



Specialist Medical Review Council

Reasons for Decisions

*Section 196W
Veterans' Entitlements Act 1986*

Re: Statements of Principles Nos. 22 & 23 of 2010 concerning Alzheimer-type Dementia

Request for Review Declaration No. 21

SUMMATION

1. In relation to the Repatriation Medical Authority (the RMA) Statement of Principles No. 22 of 2010 concerning Alzheimer-type dementia and death from Alzheimer-type dementia, made under subsection 196B (2) of the *Veterans' Entitlements Act 1986* (the VEA), the Specialist Medical Review Council (the Council) under subsection 196W of the VEA:

DECLARES that it is of the view that there was **insufficient sound medical-scientific evidence** on which the RMA could have relied to amend the Statement of Principles to include a factor or factors for exposure to ionising radiation.

2. In relation to the RMA Statement of Principles No. 23 of 2010 concerning Alzheimer-type dementia and death from Alzheimer-type dementia, made under subsection 196B (3) of the VEA, the Council under subsection 196W of the VEA:

DECLARES that it is of the view that there was **insufficient sound medical-scientific evidence** on which the RMA could have relied to amend the Statement of Principles to include a factor or factors for exposure to ionising radiation.

3. The Council RECOMMENDS that the RMA conduct a new investigation to find out whether there is new information available about how Alzheimer-type dementia may be suffered or sustained, and in particular, whether exposure to ionising radiation, if found to exist in a particular case, could provide a link or element in a reasonable hypothesis connecting Alzheimer-type dementia or death from

Alzheimer-type dementia to relevant service, and if so whether it is more probable than not.

THE SPECIALIST MEDICAL REVIEW COUNCIL

4. The Council is a body corporate established under section 196V of the VEA, and consists of such number of members as the Minister for Veterans' Affairs determines from time to time to be necessary for the proper exercise of the function of the Council as set out in the VEA. The Minister must appoint one of the Councillors to be the Convener.
5. When a review is undertaken the Council is constituted by three to five Councillors selected by the Convener. When appointing Councillors, the Minister is required to have regard to the branches of medical-science that would be necessary for deciding matters referred to the Council for review.
6. The Convener for this review was Professor Charles Guest, of the College of Medicine, Biology and Environment, Australian National University, and currently President of the Faculty of Public Health Medicine, Australasian College of Physicians.
7. The other members of the Council were:
 - (i) Dr Roger Clarnette who is a Geriatrician and clinical Associate Professor, Faculty of Medicine, Dentistry and Health Sciences in the School of Medicine and Pharmacology at University of Western Australia. He is also the Medical Director of the Clinical Trials Division at the McCusker Alzheimer's Research Foundation Inc, a position he has held since 2000. He leads the Clinical Trials Division and assists Professor Ralph Martins and his team with medical expertise in his research studies at the McCusker Foundation.
 - (ii) Professor Mark Khangure who is a Clinical Professor at the University of Western Australia and previously a consultant Neuroradiologist at the Perth teaching hospitals for over 25 years. He was HOD Radiology at Royal Perth Hospital. He is currently in clinical practice as a Neuroradiologist with SKG Radiology at St John of God Hospitals Subiaco and Murdoch and at Hollywood Private Hospital. Professor Khangure is Chief Accreditation Officer of the RANZCR Education Board.
 - (iii) Dr Bradley Ng, who is a Consultant Psychiatrist at Older Persons Mental Health and at the Dementia Support Wing of the Geriatric Assessment & Rehabilitation Unit, both at Robina Hospital, Gold Coast, Queensland.
 - (iv) Dr Rick Tinker who is the Director of the Environmental and Radiation Health Branch, Australian Radiation Protection and Nuclear Safety Agency. He is responsible for assessing the impact on health of radiation exposures to workers, the public, and the environment in planned, existing, and emergency situations. He

has over 15 years' experience in research and measurement of radiation and assessment of health impacts and has played a leading role in advancing radiation protection in Australia.

