



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
FIBROSING INTERSTITIAL LUNG DISEASE
(Reasonable Hypothesis)
(No. 85 of 2021)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

Dated 20 August 2021

The Common Seal of the
Repatriation Medical Authority
was affixed to this instrument
at the direction of:

Professor Terence Campbell AM
Chairperson

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1 Name

This is the Statement of Principles concerning *fibrosing interstitial lung disease (Reasonable Hypothesis)* (No. 85 of 2021).

2 Commencement

This instrument commences on 20 September 2021.

3 Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

4 Repeal

The Statement of Principles concerning fibrosing interstitial lung disease No. 53 of 2013 (Federal Register of Legislation No. F2013L01640) made under subsections 196B(2) and (8) of the VEA is repealed.

5 Application

This instrument applies to a claim to which section 120A of the VEA or section 338 of the *Military Rehabilitation and Compensation Act 2004* applies.

6 Definitions

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

7 Kind of injury, disease or death to which this Statement of Principles relates

- (1) This Statement of Principles is about fibrosing interstitial lung disease and death from fibrosing interstitial lung disease.

Meaning of fibrosing interstitial lung disease

- (2) For the purposes of this Statement of Principles, fibrosing interstitial lung disease:
- (a) means a diverse group of lung diseases characterised by progressive fibrosis of the pulmonary interstitium with or without chronic inflammation; and
 - (b) excludes:
 - (i) bronchiolitis obliterans organising pneumonia;
 - (ii) desquamative interstitial pneumonia;
 - (iii) hypersensitivity pneumonitis (also known as extrinsic allergic alveolitis);
 - (iv) pulmonary manifestations of systemic diseases; and

- (v) respiratory bronchiolitis-associated interstitial lung disease.

Note: Clinical features typically include shortness of breath, chronic cough, restrictive pattern on lung function tests and impaired diffusing capacity of the lungs for carbon monoxide. Radiographic imaging reveals variable patterns of interstitial fibrosis.

Death from fibrosing interstitial lung disease

- (3) For the purposes of this Statement of Principles, fibrosing interstitial lung disease, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's fibrosing interstitial lung disease.

Note: *terminal event* is defined in the Schedule 1 - Dictionary.

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that fibrosing interstitial lung disease and death from fibrosing interstitial lung disease can be related to relevant service rendered by veterans, members of Peacekeeping Forces, or members of the Forces under the VEA, or members under the MRCA.

Note: *MRCA*, *relevant service* and *VEA* are defined in the Schedule 1 - Dictionary.

9 Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting fibrosing interstitial lung disease or death from fibrosing interstitial lung disease with the circumstances of a person's relevant service:

- (1) having smoked tobacco products:
 - (a) in an amount of at least 10 pack-years before the clinical onset of fibrosing interstitial lung disease; and
 - (b) commencing at least 5 years before the clinical onset of fibrosing interstitial lung disease;

Note: *one pack-year* is defined in the Schedule 1 - Dictionary.

- (2) inhaling respirable asbestos fibres in an enclosed space, at the time material containing asbestos was being applied, removed, cut, drilled, dislodged or disturbed:
 - (a) for a cumulative period of at least 1,000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (b) where the first inhalation of asbestos fibres commenced at least 5 years before the clinical onset of fibrosing interstitial lung disease;

Note: Disturbance of debris or dust contaminated with asbestos fibres already present in an enclosed space may result in exposure to respirable asbestos fibres.

- (3) inhaling respirable asbestos fibres in an open environment, at the time material containing asbestos was being applied, removed, cut, drilled, dislodged or disturbed:
- (a) for a cumulative period of at least 3,000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (b) where the first inhalation of asbestos fibres commenced at least 5 years before the clinical onset of fibrosing interstitial lung disease;

Note: Disturbance of debris or dust contaminated with asbestos fibres already present in an open environment may result in exposure to respirable asbestos fibres.

- (4) inhaling beryllium dust or fumes before the clinical onset of fibrosing interstitial lung disease;

Note: *inhaling beryllium dust or fumes* is defined in the Schedule 1 - Dictionary.

