apply generally. Because the descriptive stem was consciously developed to permit the exercise of medical judgement by aviation medical examiners, the Ministry does not agree that it is too strict. Nor do we agree that the more specific standards prescribed are too strict. The latter reflect present international standards and in some cases provide a more liberal approach e.g. diabetes. Further, the failure to meet the standards would not be fatal to an application for a medical certificate. The Act permits the issue of a medical certificate to those who do not meet the standards, provided certain conditions are met, such as obtaining a positive accredited medical conclusion (AMC).

**Origin Pacific** and two other **submitters** would like to see the numerical risk description used. One **submitter** asks, why exclude the numerical risk description when it is well defined? **Origin Pacific** comment that by recording decisions made by aviation medical examiners and their reasons, better risk assessments will be achieved over time.

**MOT comment:** A numerical risk description has the advantages of being relatively unambiguous and requiring no further definition. However, it can be too rigid a measure and some aspects of regulatory medicine are not easily defined in this way, for example functional incapacity and unsafe behaviour. On balance, a word picture description alone seems preferable. It may be appropriate for the GDs to refer to numerical risk descriptions.

**Sports Aircraft Association of New Zealand (SAANZ)** believes that the cardiovascular standards should be more closely aligned to the recommendations made in the Corkill-Janvrin report

**MOT comment:** The cardiovascular standards are aligned with the Corkill-Janvrin recommendations as closely as can be achieved without using numerical risk descriptors.

Some **submitters** recommended that the rule should be more closely modelled on the ICAO, Australian (CASA), or FAA rules and be more consistent with the recommendations of the Select Committee, Corkill-Janvrin report and New Zealand's TTMRA obligations. [The Transport and Industrial Relations Select Committee reported on the Civil Aviation Amendment Bill (No. 2), which became the Civil Aviation (Medical Certification) Amendment Act 2001].

**MOT comment:** It would be impossible to draft the rule in a way that is consistent with the ICAO, CASA and FAA standards, the Select Committee's recommendations, and the Corkill-Janvrin report because these documents are not compatible in every respect. For example, Corkill-Janvrin recommends adopting ICAO standards for class 2 medical certificates rather than the less stringent CASA standards. Thus, while the rule should draw on aspects of these standards and recommendations, there will necessarily be compromises.

#### ICAO/CASA/FAA standards

As noted above, other options for expressing the aviation medical standards will be explored, including re-consideration of the approaches taken by ICAO, CASA and FAA.

#### Select Committee recommendations

The report of the Transport and Industrial Relations Committee on the Civil Aviation Amendment Bill (No. 2) proposed the inclusion of the "flexibility" concept in the Bill and also expressed a preference for the FAA approach in relation to delegating the Director's powers to aviation medical examiners. It is unclear in what respect the draft rule is inconsistent with the Committee's report. In our view, there is no inconsistency.

#### Corkill-Janvrin Report

A comparison of the NPRM with the Corkill-Janvrin recommendations was included on pages 9 to 11 of the NPRM. We have reconsidered the submission that the NPRM should be more consistent with the Corkill-Janvrin report and have concluded that the table adequately explains the reasons for any divergence.

#### Trans-Tasman Mutual Recognition Act

The rule will be subject to New Zealand's TTMRA obligations, in accordance with section 5 of the Trans-Tasman Mutual Recognition Act 1997, which states-

"Every law of New Zealand must, unless it or this Act otherwise expressly provides, be read subject to this Act".

In relation to the "subrules", i.e. the standards set out in each subparagraph (2) of 67.103, 67.105 and 67.107, one **submitter**–

- Queries their intent and suggests they contain significant tautology or internal inconsistency;
- Suggests the standards start with a general provision that an applicant *must* have no condition of a particular organ system, followed by provisions that state the applicant *should* have no history or diagnosis of specific conditions of that organ system;
- Queries the intent behind the words "have no history or diagnosis of any of the following conditions, to an extent that is likely …" and suggests that "have no history or diagnosis of any of the following conditions such that the condition is likely …" would be better.

**MOT comment:** The draft rule prescribes a general standard applying to an organ system followed by particular standards applying to specified conditions falling within the general standard. Legislation often clarifies the application of a general provision to a specific set of circumstances, including when there is a desire to give guidance. Having said that, it may be desirable to clarify the relationship between the general provision and the specific provisions by adding words such as "without limiting paragraph (b)(1)" at the beginning of (b)(2). Exceptions to the general standards need to be clear.

The purpose of civil aviation rules is to prescribe enforceable standards, not communicate guidance material. Accordingly, it is not appropriate to provide that a person "should" comply with specific standards. In the context of aviation medical certification, the general directions and the medical manual are the appropriate place for this.

In the phrase "have no history or diagnosis of any of the following conditions, to an extent that is likely", the emphasis is not on the condition *per se* but rather on the "history or diagnosis of the condition" (i.e., the extent to which the particular history or diagnosis of the condition in the applicant is able to produce the specified consequences). The suggested re-wording would, if anything, shift the emphasis to the condition, which is not the intent.

Some **submitters** believe that more GDs need to be issued before they can assess how workable the rule will be. Further consultation on the draft NPRM should only proceed once a number of key GDs are available for review.

**MOT comment:** The preparation of GDs will provide a clearer picture of how the rule will work. The rule is intended to stand-alone but will eventually be complemented by the GDs. However, it will not be possible to prepare a full suite of GDs simultaneously, without unduly delaying the rule. It is intended that a few key GDs will be prepared for consultation before new part 67 is made. These should enable submitters to assess how the GDs will interact with the rule.

Some **submitters** believe the draft rule leaves it to the GDs to prescribe medical standards. GDs should be reserved for administrative functions specified for them in the Act and medical standards should be contained in the rule. **Guild of Air Pilots and Air Navigators (GAPAN)** noted that they were comfortable with the use of GDs to set medical standards because it allows changes to be made quickly in response to developments in medical information

**MOT comment:** Medical standards should be contained in the rule and, as already discussed, other options for expressing the threshold to be met by an applicant for a medical certificate will be explored. The Act clearly permits GDs to cover more than administrative functions. For example, they may specify the requirements of examinations or other clinical matters, including, but not limited to, the significance of results of examinations for the purpose of determining eligibility. These must be "reasonable" and subject to adequate consultation with industry and health professionals; it not, they will be vulnerable to legal challenge.

**Airways Corporation of New Zealand (Airways)** recommends that a GD should be developed specifically to cover issues for class 3 medical certificates, relating to issues such as colour perception and pregnancy in air traffic controllers.

**MOT comment:** The GDs could be drafted to cover class 3 issues however this is an issue for the Director to determine.

One **submitter** questions where the time periods for tests such as ECG will be laid down.

**MOT comment:** The frequency of testing for the purpose of issuing a medical certificate will depend on the duration of the medical

certificate applied for. For other specific tests, it is envisaged that GDs will be used.

Some **submitters** commented that a great deal of the rule appears to be unnecessarily repetitive and recommend introducing the stem in a more generic way. The lists of conditions could be less prescriptive and briefer.

**MOT comment:** It would be worthwhile reviewing the rule with a view to reducing any unnecessary repetition. The lists of conditions are necessarily prescriptive, reflecting international practice. (We note that, on this issue, most submitters believe the rule should be more prescriptive.)

Some **submitters** were concerned that the Act and the rule may conflict.

**MOT comment:** There should be no conflict between the Act and the rule. In the event of any inconsistency, the rule will be read subject to the Act.

A number of **submitters** believe that medical certificates should be mandatory for all pilots and a Class 4 medical certificate should be included to cover recreational and sport pilots.

**MOT comment:** The CAA is working on the policy considerations concerning the medical certification of recreational flying as part of the development of Part 61. One of the issues is deciding the standard of medical check to be imposed on recreational pilots. Once that has been determined, it will be clear whether there is a need for medical certification provisions under Part 67. If there is a need to formally prescribe medical standards then Part 67 will definitely need to deal with these but if the standard requires a medical certificate issued by a General Practitioner, this may not be necessary.

Aircraft Owners' and Pilots' Association (New Zealand) Inc (AOPA), Royal New Zealand Aero Club Inc (RNZAC), SAANZ and Combined New Zealand Aviation Medicine Forum (CNZAMF) were critical of the consultation process, commenting that interest groups have not had meaningful input into the rule development process and that their views have not been reflected in the NPRM.

**MOT comment:** There are 3 main criticisms of the consultation process-

- not enough meetings;
- inadequate minuting of the meeting on 14 February 2003;
- issues raised by industry were not incorporated into the NPRM.

The criticisms concern the informal consultation held prior to the preparation and publication of the NPRM for comment. These criticisms are firmly rejected and it should be noted that, at the time they were made, the consultation process had not been completed.

It is difficult to accept the view that there has been no meaningful input into the rule development process. The Ministry convened a meeting in December 2002 with key representatives of the industry prior to commencement of formal consultation. At that meeting, industry representatives were presented and briefed on a draft NPRM. Subsequently, a full-day meeting was held in February 2003 that identified the issues of concern to the industry. These were discussed in depth and the following list of action points agreed by and copied to attendees:

Risk criteria	<ul> <li>Industry recommends use of word picture rather than numerical picture.</li> <li>Risk criteria could appear elsewhere – GDs? Manual?</li> </ul>
General directions	<ul> <li>Issue GDs for temporary medical conditions/hearing impairment for formal (statutory) consultation.</li> <li>Consultation timeframe – 6 weeks</li> <li>Consider user-friendly guide for pilots – poster/"how to"/GAP booklet</li> </ul>
Unsafe behaviour	<ul> <li>Consider FAA description 67.113 as alternative</li> <li>CAA define rather than rely on common law interpretation</li> <li>Consider Bill of Rights implications</li> </ul>

	prior to issue of NPRM
	• Do other tools (i.e. fit and proper person)
	provide mechanism for management?
Date of issue	• WOF approach extended to 30 days –
	check out 1 calendar month
	• NOTE: TRY TO CONSISTENTLY
	APPLY DATES
Reconfirm validity	Written confirmation – safety driven
dates with CASA	Class 1 - extended currency over 40
	• Class 2 - 5 yrs => 4 years
90 days	Remove from rule
	Publish GD relating to
	tests/examinations/reports
	Interim declaration
Medical standards	• Class 2 visual – 6/6, 6/9 check with CASA
Conditions/	With medical certificate or some other
endorsements, etc	mechanism?

Responses to these issues were recorded in a memorandum to industry representatives who attended the meeting of 9 July 2003. The issues were also considered and addressed in the drafting of the NPRM. This did not always result in the amendment of the draft rule to reflect any particular individual's or group's views. The reasons for this were explained in the preamble.

It is well established that while consultation requires more than mere notification, it does not require agreement or negotiations toward agreement. In its report, *Inquiry into Instruments Deemed to be Regulations – An Examination of Delegated Legislation* (Report of the Regulations Review Committee, I. 16R, 1999), the Regulations Review Committee summarised the legal requirements for consultation as follows:

• The essence of consultation is the communication of a genuine invitation to give advice and genuine consideration of that advice.