THE LEGISLATION

8. The legislative scheme for the making of Statements of Principles is set out in Parts XIA and XIB of the VEA. Statements of Principles operate as templates, which are ultimately applied by decision-makers in determining individual claims for benefits under the VEA and the *Military Rehabilitation and Compensation Act 2004* (the MRCA)¹.
9. Fundamental to Statements of Principles is the concept of 'sound medical-scientific evidence', which is defined in section 5AB(2) of the VEA. Information about a particular kind of injury, disease or death is taken to be sound medical-scientific evidence if:
 - (a) the information
 - (i) is consistent with material relating to medical science that has been published in a medical or scientific publication and has been, in the opinion of the Repatriation Medical Authority, subjected to a peer review process; or
 - (ii) in accordance with generally accepted medical practice, would serve as the basis for the diagnosis and management of a medical condition; and
 - (b) in the case of information about how that injury, disease or death may be caused meets the applicable criteria for assessing causation currently applied in the field of epidemiology.²
10. The functions of the Council are set out in section 196W of the VEA. In this case, the Council was asked (under section 196Y of the VEA) by a person eligible to make a claim for a pension, to review the contents of:
 - Statement of Principles No. 22 of 2010 concerning Alzheimer-type dementia and death from Alzheimer-type dementia, being a Statement of Principles determined by the RMA under section 196B(2)³ of the VEA ('the **reasonable hypothesis test**') and

¹ See sections 120, 120A and 120B of the VEA and sections 335, 338 and 339 of the MRCA.

² This has been held to mean 'information which epidemiologists would consider appropriate to take into account' see *Repatriation Commission v Vietnam Veterans' Association of Australia NSW Branch Inc* (2000) 48 NSWLR 548 (the New South Wales Court of Appeal decision) per Spigelman CJ at [117].

³ 196B(2) provides;

If the Authority is of the view that there is sound medical-scientific evidence that indicates that a particular kind of injury, disease or death can be related to:

- (a) operational service rendered by veterans; or
- (b) peacekeeping service rendered by members of Peacekeeping Forces; or
- (c) hazardous service rendered by members of the Forces; or
- (caa) British nuclear test defence service rendered by members of the Forces; or
- (ca) warlike or non-warlike service rendered by members;

- Statement of Principles No. 23 of 2010 concerning Alzheimer-type dementia and death from Alzheimer-type dementia being a Statement of Principles determined by the RMA under section 196B(3)⁴ of the VEA ('the **balance of probabilities** test').
11. Specifically, the Applicant contended that the RMA should have included exposure to ionising radiation as a factor or factors in Statements of Principles Nos. 22 and 23 of 2010 concerning Alzheimer-type dementia and death from Alzheimer-type dementia.
 12. In conducting its review, the Council must review all the information that was available to (before) the RMA at the time it determined, amended, or last amended the Statements of Principles (the relevant times) and is constrained to conduct its review by reference to that information only.⁵
 13. Under section 196W of the VEA, the Council can only reach the view that a Statement of Principles should be amended on the basis of sound medical-scientific evidence.

BACKGROUND

Application for review by the Council

14. On 22 April 2010, the RMA under subsections 196B(2) and (3) of the VEA determined Statements of Principles Nos. 22 and 23 in respect of Alzheimer-type dementia and death from Alzheimer-type dementia. The Statements of Principles took effect from 12 May 2010.

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:

- (d) the factors that must as a minimum exist; and
- (e) which of those factors must be related to service rendered by a person;

before it can be said that a reasonable hypothesis has been raised connecting an injury, disease or death of that kind with the circumstances of that service.

- ⁴ 196B(3) provides;

If the Authority is of the view that on the sound medical-scientific evidence available it is more probable than not that a particular kind of injury, disease or death can be related to:

- (a) eligible war service (other than operational service) rendered by veterans; or
- (b) defence service (other than hazardous service and British nuclear test defence service) rendered by members of the Forces; or
- (ba) peacetime service rendered by members;

the Authority must determine a Statement of Principles in respect of that kind of injury, disease or death setting out:

- (c) the factors that must exist; and
- (d) which of those factors must be related to service rendered by a person;

before it can be said that, on the balance of probabilities, an injury, disease or death of that kind is connected with the circumstances of that service.

