Aeronautical Engineers Australia

Working together

Aeromedical Aircraft Certification and the use of inhaled Nitric Oxide (iNO)

Ian Kitson Principal Engineer - Adelaide

August 2011

Introduction

- Requirement
- Risks
- Regulatory Environment
- Demonstrating Compliance
- Risk Mitigation
- Certification
- Continued Airworthiness
- Next steps

Aeronautical Engineers Australia
Working together

Requirement

Ability to administer inhaled Nitric Oxide to patients, including Neonatal patients, during flight in pressurized fixed wing aircraft.

Aeronautical Engineers Australia
Working together

Risks

Nitric oxide is a colourless, odourless and toxic gas

- Hazardous at concentration levels above 25 ppm
- May be lethal at concentration levels above 100 ppm
- Reacts with air to produce Nitrogen Dioxide NO_2 which is more hazardous and should be limited to exposure levels of less than 1 ppm.
- Nitric oxides react with water to produce Nitric Acid
- Nitric oxides react with VOC's to produce Ozone (O_3)

Risks

- Typically supplied in 350 Lt bottle at 1800 psi
- Bottle is fitted with shut-off valve and pressure regulator.
- Bottle contains 9-11% Nitric Oxide, remainder is gaseous Nitrogen

Aeronautical Engineers Australia
Working together

Risks

Existing Safety Advice:

• If the cylinder is leaking, eliminate all potential ignition sources and evacuate area of personnel. Inform manufacturer/supplier of leak. Wear appropriate PPE and carefully move it to a well ventilated remote area, then allow to discharge.

• Use with adequate natural ventilation. Open windows and doors where possible. In poorly ventilated areas, mechanical extraction ventilation is recommended. Maintain vapour levels below the recommended exposure standard.

• Wear safety glasses and leather gloves. Where an inhalation risk exists, wear a Type NO (Nitrogen Oxides) Respirator or an Air-line respirator.

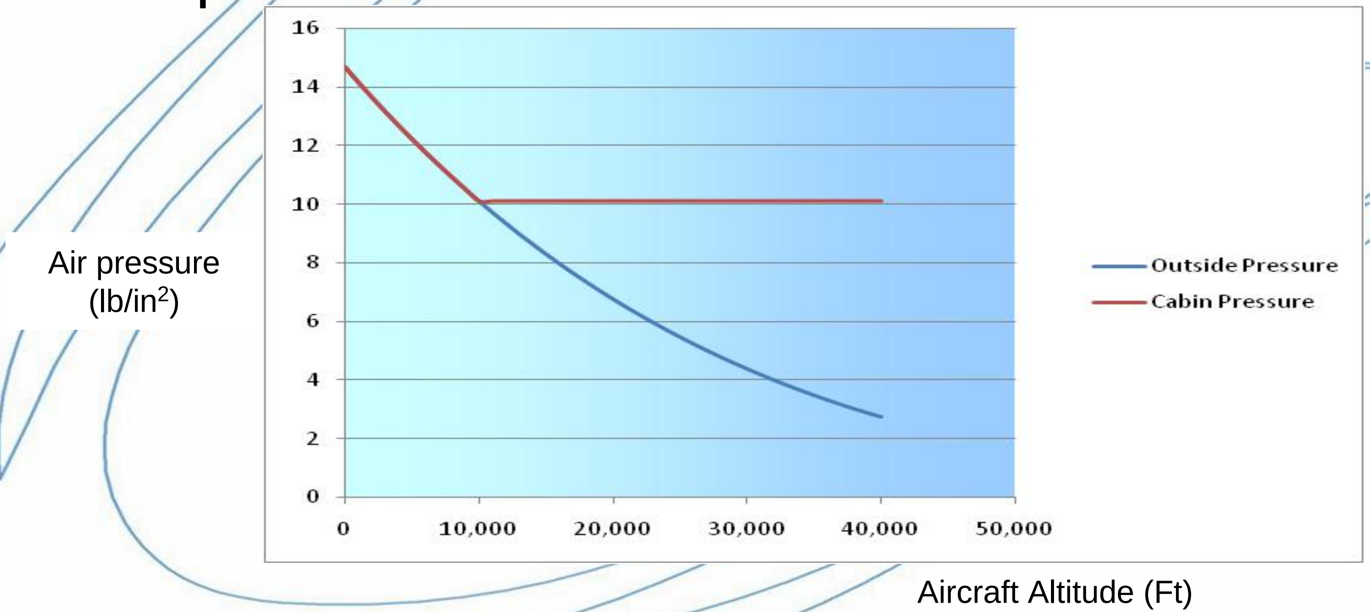
Risks

- Rotary wing Aeromedical aircraft have an un-pressurised cabin.
  - Doors and windows can be opened in flight
  - Therefore fresh air is readily available.

