



Australian Government
Repatriation Medical Authority

**Statement of Principles
concerning
MALIGNANT NEOPLASM OF UNKNOWN
PRIMARY SITE
(Reasonable Hypothesis)
(No. 103 of 2022)**

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

Dated 21 October 2022

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 *malignant neoplasm of unknown primary site (Reasonable Hypothesis)* (No. 103 of 2022).

2 Commencement

This instrument commences on 21 November 2022.

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 unknown primary site No. 80 of 2014 (Federal Register of Legislation No. F2014L01142) made under subsections 196B(2) and (8) of the VEA is repealed.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 unknown primary site and death from malignant neoplasm of unknown primary site.

Meaning of malignant neoplasm of unknown primary site

- (2) For the purposes of this Statement of Principles, malignant neoplasm of unknown primary site:
- (a) means a histologically confirmed metastatic malignant neoplasm for which the primary tumour site cannot be identified after a complete history, physical examination and appropriate diagnostic investigations have been carried out; and
 - (b) excludes:
 - (i) haematolymphoid tumours (including non-Hodgkin lymphoma and Hodgkin's lymphoma);

- (ii) malignant melanoma; and
- (iii) mesenchymal tumours (including soft tissue sarcoma).

Note: Histological types of malignant neoplasm of unknown primary site include adenocarcinomas, squamous cell carcinomas, neuroendocrine tumours and poorly differentiated or undifferentiated neoplasms.

- (3) While malignant neoplasm of unknown primary site attracts ICD-10-AM code C80, in applying this Statement of Principles the meaning of malignant neoplasm of unknown primary site 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 unknown primary site

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

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 unknown primary site and death from malignant neoplasm of unknown primary site 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 unknown primary site or death from malignant neoplasm of unknown primary site 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 malignant neoplasm of unknown primary site; and
 - (b) commencing at least 5 years before the clinical onset of malignant neoplasm of unknown primary site; and

if smoking has ceased before the clinical onset of malignant neoplasm of unknown primary site, then that onset occurred within 20 years of cessation;

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

(2) consuming alcohol:

- (a) in an amount of at least 200 kilograms before the clinical onset of malignant neoplasm of unknown primary site; and
- (b) where consumption of alcohol commenced at least 5 years before the clinical onset of malignant neoplasm of unknown primary site; and

if consumption of alcohol has ceased before the clinical onset of malignant neoplasm of unknown primary site, then that onset occurred within 40 years of cessation;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

(3) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to at least one location in the body, at least 5 years before the clinical onset of malignant neoplasm of unknown primary site;

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

(4) for squamous cell carcinoma of unknown primary site of the head and neck only, having infection of the epithelium of the:

- (a) oral cavity;
- (b) oropharynx; or
- (c) larynx;

with human papillomavirus type 16 or 18 before the clinical onset of malignant neoplasm of unknown primary site;

Note: **squamous cell carcinoma of unknown primary site of the head and neck** is defined in the Schedule 1 - Dictionary.

(5) for squamous cell carcinoma of unknown primary site involving the inguinal lymph nodes only, having infection of the epithelium of the:

- (a) anus or anal canal;
- (b) cervix;
- (c) penis;
- (d) vagina; or
- (e) vulva;

with a specified human papillomavirus before the clinical onset of malignant neoplasm of unknown primary site;

Note: **specified human papillomavirus** is defined in the Schedule 1 - Dictionary.

- (6) for squamous cell carcinoma of unknown primary site of the head and neck only, having infection with Epstein-Barr virus before the clinical onset of malignant neoplasm of unknown primary site;

Note: *squamous cell carcinoma of unknown primary site of the head and neck* is defined in the Schedule 1 - Dictionary.

- (7) having diabetes mellitus before the clinical onset of malignant neoplasm of unknown primary site;
- (8) for adenocarcinoma of unknown primary site only, consuming an average of at least 25 grams per day of processed meat product, for at least 5 consecutive years within the 20 years before the clinical onset of malignant neoplasm of unknown primary site;

Note: *processed meat product* is defined in the Schedule 1 – Dictionary.

- (9) inability to obtain appropriate clinical management for malignant neoplasm of unknown primary site.

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(9) applies only to material contribution to, or aggravation of, malignant neoplasm of unknown primary site where the person's malignant neoplasm of unknown primary site 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:

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 unknown primary site—see subsection 7(2).

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.

processed meat product means meat, offal or meat by-products that have been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavour or improve preservation, including ham, frankfurters, salami and bacon.

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 human papillomavirus means human papillomavirus type 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 67, 68, 70, 73 or 82.

squamous cell carcinoma of unknown primary site of the head and neck means the presence of squamous cell carcinoma in one or more lymph nodes within the head and neck region that are not solely in the supra-clavicular region, and where the primary tumour site cannot be identified after a complete history, physical examination and appropriate investigations have been carried out.

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*.