From:	Heffernan, Emily (AU)
To:	Justine Stansen
Cc:	Fox, Chris (AU)
Subject:	Hazelwood Mine Fire Inquiry - KWM letter dated 15 October 2015 [KWM-Documents.FID1770821]
Date:	Thursday, 15 October 2015 8:06:11 PM
Attachments:	4663_001.pdf Attachment A to KWM letter dated 15 October 2015.pdf Attachment B to KWM letter dated 15 October 2015.pdf Attachment C to KWM letter dated 15 October 2015.pdf Attachment D to KWM letter dated 15 October 2015.pdf Attachment E to KWM letter dated 15 October 2015.pdf Attachment F to KWM letter dated 15 October 2015 (Part 1).pdf Attachment F to KWM letter dated 15 October 2015 (Part 2).pdf Philip McCloud CV.PDF

Dear Justine,

Please find attached our letter dated 15 October 2015, together with its enclosures.

Regards,

Emily Heffernan | Senior Associate
King & Wood Mallesons
[redacted]

KING&WOOD MALLESONS

[redacted]

www.kwm.com

15 October 2015

Chris Fox
Partner
[redacted]

Emily Heffernan
Senior Associate
[redacted]

Ms Justine Stansen
Principal Legal Advisor
Hazelwood Mine Fire Inquiry
[redacted]

By email

Dear Justine,

Hazelwood Mine Fire Inquiry – Term of Reference 6

Thank you for your email dated 14 October 2015 which, amongst other things, advised that the Board has determined to postpone the hearing in relation to the subsequent reports of Associate Professor Barnett to next Thursday, 22 October 2015.

We also refer to your email received a short time ago advising that the Board is now convening an expert conclave on Monday to consider these additional reports and whether they have any significance to the questions the Board is considering. This conclave is to include participants beyond the previously invited experts.

As you know from our letters dated 6 and 13 October 2015, our client's primary position is that it objects to the admission by the Board of these further reports of Associate Professor Barnett, which have been produced after hearings into TOR6 concluded. That objection remains.

Without prejudice to our primary position, procedural fairness requires that there is an adequate interval between the receipt of further material and any hearing. We do not see how the Board's decision to postpone the hearing by a week will address this requirement. As is evident from the *Commentary* document of Professor Gordon received only yesterday, and as is apparent in any event, the proposed new evidence is far from settled. Professor Gordon draws attention to a range of ambiguities, uncertainties and unknowns with the methodology and modelling (including its inputs, assumptions, parameters and variables) used by Associate Professor Barnett for the conclusions he asserts in his new reports. These difficulties are underlined by the decision of the Board to hold an expert conclave in relation to the new Barnett reports, which it is contemplated will produce yet further material, which will only be received shortly before the new hearing date.

We note your comments in your 14 October 2015 email about the tight time frame to which the Board is working. That is understood by our client, and the workload of the Board is acknowledged. However the present difficulty only arises because of the Board's preparedness to date to admit after the event the subsequent reports of Associate Professor Barnett, and to have a hastily convened hearing (and now further expert conclave) in relation to them in circumstances where the relevant reports and analyses in any event are not in a proper or stable state to be fairly interrogated and responded to. The timetable to which the Board is working, compromised as it is by the decision to entertain the intervention of Associate Professor Barnett's latest reports, cannot be achieved by sacrificing procedural fairness.

kwm

KING&WOOD MALLESONS

Subject to these concerns and objections:

1. As there is now to be a further expert conclave which is to involve experts beyond the previous four invited experts, our client wishes an expert retained by it also to be involved. The expert is Dr Philip McLeod of McCloud Consulting Group. Two letters from Dr McCloud are referred to below and are attached to this letter, together with Dr McCloud's CV. Dr McCloud has confirmed that he is able to attend the conclave on Monday, and is available to give evidence at the hearing on 22 October 2015 if required. Please let us know if there is any difficulty with Dr McCloud participating with the other experts in the conclave, and assuming that there is no difficulty, please provide us with the relevant details for the conclave.

2. As regards the query in your email dated 14 October 2015 as to whether the parties wish to ask Dr Johnston questions at the hearing on 22 October 2015, this presumably is moot given that Dr Johnston has now been invited to attend the expert conclave, and has confirmed that she is available to give evidence on 22 October 2015.