- (5) inhaling respirable crystalline silica dust at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut, ground or polished, or used in construction, manufacturing, cleaning or blasting:

- (a) for a cumulative period of at least 1,500 hours before the clinical onset of fibrosing interstitial lung disease; and
- (b) the first inhalation of respirable crystalline silica dust commenced at least 1 year before the clinical onset of fibrosing interstitial lung disease;

- (6) having acute silicosis within the 6 months before the clinical onset of fibrosing interstitial lung disease;

Note: *acute silicosis* is defined in the Schedule 1 - Dictionary.

- (7) inhaling or intravenously injecting a talc-containing compound or mixture, on more days than not, for a period of at least 2 years, before the clinical onset of fibrosing interstitial lung disease;

- (8) inhaling respirable coal dust while engaged in the mining or transport of coal:

- (a) for a cumulative period of at least 3,000 hours before the clinical onset of fibrosing interstitial lung disease; and
- (b) where the first inhalation of respirable coal dust occurred at least 5 years before the clinical onset of fibrosing interstitial lung disease;

- (9) inhaling respirable dust generated from hard metal or diamond-cobalt, while engaged in the manufacture, utilisation or maintenance of tools composed of hard metal or diamond-cobalt, for a cumulative period of at least 120 hours before the clinical onset of fibrosing interstitial lung disease;

Note: *hard metal* is defined in the Schedule 1 - Dictionary.

- (10) inhaling a toxic gas or fumes resulting in:
- (a) signs and symptoms of severe acute lower respiratory damage requiring medical attention within 48 hours after exposure; and
 - (b) the persistence of respiratory signs and symptoms for at least 1 week after exposure, within the 1 year before the clinical onset of fibrosing interstitial lung disease;

Note: Types of toxic gases or fumes include anhydrous ammonia fumes, smoke, oxides of sulphur, oxides of nitrogen, chlorine, phosgene, humidifier detergents, perfluoroisobutylene (may be released in fires of military vehicles containing Teflon) and zinc chloride smoke from smoke bombs.

- (11) having paraquat poisoning within the 6 months before the clinical onset of fibrosing interstitial lung disease;

Note: *paraquat* is defined in the Schedule 1 - Dictionary.

- (12) inhaling mustard gas within the 20 years before the clinical onset of fibrosing interstitial lung disease;

- (13) having received a cumulative equivalent dose of at least 0.2 sievert of ionising radiation to the lung at least 6 months before the clinical onset of fibrosing interstitial lung disease;

Note: *cumulative equivalent dose* is defined in the Schedule 1 - Dictionary.

- (14) undergoing a course of therapeutic radiation for cancer, where the affected lung was in the field of radiation, at least 6 months before the clinical onset of fibrosing interstitial lung disease;

- (15) having received iodine-131 (radioactive iodine) as therapy for widespread pulmonary metastases from a malignant neoplasm of the thyroid, at least 6 months before the clinical onset of fibrosing interstitial lung disease;

- (16) having received yttrium-90 microspheres as therapy for primary or metastatic liver tumours, at least 3 months before the clinical onset of fibrosing interstitial lung disease;

- (17) having acute respiratory distress syndrome within the 6 months before the clinical onset of fibrosing interstitial lung disease;

Note: *acute respiratory distress syndrome* is defined in the Schedule 1 - Dictionary.

- (18) being treated with a cytotoxic agent for a malignant neoplasm or in association with haematopoietic stem cell transplantation, before the clinical onset of fibrosing interstitial lung disease;

- (19) taking a drug from the specified list of drugs within the 6 months before the clinical onset of fibrosing interstitial lung disease;

Note: *specified list of drugs* is defined in the Schedule 1 - Dictionary.