- ⁵ *Vietnam Veterans' Association (NSW Branch) Inc v Specialist Medical Review Council and Anor* (full Federal Court decision) (2002) 72 ALD 378 at paragraph 35 per Branson J.

15. On 4 May 2010 the Statements of Principles were registered on the Federal Register of Legislative Instruments.
16. On 11 May 2010 in accordance with section 42 of the *Legislative Instruments Act 2003* the Statements of Principles were tabled in the House of Representatives and in the Senate.
17. An Application for Review of Statements of Principles Nos. 22 and 23 in respect of Alzheimer-type dementia and death from Alzheimer-type dementia was received by the Council on 12 May 2010. The Application contended that the Statements of Principles should include a factor or factors concerning exposure to ionising radiation.
18. Pursuant to section 196ZB of the VEA the Council published in the Gazette a Notice of its Intention to carry out a review of all the information available to the RMA about Alzheimer-type dementia and invited eligible persons or organisations so authorised to make submissions to the Council.⁶ The Council gazetted a subsequent notice as to the dates by which written submissions must be received by the Council.⁷

The information sent by the RMA to the Council

19. By email dated 28 June 2010 the RMA, under section 196K of the VEA, sent to the Council the information the RMA advised was available to (before) it at the relevant times, as listed in Appendix B.
20. By agreement between the RMA and the Council, information the RMA advised was available to (before) it at the relevant times is posted on a secure website (referred to as FILEForce). It is made accessible by the Council to the Repatriation Commission and the Military Rehabilitation and Compensation Commission (the Commissions), the Applicant, and other participants in the review via confidential password. The information which was available to (before) the RMA at the relevant times was posted on FILEForce on 7 July 2010.

Notification of Preliminary Decisions on Proposed Scope of Review and Proposed Pool of Information

21. In separate letters, dated 20 May 2013, to each of the Applicant and the Commissions, the Council in summary:
 - advised of the Council's preliminary decisions on the proposed scope of the review and proposed pool of information;
 - invited the Applicant and Commissions to make any written comments as to the Council's preliminary decisions by close of business on 21 June 2013; and

⁶ Gazette Notice No. No 43, 3 November 2010

⁷ Gazette Notices No. GN 33, 22 August 2012

- advised that if any written comments were made, any complementary oral comments could be made at a hearing of oral submissions complementing the written submissions.
22. The Commissions made no comment on, and sought no amendment to, the Council's proposed scope of review. Nor did the Commissions propose any alteration to the Council's proposed decision on the pool of information.
23. The Applicant made comments in response to the Council's letter as detailed in [35] - [37].

Proposed Scope of Review

24. The Council's preliminary decision on the proposed scope of the review, as advised to the Applicant and Commissions on 20 May 2013, was as follows:

Without limiting the scope of the Council's review of (some or the whole of) the contents of the Statements of Principles, the Council proposed to have particular regard to whether there was sound medical-scientific evidence upon which the RMA could have relied to amend either or both of the Statements of Principles in any or all of the following ways:

(i) the possible inclusion of a factor or factors in Statement of Principles No. 22 of 2010 for exposure to ionising radiation; and

(ii) the possible inclusion of a factor or factors in Statement of Principles No. 23 of 2010 for exposure to ionising radiation.

Proposed Pool of Information

25. As mentioned above, the RMA is obliged under section 196K of the VEA to send to the Council all the information that was available to it (the RMA) at the relevant times. That comprises all the information that was available to the RMA when it determined the original Statements of Principles in respect of Alzheimer-type dementia and death from Alzheimer-type dementia in 1995 and all the information subsequently available at all times when the Statements of Principles have been amended, or revoked and replaced, up to and including the information which was available in April 2010 when the RMA determined the Statements of Principles under review. In other words, within 28 days after being notified that the Council has been asked to conduct a review, the RMA must send to the Council all the information in respect of Alzheimer-type dementia and death from Alzheimer-type dementia which was in the possession of the RMA at the time it (the RMA) made the decision that triggered the Council's review.
26. The Council's preliminary decision on the proposed pool of information was that the pool of information should comprise the information:
- that was available to (before) the RMA at the relevant times;
 - which was sent by the RMA to the Council under section 196K of the VEA;