3. In relation to the penultimate paragraph of your email dated 14 October 2015, subject to our client's objections to the admission of the further Barnett reports and the holding of a hearing in relation to them, our client has previously advised Counsel Assisting that it wishes to ask questions of the experts at any such hearing into the further Barnett reports. We confirm that application.

4. In accordance with paragraph 22 of *Practice Direction No.2 – Public Hearing for Term of Reference 6* we advise that there are a small number of documents which at this stage our client wishes to put to witnesses at the hearing on 22 October 2015. These documents are as follows (copies attached):

    a. Summary of total deaths recorded by postcode of usual place of residence in eight postcode areas in the period 9 February – 25 March in the years 2009 – 2015 as per Births, Deaths and Marriages (**BD&M**) mortality data received from the Board on 8 October 2015;

    b. Summary of daily deaths recorded by postcode of usual place of residence - four postcode areas in the period 9 February – 26 March 2014 as per BD&M mortality data received from the Board on 8 October 2015;

    c. *2014 Hazelwood Mine Fire Inquiry Report* – pages 277 and 280;

    d. Map prepared by King & Wood Mallesons overlaying CSIRO Mine Fire air pollution modelling with postcode boundaries determined in reference to Australian Statistical Geography Standard;

    e. Map prepared by King & Wood Mallesons overlaying CSIRO Mine Fire air pollution modelling with postcode boundaries determined in reference to municipal suburb boundaries; and

    f. Letters from Dr Philip McCloud, McCloud Consulting Group, to King & Wood Mallesons dated 13 and 14 October 2015.

Finally, as regards the BD&M data received from the Board on 8 October 2015, we note that this data is not formally in evidence. Our client requests that this data is formally tendered by Counsel Assisting at any hearing in relation to the further Barnett reports, and is also provided to the relevant persons participating in the conclave on Monday.

Yours sincerely,

King & Wood Mallesons

Hazelwood Mine Fire Inquiry – Term of Reference 6

Births, Deaths & Marriages (BD&M) data supplied to the parties by the Board on 8 October 2015 – summary of total recorded deaths by postcode of usual place of residence during the period 9 February - 25 March in the years 2009 - 2015

Postcode	2009	2010	2011	2012	2013	2014	2015
3840 (Morwell)	28	12	16	20	17	18	22
3842 (Churchill)	7	3	2	2	4	6	6
3825 (Moe)	18	23	23	22	23	32	29
3844 (Traralgon)	25	21	20	23	18	27	20
4 postcode total	**78**	**59**	**61**	**67**	**62**	**83**	**77**
3869 (Yinnar)	0	1	0	2	1	0	3
3870 (Boolara)	1	2	1	1	0	0	1
6 postcode total	**79**	**62**	**62**	**70**	**63**	**83**	**81**
3854 (Glengarry)	1	3	0	0	0	1	0
3856 (Toongabbie)	0	0	0	1	0	2	0
8 postcode total	**80**	**65**	**62**	**71**	**63**	**86**	**81**

Notes:

- ***4 postcodes*** *(3840, 3842, 3825, 3844) – studied by Associate Professor Barnett in his report dated 25 September 2015.*
- ***6 postcodes*** *(3840, 3842, 3825, 3844, 3869, 3870) - studied by Associate Professor Barnett in his report dated December 2014.*
- ***8 postcodes*** *(3840, 3842, 3825, 3844, 3869, 3870, 3854, 3856) - those postcodes for which data was requested from BD&M by the Board – as referred to in the Witness Statement of Dawn Sims.*

Hazelwood Mine Fire Inquiry – Term of Reference 6

Births, Deaths and Marriages (BD&M) data supplied to the parties by the Board on 8 October 2015 – summary of daily deaths recorded in postcodes 3840, 3842, 3825 and 3844 during the period 9 February – 26 March 2014

