Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MALIGNANT NEOPLASM OF THE BLADDER
(Balance of Probabilities)
(No. 84 of 2019)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(3) of the *Veterans' Entitlements Act 1986*.

Dated 23 August 2019

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



Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *malignant neoplasm of the bladder (Balance of Probabilities)* (No. 84 of 2019).

2 Commencement

This instrument commences on 23 September 2019.

3 Authority

This instrument is made under subsection 196B(3) of the *Veterans' Entitlements Act 1986*.

4 Repeal

The Statement of Principles concerning malignant neoplasm of the bladder No. 97 of 2011 (Federal Register of Legislation No. F2011L01730) made under subsections 196B(3) and (8) of the VEA is repealed.

5 Application

This instrument applies to a claim to which section 120B of the VEA or section 339 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 bladder and death malignant neoplasm of the bladder.

Meaning of ***malignant neoplasm of the bladder***

(2) For the purposes of this Statement of Principles, malignant neoplasm of the bladder:

(a) means a primary malignant neoplasm arising from the epithelial cells of the urinary bladder, including the ureteric orifice and the urethral orifice of the bladder; and

(b) includes urothelial carcinoma (also known as transitional cell carcinoma), squamous cell carcinoma, adenocarcinoma, small cell carcinoma and carcinoma in situ; and

(c) excludes soft tissue sarcoma, carcinoid tumour, non-Hodgkin lymphoma and Hodgkin's lymphoma.

(3) While malignant neoplasm of the bladder attracts ICD-10-AM code C67 or D09.0, in applying this Statement of Principles the meaning of malignant neoplasm of the bladder 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 bladder***

(5) For the purposes of this Statement of Principles, malignant neoplasm of the bladder, 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 bladder.

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

8 Basis for determining the factors

On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not that malignant neoplasm of the bladder and death from malignant neoplasm of the bladder can be related to relevant service rendered by veterans 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 exist before it can be said that, on the balance of probabilities, malignant neoplasm of the bladder or death from malignant neoplasm of the bladder is connected with the circumstances of a person's relevant service:

(1) smoking at least five pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of malignant neoplasm of the bladder, where smoking commenced at least ten years before the clinical onset of malignant neoplasm of the bladder;

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

(2) having received a cumulative equivalent dose of at least 0.5 sievert of ionising radiation to the bladder at least ten years before the clinical onset of malignant neoplasm of the bladder;

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

(3) inhaling, ingesting or having cutaneous contact with high concentrations of polycyclic aromatic hydrocarbons, through work involving the specified industrial or manufacturing process 1:

(a) for a cumulative period of at least 3 500 hours before the clinical onset of malignant neoplasm of the bladder; and
(b) where the first exposure occurred at least ten years before the clinical onset of malignant neoplasm of the bladder.

Note: ***polycyclic aromatic hydrocarbons*** and ***specified industrial or manufacturing process 1*** are defined in the Schedule 1 - Dictionary.

(4) inhaling, ingesting or having cutaneous contact with an agent from the specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons:

(a) for a cumulative period of at least 3 500 hours before the clinical onset of malignant neoplasm of the bladder; and
(b) where the first exposure occurred at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note: ***specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons*** is defined in the Schedule 1 – Dictionary.

(5) inhaling, ingesting or having cutaneous contact with an aromatic amine from the specified list of aromatic amines:

(a) for a cumulative period of at least 2 000 hours before the clinical onset of malignant neoplasm of the bladder; and
(b) where the first exposure occurred at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note 1: Inhaling, ingesting or having cutaneous contact with an aromatic amine does not include exposure due to cigarette smoke or hair dyes.

Note 2: ***specified list of aromatic amines*** is defined in the Schedule 1 – Dictionary.

(6) inhaling, ingesting or having cutaneous contact with a high concentration of an aromatic amine, through work involving the specified industrial or manufacturing process 2:

(a) for a cumulative period of at least 3 500 hours before the clinical onset of malignant neoplasm of the bladder; and
(b) where the first exposure occurred at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note 1: Inhaling, ingesting or having cutaneous contact with a high concentration of an aromatic amine does not include exposure due to cigarette smoke or hair dyes.

Note 2: ***specified industrial or manufacturing process 2*** is defined in the Schedule 1 – Dictionary.

(7) inhaling, ingesting or having cutaneous contact with tetrachloroethylene for a cumulative period of at least 10 000 hours before the clinical onset of malignant neoplasm of the bladder, where

the first exposure occurred at least ten years before the clinical onset of malignant neoplasm of the bladder;

(8) being exposed to arsenic as specified before the clinical onset of malignant neoplasm of the bladder, where the first exposure to arsenic occurred at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note: ***being exposed to arsenic as specified*** is defined in the Schedule 1 – Dictionary.

(9) working as a painter for a cumulative period of at least 10 000 hours before the clinical onset of malignant neoplasm of the bladder, where that work began at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note: ***working as a painter*** is defined in the Schedule 1 – Dictionary.