- Time to evacuate the aircraft must include descent and landing.
  - Interim protection measures may be needed dependant on local terrain.

Risks

- Most current fixed wing Aeromedical aircraft have a pressurised cabin.



Risks

- As the cabin is pressurised.
  - Opening doors and windows isn't possible
  - Availability of fresh air is limited to capacity of aircraft air conditioning / pressurisation system.
- Typical pressurised cabin volume is 10-20m^3
  - About the same as a small motor home, by any measure this is a confined space.
- Time to evacuate the aircraft must include transit time to nearest suitable airfield and landing.
  - Interim protection measures must be used

Risks

- Critical Failure Cases – Total loss of bottle contents to occupied space
  - Bottle rupture
  - Bottle / shut-off valve separation
  - Failed Pressure regulator valve (Open flow)

All of these failures will be readily detected.

Risks

- Latent Failure Cases – Undetected loss of bottle contents to occupied space
  - Low pressure hose failures
  - Regulator failure (unintended flow)
  - Ventilator failure (unintended flow)
  - Human error (incorrect flow set)

These failures could go undetected until exposure symptoms are apparent.

Regulatory Environment

To sum up Civil Aviation:-

Safe flights use registered and
Certificated aircraft,
Maintained by qualified people,
Flown by qualified people in airspace
Controlled by qualified people

All civil aircraft are certified by CASA under Part 21 of the Civil Aviation Safety Regulations 1998.

The type design standard of the aircraft is agreed at the time of certification and must be strictly adhered to at all times.

Regulatory Environment

Aeronautical Engineers Australia
Working together

An Aeromedical aircraft is also a place of work

Occupational health and safety legislation can be applicable

Notwithstanding the regulations; there is a "Duty of Care" placed on all of us when conducting any business which can affect the safety of ourselves and others.

Recently introduced CASA regulations Part21M now requires the person authorised to find compliance with the regulations for design changes to also state the design change is "**Safe for its intended use**".

Aeronautical Engineers Australia
Working together

Regulatory Environment:-

• Airworthiness regulations

Example Aircraft:- Pilatus PC-12 / 47E

The agreed certification basis for the aircraft is United States Federal Aviation Regulations Part 23 amendments 1 to 50 inclusive.

Any changes made to the aircraft must be compliant with these regulations. Compliance must be shown before the change can be certified.

Following the introduction of a Nitric Oxide capability specific compliance will have to be shown with at least the following:-

Aeronautical Engineers Australia
Working together

Regulatory Environment:-

• Airworthiness regulations

FAR23 Subpart D – Design & Construction

Sec. 23.831

Ventilation.

(a) Each passenger and crew compartment must be suitably ventilated. Carbon monoxide concentration may not exceed one part in 20,000 parts of air.
(b) **[**For pressurized airplanes,**]** the ventilating air in the flight crew and passenger compartments must be free of harmful or hazardous concentrations of gases and vapours in normal operations and in the event of reasonably probable failures or malfunctioning of the ventilating, heating, pressurization, or other systems and equipment. If accumulation of hazardous quantities of smoke in the cockpit area is reasonably probable, smoke evacuation must be readily accomplished starting with full pressurization and without depressurizing beyond safe limits.

Aeronautical Engineers Australia
Working together

Regulatory Environment:-

• Airworthiness regulations

FAR23 Subpart F – Equipment

Sec. 23.1309
Equipment, Systems and Installations.

(a) Each item of equipment, each system, and each installation:
(1) When performing its intended function, may not adversely affect the response, operation, or accuracy of any--
(i) Equipment essential to safe operation; or
(ii) Other equipment unless there is a means to inform the pilot of the effect.
(2) In a single-engine airplane, must be designed to minimize hazards to the airplane in the event of a probable malfunction or failure.
(3) In a multiengine airplane, must be designed to prevent hazards to the airplane in the event of a probable malfunction or failure.
Etc….Etc…

Sec. 23.1309

Equipment, systems, and installations.

