



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MALIGNANT NEOPLASM OF THE LIVER
(Reasonable Hypothesis)
(No. 31 of 2020)

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

Dated 24 April 2020

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

A handwritten signature in black ink, appearing to read 'N. Saunders'.

Professor Nicholas Saunders AO
Chairperson

Contents

1	Name	3
2	Commencement	3
3	Authority	3
4	Repeal	3
5	Application.....	3
6	Definitions.....	3
7	Kind of injury, disease or death to which this Statement of Principles relates	3
8	Basis for determining the factors	4
9	Factors that must exist.....	4
10	Relationship to service	7
11	Factors referring to an injury or disease covered by another Statement of Principles.....	8
Schedule 1 - Dictionary		9
1	Definitions.....	9

1 Name

This is the Statement of Principles concerning *malignant neoplasm of the liver (Reasonable Hypothesis)* (No. 31 of 2020).

2 Commencement

This instrument commences on 25 May 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning malignant neoplasm of the liver No. 21 of 2011 (Federal Register of Legislation No. F2011L00500) made under subsections 196B(2) and (8) of the VEA is repealed.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 malignant neoplasm of the liver and death from malignant neoplasm of the liver.

Meaning of malignant neoplasm of the liver

- (2) For the purposes of this Statement of Principles, malignant neoplasm of the liver:
- (a) means a primary malignant neoplasm arising from the hepatocytes; and
 - (b) excludes:
 - (i) carcinoid tumour;
 - (ii) Hodgkin's lymphoma;
 - (iii) malignant neoplasm of the bile duct;
 - (iv) non-Hodgkin lymphoma; and
 - (v) soft tissue sarcoma.

Note: Malignant neoplasm of the liver is also known as hepatocellular carcinoma.

- (3) While malignant neoplasm of the liver attracts ICD-10-AM code C22.0, in applying this Statement of Principles the meaning of malignant neoplasm of the liver is that given in subsection (2).
- (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification* (ICD-10-AM), Tenth Edition, effective date of 1 July 2017, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-296-4.

Death from malignant neoplasm of the liver

- (5) For the purposes of this Statement of Principles, malignant neoplasm of the liver, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's malignant neoplasm of the liver.

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 malignant neoplasm of the liver and death from malignant neoplasm of the liver 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 malignant neoplasm of the liver or death from malignant neoplasm of the liver with the circumstances of a person's relevant service:

- (1) having cirrhosis of the liver before the clinical onset of malignant neoplasm of the liver;
- (2) having chronic infection with hepatitis B virus before the clinical onset of malignant neoplasm of the liver;
- (3) having chronic infection with hepatitis C virus before the clinical onset of malignant neoplasm of the liver;

Note: *chronic infection with hepatitis B virus* is defined in the Schedule 1 - Dictionary.

Note 1: In the past, hepatitis C viral infection may have been classified as non-A, non-B hepatitis.

Note 2: *chronic infection with hepatitis C virus* is defined in the Schedule 1 - Dictionary.

- (4) having chronic infection with hepatitis D virus before the clinical onset of malignant neoplasm of the liver;

Note: *chronic infection with hepatitis D virus* is defined in the Schedule 1 - Dictionary.

- (5) having infection with human immunodeficiency virus before the clinical onset of malignant neoplasm of the liver;

- (6) having chronic hepatitis before the clinical onset of malignant neoplasm of the liver;

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

- (7) having diabetes mellitus for at least five years before the clinical onset of malignant neoplasm of the liver;

- (8) being overweight or obese for at least five years within the 20 years before the clinical onset of malignant neoplasm of the liver;

Note: *being overweight or obese* is defined in the Schedule 1 - Dictionary.

- (9) for males, consuming at least 110 kilograms of alcohol within any ten year period at least five years before the clinical onset of malignant neoplasm of the liver;

Note: Alcohol is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

- (10) for females, consuming at least 55 kilograms of alcohol within any ten year period at least five years before the clinical onset of malignant neoplasm of the liver;

Note: Alcohol is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

- (11) smoking at least ten pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of malignant neoplasm of the liver, and:

(a) smoking commenced at least five years before the clinical onset of malignant neoplasm of the liver; and

(b) where smoking has ceased, the clinical onset of malignant neoplasm of the liver has occurred within 20 years of cessation;

Note: *pack-years of cigarettes, or the equivalent thereof in other tobacco products* is defined in the Schedule 1 - Dictionary.

- (12) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the liver at least five years before the clinical onset of malignant neoplasm of the liver;

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

- (13) being treated with systemic immunosuppressive therapy for solid organ, stem cell or bone marrow transplantation before the clinical onset of malignant neoplasm of the liver;

- (14) being exposed to high levels of dietary aflatoxins, on more days than not, for a period of at least five years within the 30 years before the clinical onset of malignant neoplasm of the liver;

Note: *being exposed to high levels of dietary aflatoxins* is defined in the Schedule 1 - Dictionary.

