

## **Explanatory Statement**

### **Civil Aviation Safety Regulations 1998**

#### **CASA 39/20 — Drug and Alcohol Testing by CASA under Subpart 99.C of CASR Instrument 2020**

##### **Purpose**

This legislative instrument, made for and under various provisions of Part 99 of the *Civil Aviation Safety Regulations 1998 (CASR)*, provides various approvals, procedures, methods and standards required for CASA to conduct drug and alcohol testing of people who perform safety-sensitive aviation activities (**SSAAs**).

##### **Legislation**

Under subsection 9 (1) of the *Civil Aviation Act 1988* (the *Act*), CASA has the function of conducting the safety regulation of civil air operations by means that include administering Part IV of the Act.

Part IV of the Act includes section 34. Under section 34, regulations may make provision for drug and alcohol management plans (**DAMPs**) for people who perform SSAAs, and for CASA to conduct drug and alcohol testing of such people.

Subsection 98 (1) of the Act additionally provides that the Governor-General may make regulations prescribing matters required or permitted by the Act to be prescribed or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The purpose of Part 99, *Drug and alcohol management plans and testing (CASR Part 99)*, is to give effect to Part IV of the Act, by establishing a framework for the development of DAMPs, similar to those already in place in other transport sectors, and by introducing a drug and alcohol testing regime for all persons involved in SSAAs.

Subsection 98 (5D) of the Act provides that a legislative instrument made under the Act or the regulations may apply, adopt or incorporate any matter contained in any instrument or other writing as in force or existing from time to time, even if the other instrument or writing does not yet exist when the legislative instrument is made.

##### **Legislative instrument under CASR Part 99**

Under certain provisions of CASR Part 99, CASA may make a legislative instrument for the purposes of conducting drug and alcohol testing. Under regulation 99.130 of CASR, for drug and alcohol testing under Subpart 99.C, CASA may, by legislative instrument, approve breathalysers for use in alcohol testing, and drug testing devices for use in initial drug testing.

Under regulation 99.140 of CASR, an approved tester must take and prepare a body sample for drug testing in accordance with the procedures set out in a legislative instrument made by CASA for the purposes of the regulation.

Under subregulation 99.145 (2) of CASR, an approved tester must ensure that the approved drug testing device is stored, tested, maintained and operated in accordance with the legislative instrument made by CASA for the purposes of the subregulation.

Under regulation 99.150 of CASR, CASA must, by legislative instrument, specify a method for determining sample identifiers that are to be allocated to body samples that approved testers take under Subpart 99.C and send for confirmatory drug tests.

Under regulation 99.245 of CASR, an approved tester must take body samples for alcohol testing in accordance with the procedures set out in a legislative instrument made by CASA for the purposes of the regulation.

Under subregulation 99.250 (3) of CASR, an approved tester must ensure that the breathalyser is stored, tested, maintained and operated in accordance with a legislative instrument made for the purposes of the subregulation.

Under paragraph 99.445 (3) (b) of CASR, CASA may approve a person to conduct confirmatory drug tests for the purposes of Part IV of the Act if the National Association of Testing Authorities accredits the person to AS 4760, *Procedures for specimen collection and the detection and quantitation of drugs in oral fluid*, or to another Standard that is declared by CASA in a legislative instrument made for the purposes of the paragraph.

### **Background**

Instrument CASA 125/09, *Drug and alcohol testing by CASA under Subpart 99.C of CASR 1998*, commenced on 1 April 2009. It:

- (a) approved breathalysers for use in alcohol testing under Subpart 99.C of CASR; and
- (b) approved drug testing devices for use in initial drug testing under Subpart 99.C of CASR; and
- (c) approved procedures for an approved tester to take and prepare a body sample for drug testing under Subpart 99.C of CASR; and
- (d) provided instructions for storing, testing, maintaining and operating a drug testing device approved for use in an initial drug test under Subpart 99.C of CASR; and
- (e) determined the method for sample identifiers to be allocated to body samples that approved testers take under Subpart 99.C of CASR and to send for confirmatory drug tests; and
- (f) set out the procedures for an approved tester to take body samples for alcohol testing under Subpart 99.C of CASR; and
- (g) provided instructions for storing, testing, maintaining and operating a breathalyser approved for use in an initial alcohol test under Subpart 99.C of CASR; and
- (h) declared another Standard to which the National Association of Testing Authorities may accredit a person if the person is approved by CASA to conduct confirmatory drug tests for the purposes of Part IV of the Act.