- The effort made by those consulting should be genuine, not a formality; it should be a reality, not a charade.
- Sufficient time should be allowed to enable the tendering of helpful advice and for that advice to be considered. The time need not be ample, but must be at least enough to enable the relevant purpose to be fulfilled.
- It is implicit that the party consulted will be (or will be made) adequately informed to enable it to make an intelligent and useful response. The party obliged to consult while quite entitled to have a working plan in mind, should listen, keep an open mind, and be willing to change and if necessary start the decision making process afresh.
- The parties may have quite different expectations about the extent of consultation.
- Consultation does not mean the same thing as negotiation.

The Ministry acknowledges that it would have been preferable to have formal minutes of the meeting on 14 February 2003. The Ministry is nevertheless confident that the informal and formal consultation undertaken on the draft rule meets the legal requirements referred to above. It may be that the informal consultation led to expectations that a consensus would be reached on the content of the draft rule. Such expectations do not recognise that points raised during consultation may not be accepted, may be outweighed by other matters, or may be inconsistent with informed judgement. It also does not recognise the potential for negotiated agreement on issues prior to the public consultation process to undermine that process, which requires the Minister to be open to persuasion on all issues. The NPRM itself demonstrates this.

**New Zealand Air Line Pilots Association (ALPA)** opposes the direction the CAA has been allowed to take in producing the NPRM.

**MOT comment:** It must be noted that the Ministry produced the NPRM, not the CAA. It is acknowledged that ALPA does not agree with the approach we have taken in rule.

**ALPA** also commented that MOT shows an inadequate grasp of the arguments against numerous clauses in the NPRM and provides an inadequate explanation for many decisions.

**MOT comment:** The Ministry is not able to respond specifically to this point, as ALPA did not set out the arguments or clauses they refer to in their submission. Nor do they provide any additional argument to consider. In preparing the NPRM, all issues raised up to that point were considered carefully. That consideration was set out fully in the NPRM.

**ALPA** opposes the transfer of responsibility away from the CAA and believes the CAA should take responsibility and liability for central assessments of complex cases referred to it by medical examiners.

**MOT comment:** The delegation provisions for medical certification are contained in the Civil Aviation Act. The comments are, therefore, beyond the scope of the rewrite of Rule Part 67 project to address.

One **submitter** comments that FlightFit and National Health Foundation (NHF) tables are not identical. Clarification of the difference is needed.

**MOT comment:** The NPRM does not refer to Flight Fit or NHF tables. The CAA advises that the NHF tables are used and FlightFit is not. If alternative risk assessment tools are to be used they will need to be cross-referenced to provide an appropriate level of concordance, or the requirements structured so as to accommodate the differences.

One **submitter** questions why standard medical assessments are not applied in the rule when they are provided for in the Civil Aviation Act.

**MOT comment:** The Minister may make rules establishing the criteria for "standard medical assessments". The Act requires the Director to delegate to aviation medical examiners the power to issue certificates to those who meet the criteria for a standard medical assessment. The Director may also delegate his other medical certification powers.

The Director's delegations to aviation medical examiners go further than required by the Act so there is no need to specify the criteria for a standard medical assessment. One **submitter** suggests using the outline of the introduction to form the basis of a GAP booklet as a communication tool.

**MOT comment:** The Ministry acknowledges this helpful suggestion and will ensure that it is passed on to the CAA, which has responsibility for GAP booklets.

**RNZAC** would like a functional mechanism retained for aviation medical examiners to deliver practical variations from a standard where there is little or no risk to the public or New Zealand or the wider aviation community.

**MOT comment:** There is already a mechanism permitting variation from the standards, i.e. "flexibility" under the Act. If there is little or no risk, flexibility will enable a medical examiner having the appropriate delegations from the Director to issue a medical certificate despite the applicant's failure to meet the standards.

One **submitter** suggests a stress test for all pilots and alcohol and drug testing for all commercial aircrew before and after flight.

**MOT comment:** The stress ECG is used as a screening test for (mainly) ischaemic heart disease. It is the Ministry's understanding that while this test is worthwhile for persons identified as potentially having cardiovascular risk factors, it is not necessary for a broader population. Using a stress test on every applicant is likely to cause unnecessarily grounding and would require expensive testing to confirm that, in many cases, applicants do in fact meet the standards.

Alcohol and drug-testing of pilots is a matter that requires careful consideration and raises Privacy Act and Bill of Rights Act issues. As such, it is a matter more appropriate for parliamentary enactment. The *Legislation Advisory Committee Guidelines* advise that Parliament should not delegate the power to legislate in creating a power of search and seizure, which is essentially what alcohol and drug testing requires. A rule that purported to provide for this would be at great risk of being brought to the attention of the House of Representatives by the Regulations Review Committee and could potentially be "disallowed".

Aviation Medical Society of Australia and New Zealand (AMSANZ) and ALPA believe clauses should be inserted to protect the confidentiality of an applicant's medical information that is held by the Director.

**MOT comment:** The provisions of the Privacy Act and Health Information Privacy Code make the inclusion of a clause to protect medical information somewhat redundant but there is no objection to its inclusion, if it would clarify the matter.

One **submitter** agrees that the methodology, reporting and interpretation of data (rather than risk, which is specified in the standards) should be in the GDs.

**MOT comment:** The submitter's comment is noted.

One **submitter** believes a new rule should be considered to cover a gap in section 27C(1) of the Act so that an applicant must report a change in health status, even if the applicant is not a "licence holder".

**MOT comment:** A new rule is not required. Once an aviation document is issued, the applicant becomes a licence holder and must comply with section 27C. Section 27C states that a licence holder who "is aware of" a change in medical condition must advise the Director. This would apply to a licence holder who became aware of the change after applying for a medical certificate but prior to becoming a "licence holder". (It should be noted that, if the applicant is a pilot who does not hold an aviation document, he or she is nevertheless required to hold a medical certificate and will therefore fall within the definition of a "licence holder", thus triggering the obligation before the medical certificate is information about their health and this is made clear on the application form for a medical certificate).

One **submitter** agrees that the removal of validity periods for examination and test results is appropriate, provided the expiry of the medical certificate is related to the date of the application, medical history and examination, not the date of assessment (i.e. duration is determined from the date of this data) **MOT comment:** The submitter appears to be saying that, unless the duration of a certificate is determined from the date of the examination, the examination results may be valid for too long without an "acceptability" period. For reasons discussed below, it may not be appropriate to determine duration from the date of the examination. Upon further consideration, the period of acceptability of test results may need to be dealt with in the rule and possibly the GDs.

#### Specific comments on the NPRM

In the definitions of "medical assessment report" and "medical certificate" in rule 1.1, one **submitter** suggests that the medical certificate comprise 2 parts–

- one part that looks like the medical certificate and records information required by the operator; and
- a second part that looks like the medical assessment form and records information for the purposes of the applicant, future medical examiners and the CAA, but not the operator.

**MOT comment:** To create a certificate in 2 parts would undermine the clear intent of the Act, especially in relation to section 27B(2) certificates, which must be endorsed with any conditions, restrictions and endorsements necessary for the safe performance of duties. These must, therefore, be disclosed to the operator.

In the definition of "psychoactive substances" in rule 1.1, one **submitter** suggests "coffee" be replaced with "caffeine".

**MOT comment:** The definition of "psychoactive substances", which excludes "coffee", comes straight from Annex 1 of the Chicago Convention.

In the definition of "unsafe behaviour" in rule 1.1, one **submitter** suggests that "overt acts" be replaced by "overt act".

**MOT comment:** The references to "unsafe behaviour" may need to be deleted altogether, in light of submissions received on the approach to describing the medical standards. [The definition has since been deleted].

Airways, AMSANZ, GAPAN, AOPA and ALPA believe the Director should have the power to issue exemptions. Comments include:

- Aviation medical examiners should not examine marginal cases.
- Exemptions are consistent with the ICAO framework and the Civil Aviation Act.
- There will be occasions where a class 3 medical certificate holder may not meet the standards of Part 67 but would still be considered fit for operational duties by Airways.

**MOT comment:** It is reasonable to enable medical examiners (acting under delegation from the Director) to exercise medical judgement in deciding whether a person should be issued a certificate. If a case is "marginal" in the sense that the medical standards are not met, an AMC will be sought, and for this the Director must identify experts. Support is also available from CAA's Central Medical Unit to determine whether the standards are met.

The Act provides a type of "exemption process" that enables a person to obtain an aviation medical certificate if he or she does not meet the standards. The mechanism is "flexibility", and requires the fulfilment of the following conditions-

- an AMC indicates that in special circumstances the applicant's failure to meet any medical standard prescribed in the rules is such that the exercise of the privileges to which a medical certificate relates is not likely to jeopardise aviation safety; and
- the relevant ability, skill, and experiences of the applicant and operational conditions have been given due consideration; and
- the medical certificate is endorsed with any conditions, restrictions, or endorsements when the safe performance of the applicant's duties is dependent on compliance with those conditions, restrictions, or endorsements.

To empower the Director to issue exemptions would circumvent these requirements and therefore be inconsistent with the Act. That is why rule 67.3 expressly prohibits the grant of exemptions from the medical standards.

Further, the flexibility concept is based almost word for word on the approach taken in ICAO to exemptions. The Ministry therefore considers the flexibility concept to be entirely consistent with ICAO.

The Ministry notes that it is the Director's responsibility to determine eligibility for medical certification. In some cases, a certificate can be issued to a person who does not meet the standards because of the flexibility mechanism discussed above.

One **submitter** asks who the medical certificate application fee in 67.55(1) should go to and suggests that the wording be clarified.

**MOT comment:** The provision makes it clear that the fee goes to the Director. It will be collected by the medical examiner, who may charge a separate fee for the examination, as he or she so determines.

One **submitter** is concerned that the requirement in 67.55(1) to complete all applications on form CAA 24067-001 will preclude the issue of a medical certificate without a full medical history and examination. In some cases it is necessary to limit the duration of a medical certificate because of one aspect of a licence holder's health. If a private pilot with asthma requires a full medical history and examination every year, checks on height, weight, blood pressure, vision and hearing - none of which are related to asthma - will be required. These only need to be checked in other private pilots every four years.

**MOT comment:** It is highly questionable whether the Act would permit the Director to issue a medical certificate without being satisfied that the applicant meets *all* the standards in the rules. The medical history and examination are pivotal to this. It is difficult to see how the Director could give the matter adequate consideration without having a full medical history. If a person has a problem with a particular aspect of his or her health but otherwise meets the standards, the Director may issue the certificate for the maximum duration, subject to a condition that the licence holder undergoes annual testing and that testing produces acceptable results.

One **submitter** recommends that the fee in 67.55(1) should not be set by regulation, as the assessors are independent from the CAA.

**MOT comment:** The Director is empowered by the Act to issue medical certificates but is required to delegate these powers to aviation medical examiners. "Assessors" exercising these delegated powers are not independent of the Director. The fee referred to is an application fee for costs associated with the administration of the aviation medical system (not the fee for carrying out the examination, for which the aviation medical examiner can charge what he or she likes). There must be a legislative basis for such charges.

