



Australian Government  
Repatriation Medical Authority

Statement of Principles  
concerning  
**MALIGNANT NEOPLASM OF THE BILE  
DUCT**

**No. 69 of 2015**

for the purposes of the

*Veterans' Entitlements Act 1986*  
and  
*Military Rehabilitation and Compensation Act 2004*

**Title**

1. This Instrument may be cited as Statement of Principles concerning malignant neoplasm of the bile duct No. 69 of 2015.

**Determination**

2. The Repatriation Medical Authority under subsection **196B(2)** and **(8)** of the *Veterans' Entitlements Act 1986* (the VEA):
  - (a) revokes Instrument No. 21 of 2007, as amended, concerning malignant neoplasm of the bile duct; and
  - (b) determines in its place this Statement of Principles.

**Kind of injury, disease or death**

3.
  - (a) This Statement of Principles is about **malignant neoplasm of the bile duct** and **death from malignant neoplasm of the bile duct**.
  - (b) For the purposes of this Statement of Principles, "**malignant neoplasm of the bile duct**" means a primary malignant neoplasm arising from the cells of the intrahepatic or extrahepatic bile duct, including the ampulla of Vater and the cystic duct. This definition excludes soft tissue sarcoma, carcinoid tumour, non-Hodgkin's lymphoma and Hodgkin's lymphoma.

- (c) Malignant neoplasm of the bile duct attracts ICD-10-AM code C22.1 or C24.
- (d) In the application of this Statement of Principles, the definition of "**malignant neoplasm of the bile duct**" is that given at paragraph 3(b) above.

#### **Basis for determining the factors**

- 4. The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that **malignant neoplasm of the bile duct** and **death from malignant neoplasm of the bile duct** 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 *Military Rehabilitation and Compensation Act 2004* (the MRCA).

#### **Factors that must be related to service**

- 5. Subject to clause 7, at least one of the factors set out in clause 6 must be related to the relevant service rendered by the person.

#### **Factors**

- 6. The factor that must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting **malignant neoplasm of the bile duct** or **death from malignant neoplasm of the bile duct** with the circumstances of a person's relevant service is:
  - (a) having chronic infestation of the hepatobiliary tract with the liver flukes *Clonorchis sinensis* or *Opisthorchis viverrini* before the clinical onset of malignant neoplasm of the bile duct; or
  - (b) having primary sclerosing cholangitis before the clinical onset of malignant neoplasm of the bile duct; or
  - (c) having inflammatory bowel disease before the clinical onset of malignant neoplasm of the bile duct; or
  - (d) having cholelithiasis before the clinical onset of malignant neoplasm of the bile duct; or
  - (e) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the bile ducts at least five years before the clinical onset of malignant neoplasm of the bile duct; or
  - (f) having cirrhosis of the liver before the clinical onset of malignant neoplasm of the bile duct; or
  - (g) having chronic infection with the hepatitis B virus at the time of the clinical onset of malignant neoplasm of the bile duct; or
  - (h) having chronic infection with the hepatitis C virus at the time of the clinical onset of malignant neoplasm of the bile duct; or
  - (i) being obese for at least five years within the 20 years before the clinical onset of malignant neoplasm of the bile duct; or

- (j) having diabetes mellitus for at least five years before the clinical onset of malignant neoplasm of the bile duct; or
- (k) inhaling respirable asbestos fibres in an enclosed space:
  - (i) for a cumulative period of at least 1 000 hours before the clinical onset of malignant neoplasm of the bile duct; and
  - (ii) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
  - (iii) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the bile duct; or
- (l) inhaling respirable asbestos fibres in an open environment:
  - (i) for a cumulative period of at least 3 000 hours before the clinical onset of malignant neoplasm of the bile duct; and
  - (ii) at the time material containing respirable asbestos fibres was being applied, removed, dislodged, cut or drilled; and
  - (iii) where the first inhalation of respirable asbestos fibres commenced at least five years before the clinical onset of malignant neoplasm of the bile duct; or
- (m) undergoing stem cell, bone marrow or solid organ transplantation before the clinical onset of malignant neoplasm of the bile duct; or
- (n) smoking at least 15 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of malignant neoplasm of the bile duct, and:
  - (i) smoking commenced at least five years before the clinical onset of malignant neoplasm of the bile duct; and
  - (ii) where smoking has ceased, the clinical onset of malignant neoplasm of the bile duct has occurred within 20 years of cessation; or
- (o) inability to obtain appropriate clinical management for malignant neoplasm of the bile duct.

**Factors that apply only to material contribution or aggravation**

7. Paragraph 6(o) applies only to material contribution to, or aggravation of, malignant neoplasm of the bile duct where the person's malignant neoplasm of the bile duct was suffered or contracted before or during (but not arising out of) the person's relevant service.

**Inclusion of Statements of Principles**

8. In this Statement of Principles if a relevant factor applies and that factor includes an injury or disease in respect of which there is a Statement of Principles then the factors in that last mentioned Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

## Other definitions

9. For the purposes of this Statement of Principles:

**"being obese"** means having a Body Mass Index (BMI) of 30 or greater.

The  $BMI = W/H^2$  and where:

W is the person's weight in kilograms; and

H is the person's height in metres;

**"chronic infection with the hepatitis B virus"** means:

- (a) the presence of HBsAg or hepatitis B virus (HBV) deoxyribonucleic acid (DNA), in the absence of IgM Anti-HBc on serological testing; or
- (b) positive serology for hepatitis B plus evidence of chronic hepatitis or other chronic changes on liver biopsy;

**"chronic infection with the hepatitis C virus"** means:

- (a) positive polymerase chain reaction testing for hepatitis C virus (HCV) ribonucleic acid (RNA);
- (b) the presence of anti-HCV and elevated serum aminotransferase levels, more than six months after evidence of an acute hepatitis C infection; or
- (c) positive serology for hepatitis C plus evidence of chronic hepatitis or other chronic changes on liver biopsy;

**"cumulative equivalent dose"** means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation-related sources and radiation from nuclear explosions or accidents;

**"death from malignant neoplasm of the bile duct"** 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 bile duct;

**"ICD-10-AM code"** means a number assigned to a particular kind of injury or disease in The International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM), Eighth Edition, effective date of 1 July 2013, copyrighted by the Independent Hospital Pricing Authority, and having ISBN 978-1-74128-213-9;

**"pack-years of cigarettes, or the equivalent thereof in other tobacco products"** means a calculation of consumption where one pack-year of cigarettes equals 20 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;

**"primary sclerosing cholangitis"** means an autoimmune disorder characterised by a progressive, inflammatory, sclerosing process in the bile ducts;

**"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;

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

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

### **Application**

- 10.** This Instrument applies to all matters to which section 120A of the VEA or section 338 of the MRCA applies.

### **Date of effect**

- 11.** This Instrument takes effect from 1 June 2015.

Dated this **first** day of **May**  
2015

The Common Seal of the )  
Repatriation Medical Authority )  
was affixed at the direction of: )



PROFESSOR NICHOLAS SAUNDERS AO  
CHAIRPERSON