Explanatory Statement

Civil Aviation Safety Regulations 1998

Exemption — DAMP organisations collecting and screening specimens

**Legislation – exemption**

Under subsection 98 (1) of the *Civil Aviation Act 1988* (the ***Act***), the Governor-General may make regulations for the Act and the safety of air navigation. Under subsection 98 (5A) of the Act, the regulations may empower CASA to issue instruments in relation to matters affecting the safe navigation and operation, maintenance, and airworthiness of aircraft, and design standards for aircraft.

Subregulation 11.160 (1) of the *Civil Aviation Safety Regulations 1998* (***CASR 1998***) provides that, for subsection 98 (5A) of the Act, CASA may grant an exemption from a provision of the regulations, including the *Civil Aviation Regulations 1988* (***CAR 1988***), in relation to a matter mentioned in that subsection. Under subregulation 11.160 (2), an exemption may be granted to a person, or to a class of persons, and may specify the class by reference to membership of a specified body or any other characteristic. Subregulation 11.205 (1) provides that an exemption may be made subject to any condition necessary in the interests of the safety of air navigation.

Under regulation 11.225 of CASR 1998, an exemption must be published on the Internet. Under subregulation 11.230 (1), an exemption ceases on the day specified within it (but no longer than 3 years after its commencement) or, if no day is specified, 3 years after commencement.

Under subsection 33 (3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

**Legislation — drug and alcohol**

Under subsection 9 (1) of 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 safety-sensitive aviation activities (***SSAA***), and for CASA to conduct drug and alcohol testing of such people.

The *Civil Aviation Safety Amendment Regulations 2008 (No. 1)* commenced on 23 September 2008 and amended CASR 1998 by inserting a new Part 99, *Drug and alcohol management plans and testing* (***CASR Part 99***).

The purpose of the amendment regulations was 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 random drug and alcohol testing regime for all persons involved in SSAA.

Under the definitions in subregulation 99.010 (1) of CASR 1998, a ***DAMP*** means a drug and alcohol management plan that complies, or purports to comply, with the requirements of regulation 99.045.

Under subparagraph 99.045 (b) (ii), a DAMP must include a drug and alcohol testing program that, among other things, meets the requirements specified in regulation 99.050.

Under subparagraph 99.050 (1) (a) (ii), oral fluid testing for drugs must be in accordance with the Standard mentioned in paragraph (c) of the definition of ***relevant Standard***, namely, AS 4760, *Procedures for specimen collection and the detection and quantitation of drugs in oral fluid*.

Under subparagraph 99.050 (1) (a) (iii), urine testing for drugs must be in accordance with the Standard mentioned in paragraph (d) of the definition of ***relevant Standard***, namely, AS/NZS 4308, *Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine.*

**Instrument**

This instrument of exemption repeals and replaces instrument CASA EX112/13. It has removed the list of compliant devices previously specified in subsection 6 (2) of CASA EX112/13 and replaced it with a new subsection 7 (2) that requires collection and testing devices to conform to the requirements of, and be verified in accordance with, Appendix B of AS/NZS 4308.

The exemption applies to areas *outside* Australian capital cities (as defined). It does not apply within capital cities.

The reason it does not apply within capital cities is that, in CASA’s view, Australian capital cities currently have an adequate number of Standards-accredited collecting agencies to meet collecting and testing demand. There are also, within the capital cities, appropriate training opportunities for doctors and nurses to meet the Standard and become accredited for this potentially expanding role. It is CASA’s intention to allow non-conformance with the Standards only where it is clearly necessary.

The circumstances outside capital cities are different to those within capital cities — there is not an adequate number of reasonably accessible Standards-accredited collecting agencies to meet demand, nor is there reasonably accessible training for Standards accreditation of doctors and nurses (and others).

The exemption, therefore, is intended to assist DAMP organisations in remote and regional Australia by facilitating the use of doctors and nurses in such areas. To address the contingency, medical professionals in these areas can carry out drug testing for DAMPs provided they meet certain conditions of the exemption.

**Training requirements under the oral fluid and urine Standards**

Clause 1.3.13 of AS 4760 *for oral fluid testing for drugs*, defines a ***collector*** as a person who has successfully completed a course of instruction in compliance with the Standard for specimen collection, storage, handling and despatch, and received a statement of attainment in accordance with the Australian Quality Training Framework (***AQTF***).

Clause 3.1 provides that on-site testing for oral fluids shall be performed by a technician from an accredited collecting agency. Clause 1.3.38 of AS 4760 requires that a ***technician*** must have successfully completed a course of instruction in compliance with the Standard for on-site testing, and received a statement of attainment in accordance with the AQTF.

Clause 1.3.24 of AS/NZS 4308 *for urine testing for drugs* defines ***on-site screening*** as a screening test carried out at the point of collection. Clause 1.3.32 defines ***screening tests*** as methods used to exclude the presence of a drug, or class of drugs, and to identify whether specimen integrity is compromised. Collection for this purpose is done by a collector.