Instrument CASA 125/09, *Drug and alcohol testing by CASA under Subpart 99.C of CASR 1998*, is being repealed and replaced by *CASA 39/20 — Drug and Alcohol Testing by CASA under Subpart 99.C of CASR Instrument 2020*, to do the above things, but also approve the use of the Abbott SoToxa device which is being substituted for the Alere DDS-2 device.

### **Document incorporated by reference**

The instrument refers to the tamper-evident seals marked “A” and “B” provided in the *CASA Transmission of sample to approved laboratory form*. The instrument incorporates this form as existing from time to time. This form is for use by approved testers only and is, therefore, not publicly available on the CASA website. However, CASA will make it available for inspection at a CASA office for free by prior arrangement.

The instrument also refers to the instructions of various device manufacturers, and these are incorporated by reference as they exist from time to time. The instructions are available free of charge as follows:

- (a) the Abbott SoToxa device instructions are available free of charge at: <https://www.aleretoxicology.co.uk/en/home/products-services/drug-testing/products/dds2.html>;
- (b) the Lion alcolmeter®SD-400 device instructions are available free of charge at: [https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.pacdata.sys.com.au%2Fmedia%2F3876fc87-e954-412e-ae40-87f8707eae62](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.pacdata.sys.com.au%2Fmedia%2F3876fc87-e954-412e-ae40-87f8707eae62;);
- (c) the Dräger Alcotest 9510 device instructions are available free of charge at: <https://www.manualslib.com/download/1233387/Dr-Ger-Alcotest-9510.html>;
- (d) the Securetec Detektions-Systeme AG Drug Wipe 5S device instructions are available free of charge at: [https://www.securetec.net/wp-content/uploads/2018/08/S505G\\_Instructions\\_70135\\_EN\\_v03\\_2018-10-10.pdf](https://www.securetec.net/wp-content/uploads/2018/08/S505G_Instructions_70135_EN_v03_2018-10-10.pdf).

Finally, the instrument also refers to ISO/IEC 17025-2005 *General requirements for the competence of testing and calibration laboratories* (ISO standard). This standard is not available free of charge. It, and its successor, are available for purchase from the *International Organization for Standardization*: <https://www.iso.org/standard/66912.html>. However, CASA will make it available for inspection at a CASA office for free by prior arrangement.

### **Details of the legislative instrument**

Details of the legislative instrument are set out in Attachment 1.

### **Legislation Act 2003 (the LA)**

The various provisions mentioned above expressly indicate that certain matters are to be provided for by legislative instrument. The instrument is, therefore, a legislative instrument, subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LA.

### **Consultation**

Consultation under section 17 of the LA has not been considered necessary for this instrument. The equipment approvals and testing procedures are based on existing national drug and alcohol testing protocols and procedures and apply only to the procedures to be followed by CASA. They also largely replicate matters that have been in operation since 2009 in instrument CASA 125/09, *Drug and alcohol testing by CASA under Subpart 99.C of CASR 1998*.

However, in practical terms, there has been only a change in name as the SoToxa device. Whilst the instrument substitutes the Abbott SoToxa device for the Alere DDS-2 device,

the Abbott SoToxa device is the same as the Alere DDS-2 device but Alere Inc became a subsidiary of Abbott Medical Laboratories in about 2017, and the name of the Alere DDS-2 device was changed to the Abbott SoToxa device in 2020.

**Office of Best Practice Regulation (OBPR)**

A preliminary assessment of business compliance costs indicates that the legislative instrument, as such, will have no cost impact on business. A Regulatory Impact Statement was required for the *Civil Aviation Safety Amendment Regulations 2008 (No. 1)* (the initial making of Part 99 of CASR) and, accordingly, CASA prepared RIS ORR ID: 8301A which was accepted by OBPR.

**Statement of Compatibility with Human Rights**

The Statement of Compatibility with Human Rights at Attachment 2 has been prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. The instrument is compatible with the relevant human rights because, the extent that it may limit human rights, those limits are reasonable, necessary and proportionate.

**Commencement and making**

The instrument commences on the day after it is registered. It has been made by CASA's Executive Manager, Legal, International & Regulatory Affairs, relying on the power of delegation under subregulation 11.260 (1) of CASR.

**Attachment 1****Details of the legislative instrument for drug and alcohol testing****Section 1**

This section provides the name of the instrument.

**Section 2**

This section provides that the instrument commences on the day after it is registered.

**Section 3**

This section provides that instrument CASA 125/09, *Drug and alcohol testing by CASA under Subpart 99.C of CASR 1998*, is repealed.