Date	Total recorded deaths in postcodes 3840, 3842, 3825, 3844
9 February 2014	2
10 February 2014	4
11 February 2014	1
12 February 2014	4
13 February 2014	2
14 February 2014	0
15 February 2014	1
16 February 2014	2
17 February 2014	1
18 February 2014	0
19 February 2014	2
20 February 2014	0
21 February 2014	2
22 February 2014	3
23 February 2014	0
24 February 2014	0
25 February 2014	4
26 February 2014	1
27 February 2014	1
28 February 2014	2
1 March 2014	3
2 March 2014	1
3 March 2014	2
4 March 2014	0
5 March 2014	3
6 March 2014	4
7 March 2014	1
8 March 2014	1
9 March 2014	2
10 March 2014	1
11 March 2014	1
12 March 2014	2
13 March 2014	1
14 March 2014	3
15 March 2014	2
16 March 2014	4
17 March 2014	0
18 March 2014	3
19 March 2014	2
20 March 2014	1
21 March 2014	1
22 March 2014	3
23 March 2014	3
24 March 2014	4
25 March 2014	3
26 March 2014	5
TOTAL	**88**

PARTICULATE MATTER ($PM_{2.5}$)

Figure 4.27 Validated and indicative $PM_{2.5}$ levels for Morwell and Traralgon from 9 February 2014 – 31 March 2014 (daily averages)[44]

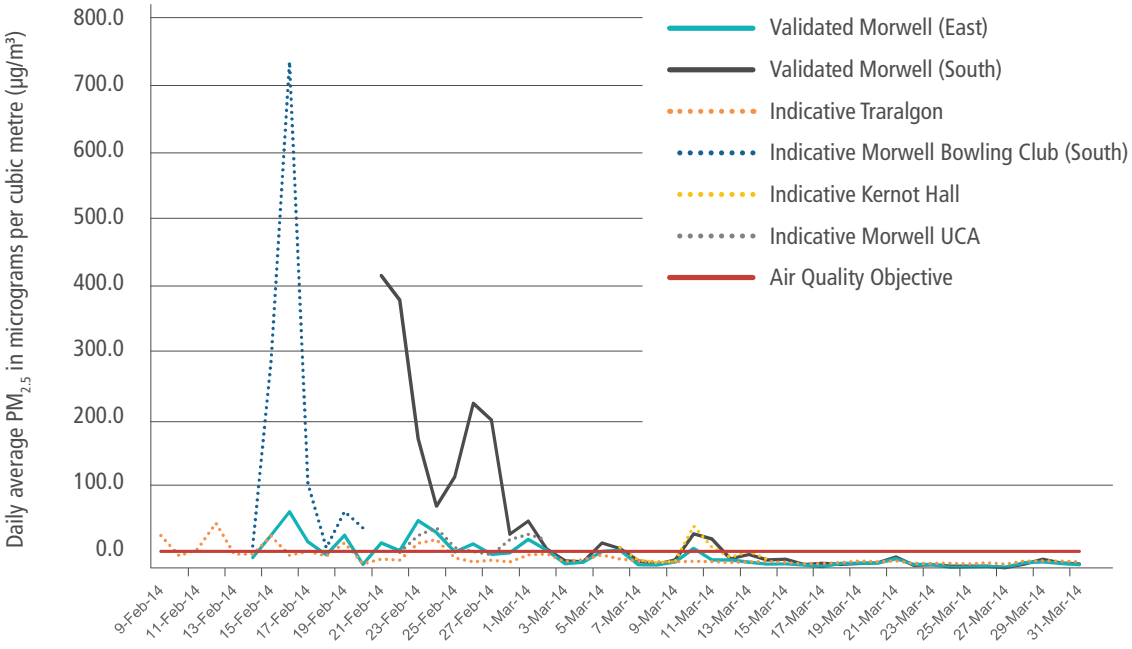


Figure 4.27 adapted from an EPA graph shows validated data (solid line) and indicative data plotted retrospectively (dotted line) for daily averages of $PM_{2.5}$ in Morwell from 9 February to 31 March 2014. The Victorian standard (advisory) for $PM_{2.5}$ is 25 µg/m³ measured over one day. This standard is indicated in Figure 4.27 by the red line.

The graph shows that there were three peaks (above the red line) of increased levels of $PM_{2.5}$ between 15 February 2014 and 16 February 2014, and around 21 February 2014 and 26 February 2014.