- (15) inhaling a cumulative dose of at least 1 250 ppm-years of gaseous vinyl chloride at least five years before the clinical onset of malignant neoplasm of the liver;

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

- (16) inhaling gaseous vinyl chloride for a cumulative period of at least 5 000 hours while working in the production or processing of vinyl chloride monomer or polyvinyl chloride, at least five years before the clinical onset of malignant neoplasm of the liver;

- (17) inhaling respirable asbestos fibres in an enclosed space:

- (a) for a cumulative period of at least 1 000 hours before the clinical onset of malignant neoplasm of the liver; and
- (b) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
- (c) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the liver;

- (18) inhaling respirable asbestos fibres in an open environment:

- (a) for a cumulative period of at least 3 000 hours before the clinical onset of malignant neoplasm of the liver; and
- (b) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
- (c) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the liver;

- (19) an inability to undertake any physical activity greater than three METs for at least ten years within the 15 years before the clinical onset of malignant neoplasm of the liver;

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

- (20) using the combined oral contraceptive pill for a continuous period of at least three years before the clinical onset of malignant neoplasm of the liver, and where the use of the combined oral contraceptive pill has ceased, the clinical onset of malignant neoplasm of the liver has occurred within 30 years of cessation;

Note: *combined oral contraceptive pill* is defined in the Schedule 1 - Dictionary.

- (21) taking or being treated with an anabolic-androgenic steroid:
- (a) for a continuous period of at least three years; and
 - (b) to a cumulative total of at least 14 grams; and
 - (c) where the cumulative total dose of anabolic-androgenic steroid was taken at least five years before the clinical onset of malignant neoplasm of the liver; and
 - (d) where taking or being treated with the steroid has ceased, the clinical onset of malignant neoplasm of the liver has occurred within 20 years of cessation;
- (22) chewing betel quid or areca nut on more days than not, for at least five years before the clinical onset of malignant neoplasm of the liver, and where chewing of betel quid or areca nut has ceased, the clinical onset has occurred within 20 years of cessation;
- (23) being exposed to arsenic as specified before the clinical onset of malignant neoplasm of the liver, where the first exposure to arsenic occurred at least ten years before the clinical onset of malignant neoplasm of the liver;
- Note: *being exposed to arsenic as specified* is defined in the Schedule 1 - Dictionary.
- (24) having steatohepatitis for at least five years before the clinical onset of malignant neoplasm of the liver;
- (25) having autoimmune chronic active hepatitis or primary biliary cholangitis before the clinical onset of malignant neoplasm of the liver;
- Note: *autoimmune chronic active hepatitis* is defined in the Schedule 1 - Dictionary.
- (26) having a disorder from the specified list of disorders before the clinical onset of malignant neoplasm of the liver;
- Note: *specified list of disorders* is defined in the Schedule 1 - Dictionary.
- (27) inability to obtain appropriate clinical management for malignant neoplasm of the liver.

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 factor set out in subsection 9(27) applies only to material contribution to, or aggravation of, malignant neoplasm of the liver where the person's malignant neoplasm of the liver 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:

autoimmune chronic active hepatitis means a chronic disorder of autoimmunity characterised by continuing hepatocellular necrosis and inflammation and seroimmunologic abnormalities.

being exposed to arsenic as specified means:

- (a) consuming drinking water with an average arsenic concentration of at least 50 micrograms per litre for a cumulative period of at least ten years; or
- (b) consuming drinking water resulting in a cumulative total arsenic exposure equivalent to having consumed drinking water containing at least 50 micrograms per litre for at least ten years; or
- (c) having clinical evidence of chronic arsenic toxicity.

being exposed to high levels of dietary aflatoxins means living or working in a geographic region or country where food items, particularly grains and nuts, are regularly contaminated with high levels of aflatoxins, and consuming these food items as a major part of the diet.

Note: Geographic regions or countries where food items are regularly contaminated with high levels of aflatoxins include sub-Saharan Africa, Southeast Asia, Eastern Mediterranean and China.

being overweight or obese means having a Body Mass Index (BMI) of 25 or greater.

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

BMI means W/H^2 where:

W is the person's weight in kilograms; and

H is the person's height in metres.

chronic hepatitis means biochemical evidence of continuing or relapsing hepatocellular necrosis and hepatic inflammation for at least six months.

chronic infection with hepatitis B virus means infection with hepatitis B virus resulting in a chronic infection of at least six months duration, and which must be confirmed by laboratory testing for hepatitis B serological or nucleic acid markers.

chronic infection with hepatitis C virus means infection with hepatitis C virus resulting in a chronic infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis C serological or nucleic acid markers.

chronic infection with hepatitis D virus means infection with hepatitis D virus resulting in a chronic infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis D serological or nucleic acid markers.

combined oral contraceptive pill means contraceptive pills containing estrogen and progestogen.

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.

malignant neoplasm of the liver—see subsection 7(2).

MET means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute, or 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

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

pack-years of cigarettes, or the equivalent thereof in other tobacco products means a calculation of consumption where one pack-year of cigarettes equals twenty tailor-made cigarettes per day for a period of one calendar year, or 7 300 cigarettes. One tailor-made cigarette approximates one gram of tobacco or one gram of cigar or pipe tobacco by weight. One pack-year of tailor-made cigarettes equates to 7.3 kilograms of smoking tobacco by weight. Tobacco products mean cigarettes, pipe tobacco or cigars, smoked alone or in any combination.

ppm-years means parts per million multiplied by years of exposure.

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 disorders means:

- (a) acute intermittent porphyria;
- (b) alpha-1 antitrypsin deficiency;
- (c) Budd-Chiari syndrome;
- (d) haemochromatosis;

- (e) porphyria cutanea tarda; or
- (f) Wilson's disease.

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.

VEA means the *Veterans' Entitlements Act 1986*.