**Section 4**

This section provides, by way of identification, that the instrument is a legislative instrument providing for certain matters under Subpart 99.C of CASR.

**Subsection 5 (1)**

This subsection provides that for paragraph 99.130 (a) of CASR, the breathalysers mentioned in Schedule 1 are approved for use in alcohol testing under Subpart 99.C of CASR.

**Subsection 5 (2)**

This subsection provides that for paragraph 99.130 (b) of CASR, the drug testing device mentioned in Schedule 2 is approved for use in initial drug testing under Subpart 99.C of CASR.

**Subsection 5 (3)**

This subsection provides that for regulation 99.140 of CASR, the procedures for an approved tester to take and prepare a body sample for drug testing under Subpart 99.C of CASR are set out in Schedule 3.

**Subsection 5 (4)**

This subsection provides that for subregulation 99.145 (2) of CASR, the procedures for storing, testing, maintaining and operating a drug testing device approved for use in an initial drug test under Subpart 99.C of CASR are set out in Schedule 4.

**Subsection 5 (5)**

This subsection provides that for regulation 99.150 of CASR, the method for determining sample identifiers to be allocated to body samples that approved testers take under Subpart 99.C of CASR and send for confirmatory drug tests, is specified in Schedule 5.

**Subsection 5 (6)**

This subsection provides that for regulation 99.245 of CASR, the procedures for an approved tester to take body samples for alcohol testing under Subpart 99.C of CASR are set out in Schedule 6.

### **Subsection 5 (7)**

This subsection provides that for subregulation 99.250 (3) of CASR, the procedures for storing, testing, maintaining and operating a breathalyser approved for use in an initial or confirmatory alcohol test under Subpart 99.C of CASR are set out in Schedule 7.

### **Subsection 5 (8)**

This subsection provides that for paragraph 99.445 (3) (b) of CASR, another Standard to which the National Association of Testing Authorities may accredit a person if the person is to be approved by CASA to conduct confirmatory drug tests for the purposes of Part IV of the Act is declared in Schedule 8.

### **Schedule 1      Approved breathalysers**

Clause 1 of this Schedule describes the approved breathalyser for use in initial alcohol testing as the Lion Alcometer SD400, manufactured by Lion Laboratories Limited.

Clause 2 of this Schedule describes the approved breathalyser for use in initial and confirmatory alcohol testing as the Dräger Alcotest 9510 Aus manufactured by Draeger Australia Pty Ltd.

### **Schedule 2      Approved drug testing device — initial drug testing**

This Schedule describes the approved drug testing device for use in initial drug testing as:

- (a) the DrugWipe 5S manufactured by Securetec Detektions-Systeme AG; and
- (b) the SoToxa manufactured by Abbott.

### **Schedule 3      Procedures for taking and preparing body samples for drug testing**

Item 1 of this Schedule sets out the detailed procedures for an approved tester to take and prepare a body sample for the conduct of an initial drug test using the DrugWipe 5S or Abbott SoToxa approved drug testing devices.

Item 2 of this Schedule sets out the procedures for an approved tester to take and prepare a body sample for the conduct of a confirmatory test on a further body sample taken under subregulation 99.170 (1), where the result of an initial drug test using the Abbott SoToxa approved drug testing device on an earlier body sample is a positive result.

### **Schedule 4      Procedures – approved drug testing device for use in initial drug testing – storing, testing, maintaining and operating the device**

Storing, testing, maintaining and operating a drug testing device approved for use in an initial drug test must be in accordance with this Schedule.

Storing and testing must be conducted in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory.

Maintenance of the Abbott SoToxa must be conducted in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory. Inspection, cleaning, recalibration and other maintenance is to be carried out by Abbott or another

person approved by it, at least once every 12 months. Any necessary repairs are to be undertaken by Abbott or another person approved by it.

Operating the devices must be conducted in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory.

## **Schedule 5      Method — determining sample identifiers to be allocated to body samples**

Clause 1 of this Schedule provides that the Schedule specifies the method for determining sample identifiers to be allocated to body samples that approved testers take under Subpart 99.C of CASR and send for confirmatory drug tests.

Clause 2 provides that CASA, or a person authorised in writing by CASA (the *approving authority*), must, from time to time, approve a group of sequences of sample identification numbers for each approved tester to use in accordance with this Schedule.

Clause 3 provides that the approving authority must ensure that sufficient approved groups of sequences of sample identification numbers are available to ensure that each approved tester is assigned sufficient numbers to enable the approved tester to allocate a number to a body sample in accordance with clauses 5 and 6 below.