One **submitter** asks whether being personally known by the medical examiner has been considered as an exception to the photographic identification requirement in 67.55(2) and if not, why not?

**MOT comment:** Under the Act, the Director is responsible for the issue of medical certificates. The standard of identification required must reflect this. A formal declaration of personal knowledge of the applicant would not, without photographic identification, be enough for the Director to be certain that the applicant was the person referred to in the declaration. This is particularly important in the context of enforcement. If there were no requirement for photographic identification, the Director would be obliged to rely on the ME's willingness to testify to the identity of the person.

One **submitter** comments that the Land Transport Safety Authority [now, Land Transport New Zealand] does not guarantee a driver's licence as a form of identification. Another **submitter** believes 67.55(2)(ii) should be deleted or modified, commenting that a New Zealand driver's licence is not an identity card.

**MOT comment:** The Ministry notes that a New Zealand drivers licence is an acceptable form of identity for the purposes of Land Transport (Driver Licensing) Rule 1999 (see cl 10(1)(b) of that rule). It is not essential to produce a drivers licence as identification but applicants may do so if they wish.

One **submitter** believes 67.55(3), which requires applicants for medical certificates to produce the licence for which the certificate is required, as well as the most recent medical certificate and assessment, should be deleted. Another **submitter** notes that it is hard enough to get pilots to remember to bring along the last medical certificate, let alone the last assessment form.

**MOT comment:** It is not clear why the provision should be deleted. It requires applicants to produce crucial information for determining the applicability of the standards and eligibility for the certificate applied for. Difficulty in remembering the documentation does not seem sufficient to warrant omitting this important provision.

One **submitter** recommended deleting the words "or not" from the requirement in 67.55(4) to provide information including "any conviction for an offence involving the possession or use of drugs or alcohol that the Director or the medical examiner may reasonably require to determine whether or not the applicant satisfied the standards for a medical certificate". Another **submitter** believes this clause should be modified because it is clumsy and an infringement of privacy.

**MOT comment:** The phrase "whether or not" is used with similar effect throughout legislation but may be replaced with "whether" in this provision. The provision's length may make it seem clumsy but it is unavoidable given the need to clarify that drug and alcohol-related offences may be evidence relevant to assessing compliance with the standards for a medical certificate. Given also that the requirement has Privacy Act implications, it needs to incorporate a legal standard to be satisfied before the Director may require disclosure, i.e. the information must be reasonably required to determine whether or not the applicant satisfies the standards for a medical certificate.

One **submitter** recommends rewording the requirement in 67.55(5) so that it requires compliance with any "reasonable" medical examination requirements.

**MOT comment:** The Ministry agrees with this recommendation. [This provision has since been removed as it is covered in the Act].

Some **submitters** believe that there is, in 67.57, a safety risk in abandoning age-related validity periods for older pilots.

**MOT comment:** The duration periods prescribed in the NPRM are maxima, i.e. a person who is eligible for a medical certificate will receive one for the duration that the Director or his/her delegate determines is appropriate up to the maximum prescribed period. Age-related risk factors would need to be included in this determination but

the NPRM does not impose express age-related restrictions. This reflects the view that determining whether (as a result of the aging process or otherwise) an applicant requires more frequent assessment of his or her state of health should be done on a case-by-case basis using medical judgement.

On the other hand, it is notable that many of the aviation medical experts who submitted comments on the NPRM recommended a return to age-related distinctions. This is required under ICAO standards and in other countries, such as Australia and the United States. The Ministry has reconsidered this issue and proposes that age-related restrictions be reinstated. Safety considerations supported by international requirements may justify reasonable age-related distinctions. If not, they will breach the Bill of Rights Act and will be vulnerable to legal challenge

One **submitter** believes that, in 67.57(a)(2), 48 months for a class 2 medical certificate is not appropriate as age increases. Age is an independent risk factor in medicine.

**MOT comment:** See discussion above.

One **submitter** recommends increasing the period for class 2 medical certificates in 67.57(a)(2) to 60 months.

MOT comment: At present, class 2 medical certificates have a maximum duration of 60 months for those under 40, 24 months for those 40 plus, and 12 months for those 50 and over. The NPRM proposed the removal of these age-related distinctions and provided for one maximum 48-month period. It is acknowledged that is a reduction for those under 40. However, this period is consistent with CASA, which provides a maximum duration of 48 months for those under 40 and 24 months for those aged 40 years and older. Further, the Ministry notes that 48 months is twice the period currently provided by ICAO. (Having said that, we acknowledge that the draft ICAO revision proposes 60 months for those under 50 reducing to 12 months for those aged 50 years or older.) In removing the age-related distinction in the NPRM, a slight reduction in maximum duration is considered appropriate and is more consistent with CASA. However, the Ministry proposes that age-related distinctions be reconsidered, and the maximum duration for the younger group should also be

reconsidered. [ICAO has since adopted a 60 month maximum period of duration for those under 40, and 24 months for those 40 years old or more].

**Airways** recommends that the duration of a class 3 medical certificate be amended to read "up to 48 months" to align with ICAO.

**MOT comment:** At present, ICAO provides a maximum duration of 24-months for class 3 medical certificates. The NPRM is consistent with this. ICAO has proposed increasing the duration to 48 months but that has not yet been adopted. The Ministry supports the change to 48 months. [ICAO has since adopted this for those under 40].

In relation to 67.57(b), one **submitter** recommends relating expiry of a medical certificate to the date of the application and medical history and examination. These provide data with which eligibility for a medical certificate may be predicted. Expiry should be determined from the date this data is obtained, not the date of issue, which may be weeks or months later.

MOT comment: Relating expiry to application, history and examination dates does not take account of the length of time it can take to obtain relevant information to complete the assessment of an applicant. To determine expiry by reference to the application date would mean that an application made on 1 January 2004 that is granted on 1 February would result in the "loss" of one month because the expiry date would have to be 1 January 2005. A similar problem arises if expiry is determined by date of examination - that will not necessarily be the date that all relevant information is obtained. It also creates a legal fiction to backdate the certificate to the date of the application or examination. The Director should be issuing certificates that take effect from the date of his decision; not that purport to take effect weeks earlier. This is consistent with the ICAO requirement that the period of currency must begin on the date the medical certificate is issued. In addition, aviation medical examiners must determine appropriate duration in light of an applicant's medical history. This is not a matter that needs to be provided for in the rule but is rather a question of medical judgement.

Having said that, the period for which examination reports may be relied upon is an issue that requires some direction. This may be addressed by specifying in the rule, maximum time limits for accepting examination reports for the purpose of assessing applications for medical certificates. The GDs may also have a role here in terms of specifying the time limits for the results of particular tests.

**AMSANZ** recommends amending 67.57 to provide currency periods that are consistent with those proposed in the draft ICAO Annex 1.

**MOT comment:** The Ministry agrees with this recommendation.

**GAPAN** notes that validity periods in 67.57 have increased in some areas and reduced in others. **GAPAN** accepts this if supported by a GD that further reduces the periods in a reasonable way.

**MOT comment:** It is not appropriate for GDs to prescribe reduced validity periods since this would likely go beyond their intended scope, as prescribed in the Act.

One **submitter** recommends deleting 67.57(b)(2)(ii) because a medical certificate cannot be invalidated by the issue of another medical certificate.

**MOT comment:** The Ministry agrees that a medical certificate cannot be "invalidated" by the issue of another. That is why the rule creates an express invalidation process. The intent of the provision is to ensure that an existing certificate cannot be relied upon if a new one has been issued.

One **submitter** notes that time periods for tests have not been stipulated.

**MOT comment:** The duration of a test is a matter that may be dealt with by GDs, since the Act provides that they may be issued in relation to the conduct and requirements of examinations.

One **submitter** believes there should be less "medical hunting" of older pilots and points out that some older pilots can be fitter than younger pilots.

**MOT comment:** The Ministry agrees that age is not necessarily an indication of level of fitness. The Ministry does not agree that there is medical "hunting" of older pilots, if this comment is intended to imply an undue focus on older pilots.

One **submitter** recommends making 67.57(a) subject to paragraph (c) and also subject to the provision that "in no case may a medical certificate be issued for a period exceeding the maximum currency available for the class of medical certificate plus 30 working days."

**MOT comment:** The suggested wording does not add anything to what is achieved by 67.57(a) and (c). The Ministry does not agree that "30 days" should be changed to "30 working days" because–

- the "30 day" period is based on similar allowances in Australian, Canadian, FAA, and South African standards;
- to amend the period to "30 working days" would produce inconsistent outcomes for applicants. (For example, a person with an existing medical certificate that expires during the Christmas/New Year period would effectively have an extra 9 days to apply for a later expiry date of their new certificate than if the existing medical certificate expired at some other time).

One **submitter** recommends amending 67.59 so that at least one expert who is appointed by the Director for the purpose of providing an AMC must be an expert in aviation medicine.

**MOT comment:** The matter is already covered by the proposed rule 67.59(2)(i). It would be inappropriate for the Minister to make it mandatory as this would fetter the discretion given to the Director under section 27A of the Act.

One **submitter** comments that the rules should not prohibit identifying experts for the purpose of making a decision to certificate under section 27B(1). This would help avoid incorrect refusals to certify under section 27B(1).

**MOT comment:** There is nothing to stop "experts" being consulted when considering whether an applicant meets the standards for a certificate under section 27B(1) of the Act. If an incorrect decision is

made under section 27B(1), review of the decision may be pursued through the Convener process.

One **submitter** recommends deleting 67.61(2) (which concerns the surrender of medical certificates) because it is an unnecessary complication.

**MOT comment:** It is unclear why the submitter thinks the provision is an unnecessary complication. The Act requires revoked, withdrawn, or suspended medical certificates, as well as medical certificates held by persons disqualified from holding them, to be surrendered to the Director.

One **submitter** asks whether he must give up his old medical certificate once issued with a new certificate before the old certificate expires.

**MOT comment:** The rule has been re-drafted to clarify that surrender of an existing certificate is required if the Director requests it.

One **submitter** questions the need to surrender a medical certificate when a subsequent medical certificate is issued, even if this is no more restrictive. He suggests that the requirement be amended to apply only when surrender is demanded by the Director or a person authorised by the Director.

**MOT comment:** If there is no requirement to surrender a medical certificate when a subsequent one is issued, the holder may continue to use the old certificate with impunity. This clearly has safety implications, especially, for example, if there has been a change to the holder's state of health requiring the imposition of conditions. However, the Ministry recognises that this will only be an issue where the subsequent certificate is issued before the expiry of the existing one. The rule has been re-drafted to require surrender, if the Director requests it.

One **submitter** recommends deleting 67.61(3) because it is an unnecessary complication.

**MOT comment:** It is unclear why the submitter thinks this is an unnecessary complication. The reason for its inclusion is discussed above.

One **submitter** recommends that the fee in 67.63(b)(1) for a replacement medical certificate should not be set by regulation but by the Doctor re-issuing the certificate.

**MOT comment:** The issue of a replacement certificate is a service provided by the Director of Civil Aviation. It may be delegated to aviation medical examiners but the associated fee remains a fee for costs associated with the administration of the aviation medical system

One **submitter** recommends rewriting the medical standards for all medical certificates to include "sudden unexpected" incapacity.