(a) Each item of equipment, each system, and each installation:
(1) When performing its intended function, may not adversely affect the response, operation, or accuracy of any--
(i) Equipment essential to safe operation; or
(ii) Other equipment unless there is a means to inform the pilot of the effect.
(2) In a single-engine airplane, must be designed to minimize hazards to the airplane in the event of a probable malfunction or failure.
(3) In a multiengine airplane, must be designed to prevent hazards to the airplane in the event of a probable malfunction or failure.
[(4) In a commuter category airplane, must be designed to safeguard against hazards to the airplane in the event of their malfunction or failure.]
(b) The design of each item of equipment, each system, and each installation must be examined separately and in relationship to other airplane systems and installations to determine if the airplane is dependent upon its function for continued safe flight and landing and, for airplanes not limited to VFR conditions, if failure of a system would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions. Each item of equipment, each system, and each installation identified by this examination as one upon which the airplane is dependent for proper functioning to ensure continued safe flight and landing, or whose failure would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions, must be designed to comply with the following additional requirements:
(1) It must perform its intended function under any foreseeable operating condition.
(2) When systems and associated components are considered separately and in relation to other systems--
(i) The occurrence of any failure condition that would prevent the continued safe flight and landing of the airplane must be extremely improbable; and
(ii) The occurrence of any other failure condition that would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions must be improbable.
(3) Warning information must be provided to alert the crew to unsafe system operating conditions and to enable them to take appropriate corrective action. Systems, controls, and associated monitoring and warning means must be designed to minimize crew errors that could create additional hazards.
(4) Compliance with the requirements of paragraph (b)(2) of this section may be shown by analysis and, where necessary, by appropriate ground, flight, or simulator test. The analysis must consider--
(i) Possible modes of failure, including malfunctions and damage from external sources;
(ii) The probability of multiple failures and the probability or undetected faults;
(iii) The resulting effects of the airplane and occupants, considering the stage of flight and operating conditions; and
(iv) The crew warning cues, corrective action required, and the crew's capability of determining faults.
(c) Each item of equipment, each system, and each installation whose functioning is required by this chapter and that requires a power supply is an "essential load" on the power supply. The power sources and the system must be able to supply the following power loads in probable operating combinations and for probable durations:
(1) Loads connected to the power distribution system with the system functioning normally.
(2) Essential loads after failure of--
(i) Any one engine on two-engine airplanes; or
(ii) Any two engines on an airplane with three or more engines; or
(iii) Any power converter or energy storage device.
(3) Essential loads for which an alternate source of power is required, as applicable, by the operating rules of this chapter, after any failure or malfunction in any one power supply system, distribution system, or other utilization system.
(d) In determining compliance with paragraph (c)(2) of this section, the power loads may be assumed to be reduced under a monitoring procedure consistent with safety in the kinds of operations authorized. Loads not required in controlled flight need not be considered for the two-engine-inoperative condition on airplanes with three or more engines.
(e) In showing compliance with this section with regard to the electrical power system and to equipment design and installation, critical environmental and atmospheric conditions, including radio frequency energy and the effects (both direct and indirect) of lightning strikes, must be considered. For electrical generation, distribution, and utilization equipment required by or used in complying with this chapter, the ability to provide continuous, safe service under foreseeable environmental conditions may be shown by environmental test, design analysis, or reference to previous comparable service experience on other airplanes.
(f) As used in this section, "systems" refers to all pneumatic systems, fluid systems, electrical systems, mechanical systems, and powerplant systems included in the airplane design, except for the following:
(1) Powerplant systems provided as part of the certificated engine.
(2) The flight structure (such as wing, empennage, control surfaces and their systems, the fuselage, engine mounting, and landing gear and their related primary attachments) whose requirements are specific in subparts C and D of this part.

Aeronautical Engineers Australia
Working together

Regulatory Environment:-

• Airworthiness regulations

FAR23 Subpart F – Equipment

Sec. 23.1309 Continued

Equipment, Systems and Installations.

(3) Warning information must be provided to alert the crew to unsafe system operating conditions and to enable them to take appropriate corrective action. Systems, controls, and associated monitoring and warning means must be designed to minimize crew errors that could create additional hazards.