Subclause 4 (1) provides that the approving authority must, from time to time, assign to an approved tester, sample identification numbers from the group of sequences approved and in the order in which they were so approved.

Subclause 4 (2) provides that the approving authority must assign sufficient numbers to enable the approved tester to cover the number of confirmatory tests that may arise from the volume of initial drug tests anticipated to be undertaken by the approved tester during a period agreed between the approving authority and the approved tester.

Subclause 4 (3) provides that no sequence of numbers assigned by an approving authority to an approved tester may later be assigned by the approving authority to any other approved tester.

Subclause 4 (4) provides that the approving authority must maintain a record of each sequence of numbers assigned by it, and of the approved tester to whom it is assigned, and will make that record available to CASA on request.

Subclause 5 (1) provides that when an approved tester conducts an initial drug test for which a positive result is recorded, the approved tester is to allocate to the body sample that is to be sent for a confirmatory drug test a sample identification number chosen from, and in the order in which it appears in, a sequence of numbers assigned by the approving authority to the approved tester.

Subclause 5 (2) provides that the approved tester is to add to the number so allocated the date of birth of the donor of the sample, expressed in the form “dd/mm/yy”, where “dd” is a 2-digit designation of the day, “mm” is a 2-digit designation of the month, and “yy” is a 2-digit designation of the year.

Subclause 5 (3) provides that the combination of the allocated sample identification number and the donor's date of birth constitutes the **sample identifier** mentioned in Subpart 99.C of CASR.

Subclause 5 (4) provides that except for the purposes of clause 6 below, an approved tester is not to allocate the same sample identification number to more than 1 body sample.

Subclause 6 (1) provides that when a body sample is divided by an approved tester into a Sample A and a Sample B, the same sample identification number is to be allocated to each of Sample A and Sample B when the samples are placed into separate specimen tubes.

Subclause 6 (2) provides that the allocated sample identification number (together with the donor's date of birth) is to be placed on each such tube. The approved tester must ensure that 1 such tube is marked "Sample A" and the second such tube is marked "Sample B".

Subclause 7 (1) provides that when the approval of a person as an approved tester expires or is otherwise terminated, any sample identification numbers assigned to the tester and not allocated in accordance with clause 5 or 6 are to be returned to the approving authority that assigned them to the tester.

Subclause 7 (2) provides that the approving authority must note the return of assigned numbers in the record mentioned in subclause 4 (4) above.

## **Schedule 6      Procedures for taking body samples for alcohol testing**

This Schedule refers to the detailed procedures for an approved tester to take body samples for alcohol testing using a Lion Alcometer SD400 or a Drager Alcotest 9510 Aus.

If an individual fails to provide an adequate breath sample or sufficient volume of breath after 3 attempts as provided for by 2 provisions in table item 2A of item 1, Table 1 in Schedule 6, a note to the relevant provisions explains that CASA will consider and advise the individual on the legal implications of failure to provide a sample. The provisions explain that the individual must also be advised that they can no longer perform SSAAs until notified by CASA

The following provisions of CASR set out the consequences of a failure to provide a body sample to an approved tester:

- (a) regulation 99.330 provides it is an offence for a person to refuse or fail to give a body sample to an approved tester for a drug or alcohol test under Subpart 99.C if:
  - (i) the person is performing or available to perform an applicable SSAA; and
  - (ii) at the time the person is performing or available to perform the applicable SSAA, the person is required to give a body sample for a drug or alcohol test by the approved tester; and
  - (iii) the approved tester, in requiring and taking or seeking to take the body sample, complies with the requirements of this Part or any legislative instrument made under Part 99.



- (b) regulation 99.335 provides it is an offence for a person performing or available to perform an applicable SSAA who is required by an approved tester to provide a body sample for a drug or alcohol test under Subpart 99.C to: (a) refuse to provide a body sample to be tested; or (b) fail to provide a body sample to be tested — to again perform or be available to perform an applicable SSAA until the person is drug or alcohol tested under Part 99.

Further, under regulation 99.415 of CASR, CASA may vary, suspend or cancel a person's civil aviation authorisation in the interests of aviation safety in various circumstances, including:

- (a) if the person gives a body sample for drug or alcohol testing under Subpart 99.C; and a confirmatory alcohol test or confirmatory drug test is conducted on the sample; and the test result is a positive result; and
- (b) if a person refuses to give a body sample for drug or alcohol testing under Subpart 99.C; and
- (c) if CASA determines that a person has contravened the requirements of a regulation in Division 99.E.2 (other than subregulation 99.325 (1)); and
- (d) if CASA determines that a person has contravened the requirements of a regulation in Subpart 99.B or 99.F.