**MOT comment:** The Ministry believes that "sudden unexpected" incapacity would be caught by the descriptive stem, especially "elevated risk of incapacitation". However, other options to express the standard will be explored.

One **submitter** notes that "sequelae" in 67.103(b)(2)(ii) is plural and recommends that the singular should be used.

**MOT comment:** The Ministry agrees that the tendency is for legislation to adopt the singular form.

One **submitter** notes that the medical standards would not include the results of radiotherapy. He recommends including a reference to persons undergoing "treatment(s)". He also comments that the standards do not cover instances when an applicant has completed a course of drugs but the side effects cause problems, for example cardiomyopathy from chemotherapy.

**MOT comment:** The Ministry agrees that the medical standards should capture a person undergoing treatment, or experiencing side-effects.

**ALPA** would like to see the WHO classification for the nervous system adopted in 67.103(c), 67.105(c) and 67.107(c).

**MOT comment:** The difficulty with incorporating external sources such as the WHO classification is that they are often out of date. It may be appropriate to refer to them in the GDs in relation to interpreting the results of examinations, rather than prescribing in the rules. (The Director is, for example, proposing to use the New Zealand Standards in this way with respect to the hearing GD).

Two **submitters** comment that 67.103(c)(2)(v), (vi) and (vii) are covered by 67.103(c)(2)(iv). One submitter also believes that 67.103(c)(2)(viii) and (ix) are superfluous.

**MOT comment:** Draft rules 67.103(c)(2)(v), (vi), (vii), (viii) and (ix) may be covered by the more general statement but specific mention of the conditions referred to in these rules is considered appropriate in order to remove any potential ambiguity. This approach is also taken in other parts of the NPRM where general standards are first stated and then more specific standards follow. The argument that the specific standards are superfluous would, taken to the extreme, result in reducing the class 1 medical standard to a single sentence, i.e. that found in 67.103(b)(1).

One **submitter** queries why 67.103(c)(2)(iii) implies that a loss of consciousness from a known cause might be all right. He also questions the necessity of this sub-clause as it is covered by 67.103(c)(1).

**MOT comment:** The words "for which there is no satisfactory explanation" are not necessary and should be removed.

**Air New Zealand (ANZ)** and **GAPAN** suggest the history of seizures standard in 67.103(c)(4) is possibly too rigid to cover circumstances of childhood epilepsy. One **submitter** recommends using "elevated risk of functional incapacity or incapacitation" rather than "elevated risk of convulsions" for consistency with every other stem.

**MOT comment:** The Ministry notes that if a childhood epilepsy syndrome doesn't result in an increased risk of a convulsion then the standard will be met. The "elevated risk of functional incapacity" aspect is already covered by 67.103(c)(1), which contains the general standard applying in relation to the nervous system. 67.103(c)(4) is a more specific standard recognising the particular risk to aviation safety

created by conditions that produce convulsions. This rule attempts to make it clear that an increased risk of convulsion is not acceptable.

One **submitter** recommends replacing "circulatory tree" in 67.103(d)(1) with "circulation" or circulatory system".

**MOT comment:** The Ministry understands that the reference to circulatory tree falls more clearly within the cardiovascular system, than the suggested replacement terms.

One **submitter** notes that existing Part 67 refers to myocardial infarction and coronary artery disease whereas proposed new Part 67 only refers to coronary artery disease - not all myocardial infarctions are caused by coronary artery disease.

**MOT comment:** The Ministry agrees that not all myocardial infarctions are caused by coronary artery disease. However, other causes of myocardial infarction (for example cocaine use) are covered both in 67.103(d)(1) and elsewhere.

One **submitter** questions why initial caps are used for left and right bundle branch blocks in 67.103(d)(2)(ii) and (iii).

**MOT comment:** The Ministry agrees that the upper case lettering is not necessary.

One **submitter** believes that left bundle branch block and right bundle branch block would be included in (d)(2)(v) unless ischaemic causes have been excluded. One **submitter** queries whether 67.103(d) is intended to cover all disturbances in rhythm. Atrial fibrillation is not a disturbance of the conduction system nor are many of the ventricular tachycardias. He suggests it might be better to require flexibility for those who are pacemaker dependent rather than removing the reference from the standard but notes that those who are pacemaker dependent do have an abnormality of the conduction system. He asks about AICDs and queries whether there should be an additional subclause (vi) to cover valvular disease or just aortic stenosis.

**MOT comment:** The two specific conduction abnormalities are named for clarity reasons and (d)(2)(v) covers other such abnormalities. The Ministry's understanding is that left bundle branch

block is much more likely to be due to ischaemia. The rule therefore clarifies that all left bundle branch block cases need to be considered in accordance with the flexibility provision in section 27B(2) of the Act.

The comment made about disturbances in rhythm is a valid one. The rule should be amended to address this.

Pacemakers and valvular heart disease could be specifically included in the rule. That would not be inconsistent with the approach and might further remove ambiguity. The rule should be re-drafted to reflect this. Aortic stenosis is a valvular condition so it will be covered but not specifically mentioned.

The Ministry understands that to have an AICD, one would also have some significant underlying cardiac pathology, which would be covered by the other provisions in the rule.

One **submitter** believes asthma should be acceptable in 67.103(e); not only if there is adequate control with inhaled steroids only, but also if the condition is complete remission.

**MOT comment:** If the condition is in complete remission, it will not be "likely to produce any significant degree of functional incapacity, elevated risk of incapacitation, or unsafe behaviour". If that is the case, the history or diagnosis of asthma will be "acceptable". It is the stem that captures the degree and relevance of a particular medical condition.

One **submitter** recommends an additional subclause (f)(4) in 67.103, "Obstruction or elevated risk of obstruction of the gallbladder".

**MOT comment:** Biliary disease is covered by the more general rules such as 67.103(f)(1) and (2). It may not warrant specific mention because, despite being fairly common, it is not of the same overall significance as, for example, convulsions.

One **submitter** recommends changing the heading of 67.103(g) to "Reticulo-endothelial and immune systems".

**MOT comment:** The Ministry sees no problem with making this change.

One **submitter** asks if 67.103(g)(2)(i) is serious that myeloproliferative causes of splenic enlargement or the massive splenomegaly of malaria are the sorts of splenomegaly that might be acceptable?

**MOT comment:** The comment appears to be based on a misinterpretation of the provision, which provides that an applicant must have no history or diagnosis ... (etc.) of enlargement of the spleen unless myeloproliferative and infective causes have been excluded. That is, if these are not excluded as causes of the enlargement of the spleen, the applicant will not meet the standard.

One **submitter** notes that only the urinary system is considered under the genito-urinary heading while the "genito" part is considered under the reproductive system. He suggests that the headings should be reworded.

**MOT comment:** "Genito-urinary" has a slightly wider scope than simply "urinary". Keeping the heading as "genito-urinary" clarifies that the standard applies to components of the genito-urinary system that are not necessarily reproductive.

**GAPAN** recommends the reproductive system standards in 67.103(i), 67.105(i) and 67.107(i) be amended to read "have no diagnosis of any of the following conditions, clinical effects of which are likely to produce any significant degree of functional incapacity, elevated risk of incapacitation, or unsafe behaviour: (i) menstrual disturbance' (ii) pregnancy."

**MOT comment:** The suggested drafting is very similar to the proposed rule. However, it omits the requirement that the applicant have no history of menstrual disturbance or pregnancy to an extent that is likely to produce any significant degree of functional incapacity, elevated risk of incapacitation, or unsafe behaviour. This would mean that applicants having such a history would nevertheless meet the standard unless a consistent clinical diagnosis had been obtained. This would clearly have safety implications. It is also suggested that the standard refer to the "clinical effects" of the condition. It is unclear

what such a formulation adds to this particular standard. The wording here is consistent with the rest of the standards.

One **submitter** recommends using "skin" instead of "integument" in 67.103(j) and changing the heading to "musculo-skeletal system and skin".

**MOT comment:** The integument covers more than skin; it includes subcutaneous tissues etc.

One **submitter** notes that balance is more than just the vestibular apparatus referred to in 67.103(k).

**MOT comment:** Agreed, however this rule does not refer to balance. The rule refers to a part of a system of the body and does not attempt to name all the possible related functional incapacities or incapacitations. Non-vestibular balance disturbances are covered by the relevant section of the rules, for example, 67.103(e) (the nervous system).

One **submitter** suggests that, if retained, 67.103(1)(2) should read, "have no hearing deficit in either ear detectable on conversational voice test *and* no deficit on pure tone audiometry of more than (1) etc..."

**MOT comment:** The provision is intended to set the standard, not the methodology to test for it. Testing methodology will be provided for in the GDs.

One **submitter** notes that 67.103(1)(2) provides that hearing deficits on pure tone audiometry will not be a problem except to the extent that they produce a potential flight safety problem. He comments that it is not possible to assess the extent of these deficits in terms of flight safety but other functional tests of hearing can be assessed in those terms. He recommends that the rule be changed along the following lines – "… hearing deficit on pure tone audiometry in either ear of more than (i) 35dB … or (ii) 50 dB … and other tests of hearing indicate a functional deficit to an extent …."

MOT comment: Audiometry and conversational voice tests are screening tools for the hearing standard. There is an implicit

assumption that a person who passes these screening tests will have adequate in-flight hearing performance. If the person fails, further testing will be carried out, which may result in an in-flight hearing test. These sorts of matters will be addressed in the GD dealing with hearing impairment.

One **submitter** comments that the omission of all reference in 67.103(m) to monocular and substandard vision is reasonable and can be covered by flexibility. He also recommends that the Minister set a standard for dioptre limits. In the past, an applicant for a class 1 medical certificate with more than -3 dioptres was required to use contact lenses. ICAO recently allowed high refractive index glasses as an alternative and this is reasonable for those not too far over the limit.

**MOT comment:** The question of setting a standard for dioptre limits has been considered but it is felt that the standard in the rule is the appropriate one, especially given that Annex 1 of the Convention no longer refers to dioptre limits (see std 6.3.3.2). High dioptres can lead to thick lenses and peripheral distortions but we understand that this is less of a problem with modern high refractive lens material.

One **submitter** recommends changes to the vision test in 67.103(m) in respect to focal distances criteria (distances of 60cm to 80cm are recommended) and light intensity value for eye testing to be clearly defined.

**MOT comment:** It is not clear why 60cm or 80cm would be preferable to the submitter. Annex 1 of the Convention refers to both 30 - 50cm and 100cm, which is mirrored in the draft standards.

One **submitter** notes the change in 67.103(m)(4) that vision must be measured binocularly.

**MOT comment:** It is agreed that "binocularly" is the correct word.

One **submitter** recommends that the rule be more specific about correcting lenses. In particular, if the applicant requires distance correction, the near and immediate vision standards must be achieved with correcting lenses in place, with or without a near vision aid, as is required. Full frame reading glasses are not acceptable for class 1 or 2. The **submitter** is not convinced that the type of corrective lenses being

worn will be covered by the general provision in 67.103(m)(1) because this does not fall within "a history or diagnosis of a vision disorder". In other words, there is nothing that says the correction must be suitable and safe for aviation purposes. There is nothing that would allow the Director to force an applicant to have spare glasses.