In their joint expert report to the Board, Dr Torre and Ms Richardson advised that from 14 February 2014 until 31 March 2014, in the area south of Commercial Road, Morwell, there were:

- 21 days where the levels of $PM_{2.5}$ exceeded the advisory reporting standard (greater than 25 µg/m³)
- seven days that would be classified as hazardous in the $PM_{2.5}$ Health Protection Protocol (equal or greater than 157 µg/m³)
- four days where the levels (indicative and validated) were in the extreme category in the $PM_{2.5}$ Health Protection Protocol (greater than 250 µg/m³).[45]

Due to the need for scientific calibration of data, indicative data was not available to the EPA and the Department of Health until after the fire was controlled (which was on 10 March 2014).[46]

The highest validated recording of $PM_{2.5}$, as shown in Figure 4.27 was over 400 µg/m³ (on about 21 February 2014). This is approximately 16 times the daily National Ambient Air Quality standard of 25 µg/m³.

The highest indicative recording of $PM_{2.5}$, as shown in Figure 4.27, was over 700 µg/m³ between 15 and 16 February 2014. This is approximately 28 times the daily National Ambient Air Quality standard of 25 µg/m³.

PARTICULATE MATTER (PM_{10})

Figure 4.31 Validated and indicative results for PM_{10} levels in Morwell and Traralgon from 9 February 2014 – 31 March 2014 (daily averages)[51]