A decision to vary, suspend or cancel a person's civil aviation authorisation on any of these basis would be subject to independent merits review: section 31 of the *Civil Aviation Act 1998*.

## **Schedule 7      Procedures – approved breathalyser for use in initial or confirmatory alcohol testing – storing, testing, maintaining and operating the breathalyser**

Storing, testing, maintaining and operating a breathalyser approved for use in an initial or confirmatory alcohol test must be in accordance with this Schedule as follows.

### **For the Lion Alcometer SD400:**

#### **Storing:**

The device is to be stored in clean and dry conditions and not exposed to extreme weather conditions.

#### **Testing:**

The device is to be tested in a manner not inconsistent with the manufacturer's instructions provided that compliance with any action recommended by the manufacturer in the instructions is mandatory.

#### **Maintaining:**

The device is to be maintained in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory. The device is to be cleaned only with a slightly damp cloth and not exposed to cleaning products that contain solvents.

**Operating:**

The device is to be operated in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that various specified requirements are met.

**For the Drager Alcotest 9510 Aus:****Storing:**

The device is to be stored in its travel case in clean and dry conditions and not exposed to extreme weather conditions.

**Testing:**

The device is to be verified to National Measurement Institute standard R126 so that after verification only the time and date may be varied, or the location of testing inserted, by another person. The verification is to be conducted in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory.

**Maintaining:**

The device is to be maintained in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory. The device is to be cleaned only with a slightly damp cloth and not exposed to cleaning products that contain solvents.

**Operating:**

The device is to be operated in a manner not inconsistent with the manufacturer's instructions for use of the device, provided that compliance with any action recommended in those instructions is to be regarded as mandatory. Results are to be printed using a thermal-type printer. Connection to another printer or to a PC or modem is not required. A clean unused mouthpiece is to be used for every test. Only mouthpieces manufactured or supplied by Draeger Australia Pty Ltd are to be used.

## **Schedule 8      Another standard – National Association of Testing Authorities accreditation – confirmatory drug tests**

This Schedule provides that another standard to which the National Association of Testing Authorities may accredit a person if the person is to be approved by CASA to conduct confirmatory drug tests for the purposes of Part IV of the Act, is the ISO/IEC 17025-2005, *General requirements for the competence of testing and calibration laboratories*, being the international standard so numbered as in force from time to time and published jointly by the International Organization for Standardization and the International Electrotechnical Commission, as applied by the National Association of Testing Authorities in the field of Forensic Services on the recommendation of the Forensic Science Accreditation Advisory Committee.

**Attachment 2****Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the  
Human Rights (Parliamentary Scrutiny) Act 2011*

**CASA 39/20 — Drug and Alcohol Testing by CASA under Subpart 99.C  
of CASR Instrument 2020**

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the legislative instrument**

The instrument replaces procedures and approvals for alcohol and drug tests by the Civil Aviation Safety Authority (*CASA*) on persons who perform, or are available to perform, safety-sensitive aviation activities (*SSAAs*) under Part 99 of the *Civil Aviation Safety Regulations 1998* (*CASR*).

**Human rights implications**

The legislative instrument potentially engages with the right to privacy, including the right to protection of one's reputation, as it relates to the taking of body samples for the conduct of alcohol and drug tests on persons who perform, or are available to perform, SSAAs. The instrument also potentially engages with the right to work and rights at work, as a person may be required to undergo body sampling at work in accordance with the procedures for the taking of body samples for alcohol and drug testing and may be prevented, under Part 99 of CASR, from working if confirmatory alcohol or drug testing of a sample taken using these procedures shows a positive result.

However, any limits on these human rights are reasonable, necessary and proportionate because they promote aviation safety. Part 99 of CASR sets out a scheme for the drug and alcohol testing of persons who perform SSAAs. The scheme is administered by CASA and is designed to ensure persons do not perform aviation-related duties while adversely affected by drugs or alcohol. The instrument assists in ensuring that persons who perform SSAAs are fit to perform those activities, thereby promoting the safety of aviation activities. Further, the limitations promote the right of other persons to have a safe workplace and the obligations imposed by the *Privacy Act 1988* continue to apply.

**Conclusion**

This legislative instrument is compatible with human rights because, to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate.

**Civil Aviation Safety Authority**