- (20) having chronic or recurrent diffuse alveolar haemorrhage before the clinical onset of fibrosing interstitial lung disease;
- Note: *diffuse alveolar haemorrhage* is defined in the Schedule 1 - Dictionary.
- (21) having exogenous lipoid pneumonitis at the time of the clinical onset of fibrosing interstitial lung disease;
- Note: *exogenous lipoid pneumonitis* is defined in the Schedule 1 - Dictionary.
- (22) having tropical pulmonary eosinophilia for at least the 6 months before the clinical onset of fibrosing interstitial lung disease;
- Note: *tropical pulmonary eosinophilia* is defined in the Schedule 1 - Dictionary.
- (23) inhaling a vapour, gas, dust or fumes produced by a substance from the specified list of substances, or smoke from fire, in an enclosed space:
- (a) for a cumulative period of at least 5,000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical onset of fibrosing interstitial lung disease, then that onset occurred within 20 years of cessation;
- Note: *specified list of substances* is defined in the Schedule 1 - Dictionary.
- (24) inhaling a vapour, gas, dust or fumes produced by a substance from the specified list of substances, or smoke from fire, in an open environment:
- (a) for a cumulative period of at least 10,000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical onset of fibrosing interstitial lung disease, then that onset occurred within 20 years of cessation;
- Note: *specified list of substances* is defined in the Schedule 1 - Dictionary.
- (25) inhaling smoke from the combustion of wood, charcoal, coal or other biomass or fossil fuel, in an enclosed space:
- (a) for a cumulative period of at least 5,000 hours before the clinical onset of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical onset of fibrosing interstitial lung disease, then that onset occurred within 20 years of cessation;
- (26) having smoked tobacco products:
- (a) in an amount of at least 5 pack-years before the clinical worsening of fibrosing interstitial lung disease; and
 - (b) commencing at least 1 year before the clinical worsening of fibrosing interstitial lung disease;
- Note: *one pack-year* is defined in the Schedule 1 - Dictionary.

- (27) inhaling respirable asbestos fibres at the time material containing asbestos was being applied, removed, cut, drilled, dislodged or disturbed:
- (a) for a cumulative period of at least 1,000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (b) within the 2 years before the clinical worsening of fibrosing interstitial lung disease;

Note: Disturbance of debris or dust contaminated with asbestos fibres already present in an enclosed space or an open environment may result in exposure to respirable asbestos fibres.

- (28) inhaling beryllium dust or fumes before the clinical worsening of fibrosing interstitial lung disease;

Note: *inhaling beryllium dust or fumes* is defined in the Schedule 1 - Dictionary.

- (29) inhaling respirable crystalline silica dust at the time material containing respirable crystalline silica dust was being produced, excavated, drilled, cut, ground or polished, or used in construction, manufacturing, cleaning or blasting:

- (a) for a cumulative period of at least 1,500 hours before the clinical worsening of fibrosing interstitial lung disease; and
- (b) the first inhalation of respirable crystalline silica dust commenced at least 1 year before the clinical worsening of fibrosing interstitial lung disease;

- (30) having acute silicosis within the 6 months before the clinical worsening of fibrosing interstitial lung disease;

Note: *acute silicosis* is defined in the Schedule 1 - Dictionary.

- (31) inhaling or intravenously injecting a talc-containing compound or mixture, on more days than not, for a period of at least 2 years, before the clinical worsening of fibrosing interstitial lung disease;

- (32) inhaling respirable coal dust while engaged in the mining or transport of coal:

- (a) for a cumulative period of at least 3,000 hours before the clinical worsening of fibrosing interstitial lung disease; and
- (b) where the first inhalation of respirable coal dust occurred at least 5 years before the clinical worsening of fibrosing interstitial lung disease;

- (33) inhaling respirable dust generated from hard metal or diamond-cobalt, while engaged in the manufacture, utilisation or maintenance of tools composed of hard metal or diamond-cobalt, for a cumulative period of at least 120 hours before the clinical worsening of fibrosing interstitial lung disease;

Note: *hard metal* is defined in the Schedule 1 - Dictionary.

- (34) inhaling a toxic gas or fumes resulting in:
- (a) signs and symptoms of severe acute lower respiratory damage requiring medical attention within 48 hours after exposure; and
 - (b) the persistence of respiratory signs and symptoms for at least 1 week after exposure, within the 1 year before the clinical worsening of fibrosing interstitial lung disease;

Note: Types of toxic gases or fumes include anhydrous ammonia fumes, smoke, oxides of sulphur, oxides of nitrogen, chlorine, phosgene, humidifier detergents, perfluoroisobutylene (may be released in fires of military vehicles containing Teflon) and zinc chloride smoke from smoke bombs.