- which was considered by the Council to be sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:
 - (1) epidemiologists would consider appropriate to take into account; and
 - (2) in the Council's view 'touches on' (is relevant to) exposure to ionising radiation.
27. Information which the RMA advised was not available to (not before) the RMA at the relevant times, was not taken into account by the Council for the purposes of the review, as it could only be considered as 'new information'.
28. A copy of the Council's preliminary list of the proposed pool of information was forwarded to the Applicant and the Commissions and is attached at **Appendix A**.

SUBMISSION BY THE COMMISSIONS

29. The Commissions made a written submission dated May 2012. The Commissions submitted that:
- ...the RMA investigation into Alzheimer's disease, that lead to the determination of instruments 22 and 23 of 2010, does not appear to have specifically examined ionising radiation as a potential risk factor.⁸
30. From the information that was available to the RMA at the relevant times, the Commissions identified three epidemiological studies that they submitted provided some data for ionising radiation exposure and risk of Alzheimer-type dementia.
31. Of the original studies, the Commission cited:
- Kokmen *et al* 1990⁹, submitting that the study found that:

Prior radiotherapy was not associated with an increased risk of Alzheimer's disease. For any prior radiotherapy the odds ratio (OR) was 0.95 (95% confidence interval (CI), 0.66 to 1.37). For prior radiotherapy to the head only the OR was 0.65 (95% CI, 0.32 to 1.31). Risk was not related to latency between exposure and disease onset.
 - Yamada *et al* 2003, submitting that the study involving 2,463 subjects from Hiroshima:

was focused on potential lifestyle and dietary risk factors, but reported ...no association ... was seen between radiation dose (from the 1945 Hiroshima atomic bomb) and prevalence of Alzheimer's disease. No detail on the level of radiation exposure in these subjects was provided.
 - Broe *et al* 1990¹⁰, submitting that the study:

⁸ Commissions' written submission at page 5.

⁹ Kokmen E, Beard CM, Bergstralh E, Anderson, JA, et al (1990). Alzheimer's disease and prior therapeutic radiation exposure: a case-control study. *Neurology*, 40(9): 1376-9. RMA ID 3145

...examined multiple potential risk factors for Alzheimer's disease in a case-control study in Sydney. Subjects comprised 170 Alzheimer's disease cases and 170 age- and sex-matched controls. A very large number of putative associations were investigated (87 in total), including prior radiotherapy. Two cases and five controls had received prior radiotherapy (self-reported by subject or proxy), giving an odds ratio of 0.40 (95% CI, 0.08 to 1.95). No further details on the radiotherapy were provided.

32. The Commissions reviewed papers by Lindsay *et al*, 2002¹¹ which they submitted:

... reported on the Canadian Study of Health and Aging (CSHA), which provided a five year prospective analysis of risk factors for Alzheimer's disease. No association was seen with 'radiation'. No information on the type or source of radiation exposure was provided.

and

Tyas *et al*, 2001¹², which they submitted had similar methodology to the CSHA¹³ and examined occupational radiation exposure as a risk factor for Alzheimer's disease. The Commissions submitted that the study reported:

A non-statistically significant increased relative risk ... with a very wide confidence interval. No details on the type or quantity of exposure were provided.

33. The Commissions submitted that the RMA:

...also had available a number of other case-control studies reporting on general or occupation risk factors for Alzheimer's disease, but none of these had any information on ionising radiation.

34. The Commissions concluded their written submission by submitting that:

The limited evidence available to the RMA does not indicate, nor establish on the balance of probabilities, that ionising radiation is a risk factor for Alzheimer-type dementia. The Commissions' view is that the available evidence on this subject does not warrant any amendments to the Alzheimer-type dementia SOPs.