**MOT comment:** The existing rule is very detailed and there has been a deliberate move away from the approach proposed. The GDs would be the appropriate place for this sort of detail.

The application of conditions, etc., under the Act is the appropriate vehicle to require spare glasses.

One **submitter** also suggests that the vision standards read, "have a distance visual acuity" and "have an intermediate visual acuity" and queries why the word "distance" has been replaced by "distant".

**MOT comment:** Amending the rule to read "a distance visual acuity", etc., would not enhance clarity or correct grammar.

The change brings the rule into line with Annex 1 of the Chicago Convention, which uses "distant", not "distance".

One **submitter** supports the change in 67.103(m)(4) to allow near vision to be measured anywhere between 30 and 50 cm. He suggests that this read, "and have intermediate visual acuity of N14" not "and of N14". Otherwise, there will be confusion over what is meant by "near visual acuity".

**MOT comment:** The Ministry agrees that the provision should be clarified as the submitter has proposed.

One **submitter** asks whether there is to be a requirement for an audiogram in the hearing standards.

**MOT comment:** The hearing standards specify the standard of hearing required but not the means of determining this. That will be dealt with in the hearing GD. The Act authorises the issue of GDs in relation to conducting examinations and specifying their requirements.

One **submitter** notes there is no mention in 67.105(m) of intermediate vision, which has always been a requirement in the past and wonders if this is an oversight. Another **submitter** comments that it would be safer to keep the intermediate vision standards. Some instruments on the far side of the cockpit are 1m from the pilot, who may need to read them (e.g. single pilot IFR).

**MOT comment:** The omission of an intermediate standard was not an oversight. The draft class 2 medical standards cover visual acuity measured at 30-50cm and 600cm and not 30-50cm, 100cm, and 600cm as contained in the current Part 67. The ICAO medical standards (current and proposed) specify visual acuity measurement at 30-50cm and 600cm but not 100cm. Intermediate visual acuity is clearly important in many commercial aviation operations but is usually less critical for private operations.

One **submitter** believes that full frame reading glasses for class 3 certificate holders working in a radar control room should be allowed.

**MOT comment:** This is the sort of matter that will be addressed in the GDs.

One **submitter** believes there is an implication in 67.157(a) that if a person meets the criteria for the issue of a medical examiner certificate, he or she must be appointed. He comments that, if this leads to too many aviation medical examiners in one area, there might be fewer opportunities for them to gain experience.

**MOT comment:** This provision is expressly subject to section 9 of the Act. Section 9 requires the Director to issue aviation documents, if satisfied that-

- All relevant prescribed requirements are met;
- the applicant and his/her personnel are fit and proper;
- It is not contrary to the interests of aviation safety to do so.

The entitlement in 67.157(a) is therefore consistent with and subject to these requirements. In addition, the provision reflects the wording in section 27F of the Act, which provides that the Director must designate medical examiners.

A large number of medical examiners in one area may mean that each is likely to see fewer applicants and gain experience at a slower rate. However, rather than managing this by attempting to modify market forces, the preferred approach is to ensure, through review and monitoring, that the medical examiners' performance is acceptable.

One **submitter** suggests that the comma between "operational" and "circumstances" in 67.157(b)(2) be omitted.

**MOT comment:** To put the meaning of 67.157(b)(2) beyond doubt, the Ministry believes it would be preferable to amend this provision to state that the Director may issue a special medical examiner certificate, if "satisfied that there are emergency or special geographical or special operational circumstances that justify the issue of a special medical examiner certificate".

**ANZ** believes the competencies required in 67.163 of medical examiner certificate holders are too specific and there should be more distinction between grade 1 and 2 aviation medical examiners.

**MOT comment:** This issue is addressed in the summary of comments on Appendix A to the NPRM - Medical Examiner Competencies.

**ANZ** believes that the exposition requirements in 67.163 for aviation medical examiners are too detailed for the rule and do not need to be so prescriptive.

**MOT comment:** The exposition provisions are based on existing civil aviation rules imposing equally detailed exposition requirements on other aviation document holders. The level of detail is necessary given the respective roles of participants and the CAA. The Act establishes a regulatory system in which aviation document holders are responsible for monitoring their compliance with the Act and the CAA exercises an auditing function. The detailed exposition requirements make audit expectations transparent to the document holder. Nevertheless, comments on how the requirements might be refined are welcomed.

One **submitter** seeks clarification of the comment in the regulatory impact statement that aviation medical examiners may face some compliance costs from the rules relating to an exposition, but these costs are likely to be insignificant. **MOT comment:** Compliance costs may be recovered in examination fees. The development of a template would assist aviation medical examiners in the preparation of expositions. The cost involved in preparing the exposition would be offset by this.

One **submitter** asks if the term "the person's personnel" in 67.163(a)(4) can be replaced with "the personnel referred to in paragraph (a)(3)"?

**MOT comment:** The Ministry agrees that the amendment should be made.

One **submitter** recommends amending the requirement in 67.163(6) to provide details of access to adequate facilities for carrying out aviation medical examinations so that it expressly only applies to "aviation medical examinations required under the Act", not all aviation medical examinations.

**MOT comment:** The meaning of "aviation medical examination" in this provision is clear from context in which the term is used, that is, it is an aviation medical examination required under the Act.

One **submitter** is concerned that 67.165 requires the Director to delegate to all aviation medical examiners the power to issue medical certificates even if they have only just been appointed and have no experience.

**MOT comment:** The Director can only issue a certificate to doctors who meet Annex 1 of the competencies in the transition criteria. Experience is specified in those criteria. Further, we note that under section 27O(4) of the Act, the Director has the power to give directions and impose conditions on the exercise of the delegated powers.

NZAAA comments on a lack of suitably qualified medical examiners in the outlying areas.

**MOT comment:** The Ministry notes the comment about the availability of medical examiners in remote areas. There are many, often remote, locations in New Zealand that have borderline or poor immediate medical support. This also affects the aviation medical

regulatory system. Initially there were some problems with access overseas but the Ministry understands that this is no longer a problem as the CAA has trained and certificated some medical examiners in critical locations. The Ministry notes that the rule will permit the issue of "Special Medical Examiner Certificates", the holders of which may conduct medical examinations as specified in writing by the Director. This will give the Director the flexibility to appoint examiners for areas having special circumstances in relation to geography, both within and outside New Zealand.

One **submitter** queries whether it is clear, in 67.203(a)(3), that "personnel" refers to the medical examiner's personnel. He recommends replacing "make available to personnel every applicable part" with "make available to other personnel involved every applicable part…".

**MOT comment:** It is clear from context that the "personnel" referred to are the medical examiner's personnel, especially when read in conjunction with 67.163(a)(1), (2), (3), (4), (9)(iv) and (12)(iv). However, the provision could be improved along the following lines - "make every applicable part of the exposition available to personnel who require it to carry out their duties".

One **submitter** recommends that the medical assessment reports in 67.205 should form part 2 of the medical certificate, as discussed above in relation to the definitions. He also notes that the rule should allow for computer-generated versions of forms.

**MOT comment:** The Ministry's response to the first issue is set out above under the discussion on the definitions.

The rule does not, nor is it intended to, preclude computer-generated versions of forms.

**Origin Pacific** recommends removing reserved subpart F (which will set standards for "aviation examiners") to avoid confusion with other "examiners"

**MOT comment:** "Aviation examiner" is a term defined in the Act as "a health professional; and includes any registered medical practitioner to whom the Director has issued an aviation document under section

27F(2) or section 27Q(2)(c) to conduct specified examinations under Part 2A." Rules governing the issue of aviation examiners may be required in future. This subpart has been "reserved" for this purpose.

One **submitter** suggests that the role of the Deputy Convener and the means of ensuring consistency from the Convener system should be outlined in the Rule.

**MOT comment:** Section 27J of the Act provides that the deputy convener must discharge the duties of the convener if the convener is unavailable. The Ministry believes this adequately describes the functions of the Deputy Convener. It would be unusual and redundant to repeat this in the rule. Any expansion of the Deputy Convener's functions would be inconsistent with the Act and is unlikely to fall within the Minister's rule-making powers.

It is unclear whether the submitter is referring to consistency of process or consistency of outcome or both. The Act sets out the parameters of the Convener review process. Within these, the Convener or Deputy Convener must exercise expert medical judgement. This would not appear to be an appropriate matter for regulation by civil aviation rules. In any event, the Act does not empower the Minister to do so.

**AOPA** believes there is an imbalance in 67.303 in that the applicant *must* provide information to the Convener but the Director *may* provide information held by the CAA.

**MOT comment:** The provisions reflect the language in sections 27L(3)(c) and 27M(2)(b)(iii) of the Act, under which the Convener may *require* an applicant to provide any medical information reasonably necessary for the review or assessment. Draft provisions 67.303 and 67.305 are intended to make it clear that the review or assessment cannot proceed without the required information.

In addition, sections 27L(6) and 27M(5) of the Act give the Director the right to participate in the review or assessment by providing any relevant evidence. 67.303 and 67.305 are consistent with these sections. They cannot *require* the Director to provide the information because that would be contrary to the Act. Clearly, it would be in the

Director's best interests to provide any information requested since a refusal would undermine the Director's position.

**ALPA** recommends the rule require the Convener to pass copies of the preliminary and final report to the applicant as well as the Director.

**MOT comment:** The guidelines to the Convener process of August 2002 envisaged the preparation of a preliminary report for comment by the applicant and the Director. The Ministry no longer considers it appropriate to include this as a standard step in the process because–

- its purpose is unclear
- in most cases, it should not be necessary
- it would add needlessly to the time taken to complete every review.

There appear to be two purposes of a preliminary Convener report-

- To give each party further opportunity to rebut information provided by the other; and
- To enable the Convener to generate information reasonably necessary for the purposes of the review.

The Act and the process described in the draft rule ensure that the applicant and Director have ample opportunity to submit and comment on information relevant to the review. In most cases, the Ministry believes that a preliminary report would be used to re-litigate issues already canvassed by the Convener. The Ministry considers it inappropriate to require the Convener to subject his or her conclusions to such a process.

The Ministry can see little benefit in requiring a preliminary report unless the Convener wishes to use it as a means of generating information that is reasonably necessary for the purpose of the review. There is nothing to stop the Convener from doing so if he or she considers it appropriate, but it will not be necessary in most cases, nor does the Act require it.

Accordingly, the draft rule does not require the preparation of a preliminary report. Instead, this is left to the discretion of the Convener.

The Act provides that the Convener must review the decision as soon as practicable and report the results to the Director. It is then for the Director to implement the report within 10 working days or notify the licence holder or applicant of the Director's reasons for not doing so. In the Ministry's view, it is entirely consistent with the Act for the Director to copy the Convener's report to the applicant at the time the Director communicates his or her final decision.

**ALPA** would also like paragraph 1.7 from the Guide to the Role of the Convener added to Subpart G.

**MOT comment:** Paragraph 1.7 of the original guidelines summarises the statutory requirements. It would be redundant and unusual to summarise the provisions of the Act in a rule. The summary would not be authoritative, since it will be subject to the Act, and is intended to be a guide, not law.