- (35) having paraquat poisoning within the 6 months before the clinical worsening of fibrosing interstitial lung disease;

Note: *paraquat* is defined in the Schedule 1 - Dictionary.

- (36) inhaling mustard gas within the 20 years before the clinical worsening of fibrosing interstitial lung disease;

- (37) having received a cumulative equivalent dose of at least 0.2 sievert of ionising radiation to the lung at least 6 months before the clinical worsening of fibrosing interstitial lung disease;

Note: *cumulative equivalent dose* is defined in the Schedule 1 - Dictionary.

- (38) undergoing a course of therapeutic radiation for cancer, where the affected lung was in the field of radiation, at least 6 months before the clinical worsening of fibrosing interstitial lung disease;

- (39) having received iodine-131 (radioactive iodine) as therapy for widespread pulmonary metastases from a malignant neoplasm of the thyroid, at least 6 months before the clinical worsening of fibrosing interstitial lung disease;

- (40) having received yttrium-90 microspheres as therapy for primary or metastatic liver tumours, at least 3 months before the clinical worsening of fibrosing interstitial lung disease;

- (41) having acute respiratory distress syndrome within the 6 months before the clinical worsening of fibrosing interstitial lung disease;

Note: *acute respiratory distress syndrome* is defined in the Schedule 1 - Dictionary.

- (42) being treated with a cytotoxic agent for a malignant neoplasm or in association with haematopoietic stem cell transplantation, before the clinical worsening of fibrosing interstitial lung disease;

- (43) taking a drug from the specified list of drugs within the 6 months before the clinical worsening of fibrosing interstitial lung disease;

Note: *specified list of drugs* is defined in the Schedule 1 - Dictionary.

- (44) having chronic or recurrent diffuse alveolar haemorrhage before the clinical worsening of fibrosing interstitial lung disease;
Note: *diffuse alveolar haemorrhage* is defined in the Schedule 1 - Dictionary.
- (45) having exogenous lipoid pneumonitis at the time of the clinical worsening of fibrosing interstitial lung disease;
Note: *exogenous lipoid pneumonitis* is defined in the Schedule 1 - Dictionary.
- (46) having tropical pulmonary eosinophilia for at least the 6 months before the clinical worsening of fibrosing interstitial lung disease;
Note: *tropical pulmonary eosinophilia* is defined in the Schedule 1 - Dictionary.
- (47) having gastro-oesophageal reflux disease for at least the 5 years before the clinical worsening of fibrosing interstitial lung disease;
- (48) inhaling a vapour, gas, dust or fumes produced by a substance from the specified list of substances, or smoke from fire, in an enclosed space:
- (a) for a cumulative period of at least 5,000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical worsening of fibrosing interstitial lung disease, then that worsening occurred within 20 years of cessation;
- Note: *specified list of substances* is defined in the Schedule 1 - Dictionary.
- (49) inhaling a vapour, gas, dust or fumes produced by a substance from the specified list of substances, or smoke from fire, in an open environment:
- (a) for a cumulative period of at least 10,000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical worsening of fibrosing interstitial lung disease, then that worsening occurred within 20 years of cessation;
- Note: *specified list of substances* is defined in the Schedule 1 - Dictionary.
- (50) inhaling smoke from the combustion of wood, charcoal, coal or other biomass or fossil fuel, in an enclosed space:
- (a) for a cumulative period of at least 5,000 hours before the clinical worsening of fibrosing interstitial lung disease; and
 - (b) if that exposure has ceased before the clinical worsening of fibrosing interstitial lung disease, then that worsening occurred within 20 years of cessation;
- (51) inability to obtain appropriate clinical management for fibrosing interstitial lung disease.