Clause 1.3.14 defines a ***collector*** as a person who has successfully completed a course of instruction for specimen collection and on-site screening (if applicable), handling, storage and despatch of specimens and who has received a statement of attainment in accordance with the AQTF or New Zealand Qualifications Authority (***NZQA***).

**Collecting agency requirements under the urine Standard**

Clause 1.3.12 of AS/NZS 4308 defines a ***collecting agency*** as an organisation assuming professional, organisational, educational and administrative responsibility for collection, on-site screening (if applicable), storage and despatch of urine specimens, and hence parallel responsibility for collectors.

Under clause 2.2.5 of AS/NZS 4308, personnel not authorised by a collecting agency are not permitted to be in any part of a collecting site where a donor provides a specimen of urine or where such a specimen is stored.

Under Appendix A of AS/NZS 4308, on-site screening procedures are described, including the role of a collecting agency.

AS/NZS 4308 is established in such a way that, to conform to the standard, collection and testing of urine specimens can only be performed by a collector who is an employee of, or similarly associated with, a collecting agency.

**DAMP organisations in remote and regional Australia**

There are DAMP organisations located in remote and regional Australia which must, under the terms of their DAMP, conduct drug testing in accordance with the relevant Standard using technicians and collectors as defined above in terms of having successfully completed a course of instruction, and being collectors of a collecting agency.

However, in remote and regional Australia, such trained persons and collecting agencies are not available for urine or oral specimen collection and on-site urine testing. In the short to medium term, they are not likely to become available unless small DAMP organisations go to the large expense of sending appropriate persons for training in initial drug testing in one of the major Australian cities where training courses may periodically be run, and the DAMP organisation in turn establishes itself as a collecting agency with its associated overheads and requirements. Alternatively, commercial collecting agencies with trained collectors may expand their reach into remote and regional Australia, but this has not yet occurred.

**How to ensure effective DAMP testing in remote and regional Australia**

CASA considers it is not realistic at this stage to expect that the testers used by DAMP organisations in remote and regional Australia will complete such training or that the DAMP organisations will establish themselves as collecting agencies. CASA has, therefore, issued a general exemption from specific training and collection agency requirements. The exemption is, however, tightly circumscribed by conditions designed, as far as practicable, to require alternative and equivalent, or near-equivalent, tester training, and the use of proven, highly reliable, urine specimen testing equipment. It is intended in this way to protect the integrity of DAMP organisations’ drug testing. The exemption does this as follows.

**Effect of exemption and conditions**

Firstly, a DAMP organisation *in remote and regional Australia*, may use a trained collector, meaning a person who has successfully completed a course of instruction in the oral fluid standard or the urine standard (as applicable for the test conducted). A course of instruction means, in effect, an accredited course within the AQTF or the NZQA. Such a fully trained collector is in effect exempt from the requirements of AS/NZS 4308 *for the role and involvement of a collecting agency*.

However, when conducting on-site screening of urine specimens, the trained collector must use a device that conforms to the requirements of, and is verified in accordance with, Appendix B of Standard AS/NZS 4308.

On-site screening of oral fluid specimens by trained collectors, doctors, nurses or capable persons is not permitted because appropriate testing devices, that are acceptable to CASA for this kind of usage in these kinds of circumstances, are not yet available.

Secondly, a DAMP organisation *in remote and regional Australia*, may use a doctor or a nurse who has NOT completed a specific course of instruction, provided he or she has current professional responsibility (in a hospital, general practice or pathology service) in relation to the collection, storage, handling and despatch of biological specimens. Such a doctor or nurse is, in effect, also exempt from the requirements of AS/NZS 4308 for the role and involvement of a collecting agency. However, if conducting on-site screening of urine specimens, the doctor or nurse must use 1 of the 7 named devices.

Thirdly, if such a doctor or nurse, or a trained collector, is not available because of the remoteness of the location of the DAMP organisation at which testing is conducted, the testing may be done by another person (a ***capable person***) who has been trained by a doctor, nurse, trained collector, or by another person who has completed some *formal training* in the collection, storage, handling and despatch of biological specimens. (A Note explains that *formal training* acceptable to CASA includes training given by a university, an institute of technology, a technical and further education college or a similar State or Territory institution as part of an accredited training course.)

A capable person may not test unless he or she has first affirmed in writing to CASA that he or she has been trained, giving details of the identity and qualifications of the trainer and a description of the training given.

A capable person is, in effect, also exempt from the requirements of AS/NZS 4308 for the role and involvement of a collecting agency. However, if conducting on-site screening of urine specimens, the capable person must use 1 of the 7 named devices.

The DAMP organisation must report to CASA, for each DAMP reporting period, on the numbers and locations of tests where trained collectors, doctors, nurses or capable persons acted under the exemption. Reporting periods are the periods of 6 months ending immediately before 1 March and 1 September each year.

A DAMP organisation’s testing will be subject to periodic CASA audit to confirm its reliability and the competence of the DAMP testers who are used. The exemption applies only to DAMP testers under Subpart 99.B of CASR 1998. It does not apply to approved testers in CASA’s random drug testing program under Subpart 99.C of CASR 1998.

