

Replacement Explanatory Statement

Civil Aviation Safety Regulations 1998

CASA EX92/20 — Materials Flammability Airworthiness Standards (Medical Isolation Transportation Devices) Instrument 2020

Purpose

The purpose of this instrument is to enable aircraft to carry a Medical Isolation Transportation Device (*MITD*) although the MITD does not comply with materials flammability requirements contained in applicable airworthiness standards.

It is not possible to modify the design of the MITD to comply with those materials flammability requirements because the tent of the MITD is made from plastic materials that fail to meet those requirements. The tent is the component of an MITD that performs its primary function — environmentally isolating a patient and, therefore (depending upon how the MITD is configured):

- (a) protecting assisting clinicians and other individuals (including other occupants of an aircraft) from an infectious or contaminated patient; or
- (b) protecting an immunosuppressed patient from the outside environment.

Because of the COVID-19 pandemic, there is an increased need for aircraft to be able to carry MITDs for the transport of infectious patients.

Legislation — exemptions and directions

Section 98 of the *Civil Aviation Act 1988* (the *Act*) empowers the Governor-General to make regulations for the Act and in the interests of the safety of air navigation. Relevantly, the Governor-General has made the *Civil Aviation Safety Regulations 1998* (*CASR*).

Subpart 11.F of CASR provides for the granting of exemptions from particular provisions of the regulations. Subregulation 11.160 (1) of CASR provides that, for subsection 98 (5A) of the Act, the Civil Aviation Safety Authority (*CASA*) may grant an exemption from compliance with a provision of the regulations.

Under subregulation 11.160 (2) of CASR, an exemption may be granted to a person or a class of persons, and may specify the class by reference to membership of a specified body or any other characteristic.

Under subregulation 11.160 (3) of CASR, an exemption may be granted on application by a person or on CASA's own initiative.

Under subregulation 11.175 (4) of CASR, in deciding whether to renew an exemption, on application by a person, CASA must regard as paramount the preservation of at least an acceptable level of aviation safety. CASA has regard to the same test when deciding whether to renew an exemption on its own initiative.

Regulation 11.205 provides that CASA may impose conditions on an exemption if necessary in the interests of the safety of air navigation. Under regulation 11.210, it is a strict liability offence not to comply with the obligations imposed by a condition.

Regulation 11.225 of CASR requires an exemption to be published on the Internet. Under subregulation 11.230 (1), the maximum duration of an exemption is 3 years.

Subpart 11.G of CASR provides for CASA to issue directions in relation to matters affecting the safety of air navigation. Under paragraph 11.245 (1) (a) of CASR, CASA may, by instrument, issue a direction about any matter affecting the safe navigation and operation of aircraft. Subregulation 11.245 (2) of CASR provides that CASA may issue such a direction if CASA is satisfied that it is necessary to do so in the interests of the safety of air navigation, if the direction is not inconsistent with the Act, and for the purposes of CASA's functions.

Under paragraph 11.250 (a) of CASR, a direction under regulation 11.245 ceases to be in force on the day specified in the direction. Under regulation 11.255, it is an offence of strict liability to contravene a direction under regulation 11.245.

Legislation – Certification and airworthiness requirements – Part 21 of CASR

Part 21 of CASR sets out certification and airworthiness requirements for aircraft and parts, including rules dealing with modification/repair design approvals and matters relating to approved design organisations.

Regulation 21.006A of CASR provides for CASA, an authorised person or an approved design organisation to approve a change to a flight manual for an aircraft.

Regulation 21.009 of CASR sets out requirements related to the approval of technical data for designs submitted to CASA, an authorised person or a relevant approved design organisation in connection with applications of specified kinds. Those applications include, at paragraph 21.009 (1) (f), an application for a modification/repair design approval.

Subregulation 21.009 (2) of CASR provides that, subject to regulation 11.055, CASA or (relevantly) the authorised person or approved design organisation must approve the technical data if satisfied that the technical data demonstrates that the design complies with the related applicable airworthiness standards.