(10) having renal stone disease or a bladder stone at least ten years before the clinical onset of malignant neoplasm of the bladder;

(11) having chronic renal failure at least one year before the clinical onset of malignant neoplasm of the bladder;

Note: ***chronic renal failure*** is defined in the Schedule 1 – Dictionary.

(12) having an infection of the bladder with *Schistosoma haematobium* at least ten years before the clinical onset of malignant neoplasm of the bladder;

(13) having an indwelling bladder catheter or other foreign body in the bladder for a continuous period (excepting routine catheter changes) of at least ten years, before the clinical onset of malignant neoplasm of the bladder;

(14) having neurogenic bladder at least ten years before the clinical onset of malignant neoplasm of the bladder;

Note: ***neurogenic bladder*** is defined in the Schedule 1 – Dictionary.

(15) ingesting aristolochic acid as specified at least four years before the clinical onset of malignant neoplasm of the bladder;

Note: ***ingesting aristolochic acid as specified*** is defined in the Schedule 1 – Dictionary.

(16) consuming a total of at least 250 grams of phenacetin at least five years before the clinical onset of malignant neoplasm of the bladder;

Note: ***phenacetin*** is defined in the Schedule 1 – Dictionary.

(17) being treated with systemic cyclophosphamide or systemic ifosfamide, at least five years before the clinical onset of malignant neoplasm of the bladder;

(18) being treated with chlornaphazine at least five years before the clinical onset of malignant neoplasm of the bladder;

(19) inability to obtain appropriate clinical management for malignant neoplasm of the bladder.

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(19) applies only to material contribution to, or aggravation of, malignant neoplasm of the bladder where the person's malignant neoplasm of the bladder 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(3) 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:

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.

chronic renal failure means:

(a) having a glomerular filtration rate of less than 15 mL/min/1.73 m^2 for a period of at least three months; or
(b) a need for renal replacement therapy (dialysis or transplantation) for treatment of complications of decreased glomerular filtration rate which would otherwise increase the risk of morbidity and mortality; or
(c) undergoing chronic dialysis.

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 the *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.

ingesting aristolochic acid as specified means:

(a) consuming a total of at least 60 grams of plant material of the genus *Aristolochia* as a constituent of herbal medication; or
(b) consuming plant material of the genus *Aristolochia* or foods containing plant material of the genus *Aristolochia*, as part of the regular diet for a period of at least 15 months.

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

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

neurogenic bladder means flaccid, spastic or mixed bladder dysfunction caused by neurological damage affecting the bladder.

Note: Examples of a cause of neurogenic bladder include, but are not limited to, spinal cord injury, cerebrovascular accident, Parkinson's disease and diabetic autonomic neuropathy.

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.

phenacetin means an aniline derivative that has analgesic and antipyretic properties, that was formerly used as a constituent of several over-the-counter compound analgesic medications, including Bex or Vincent's powder, Empirin Compound and Bromo seltzer.

polycyclic aromatic hydrocarbons means hydrocarbons with three or more condensed aromatic rings in which certain carbon atoms are common to two or three rings. Polycyclic aromatic hydrocarbons occur in crude oil, shale oil and coal tars, and can be formed during the combustion of organic material or during high temperature processing of crude oil, coal, coke or other industrial carbon compounds.

relevant service means:

(a) eligible war service (other than operational service) under the VEA;
(b) defence service (other than hazardous service and British nuclear test defence service) under the VEA; or
(c) peacetime service under the MRCA.

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

soot means a carbonaceous by-product material produced from the incomplete combustion of fossil fuel or other carbon-containing material, including airborne, residual, pyrolysed fuel particles such as coal, cenospheres, charred wood and petroleum coke.

specified industrial or manufacturing process 1 means:

(a) aluminium production; or
(b) coal gasification; or
(c) iron or steel foundries or smelters.

specified industrial or manufacturing process 2 means:

(a) auramine production; or
(b) magenta production; or
(c) rubber manufacturing.

specified list of agents containing high concentrations of polycyclic aromatic hydrocarbons means:

(a) coal tar pitch during paving and roofing; or
(b) soot during the cleaning of chimneys or flues.

Note: ***soot*** is also defined in the Schedule 1 – Dictionary.

specified list of aromatic amines means:

(a) 2-naphthylamine;
(b) 4-aminobiphenyl;
(c) benzidine; or
(d) ortho-toluidine.

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*.

working as a painter:

(a) means applying paint, including solvent- or water-based conventional paint, spray paint, varnish, enamel, lacquer, water-emulsion and solution finish, nonaqueous dispersion or organosol, plastisol, and powder coating, during the course of activities such as building, maintenance and construction, interior and exterior decoration, artistic painting, and wood and metal painting; and
(b) includes mixed activities in which application of paint occurs with other tasks, such as wallpapering and plastering, and activities that are preparatory to painting, such as mixing paints, maintaining painting equipment, and background preparation of surfaces for application of paint.