



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
MALIGNANT NEOPLASM OF THE BREAST
(Reasonable Hypothesis)
(No. 84 of 2023)

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

Dated 25 August 2023.

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 the breast (Reasonable Hypothesis)* (No. 84 of 2023).

2 Commencement

This instrument commences on 26 September 2023.

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 breast No. 96 of 2014 (Federal Register of Legislation No. F2014L01383) made under subsections 196B(2) and (8) of the VEA is repealed.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 breast and death from malignant neoplasm of the breast.

Meaning of malignant neoplasm of the breast

- (2) For the purposes of this Statement of Principles, malignant neoplasm of the breast:
- (a) means a primary malignant neoplasm arising from the epithelial cells of the breast of males and females; and
 - (b) includes:
 - (i) carcinoma in situ; and
 - (ii) Paget disease of the breast; and
 - (c) excludes:
 - (i) haematolymphoid tumours including non-Hodgkin lymphoma and Hodgkin lymphoma;

- (ii) malignant melanoma; and
 - (iii) mesenchymal tumours including soft tissue sarcoma.
- (3) While malignant neoplasm of the breast attracts ICD-10-AM code C50 or D05, in applying this Statement of Principles the meaning of malignant neoplasm of the breast 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 breast

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

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

- (1) having received a cumulative equivalent dose of at least 0.1 sievert of ionising radiation to the breast at least 5 years before the clinical onset of malignant neoplasm of the breast;

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

- (2) taking menopausal hormone therapy for at least 1 year before the clinical onset of malignant neoplasm of the breast, and if the use of menopausal hormone therapy has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 5 years of cessation;

Note: *menopausal hormone therapy* is defined in the Schedule 1 - Dictionary.

- (3) using a combined oral contraceptive pill containing both estrogen and a progestogen:
 - (a) for a continuous period of between 2 and 5 years where:
 - (i) usage commenced at least 5 years before the clinical onset of malignant neoplasm of the breast; and
 - (ii) if usage has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 10 years of cessation; or
 - (b) for a continuous period of at least 5 years where:
 - (i) usage commenced at least 5 years before the clinical onset of malignant neoplasm of the breast; and
 - (ii) if usage has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 15 years of cessation;
- (4) taking diethylstilbestrol while pregnant before the clinical onset of malignant neoplasm of the breast;
- (5) receiving estrogen therapy for prostate cancer for at least 15 months before the clinical onset of malignant neoplasm of the breast;
- (6) for male to female transgender persons only, receiving transgender cross-sex hormone therapy containing estrogen for at least the 2 years before the clinical onset of malignant neoplasm of the breast;
- (7) for parous females only, inability to breast feed for a cumulative period of at least 3 months before the clinical onset of malignant neoplasm of the breast;

Note 1: The period of breastfeeding could be cumulative over a number of pregnancies.

Note 2: *parous* is defined in the Schedule 1 – Dictionary.
- (8) for females aged over 35 years only, being nulliparous at the time of the clinical onset of malignant neoplasm of the breast;

Note: *nulliparous* is defined in the Schedule 1 – Dictionary.
- (9) being pregnant within the 25 years before the clinical onset of malignant neoplasm of the breast;
- (10) having a first live birth after the age of 30 years or having a first full-term pregnancy after the age of 30 years, before the clinical onset of malignant neoplasm of the breast;
- (11) having smoked tobacco products:
 - (a) in an amount of at least 10 pack-years before the clinical onset of malignant neoplasm of the breast; and

- (b) commencing at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if smoking has ceased before the clinical onset of malignant neoplasm of the breast then that onset occurred within 30 years of cessation;

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

- (12) having been exposed to second-hand smoke:

- (a) for at least 10,000 hours before the clinical onset of malignant neoplasm of the breast; and

- (b) commencing at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if exposure to second-hand smoke has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 30 years of cessation;

Note: *having been exposed to second-hand smoke* is defined in the Schedule 1 – Dictionary.

- (13) for females only, consuming alcohol:

- (a) in an amount of at least 40 kilograms before the clinical onset of malignant neoplasm of the breast; and

- (b) at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if consumption of alcohol has ceased before the clinical onset of malignant neoplasm of the breast, 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.

- (14) inability to undertake any physical activity greater than 3 METs for at least 5 consecutive years within the 30 years before the clinical onset of malignant neoplasm of the breast;

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

- (15) for males and postmenopausal females only, being obese for a period of at least 5 years within the 20 years before the clinical onset of malignant neoplasm of the breast;

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

- (16) for males and postmenopausal females only, having diabetes mellitus before the clinical onset of malignant neoplasm of the breast;

- (17) for death from malignant neoplasm of the breast only, for females aged 50 to 69 years, being prevented from accessing mammographic screening for malignant neoplasm of the breast in accordance with contemporary medical standards at the time, within the 10 years before the clinical onset of malignant neoplasm of the breast, and where:

- (a) if mammographic screening has been resumed in the interim, there has been no normal test result; and
 - (b) the opportunity for subsequent appropriate mammographic screening has not been declined;
- (18) taking digoxin, digitalis or digitoxin for a continuous period of at least 1 year before the clinical onset of malignant neoplasm of the breast, and if taking digoxin, digitalis or digitoxin has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 5 years of cessation;
- (19) inhaling ethylene oxide vapour:
- (a) at an ambient 8-hour time-weighted average concentration of at least 1.5 parts per million for a cumulative total of at least 2,500 hours within a continuous period of 10 years before the clinical onset of malignant neoplasm of the breast; or
 - (b) in an amount greater than 10 ppm-years of cumulative exposure before the clinical onset of malignant neoplasm of the breast; and

where the first exposure occurred at least 5 years before the clinical onset of malignant neoplasm of the breast;

Note 1: Inhalation of ethylene oxide vapour can occur during the sterilisation of surgical instruments or protective clothing in hospitals.

Note 2: *8-hour time-weighted average* and *ppm-years* are defined in the Schedule 1 - Dictionary.

- (20) undertaking night shift work:
- (a) on at least 3 nights per week for a minimum of 10 hours per shift; and
 - (b) for a continuous period of at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if night shift work has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 3 years of cessation;

- (21) inability to obtain appropriate clinical management for malignant neoplasm of the breast before the clinical worsening of malignant neoplasm of the breast.

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(21) applies only to material contribution to, or aggravation of, malignant neoplasm of the breast where the person's malignant neoplasm of the breast 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:

8-hour time-weighted average means the averaging of different exposure levels to ethylene oxide during an average exposure period equivalent to eight hours.

being obese means:

- (a) having a Body Mass Index (BMI) of 30 or greater; or
- (b) for males, having a waist circumference exceeding 102 centimetres; or
- (c) for females, having a waist circumference exceeding 88 centimetres.

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

BMI means W/H^2 where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

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.

having been exposed to second-hand smoke means having been in an enclosed space and inhaling smoke from burning tobacco products or smoke that has been exhaled by another person who is smoking.

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

menopausal hormone therapy means administration of estrogen preparations, often in combination with a progestogen, to offset a hormone deficiency following surgically induced or naturally occurring menopause.

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*.

nulliparous means having never given birth to a viable infant.

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.

parous means having given birth to a viable infant.

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 defined in the Schedule 1 - Dictionary.

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*.