Subpart 21.M of CASR sets out requirements for the issue of modification/repair design approvals. Regulation 21.243 of CASR relates to applying to be an approved design organisation and granting approval to an applicant. Subregulations 21.243 (2) and (3) of CASR set out the circumstances in which, subject to regulation 11.055, CASA must approve an applicant. In addition, subregulation 21.243 (6) of CASR provides that, if CASA decides to approve an applicant, CASA must determine:

- (a) the design activities that the applicant is approved to carry out; and
- (b) the aircraft and aeronautical products in relation to which the applicant is approved to carry out those design activities; and
- (c) if the applicant is approved to grant a modification/repair design approval under regulation 21.437 — whether the applicant is approved to make an equivalent level of safety determination under regulation 21.436.

Under subregulation 21.437 (1) of CASR, regulation 21.437 applies if an application for a modification/repair design approval is made to an authorised person or approved design organisation. Subregulations 21.437 (2) and (3) of CASR set out the circumstances in which, subject to regulation 11.055, the authorised person or approved design organisation must grant the approval.

Legislation – Authorisations – Part 11 of CASR

Under regulation 11.015 of CASR, an approval of technical data under regulation 21.009 of CASR and a modification/repair design approval under regulation 21.437 are authorisations under Part 11 of CASR, with Subpart 11.BA of CASR applying to the authorisations.

Under regulation 11.025 of CASR, if the regulations allow for an application for an authorisation to be made to an authorised person, a reference in Part 11 of CASR to CASA includes a reference to an authorised person to whom the application is made. For the purpose of this instrument, an authorised person is a person who is appointed by CASA under regulation 201.001 of CASR to be an authorised person for the relevant provision of CASR.

Under regulation 11.026 of CASR, if the regulations allow for an application for an authorisation to be made to an approved design organisation, a reference in Part 11 of CASR to CASA includes a reference to the approved design organisation to which the application is made in relation to such an application.

Regulation 11.055 of CASR sets out:

- (a) restrictions and conditions that CASA must meet if considering granting or issuing an authorisation that a person has applied for in accordance with CASR; and
- (b) other requirements, and discretionary actions available to CASA, related to the application process.

Regulation 11.056 of CASR provides that an authorisation may be granted subject to any condition that CASA is satisfied is necessary in the interests of the safety of air navigation. Therefore, an authorised person or approved design organisation that approves technical data under regulation 21.009, or grants a modification/repair design approval under regulation 21.437, may grant the approval subject to any condition that the authorised person or approved design organisation is satisfied is necessary in the interests of the safety of air navigation.

Under regulation 11.077, a person commits an offence of strict liability if the person breaches a condition of an authorisation.

Background

CASA has previously made 2 instruments of a similar kind:

- (a) CASA EX153/14, *Exemption — materials flammability airworthiness standards for Medical Isolation Transportation Devices*, that commenced on 14 November 2014 and was repealed at the end of 30 November 2015; and
- (b) CASA EX109/16, *Exemption — materials flammability airworthiness standards for Medical Isolation Transportation Devices*, that commenced on 6 July 2016 and was repealed at the end of 30 June 2019.

Although the instrument would provide a similar exemption for an additional 3 years, the following information is relevant:

- (a) for the reasons mentioned under the heading “Purpose”, MITDs continue to be unable to comply with materials flammability requirements contained in applicable airworthiness standards;
- (b) because of the COVID-19 pandemic, there is an increased need for aircraft to be able to carry MITDs for the transport of infectious patients;
- (c) CASA intends to amend Part 21 of CASR in a way that will avoid the need for ongoing exemptions of the same kind (see <https://www.casa.gov.au/rules-and-regulations/changing-rules/rule-development-projects/project-cs-1312-post-implementation-review-casr-subparts-21m-and-21j-and-associated-part-21>).

Overview of instrument

The instrument is intended to again enable aircraft to carry an MITD although the MITD does not comply with materials flammability requirements contained in applicable airworthiness standards.