**Origin Pacific** believes the Act should be amended to clarify the Convener role and functions.

**MOT comment:** The Ministry notes Origin Pacific's comment but believe that the Act adequately details the functions of the Convener.

**Origin Pacific** also questions why payment of the fee in 67.303(2) and 67.305(2) is made to the Ministry of Transport. They believe it could more easily be paid to the CAA. An amendment to the regulations would also be appropriate.

**MOT comment:** Payment cannot be made to the CAA because the Convener is independent of the Authority and must be seen to be so. The Convener is a ministerial appointment and it is therefore appropriate that the Ministry of Transport receives the fee on the Convener's behalf. The Ministry is aware that a change to the Civil Aviation Charges Regulations (No 2) 1991 will be required.

**ANZ** believes the medical examiner competencies in Appendix A are too specific and there should be more distinction between grade 1 and 2 aviation medical examiners.

**MOT comment:** The competencies for a Medical Examiner 1 Certificate and a Medical Examiner 2 Certificate differ primarily in degree. The holder of a Medical Examiner 2 Certificate (ME2) will be making the same sorts of considerations and decisions as the holder of a Medical Examiner 1 Certificate (ME1), only in respect of a slightly less risk critical subset of the aviation population. Because of this, the same competencies apply to the holders of both certificates although some, such as technical aviation medical training are set with a lower level for ME2s. The intent here is, in part, to make the transition from ME2 to ME1 relatively easy i.e. completion of technical aviation medicine training and some certification experience as an ME2. The intention is that there should be as many ME1s as possible and that the ME2 role will be seen as largely being a stepping stone to becoming an ME1.

One **submitter** is concerned that there is no graduated system to ensure ME2s gain the experience necessary to be considered practised in assessment skills yet they will have delegated powers to issue medical certificates. He notes that industry recommended that, having conducted the medical examination, ME2s should be able to refer an application for a medical certificate to a willing ME1 for assessment.

**MOT comment:** The CAA is developing a policy relating to the training and development of medical examiners but this does not need to be specified in rules.

One **submitter** is also concerned that the competencies required of ME1s are well below the standards expected of commercial aviation, and particularly notes that in certain areas, including assessments, they are only required to have practical experience such that they can work under supervision. The submitter expresses this concern in the context of the proposed rule changes, which will mean that few applicants fail to meet the medical standards and will therefore be certified without reference to the CAA. He further comments that the CAA is unable to audit half of the assessments and that there are no GDs.

**MOT comment:** The Ministry does not share this view. The Ministry considers that the competencies are set at a level that is appropriate and reasonable and that meets international practice.

## Notice of Proposed Rule Making August 2004

As a consequence of the issues identified in the submissions made on the NPRM of 10 July 2003, a second NPRM was published on 12 August 2004.

12 submissions were received on this NPRM.

## Summary of submissions on NPRM dated 12 August 2004

General comments on the NPRM

A **number of submitters** believe that the new approach to describing the standards (the descriptive stem) does not address incapacitation risk. They recommend adding a subparagraph to the definition of "aeromedical significance" to address incapacitation risk

**MOT comment:** The draft rule provided that a person may not have a condition that is likely to result in a reduction in the ability of that person to fly, etc. This would have encompassed a person who has a condition that is likelv to produce incapacitation. since "incapacitation" is defined as "inability" (see Oxford Concise Dictionary). That is, a person who has a condition likely to produce incapacitation has a condition that is likely to reduce his or her ability to exercise the privileges to which his or her medical certificate relates. However, we propose that a provision be added to avoid any possible confusion

ALPA, ANZ, Aviation Industry Association of NZ (Inc) (AIA) and GAPAN believe that some of the standards are unnecessarily repetitive, restate some of the content of the stem and in some cases may, in the future, be inappropriate e.g. insulin (refer subparagraph (2) of 67.103, 67.105 and 67.107). ANZ, AIA and GAPAN suggest listing the subsidiary conditions by way of example, rather than layers of additional "musts". One submitter recommends deleting each subparagraph (2) because the conditions are covered in subparagraph (1).

**MOT comment:** The approach used i.e. prescribing a general standard followed by particular standards applying to specified conditions falling within the general standard, is commonly used in legislative drafting. The lists of conditions are necessarily prescriptive reflecting international practice. Expressing the standards in this way is also

intended for the ease of reference for medical examiners. The submission in relation to insulin refers to the proposed standard applying to diabetes. If that standard is inappropriate in any particular case, the Director has the discretion to issue the medical certificate using "flexibility" as provided for in the Act. If the standard is no longer required at all, the rule could be amended.

ALPA believes the new descriptive stem is not acceptable. Specifically,-

- They do not believe that the CASA stem is incompatible with the Act.
- They believe the stem is subjective, for example, the meaning of "significant" is open to interpretation and could produce inconsistency in its application. **AOPA** and **AMSANZ** concur with this comment.
- They do not understand the difference between the two branches of the stem.
- They believe the phrase "to exercise the privileges or perform the duties to which a medical certificate relates" is "cloaking the meaning in mystery".
- They recommend aligning the stem more closely with the ICAO definition, to comply with New Zealand's obligation as a contracting party to the Convention.

**MOT comment**: The stem is based closely on the "safety relevant" concept in the Australian regulations. However, because of the differences between New Zealand and Australian legislation, to adopt that concept in the standard without amendment would blur the line between determining whether an applicant meets the standards and determining whether the medical certificate should be issued, despite the standards not being met. The latter involves the exercise of the Director's discretion to issue medical certificates using "flexibility". This is not a concept employed by the Australian legislation. It is a discretionary function that involves considerations of "safety relevance". To make safety relevance expressly part of the standards would undermine the Director's discretion to issue using "flexibility". That is, if he or she has already decided the safety relevance of an applicant's state of health under the rules, there would appear to be little scope for exercising the discretion under the Act. It would not be

consistent with Parliament's intention to render the Director's discretion redundant in this way.

The word "significant" is extensively used in legislation, including the civil aviation, land transport, marine pollution and maritime rules, as well as the current Rule Part 67 itself. It is reasonable to expect that medical examiners, as qualified doctors with specialised aviation medical knowledge, will be able to judge whether a condition is significant or not. Removal of the word "significant" would lower the threshold, resulting in more applicants failing to meet the medical standards. Further, the definition provides that regard is to be had to the general directions (GDs). This will assist interpretation of "significant" because GDs may specify requirements such as the significance of results of examinations.

The second part of the definition addresses the case where an applicant has a medical condition that produces risk-taking behaviour but does not result in a reduction in ability. The example raised by ALPA of a nervous system producing spasmodic involuntary physical movements would be covered by the first branch of the definition (i.e. "ability").

The phrase "to exercise the privileges or perform the duties to which a medical certificate relates" merely repeats the language used in the Act (refer to s27B of the Act).

The Corkill-Janvrin report recommended the adoption of CASA standards. The Ministry has received legal advice on this matter. The Ministry is comfortable that the descriptive stem gives effect to the standards in Chapter 6, Annex 1 to the Convention, albeit that these are expressed in a manner based on the "safety relevant" concept in the Australian Civil Aviation Safety Regulations 1998.

A **number of submitters** believe that the rule as currently written allows medical standards to be set in the GDs, thereby exceeding the scope of GDs as prescribed in the Civil Aviation Act. The standards should be contained in the Rule, where they are unable to be easily changed. GDs should only contain non-medical procedural information and should not impose additional standards. **AMSANZ** recommend deleting the words "having regard to any relevant general direction". **MOT comment**: Section 27G(1)(c) of the Act permits the Director to issue GDs specifying the requirements of examinations or other clinical matters, which must be reasonable, including, but not limited to,–

- the medical content of examinations:
- the interpretation and analysis of results of examinations:
- the significance of results of examinations for the purpose of determining whether or not an applicant is eligible for a medical certificate under section 27B.

It is logical that the rule should refer medical examiners to such instruments. The question of whether the empowering provisions of the Act permit the GDs exceeds the scope of the NPRM. However, the Ministry has been very conscious of the fact that the rule and the GDs are a package. At the time the Ministry released the second NPRM, the CAA released four draft GDs for comment also. This was planned so submitters could see the "whole package" of the rules and the GDs and how they work together. Submitters could raise this issue with the Director as part of the Director's consultation on the GDs. Further, in response to the statement that GDs can be easily changed, the Ministry notes that section 27G of the Act requires the Director to consult with aviation medical health professionals and representative groups within the aviation industry. The requirement to consult requires more than mere notification. Interested parties must be given a reasonable opportunity to state their views. The Director must enter consultation with an open mind, take due notice of what is said and wait until the submitters have had their say before making a decision.

**ALPA** recommends that the GDs be reserved for the administrative functions and requirements specified for them in the Civil Aviation Act.

**MOT comment:** The Ministry refers the submitter to page 8 of the Summary of Submissions (dated 6 August 2004) for the first NPRM and to section 27G(1)(c)(iii) of the Act, which expressly permits GDs to specify requirements of examinations or other clinical matters, including, but not limited to, "the significance of results of examinations for the purpose of determining whether or not an applicant is eligible for a medical certificate". This clearly

demonstrates that the GDs have more than a purely administrative function.

**ANZ, AIA and GAPAN** believe that the Convener's assessment should generally be accepted by the Director.

**MOT comment:** The comment raised by ANZ, AIA and GAPAN exceeds the scope of this NPRM. The Ministry refers the submitters to section 27L(5) of the Act, which gives the Director the discretion to implement the Convener's decision.

One **submitter** recommends that when ongoing surveillance is a condition on a medical certificate, a full examination should not be required.

**MOT comment:** The Ministry does not agree with the proposition that the Act permits medical certificates to be issued on the basis of a partial medical examination. Before a medical certificate may be issued, the Director must be satisfied that the medical standards are met unless, if they are not met, the criteria applying to the exercise of "flexibility" in section 27B(3) of the Act are satisfied. In order to be satisfied (or not) that the medical standards in the rule are met, an examination of the applicant against all the standards is required. If the Director concludes that surveillance requirements should be imposed, this can be done by issuing a medical certificate the duration of which is subject to a condition that such requirements are met.

One **submitter** is concerned that if the pilot does not fulfil his/her surveillance obligations, then the medical examiner could be held responsible for not ensuring the surveillance was carried out. Limiting the currency could remedy this concern.

**MOT comment:** Responsibility for ensuring compliance with the conditions on a medical certificate rests with the certificate holder, not the medical examiner. However, section 27C(2) of the Act requires medical examiners to advise the Director if they have grounds to suspect any change in the medical condition or the existence of any previously undetected medical condition in a licence holder that may interfere with the safe exercise of the privileges to which that person's medical certificate relates.

One **submitter** is concerned that aeroclubs have no way of checking that a pilot has met the surveillance requirements that may be imposed on his or her medical certificate.

**MOT comment:** The Ministry acknowledges this concern but we note that the rules are predicated on industry participants taking responsibility for ensuring their compliance with certification requirements and being able to demonstrate this.