¹⁰ Broe GA, Henderson AS, Creasey H, McCusker E, *et al* (1990). A case-control study of Alzheimer's disease in Australia. *Neurology*, 40(11): 1698-1707. RMA ID 3130

¹¹ Lindsay J, Laurin D, Verreault R, Hebert R, *et al* (2001). Risk factors for Alzheimer's disease: A prospective analysis from the Canadian Study of Health and Aging. *American Journal of Epidemiology*, 156(5): 445-53. RMA ID 53199

¹² Tyas SL, Manfreda J, Strain LA, Montgomery PR (2001). Risk factors for Alzheimer's disease: a population-based, longitudinal study in Manitoba, Canada. *International Journal of Epidemiology*, 30: 590-7. RMA ID 53205

¹³ The Canadian Study of Health and Aging, also discussed in the paper by Lindsay *et al*, 2002.

THE APPLICANT'S POSITION

35. As noted above, the Council advised the Applicant by letter dated 20 May 2013 of the Council's proposed decisions on the scope of review and preliminary pool of information.
36. The Council advised the Applicant that it did not understand the Applicant to have identified or made submissions about any of the information which was available to the RMA at the relevant times. The Council provided to the Applicant a further opportunity, should the Applicant wish to do so, to make a written submission about any information that was available to the RMA at the relevant times, and to appear before the Council to make an oral submission complementing the Application and any written submission the Applicant may make.
37. The Applicant in response to the Council's letter advised that:

I DO NOT have sound medical-scientific evidence to possibly amend the Statements of Principles regarding ionising radiation.

I have NO further information to submit to the SMRC.

I agree that there appears to be no evidence to support my case in Table 2 [the information that was available to the RMA at the relevant times which the Council did not propose to include in its preliminary pool of information].

I am in no position to comment on the papers in Table 1 [the preliminary pool of information], but agree that if these papers contain the only evidence available, papers discussing radiation may be topical. I believe that further evidence is still necessary.

Apparently the RMA and SMRC have missed the message I intended to give. I listed a number of factors that would suggest radiation could be an extra cause of Alzheimers.

I cannot provide hard evidence. Therefore I should not waste the time of the SMRC.

I have tried to present a case worth investigating for the benefit of serving and future servicemen, and indeed for medical science...

REASONS FOR THE COUNCIL'S DECISION

The Council's Task

38. An option open to the Council upon considering the Applicant's comments was to take steps to terminate the review. However, the Council considered whether there was utility in proceeding. While the Applicant had formed the view that there was no sound medical-scientific evidence in the proposed pool of information, or indeed in the available information, the Council took the view that it should consider for

itself whether there was sound medical-scientific evidence upon which the RMA could have relied to amend the Statements of Principles by including a factor or factors relating to exposure to ionising radiation.

39. In conducting a review the Council follows a two-step process. As mentioned above, the Council had identified the proposed pool of information, i.e. it had identified from all the information that was available to (before) the RMA at the relevant times the sound medical-scientific evidence (as that term is defined in section 5AB(2) of the VEA (see [9] above)) which in its view 'touches on' (i.e. is relevant to) the issue of whether a particular kind of injury, disease or death can be related to service. In the absence of any comment on its proposed pool of information, the Council proceeded on the basis that its proposed pool of information was the final pool of information.
40. The second step required the Council to determine whether;
- 40.1. there is sound medical-scientific evidence in the pool that indicates ('points to' as opposed to merely 'leaves open')¹⁴ the relevant possibility ie whether exposure to ionising radiation (if found to exist in a particular case) could provide a link or element in a reasonable hypothesis connecting Alzheimer-type dementia and death from Alzheimer-type dementia to relevant¹⁵ service.¹⁶ The Council had to find that the hypothesis contended for was reasonable and not one which was 'obviously fanciful, impossible, incredible or not tenable or too remote or too tenuous.'¹⁷
- 40.2. on the sound medical scientific evidence in the pool, exposure to ionising radiation (if found to exist in a particular case) could provide a relevant connection between Alzheimer-type dementia or death from Alzheimer-type dementia and relevant¹⁸ service according to a standard of satisfaction 'on the balance of probabilities', or as being more probable than not.
41. In these Reasons the association for both the Reasonable Hypothesis test (at [40.1] and the balance of probabilities test at [40.2]) are respectively referred to as the 'relevant association'.