CASA has assessed the impact on aviation safety of an aircraft carrying an MITD and is satisfied that, because of the requirements for carrying an MITD in Schedule 1 of the instrument and the following additional risk mitigators, the risk of a fire on an aircraft because the aircraft carries an MITD is extremely improbable:

- (a) only one MITD is likely to be carried on an aircraft at any one time;
- (b) an MITD carried on an aircraft will be under constant surveillance by clinicians;
- (c) an MITD is not in itself an ignition source;
- (d) although a typical MITD requires the patient to receive an oxygen supply from a ventilation pump, the resulting composition of the air inside the tent is not considered to be an oxygen-rich environment.

Content of instrument

Section 1 names the instrument.

Section 2 sets out the duration of the instrument. The note under section 2 confirms that the direction in section 7 of the instrument ceases to be in force at the same time as the instrument is repealed.

Section 3 of the instrument contains definitions of terms used in the instrument.

The note below the heading of section 3 is a signpost note, intended to assist users of the instrument to identify some relevant definitions in the Act and the regulations.

The note below the definition of ***applicable approved design organisation*** is intended to assist users of the instrument by clarifying the relationship between the definition of ***approval activity*** in regulation 21.233 of CASR and paragraphs (a) and (b) of the definition of ***applicable approved design organisation***.

Subsection 4 (1) of the instrument exempts an applicable authorised person from compliance with:

- (a) subregulation 21.009 (2) of CASR, to the extent that the subregulation requires the person, before granting a modification/repair design approval, to be satisfied that the technical data submitted by an applicant demonstrates that the applicant's design for an MITD complies with the applicable airworthiness standards for materials flammability; and
- (b) regulation 21.437 of CASR, to the extent that the regulation requires the person, before granting a modification/repair design approval, to be satisfied that an applicant's design for an MITD complies with the applicable airworthiness standards for materials flammability.

To assist users of the instrument, the note below subsection 4 (1) includes examples of airworthiness standards for materials flammability that may be relevant to an application for a modification/repair design approval.

Subsection 4 (2) of the instrument imposes the condition in subsection 5 (1) on the exemptions in subsection 4 (1).

Subsection 4 (3) of the instrument exempts an applicable approved design organisation from the same provisions of CASR, to the same extent, as subsection 4 (1) exempts an applicable authorised person.

Subsection 4 (4) of the instrument imposes the condition in subsection 5 (2) on the exemptions in subsection 4 (3).

Subsection 5 (1) of the instrument imposes a condition on the exemptions granted to an applicable authorised person by subsection 4 (1) of the instrument. It requires the person to ensure that a modification/repair design approval granted for a design for an MITD is subject to conditions that require the operator of an aircraft that carries an MITD to comply with the requirements for carrying an MITD mentioned in Schedule 1. The authorised person is empowered to impose those conditions on a modification/repair design approval by regulation 11.056 of CASR, as affected by regulation 11.025 of CASR.

Subsection 5 (2) of the instrument imposes the same condition on an applicable approved design organisation that grants a modification/repair design approval granted for a design for an MITD. The organisation is empowered to impose conditions on a modification/repair design approval by regulation 11.056 of CASR, as affected by regulation 11.026 of CASR.

The purpose of requiring a modification/repair design approval to be subject to conditions requiring compliance with the requirements in Schedule 1 is to ensure that the operator of an aircraft that carries an MITD, based on the modification/repair design approval, will continue to be bound by those requirements after this instrument is repealed. This is an important safety requirement in light of the savings provision in section 6.

Section 6 of the instrument is a savings provision that ensures any modification/repair design approval issued by an applicable authorised person or an applicable approved design organisation in accordance with the instrument will continue to have effect after the instrument is repealed.

Section 7 of the instrument directs the operator of an aircraft that carries an MITD to comply with the requirements for carrying an MITD in Schedule 1.

Schedule 1 sets out the requirements for carrying an MITD. They require the operator of an aircraft on which an MITD is carried to ensure that specific actions are taken in the interests of aviation safety, particularly the safety of the crew and other occupants of the aircraft. They include requirements for easy access to a fire extinguisher and to inform occupants of the aircraft that the MITD does not meet materials flammability standards.