Regulatory Environment:-

• Airworthiness regulations

FAR23 Subpart G--Operating Limitations and Information

Sec. 23.1585
Operating procedures.

(a) For all airplanes, information concerning normal, abnormal (if applicable), and emergency procedures and other pertinent information necessary for safe operation and the achievement of the scheduled performance must be furnished, including-----------

(j) Procedures for the safe operation of the airplane's systems and equipment, both in normal use and in the event of malfunction, must be furnished

Usually achieved through a supplement to the Aircraft Flight Manual

Demonstrating Compliance

There are many ways that compliance with the regulations can be demonstrated. But generally they will fit into one of the four categories below:

- Test
- Inspection
- Demonstration
- Analysis

Demonstrating Compliance

As far as Nitric Oxide is concerned, which method will best show compliance with the regulations.

- Test
- ~~Inspection~~
- ~~Demonstration~~
- ~~Analysis~~

Aeronautical Engineers Australia
Working together

Demonstrating Compliance

Beech 200 - Nitric Oxide Testing.

Test Plan:-

Discharge a full bottle of Nitric oxide into a pressurised cabin to simulate a critical failure condition.

During the test, measure nitric oxide & nitrogen dioxide concentration levels throughout the cabin.

Assess the test data to determine if and for what period the concentration levels are above acceptable levels.

Repeat test with unpressurised cabin and with ventilation system inoperative.

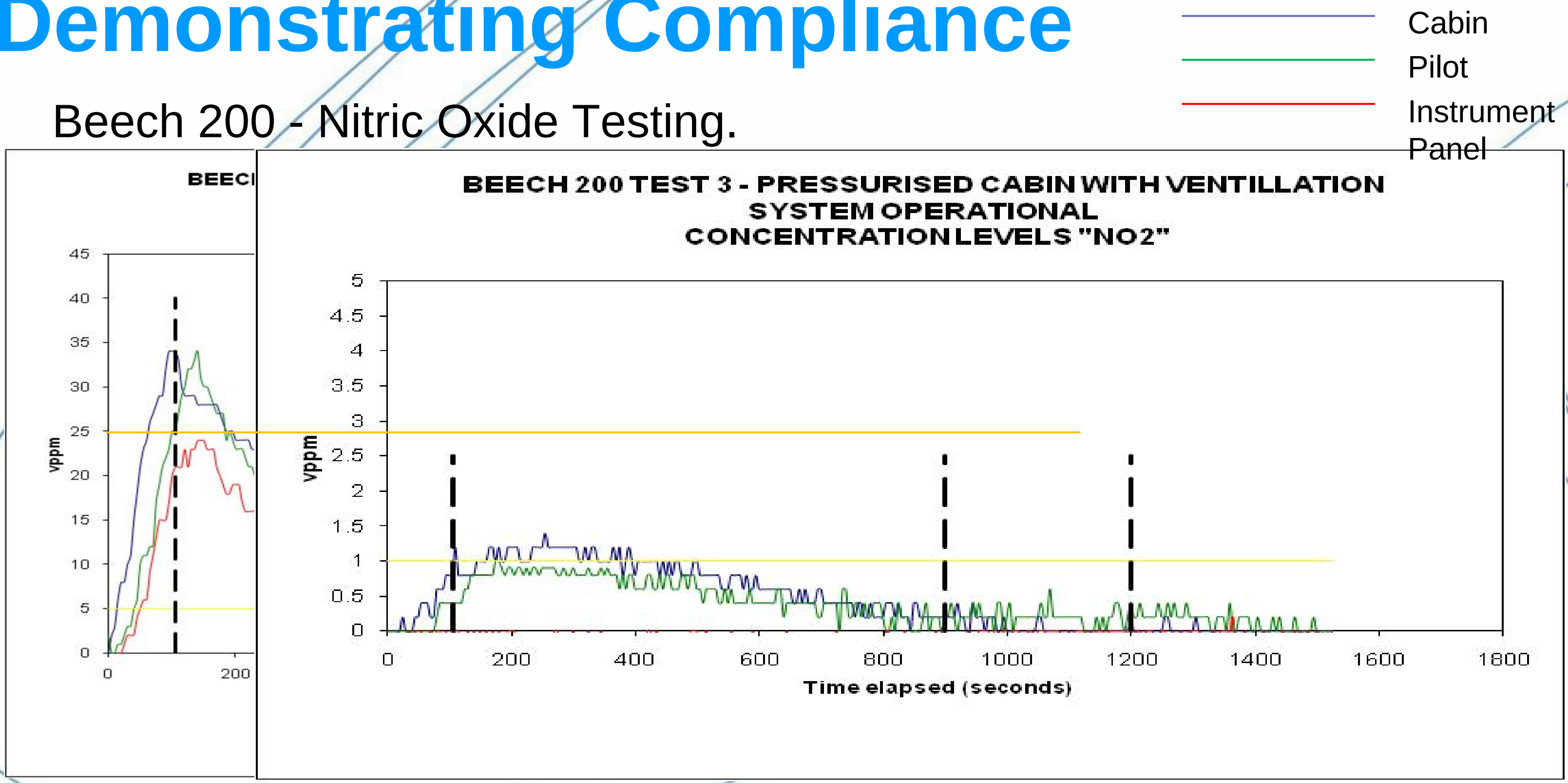
Aeronautical Engineers Australia
Working together