One **submitter** recommends removing endorsements from the medical certificate.

**MOT comment:** The Act says, "the Director may impose any conditions, restrictions or endorsements on a medical certificate." This indicates that the Act requires endorsements to appear somewhere on the medical certificate itself. In addition, the Ministry has concerns about the risk to safety in separating this information. We therefore do not agree with the submitter's recommendation as it would make the rule inconsistent with the Act and would appear to reduce safety.

One **submitter** was disappointed with some of the Ministry's responses to the previous submissions, citing the example of why pacemakers were mentioned in the rule and not AICDs.

**MOT comment:** AICDs (Automatic Implantable Cardiac (or Cardioverter) Defibrillators) would fall under 67.103, 105 and 107(d)(2). However, we propose that a provision be added to avoid any possible confusion.

One **submitter** believes that the statement made in the Summary of Submissions that there are no other substantive changes, other than those made as a result of the submissions, is incorrect. The draft GDs require a chest X-ray for smokers or ex-smokers over 55 years of age. The **submitter** believes this is a substantial change because it will greatly increase the cost of an application.

**MOT comment:** The potential costs raised by the submitter are a result of the GDs and not the rule. The Ministry therefore does not agree with the comment that the rule makes substantive changes.

**ALPA** believes that if the recommendations made in their submission are not incorporated into the rule, the Ministry will not be meeting its obligation to consult fully. **AMSANZ** does not believe that sufficient thought or consultation has been given to drafting with regard to undesirable consequences and recommend that the NPRM be withdrawn and the proper process be followed before the issue of another NPRM.

**MOT comment**: Section 34 of the Act sets out the consultation requirements when making Civil Aviation Rules. The Ministry believes the Minister's obligations under section 34 of the Act have been fulfilled. All the submissions on the NPRM dated 10 July 2003 have been carefully considered and significant changes were made to the rule as a result of those submissions. All the submissions on the NPRM dated 12 August 2004 have also been carefully considered. This document, the Summary of Submissions dated 6 August 2004 and the preamble to the NPRM dated 12 August 2004 outline the Ministry's comments on the submissions. Where the Ministry does not agree with a submitter's recommendations, an explanation has been provided as to why. It should be noted that consultation does not require the incorporation of all recommendations made by submitters into the rule.

AMSANZ has not been specific on what it means by "proper process". Nevertheless, the Ministry does not agree with their comment that the NPRM should be withdrawn.

The Ministry refers the submitters to the comments on consultation on pages 10-12 in the Summary of Submissions dated 6 August 2004.

One **submitter** recommends including a standard to specify the light intensity value in the room where eye tests are carried out, so that applicants are assured of minimum standards of light values when being tested. Another **submitter** recommends a review of the current focal eye test criteria distance related to the practical conditions in modern general aviation aircraft cockpits.

**MOT comment:** It is more appropriate that both these issues are addressed in the GDs.

One **submitter** recommends that an information booklet on Rule Part 67 is urgently required.

**MOT comment:** As noted in the Summary of Submissions dated 6 August 2004, the Ministry acknowledges this as a helpful suggestion. The Ministry has passed this on to the Director of Civil Aviation to progress.

**SAANZ** recommends the inclusion of a class 4 medical certificate in the rule, noting that it was discussed in the Corkill Janvrin Report. A class 4 medical certificate would be restricted to New Zealand airspace, therefore, it does not affect New Zealand's ICAO obligations that a holder of a private pilot's licence must hold a class 2 medical certificate. **SAANZ** recommend that to be eligible for a class 4 medical certificate, applicants must meet the LTSA medical requirements for a Class 1 (Private Motor Car) driver's licence. General Practitioners would have authority to issue class 4 medical certificates. Their submission includes a suggested template for use as the class 4 declaration of medical fitness to fly form.

**MOT comment:** The recreational pilot licence breaks new ground in New Zealand and raises a plethora of issues that require careful consideration and focussed submissions. Before any proposals for a recreational pilot medical certificate could be included in Part 67, work needs to be formally concluded in a number of areas such as-

- the applicable medical standards;
- the duration of the certificate;
- the medical examiner requirements;
- the fit with the statutory and rules framework;
- the international dimensions.

The Ministry understands that the CAA has communicated with industry groups on its proposal to facilitate this by creating a separate NPRM on the recreational pilot issue. The Ministry does not believe that the issue warrants further delaying Part 67. Instead, Part 67 can be amended, if and when the standards are agreed and a recreational pilot medical certificate is required.

## Specific comments on the NPRM

**ANZ, AIA and GAPAN** recommend the inclusion of another subclause in the definition of "aeromedical significance" in 67.3 to address incapacitation risk.

**MOT comment:** The Ministry refers to our comment above.

**One submitter** believes the word "likely" in the definition of "aeromedical significance" results in a 50% rule and that the risk of sudden loss of ability should not be "likely" but a lot less.

**MOT comment:** In law, the word "likely" does not bear the meaning suggested. Instead, it means a real risk that an event might happen; a distinct or significant possibility; a risk that might well eventuate. This does not mean that the risk must be proved on the balance of probabilities. Whether the risk exists will be a matter of judgement.

AMSANZ and ALPA believe the word "significant" in the definition of "aeromedical significance" is unclear and would lead to inconsistency in application. The purpose of the second limb is not clear. They recommend changing the definition to "Aeromedical significance means any medical condition or disability that currently renders the applicant unable to operate an aircraft safely, or to perform assigned duties safely, or is reasonably likely within the period for which the certificate is to be issued, to render the applicant suddenly unable to operate an aircraft safely, or to perform assigned duties safely". The word "specific" has been omitted because they believe it is not needed.

**MOT comment:** The Ministry agrees that the word "specific" is not necessary. The Ministry notes that some of the difficulties with the definition proposed by ALPA and AMSANZ include:

- the reference to "disability" is redundant since it would be covered by the definition of "specific medical condition";
- it only considers the "suddenness" of incapacitation, not a condition that leads to gradual incapacitation (for example, diabetes may cause ketosis and a gradual onset of incapacitation as a result);
- it would not allow the Director to use his discretion under s27B(2) of the Act to issue a medical certificate using flexibility.

**AMSANZ** recommends deleting the reference to the form CAA 24067-003 in the definition of "medical assessment report" in 67.3 and placing it in the GD. Specific forms should not be specified in the rule, only the fact that a form should be used.

**MOT comment:** The Ministry agrees with this recommendation.

One **submitter** believes that by requiring examinations to be made on a particular form the system becomes inflexible and more costly to pilots who may not require a full examination

**MOT comment:** Section 27D of the Act requires an applicant to have a medical examination, the findings of which are then reported by the medical examiner to the Director. Section 27B requires the Director to have regard to the report in assessing whether the applicant meets the standards. A medical certificate may not be issued unless the Director is satisfied that the medical standards are met unless, if they are not met, the criteria for exercising his or her discretion under section 27B(3) apply. A report based on a partial examination is unlikely to be adequate for the purpose of satisfying the Director that the standards are met. Further, the wording of the Act does not suggest that the medical examination at initial issue should differ from that required when the certificate is renewed, particularly given that when the Act provides for potentially more limited types of examination, it uses the term "specified examinations" (see section 27F(2) of the Act). The Ministry notes that it is open to the Director when issuing the certificate to make it subject to the condition that the applicant meets requirements during the duration of that medical certificate. This might involve having a periodic assessment against any particular standard (e.g. asthma).

**AMSANZ** recommends replacing the word "woman" with "female" in the definition of "specific medical condition" in 67.3, believing it is a more gender specific term.

**MOT comment:** The Ministry agrees with this recommendation.

**AMSANZ** believes that the rule should retain the ability to exempt a certificate holder from a specified requirement of the standards in the rule, as provided for in Annex 1 of the Chicago Convention. They recommend redrafting the clause to read *"The Director may grant an"* 

*exemption from a requirement in Subpart C*". **ALPA** agrees that the ability to exempt should remain, and recommends deleting this clause.

**MOT** comment: The Ministry does not agree with these recommendations. Section 27B(2) of the Civil Aviation Act provides an alternative process that is effectively an exemption process. The mechanism of flexibility can be used in cases where an applicant does not meet the medical standards prescribed in the rules. The Ministry refers the submitters to the discussion on exemptions on pages 16 and 17 in the Summary of Submissions dated 6 August 2004. The submission appears to be referring to the process set out in standard 1.2.4.8 of Annex 1 by which an applicant may be issued a medical certificate if he or she does not meet the standards. This process is already provided for in section 27B(3) of the Act. Replicating standard 1.2.4.8 would therefore be redundant, and would be read subject to the Act in the event of any inconsistency. The Act overrides the rules so the power of the Director to exercise flexibility under the Act cannot be undone by the restriction on exemption powers under the rules. However, to avoid any possible confusion, the Ministry proposes that a provision be added noting that the restriction on exemption powers under the rules does not affect the Director's power to exercise flexibility under section 27B(2) of the Act.

**AMSANZ** and **ALPA** recommend removing the reference to form CAA 24067-001 from 67.55 (which related to applications for medical certificates) and including it in the GDs.

**MOT comment:** The Ministry agrees with this recommendation.

**AMSANZ** and **ALPA** recommend removing the reference to form CAA 24067-002 from 67.57 (which relates to preparing an examination report) and including in the GDs.

**MOT comment:** The Ministry agrees with this recommendation.

**ALPA** recommends removing the reference to form CAA 24067-003 from 67.59 (which relates to medical assessment reports) and including in the GDs.

**MOT comment:** The Ministry agrees with this recommendation.

**ANZ**, **AIA** and **GAPAN** support the introduction of continuity and the re-introduction of age related limits on validity periods in 67.61.

**MOT comment:** The Ministry acknowledges this support.

One **submitter** recommends aligning 67.61(a)(1)(ii) more closely with the CASA age limit requirements.

**MOT comment:** The Ministry does not agree with this recommendation. Given ICAO's extensive research and documented consideration on the issue, the Ministry believes it is better to follow ICAO currency periods in this instance, rather than CASA.

**AMSANZ** recommends the inclusion of another provision to reduce the period of issue to 12 months for class 2 medical certificates if the applicant is over 70 years of age. They believe the risk of an incapacitating illness is significantly increased by aged 70.

**MOT comment:** The Ministry does not agree with this recommendation. Given ICAO's extensive research and documented consideration on the issue, the Ministry believes it is better to follow ICAO currency periods.

One **submitter** recommends that the certificate expiry date should be related to the date of the last full medical examination.

**MOT comment:** This comment appears to relate to the issue of a certificate on the basis of "old" examination information. There are a number of points to make in response to this. To adopt the proposal would lead to perceptions of "lost time". That is, the certificate would need to be backdated, which would mean that the time between the examination and the actual date of issue of the certificate would count as part of the maximum duration of the certificate during this period. Further, the legal authority to backdate medical certificates is questionable. Finally, the Ministry notes that the rule simply continues the status quo of issuing certificates that take effect from the date of issue. If the medical examiner is not confident that he or she can rely on examination information to issue a medical certificate for the maximum duration, he or she should issue for a shorter period.