The note below clause 1 of Schedule 1 of the instrument is a signpost note, intended to assist users of the instrument to locate the definition of *flight manual*, along with particularly relevant content of the definition.

Legislation Act 2003 (the LA)

Paragraph 98 (5A) (a) of the Act provides that CASA may issue instruments in relation to matters affecting the safe navigation and operation, or the maintenance, of aircraft. Additionally, paragraph 98 (5AA) (a) of the Act provides that an instrument issued under paragraph 98 (5A) (a) is a legislative instrument if the instrument is expressed to apply in relation to a class of persons. The instrument applies to classes of persons, being applicable authorised persons, applicable approved design organisations and operators of aircraft that carry an MITD. The instrument is, therefore, a legislative instrument, and is subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LA.

Consultation

This instrument continues the exemption previously provided by instruments CASA EX153/14 and CASA EX109/16. The explanatory statement for instrument CASA EX153/14 mentions that it was issued following consultation with the aviation industry on the airworthiness requirements for MITDs.

CASA has received a request from a design organisation to renew the exemption in CASA EX109/16. The operation of the exemption provided under instruments CASA EX153/14 and CASA EX109/16 was satisfactory, and the safety case and policy supporting the exemption under those instrument remains unchanged.

Having regard to those circumstances, and the current increased need for aircraft to be able to carry MITDs for the transport of infectious patients, CASA is satisfied that no further consultation is appropriate or reasonably practicable for this instrument for section 17 of the LA.

Office of Best Practice Regulation (OBPR)

A Regulation Impact Statement (*RIS*) is not required in this case, as the instrument is covered by a standing agreement between CASA and OBPR under which a RIS is not required for directions and exemptions (OBPR id: 14507).

Statement of Compatibility with Human Rights

The Statement of Compatibility with Human Rights at Attachment 1 has been prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

While the instrument may engage negatively with the right to the enjoyment of safe and healthy working conditions mentioned in paragraph (b) of Article 7 of the *International Covenant on Economic, Social and Cultural Rights*, the possible negative engagement is outweighed by positive engagement with the same paragraph of Article 7.

Making and commencement

The instrument has been made by a delegate of CASA relying on the power of delegation under subregulation 11.260 (1) of CASR.

The instrument commences on the day after it is registered and is repealed at the end of 31 May 2023.

Statement of Compatibility with Human Rights

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

CASA EX92/20 — Materials Flammability Airworthiness Standards (Medical Isolation Transportation Devices) 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 legislative instrument would enable aircraft to carry a Medical Isolation Transportation Device (*MITD*) although the MITD does not comply with materials flammability requirements contained in applicable airworthiness standards.

It is not possible to modify the design of the MITD to comply with those materials flammability requirements because the tent of the MITD is made from plastic materials that fail to meet those requirements. The tent is the component of an MITD that performs its primary function — environmentally isolating a patient and, therefore (depending upon how the MITD is configured):

- (a) protecting assisting clinicians and other individuals (including other occupants of an aircraft) from an infectious or contaminated patient; or
- (b) protecting an immunosuppressed patient from the outside environment.

Because of the COVID-19 pandemic, there is an increased need for aircraft to be able to carry MITDs for the transport of infectious patients.

Human rights implications

The instrument engages with the right to the enjoyment of safe and healthy working conditions mentioned in paragraph (b) of Article 7 of the *International Covenant on Economic, Social and Cultural Rights (ICESCR)*. By enabling aircraft to carry an MITD that does not comply with materials flammability requirements contained in applicable airworthiness standards, the instrument may engage negatively with that right. However, that effect is outweighed by the positive engagement with the same right that an MITD provides by protecting assisting clinicians and other individuals (including other occupants of an aircraft) from an infectious or contaminated patient.

Conclusion

While the instrument may engage negatively with the right to the enjoyment of safe and healthy working conditions mentioned in paragraph (b) of Article 7 of the ICESCR, the possible negative engagement is outweighed by positive engagement with the same right.

Civil Aviation Safety Authority