Demonstrating Compliance

Beech 200 - Nitric Oxide Testing continued.

Demonstrating Compliance

Beech 200 - Nitric Oxide Testing.



Aeronautical Engineers Australia
Working together

Risk Mitigation

Testing confirms that excess exposure will happen should a critical failure occur. Therefore, other measures must be used to protect the crew and passengers, to guard against an undetected latent failure:-

An iNO detection system is installed to alert the flight crew and/or medical staff that iNO has been detected. The trigger levels for the system are set as follows:

Independent medical advice obtained recommends a limit of 5ppm if pilot performance is to remain unaffected. The flight crew detector is mounted on the instrument panel and is set to trigger when the concentration level for the pilot's position reaches 5 ppm. This requires the instrument panel trigger to be set to 2 ppm. A similar approach is used to set the Medical crew iNO detector.

Aeronautical Engineers Australia
Working together

Risk Mitigation

The aircraft flight manual has the following procedure added.

EMERGENCY PROCEDURES
1. The following symptoms may indicate an NO gas leak. If a leak is suspected, carry out the emergency procedure specified in step 2.

- Irritation of the throat
- Irritation of the eyes
- Irritation of the skin
- Unusual odour

Aeronautical Engineers Australia
Working together

Risk Mitigation

2. In the event of an alarm being triggered (indicated by an audible 95dB alarm and/or a flashing red LED) by either of the environmental monitors or any of the above symptoms being experienced, immediately:

- Don oxygen masks and smoke goggles
- Shut off the iNO delivery system
- Land as soon as practicable.

Oxygen masks and smoke goggles are to remain on until the alarm/indication ceases. Testing has shown the cabin environment will return to an operationally safe environment in approximately 8 minutes. The levels experienced in the passenger cabin may result in some temporary side effects to the passengers, however medical opinion has deemed the concentration levels neither dangerous nor harmful.

Certification

Once the compliance data is complete and the risk mitigation activities agreed as an acceptable method for ensuring safety, the design change is presented to a CASA authorised person for approval.

Providing the Authorised person agrees with your demonstration of compliance AND they are satisfied that it is:
“safe for its intended purpose”

The approval will be granted and flight operations involving iNO can begin.

Aeronautical Engineers Australia
Working together

Continued Airworthiness

There may be some aspects of the iNO system that require ongoing checks to ensure it stays safe.

Typically :-

•Checking the iNO bottle has passed its structural integrity (Hydrostatic) test within the required test period before use.

•Checking the iNO detectors have been calibrated and the calibration certificate will not expire during use.

Must be carried out regularly to assure continued airworthiness of the iNO system.

Next Steps

New technologies are continually being developed. A recent advancement is the use of Close Coupled Field Technology on aircraft.

CCFT has been used in Hospitals and laboratories for some time to reduce the spread of infections and cross contamination of specimens.

CCFT installed in aircraft has the ability to treat cabin air and simultaneously remove all known airborne pathogens, VOCs and other unwanted gases including Nitrogen oxides.

Future Aeromedical installations may well adopt CCFT as a risk mitigation technique.

Aeronautical Engineers Australia
Working together

Thank you

Any Questions ?

Ian.kitson@aeroengaus.com.au

www.aeroengaus.com.au

Tel: 08 8260 1322 mob: 0488 049 252