10 Relationship to service

- (1) The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.
- (2) The factors set out in subsections 9(26) to 9(51) apply only to material contribution to, or aggravation of, fibrosing interstitial lung disease where the person's fibrosing interstitial lung disease was suffered or contracted before or during (but did not arise out of) the person's relevant service.

11 Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

- (1) if a factor referred to in section 9 applies in relation to a person; and
- (2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Schedule 1 - Dictionary

Note: See Section 6

1 Definitions

In this instrument:

acute beryllium disease means a rapid onset toxic pneumonitis resulting from inhaling high airborne concentrations of beryllium and characterised by non-cardiogenic pulmonary oedema.

acute respiratory distress syndrome means a clinical syndrome of severe dyspnoea of rapid onset, hypoxaemia and diffuse pulmonary infiltrates leading to respiratory failure.

Note: Examples of events that can cause acute respiratory distress syndrome include infectious pneumonia (including coronavirus disease 2019 (COVID-19)), septicaemia, lung surgery or lung contusion, severe trauma with multiple fractures, inhalational injury (including severe smoke inhalation), burns and pancreatitis.

acute silicosis means a pulmonary disease characterised by basilar filling of alveoli with lipid and proteinaceous exudative material, following exposure to high levels of respirable crystalline silica dust over a short time span.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in *Guide to calculation of 'cumulative equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Part XIA of the Veterans' Entitlements Act 1986 (Cth)*, Australian Radiation Protection and Nuclear Safety Agency, as in force on 2 August 2017.

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

diffuse alveolar haemorrhage means extravasation of blood into the alveoli and interstitium from injury to the pulmonary microcirculation.

Note: Diffuse alveolar haemorrhage can be due to taking vitamin K anticoagulants including warfarin.

exogenous lipoid pneumonitis means inflammation of the pulmonary interstitium due to the aspiration or inhalation of oil-based substances.

fibrosing interstitial lung disease—see subsection 7(2).

hard metal means material composed predominantly of cobalt and tungsten carbide.

inhaling beryllium dust or fumes means:

- (a) having a history of exposure to beryllium dust or beryllium fumes, for a cumulative period of at least 240 hours;
- (b) having a history of acute beryllium disease; or
- (c) clinical evidence of sensitisation to beryllium by positive findings on beryllium lymphocyte proliferation testing of blood or bronchoalveolar lavage fluid.

Note: *acute beryllium disease* is also defined in the Schedule 1 - Dictionary.

MRCA means the *Military Rehabilitation and Compensation Act 2004*.

one pack-year means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

paraquat means a dipyrilidium compound whose dichloride and dimethylsulphate salts are used as contact herbicides.

relevant service means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

Note: *MRCA* and *VEA* are also defined in the Schedule 1 - Dictionary.

specified list of drugs means:

- (a) amiodarone;
- (b) azathioprine;
- (c) cetuximab;
- (d) D-penicillamine;
- (e) fluoxetine;
- (f) gold salts;
- (g) leflunomide;
- (h) mTOR inhibitors including everolimus and sirolimus;
- (i) methotrexate;
- (j) mycophenolate mofetil;
- (k) nitrofurantoin;
- (l) panitumumab;
- (m) rituximab;
- (n) sulphasalazine;
- (o) tumour necrosis factor alpha antagonists;

- (p) tocinide; or
- (q) tyrosine kinase inhibitors including afatinib, erlotinib and gefitinib.

specified list of substances means:

- (a) cement;
- (b) cleaning agents;
- (c) cotton and textiles;
- (d) dental materials;
- (e) diesel engine exhaust;
- (f) metals including aluminium, cadmium, indium-tin, iron-oxide and steel;
- (g) minerals including mica, sand, silicates and stone;
- (h) organic material including from animals and plants;
- (i) welding materials; or
- (j) wood.

terminal event means the proximate or ultimate cause of death and includes the following:

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

tropical pulmonary eosinophilia means a disorder which is characterised by pulmonary infiltrations of eosinophils and blood eosinophilia, and is caused by infection with the microfilariae *Wuchereria bancrofti*, *Brugia malayi* or *Dirofilaria immitis*.

VEA means the *Veterans' Entitlements Act 1986*.