¹⁴ See full Federal Court decision at [49] per Branson J.

¹⁵ Relevant service here refers to operational, peacekeeping and hazardous service, British nuclear test defence service, and warlike or non-warlike service as those terms are defined in the VEA and the MRCA.

¹⁶ See Vietnam Veterans' Association of Australia (NSW Branch) Inc v Specialist Medical Review Council and Anor (2002) 69 ALD 553 (Moore J decision) per Moore J at [29].

¹⁷ See the full Federal Court decision in Repatriation Commission v Bey (1997) 79 FCR 364 which cited with approval these comments from Veterans' Review Board in Stacey (unreported 26 June 1985), all of which were in turn cited with approval in the Moore J decision at [33].

¹⁸ Relevant service here refers to eligible war service (other than operational service), defence service (other than hazardous service and British nuclear test defence service) and peacetime service as those terms are defined in the VEA and the MRCA.

THE SOUND MEDICAL-SCIENTIFIC EVIDENCE DOES NOT 'POINT TO' BUT MERELY 'LEAVES OPEN' THE RELEVANT ASSOCIATION

42. The Council agreed with the Commissions and the Applicant that there was nothing in the pool of information which it considered pointed to the relevant association. In fact, in the Council's view articles in the pool of information which touched on the contended exposure (and there were very few) were considered by the Council not to support the relevant association. As, in the Council's view, the reasonable hypothesis test was not met, the balance of probabilities test necessarily could not be met.

COUNCIL'S ANALYSIS OF THE NEW INFORMATION

43. As mentioned above, in conducting a review, the Council is unable to (and so did not) consider information which was not available to (not before) the RMA at the relevant times. However, having formed the view that there was nothing in the pool of information which pointed to the relevant association, and being mindful of the Applicant's comments, the Council considered whether in its view there was a basis for recommending to the RMA that it (the RMA) undertake a new investigation into how Alzheimer-type dementia may be suffered or sustained.
44. The Council has neither the capacity nor the jurisdiction to perform an investigative function, including undertaking a comprehensive literature search. However, by reason of the Councillors' specialist expertise in this kind of injury, disease or death, the Council was aware of some new information (listed at **Appendix C**) which it considered on a preliminary basis.
45. The Council considered the new information to determine whether, in the Council's view, it warranted the Council making any directions or recommendations to the RMA.
46. In the Council's view any such direction or recommendation should only be made by the Council if it formed the view that the new information:
- comprised sound medical-scientific evidence as defined in section 5AB(2) of the VEA being information which:
 - * was information epidemiologists would consider appropriate to take into account; and
 - * in the Council's view, 'touched on' (was relevant to) the contended factor; and
 - could potentially satisfy the reasonable hypothesis and/or balance of probabilities tests (as appropriate; see paragraphs [40.1] and [40.2] above for the relevant associations).

47. The Council was very conscious that it was aware only of a small number of articles which had not been identified by any systematic investigation. However, in the Council's view, the new information of which it was aware could be found to be:
- relevant to the contended factor (exposure to ionising radiation);
 - information which epidemiologists would consider appropriate to be taken into account
 - sound medical-scientific evidence.
48. While the Council did not undertake a detailed analysis of any of the new information of which it was aware, it noted the following:
- 48.1. the paper by Cherry et al 2012¹⁹:
- could be found potentially to be a positive study, with exposure to radiotherapy levels of ionising radiation potentially a link leading to Alzheimer-type dementia changes, in circumstances where such exposure causes cellular damage. This was an animal study, and while the Council noted the differences between animal and human metabolic processes it was a paper that in the Council's view epidemiologists would consider appropriate to take into account, although the weight to be attributed to it is a separate question.
- 48.2. The paper by Riudavets et al²⁰:
- considered a small sample, exposed to a high dosage (radiotherapy levels) of ionising radiation. It referred in turn to a paper which could be found to be suggestive of a possible link.
49. Overall, the Council considered that there were suggestions emerging from a variety of sources that exposure to radiation may lead to cognitive impairment and function, although the Council was not able to say whether such potential impairment was Alzheimer-type dementia.
50. The Council recommended that the RMA conduct a new investigation to find out whether there is new information available about how Alzheimer-type dementia may be suffered or sustained, and in particular, whether exposure to ionising radiation, if found to exist in a particular case, could provide a link or element in a reasonable hypothesis connecting Alzheimer-type dementia or death from Alzheimer-type dementia to relevant service, and if so whether it is more probable than not.