**Remote and regional Australia**

To focus the benefits of the exemption on those areas where compliance with the training and collection agency requirements of the Standard is unreasonably difficult, the modified exemption excludes capital cities in which such compliance is much easier because of the availability of appropriate facilities and agencies.

***Capital cities*** are defined in terms of the relevant geographical area depicted on maps in the Australian Standard Geographical Classification (ASGC), July 2011 (Australian Bureau of Statistics) for each of the State and Territory capital cities. A Note explains that, generally speaking, a capital city includes, in effect, the area from the central business district out to the edge of the greater metropolitan area of the city. The Note includes page references for the relevant maps and details of an Internet link.

**Section 99 of the Constitution**

CASA does not consider that the exemption, in its nature or terms, enlivens or offends section 99 of the Constitution. That section provides that “The Commonwealth shall not, by any law or regulation of trade, commerce, or revenue, give preference to one State or any part thereof over another State or any part thereof”.

The exemption under regulation 11.160 of CASR 1998 is not considered to be a “law or regulation of trade, commerce, or revenue”.

The exemption is not of its nature a law, legislative or legislation (although it is considered to be a legislative instrument for the registration and other purposes of the *Legislative Instruments Act 2003* (the ***LIA***)).

The exemption does not “regulate” (even administratively) any trade, commerce or revenue.

The exemption ameliorates the requirements of DAMP organisations in remote and regional Australia who, for the purposes of complying with the CASR Part 99 requirements to conduct drug tests in certain, sometimes urgent, circumstances, face serious difficulty in finding trained testers who meet the requirements of the Standard set out in CASR Part 99.

The exemption is not addressed to or at any trade, commerce or profession as such but to remote and regional DAMP organisations and how they may meet their obligations under CASR Part 99 when Standards-accredited collection agencies are not available.

DAMP organisations within capital cities face no similar difficulty. If the exemption were available to DAMP organisations in capital cities it would, eventually, undermine and neutralise the Standard against which it is preferred that drug testing be conducted as far as practicable.

As between a remote and regional DAMP organisation, and an urban DAMP organisation, there is no preference given. Each DAMP organisation must commercially engage an appropriate tester for the purposes of CASR Part 99, whether that tester is a trained collector associated with a “city” collecting agency, or a doctor or nurse or other capable person in remote or regional Australia.

It is considered that, merely as a result of the exemption, the remote and regional DAMP organisation obtains no tangible advantage in the course of its trading or commercial operations, nor any material or sensible benefit of a commercial or trading character.

The different treatment that is afforded by the exemption to DAMP organisations in remote and regional Australia arises exclusively as a consequence of the circumstances of locality and their effects on such organisations in attempting to comply with their CASR Part 99 obligations for drug testing.

**Legislative Instruments Act**

For subsection 98 (5A) of the Act, CASA may, by instrument, grant an exemption from compliance with a provision of the Regulations or Civil Aviation Orders. An instrument issued under paragraph 98 (5A) (a) of the Act is a legislative instrument if the instrument is expressed to apply to a class of persons or aircraft. The exemption applies to a class of persons being trained collectors, doctors, nurses or capable persons. The exemption is, therefore, a legislative instrument subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LIA.

**Consultation**

Consultation under section 17 of the LIA was undertaken for the initial issue of this exemption, instrument CASA EX27/09, in 2009 with the Australian Aerial Agricultural Association and with representatives of larger airlines. Further consultation with the National Association of Testing Authorities (***NATA***) lead to another issue of the exemption, instrument CASA EX82/10. No specific consultation was undertaken with respect to the previous iterations of this exemption, instruments CASA EX117/12 and CASA EX112/13.

CASA EX84/14 was instigated after receiving recommendations from NATA that CASA EX112/13 be amended to broaden the reference to devices that may be used for testing and screening. NATA advised that the list of devices specified in CASA EX112/13 had been superseded and are no longer necessarily the best available tests. Accordingly, CASA has issued CASA EX84/14 after consultation with NATA.

**Statement of Compatibility with Human Rights**

A Statement of Compatibility with Human Rights is at Attachment 1.

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

The exemption is beneficial in effect by relieving persons of an obligation to comply with certain aspects of the DAMP testing requirements. A Regulation Impact Statement (RIS) is not required because the exemption is covered by a standing agreement between CASA and OBPR under which a RIS is not required for exemptions (OBPR id: 14507).

**Making and commencement**

The exemption has been made by a delegate of CASA, relying on the power of delegation in subregulation 11.260 (1) of CASR 1998.

The instrument commences on the day after registration. The exemption expires at the end of June 2017, as if it had been repealed by another instrument.

[Instrument number CASA EX84/14]

**Attachment 1**

**Statement of Compatibility with Human Rights**

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

Exemption — DAMP organisations collecting and screening specimens

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 legislative instrument exempts doctors and nurses, who conduct drug tests under drug and alcohol management plans (***DAMPs***) for DAMP organisations, from having to meet certain additional training and other requirements of the Standard for drug testing, provided they meet particular conditions. The exemption only applies outside capital cities as defined.

**Human rights implications**

This legislative instrument does not engage any of the applicable rights or freedoms.

**Conclusion**

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

**Civil Aviation Safety Authority**