One **submitter** recommends that the period of time left to run on a current medical certificate that may be taken into account under 67.61(c) (i.e. when determining the expiry date of a new medical certificate) be increased from 30 days to six weeks. Another **submitter** recommends that medical certificates for class one and class two be issued for a period of one month in excess of the current requirement. This would allow adequate time to enable renewals to take place before the certificate expires.

**MOT comment:** The Ministry notes the comments and believe that the clause addresses the problem of "lost time" raised by the submitters. It does this by enabling a new medical certificate applied for before the expiry of an existing medical certificate to be issued with a duration that takes account of the number of days between the application for the new certificate and the expiry of the existing certificate.

**ALPA** and **AMSANZ** recommend deleting 67.55 (which requires surrender of medical certificates) as sub-paragraphs (i) and (ii) repeat section 27I(9) of the Act and paragraph (2) is *ultra vires*. It purports to authorise the Director to require surrender of a medical certificate when the Act does not require this.

**MOT comment:** The Ministry agrees with this recommendation.

**AMSANZ** recommends rewording 67.103(b)(2)(iii), 67.105(b)(2)(iii) and 67.107(b)(2)(iii) to read "*any sequela of an accident, an injury, or treatment*". This would cover the side effects from medication and radiotherapy, for example, which may impose aviation safety risks.

**MOT comment:** The Ministry does not agree with this recommendation. The three items included in this rule currently fit together reasonably well. They all refer to sources of physical trauma. Further, rule 67.103(b)(3), 67.105(b)(3) and 67.107(b)(3) already cover side-effects from medication and radiotherapy, as well as any other drug, substance, preparation or treatment that results in reduced ability.

A number of **submitters** believe the standards should not be subordinate to the GDs. **ALPA** and **AMSANZ** recommend removing

the GD reference from subparagraphs in 67.103(b)(3), (c)(3) and (4), 67.105(b)(3), (c)(3) and (4) and 67.107(b)(3), (c)(3) and (4).

**MOT comment:** The Act permits the Director to issue GDs for various purposes including specifying requirements for the significance of examination results. There is no suggestion that the rules are subordinate to the GDs. It is logical for the rule to refer medical examiners to GDs and to require medical examiners to have regard to them. This is consistent with other rules that require regard to be had to airworthiness directives (also issued by the Director under the Act). The Ministry also notes that the approach in draft Part 67 is consistent with the Act itself, which confers powers that must be exercised subject to requirements in subordinate legislation (i.e. the rules). See for example section 9 of the Act regarding the grant or renewal of an aviation document.

**AMSANZ** recommends amending 67.103(d)(1), 67.105(d)(1) and 67.107(d)(1) to read "have no history or diagnosis of any condition of *the cardiovascular system*" because the heart or circulatory tree does not need to be specified as the "cardio" part refers to the heart and the "vascular" part refers to the circulation in the word cardiovascular.

**MOT comment:** The Ministry does not agree with this recommendation. While the suggestion may be technically correct, using the phrase "heart or circulatory tree" is potentially less open to misinterpretation. "Heart or vascular system" would be similar. The use of simply "cardiovascular system", which is the heading title for that section of the standards, has the potential to be misinterpreted as being limited to the heart. Further, the use of "heart or circulatory tree" is plain English wording and thus consistent with well-established drafting practice. In addition, ICAO uses the two separately, not as an all-encompassing "cardiovascular system", in Annex 1:

6.3.2.5 The applicant shall not possess any abnormality of the heart, congenital or acquired, which is likely to interfere with the safe exercise of the applicant's licence and rating privileges. A history of proven myocardial infarction shall be disqualifying.

6.3.2.7 There shall be no significant functional nor structural abnormality of the circulatory tree.

**AMSANZ** recommends deleting 67.103(d)(2), 67.105(d)(2) and 67.107(d)(2) because the conditions are covered in 67.103(d)(1), 67.105(d)(1) and 67.107(d)(1), or they could be included in the GD for cardiovascular systems.

**MOT comment:** Rules 67.103(d)(2), 67.105(d)(2) and 67.107(d)(2) provide an increased level of resolution/prescription over 67.103(d)(1) (etc). Matters in respect of 67.103(d)(2) (etc) can be, and almost certainly will be, covered in GDs. These rules make it clear that the conditions listed preclude someone from meeting the standards. This does not, however, preclude the issue of a medical certificate using flexibility. Removing 67.103(d)(2) (etc) would leave a very general medical standard for the cardiovascular system. The implementation of that standard would be highly dependent on interpretation and GDs.

**AMSANZ** recommends changing the terminology in 67.103(d)(2)(i) to 'cardiac ischaemia' to make it consistent with 67.105(d)(2)(i) and 67.107(d)(2)(i).

**MOT comment:** The class 1 standard, at 67.103(d)(2)(i), holds professional pilots to a stricter medical standard (no coronary artery disease) than the corresponding class 2 and 3 medical standards (no cardiac ischaemia). If a single term is to be used throughout then it should probably be "coronary artery disease" and not "cardiac ischaemia". The presence of cardiac ischaemia is a substantially higher "hurdle" than the presence of coronary artery disease. Those with coronary artery disease (or likely coronary artery disease) should be assessed further to determine whether they actually have ischaemic heart disease.

In considering this submission, it has become apparent that the change to the descriptive stem used in the first NPRM has resulted in cardiovascular standards that are not adequate to encompass cardiovascular-risk. The current Part 67 states: "Applicants with evidence strongly suggestive of coronary artery disease, including the presence of excessive cardiovascular risk factors, shall be assessed as unfit unless normal myocardial perfusion can be demonstrated". Accordingly, in order for this standard to be carried over, the final rule will need to expressly provide for it in class 1, 2 and 3 medical standards. **AMSANZ** recommends deleting 67.103(e)(2), 67.105(e)(2) and 67.107(e)(2) because the conditions are covered in 67.103(e)(1), 67.105(e)(1) and 67.107(e)(1). It could be included in the GD for Respiratory System. The word "acceptable" should precede the word "control" in the third line.

**MOT comment:** Rule 67.103(e)(2) (etc) provides an increased level of resolution/prescription over 67.103(e)(1). Matters in respect of 67.103(e)(2) (etc) can be, and almost certainly will be, covered in GDs. These rules make it clear that the conditions listed preclude someone from meeting the standards. This does not, however, preclude the issue of a medical certificate using flexibility.

The Ministry considers "acceptable" is encompassed by the word "adequate" and does not believe adding the term would aid clarify

**ANZ**, **AIA** and **GAPAN** believe the wording "extent of a history of pregnancy" in 67.103(i), 67.105(i) and 67.107(i) could be expressed in better terms.

**MOT comment:** There is no consideration of "extent of a history of pregnancy" in this standard. The standard considers a history or diagnosis of pregnancy "to an extent" that it is of aeromedical significance.

**ANZ**, **AIA** and **GAPAN** suggest it might be better to include the audiometry standards in GDs, rather than 67.103(l), 67.105(l) and 67.107(l).

**MOT comment:** The Ministry considers this to be a standard and should therefore be in the rule. By putting these values in the medical standards it is clear that if someone meets them they are, all other things being acceptable, able to be issued with a medical certificate.

The role envisaged for the "clinical" GDs is largely the analysis and interpretation of results (as provided for under section 27G(1)(c) of the Act) in the light of the "to an extent that is of aeromedical significance" statement, to determine whether someone meets the standards.

**ALPA** recommends removing the reference to the CAA form in 67.155 (which relates to applications for medical examiner certificates) and including in the GDs.

**MOT comment:** The Ministry agrees with this recommendation.

**ANZ**, **AIA** and **GAPAN** are concerned that because of the shortage of medical examiners, the Director may appoint medical examiners as "special medical examiners" under 67.157 who do not meet the criteria specified for issue of a medical examiner certificate.

**MOT comment:** The Ministry notes the concern raised by the submitters. The Ministry believes the issue is outside the scope of this NPRM but has passed the concern on to the Director.

**ALPA** and **AMSANZ** believe that the Director should be obliged in 67.353 and 67.355 to provide all information to the Convener in the course of reviewing a medical certification decision or considering an application for joint referral so that the Convener is fully informed. They recommend changing the word "may" to "must".

**MOT comment:** The Ministry does not agree with this recommendation because it would mean the rule would be in conflict with the Act. Under section 27L(6) and 27M(6) of the Act the Director "may" (not "must") participate in the review process by providing relevant evidence to the Convener. However, the Ministry notes that, to date, CAA's practice has been to provide all information that it holds that is relevant to the review.

**ANZ**, **AIA** and **GAPAN** recommend that a set of competencies for Special Medical Examiners should be considered.

**MOT comment:** The Ministry does not agree with this recommendation. The Special Medical Examiner concept is intended to provide the Director with some flexibility in respect to geographic or operational exigencies. This would allow the Director to recognise these factors and utilise the services of practitioners who might not meet the competencies listed, subject to conditions etc. Describing competencies in this context has the potential to undermine the special-circumstance flexibility that this concept provides.

One **submitter** believes it is unsafe to require all examiners to be assessors, believing that examining and assessing are different skills.

**MOT comment:** The Ministry acknowledges the comment made by the submitter and agrees that examining and assessing require different skill sets. However, section 27O(2) of the Act states that the Director must delegate to suitably qualified medical examiners the power to issue medical certificates to any person who qualifies for a medical certificate under 27B(1).

## Changes to Part 67

During the development of the second NPRM for this project, the proposed definitions of **licence holder**, **medical assessment report**, **medical manual**, and **psychoactive substances** were moved from Part 1 to the definitions section of Part 67 because those terms relate more particularly to that Part and are not used in other Parts of the Civil Aviation Rules.

During the development of the draft final rules for this project, further refinements were made to the definition of **aeromedical significance** in Part 67 to address submitters concerns that the rules should reflect more closely the wording used in the Chicago Convention. This includes the insertion of a reference to safety that will not undermine the Director's power to issue a medical certificate using "flexibility". In addition,-

- definitions of cardiac pacemaker and Aviation Medical Transitional Criteria Notice were added for clarity;
- rule 67.61 was amended to clarify that a pilot aged 40 years or more may be issued with a class 1 medical certificate that specifies two periods of duration that will apply according to the types of air operation the applicant is engaged in, as permitted by ICAO;
- the obligation on the Director to issue a medical assessment report, implied by the definition of that term, was made express in rule 67.59.;
- an amendment was made to provide that application forms for medical certificates are those specified by the Director submitters had suggested that the rule refer to application forms

specified in the GDs but it has since become apparent that it is beyond the scope of the GD empowering provisions to do this;

- the requirement to comply with medical examination requirements was omitted this goes further than the Act provides and, in any case, does not appear to be necessary;
- the standard relating to the presence of excessive cardiovascular risk factors has been retained;
- the provisions relating to the Convener review process were omitted as they were beyond the scope of the rule-making powers. The Convener's procedural requirements will instead continue to be communicated in the form of guidelines published on the Ministry of Transport's website.

The comments and all the background material used in developing the rules are available to the public. Persons wishing to view the comments and background material should call at Aviation House, 10 Hutt Road, Petone.