¹⁹ Cherry JD, Liu B, Frost JL, Lemere CA, Williams JP, et al 2012, 'Galactic Cosmic Radiation Leads to Cognitive Impairment and Increased Ab Plaque Accumulation in a Mouse Model of Alzheimer's Disease, PLoS ONE, vol. 7, no. 12.

²⁰ Riudavets, Mena H, Bouffard JP, Sandberg G, Rushing EJ 2005, 'Relationship between radiation injury and Alzheimer-related neurodegenerative changes', Clin Neuropathol. vol. 24, no. 5, pp. 236-8...

51. In making this recommendation, the Council was cognisant that the Commissions in their submission stated that they had undertaken a literature search, the results of which they submitted were that:

...some further relevant reports on the Adult Health Study (Hiroshima subjects) were identified. These again showed no association between atomic radiation exposure and Alzheimer's dementia. No other epidemiological evidence concerning ionising radiation exposure and risk ... of Alzheimer's dementia was identified...

An extensive literature search undertaken by the Commissions has not identified new information that would support a further investigation of Alzheimer-type dementia and ionising radiation by the RMA.

52. While the Council took into account the Commissions' submission, it was of the view that a new investigation by the RMA was warranted. Even on the basis of the very limited new information considered by the Council, there were suggestions that ionising radiation at radiotherapy levels could be a link or element in cognitive changes, although, as noted above, the Council could not determine whether such changes were of an Alzheimer-type.
53. However, it was conceivable that ionising radiation at radiotherapy levels could be found to contribute to brain damage and cognitive dysfunction which in turn could contribute to Alzheimer-type dementia or another kind of injury, disease or death. Another question the Council considered should be considered by the RMA in a new investigation was whether ionising radiation may contribute to an acceleration of pre-existing Alzheimer-type dementia.
54. Of course, in recommending that the RMA should undertake a new investigation into how Alzheimer-type dementia may be suffered or sustained, the Council was not pre-judging the outcome of what such an investigation may elicit.

DECISION

55. The Council made the declarations summarised in **paragraphs 1, 2 and 3** above.

EVIDENCE BEFORE THE COUNCIL

56. The preliminary list of the proposed pool of information, as advised to the Applicant and the Commissions by letters dated 20 May 2012 (see [35]) is listed in **Appendix A**.

This list also identifies the information upon which the Council understands the Applicant and the Commissions relied (being information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA).

57. Information forwarded to the Council under section 196K of the VEA referable to the Council's review of Statements of Alzheimer-type Dementia Nos. 22 and 23 of 2010 is listed in **Appendix B**.
58. The information **to which the Council referred** (being information which the RMA advised was new information, that is, information which was not available to (not before) the RMA at the relevant times, and so was not considered by the Council in reaching its review decision) is listed in **Appendix C**.

ARTICLES CITED IN THE COUNCIL'S ANALYSIS

Appendices

Appendix A	<p>Preliminary list of the proposed pool of information, as advised to the Applicant and the Commissions by letters dated 20 May 2012 (see [28]) is listed in Appendix A.</p> <p>This list also identifies the information upon which the Council understands the Applicant and the Commissions relied (being information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA).</p>
Appendix B	<p>Information forwarded to the Council under section 196K of the VEA referable to the Council's review of Statements of Principles Nos. 22 and 23 of 2010.</p>
Appendix C	<p>Information which the RMA advised was available to (before) the RMA at the relevant times and which the RMA sent to the Council in accordance with section 196K of the VEA).</p>