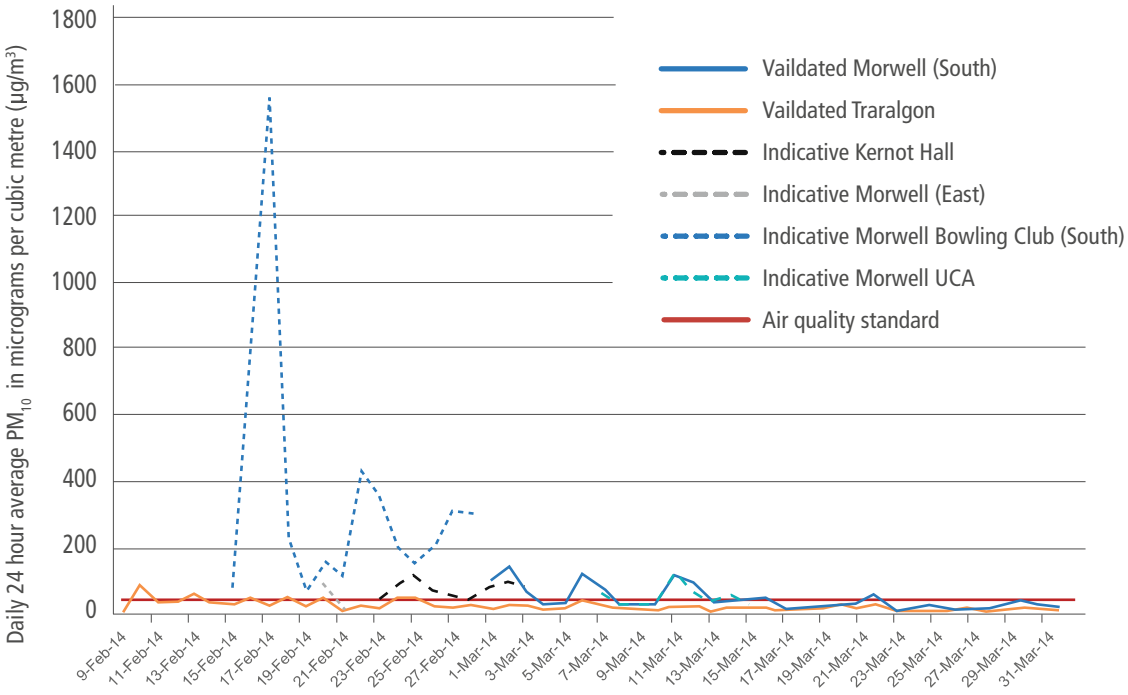
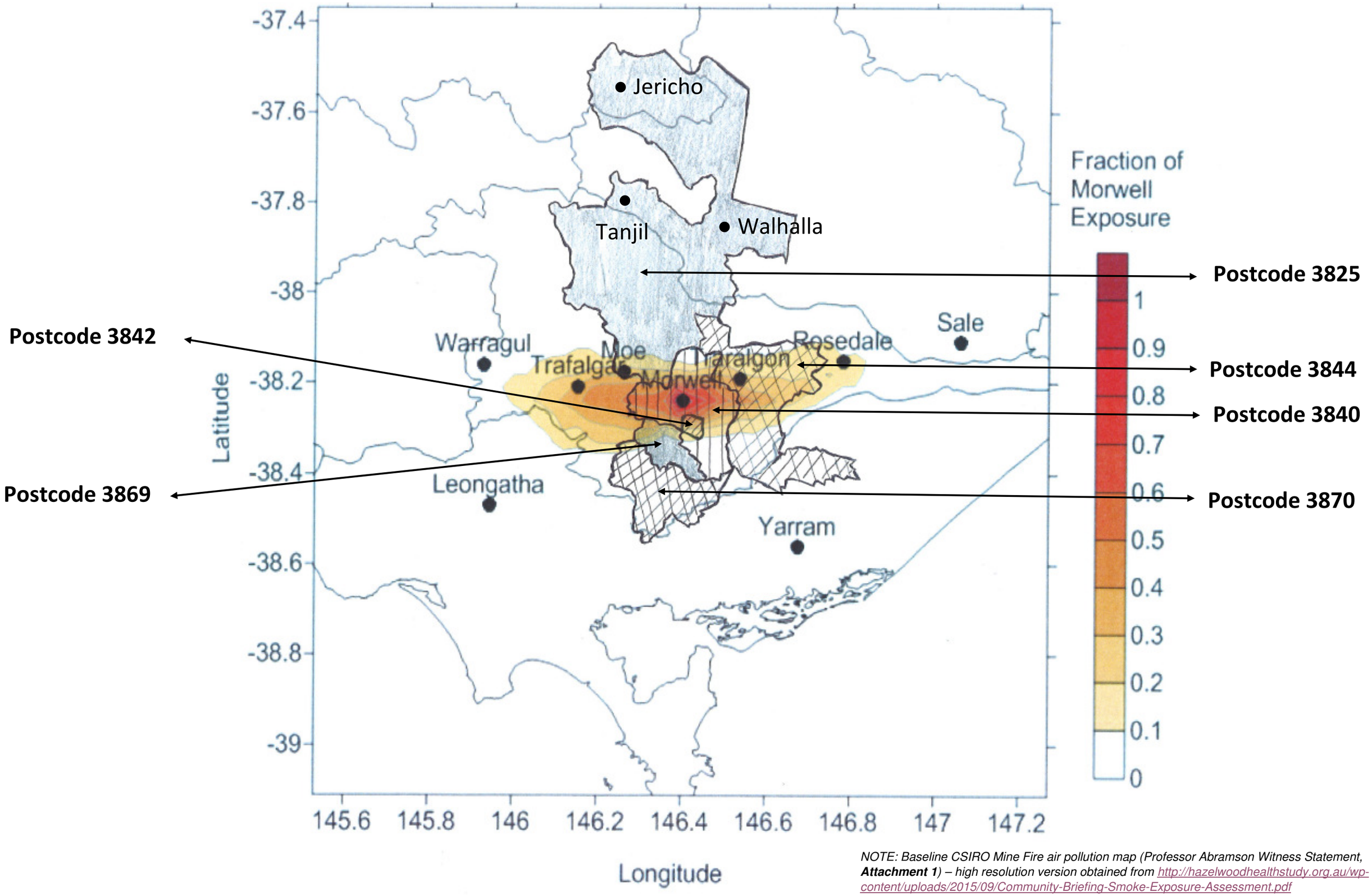


Figure 4.31 adapted from an EPA graph shows validated data (solid line) and indicative data plotted retrospectively (dotted line) for daily averages of PM_{10} in Morwell and Traralgon from 9 February 2014 to 31 March 2014. The Victorian standard for PM_{10} is 50 µg/m^3 averaged over one day. This standard is indicated on Figure 4.31 by the red line.

The EPA prioritised monitoring carbon monoxide and $PM_{2.5}$ during the mine fire, as these are of most concern to human health.[52] This explains why validated data for PM_{10} was not monitored at the Morwell Bowling Club (South) until around 27 February 2014.

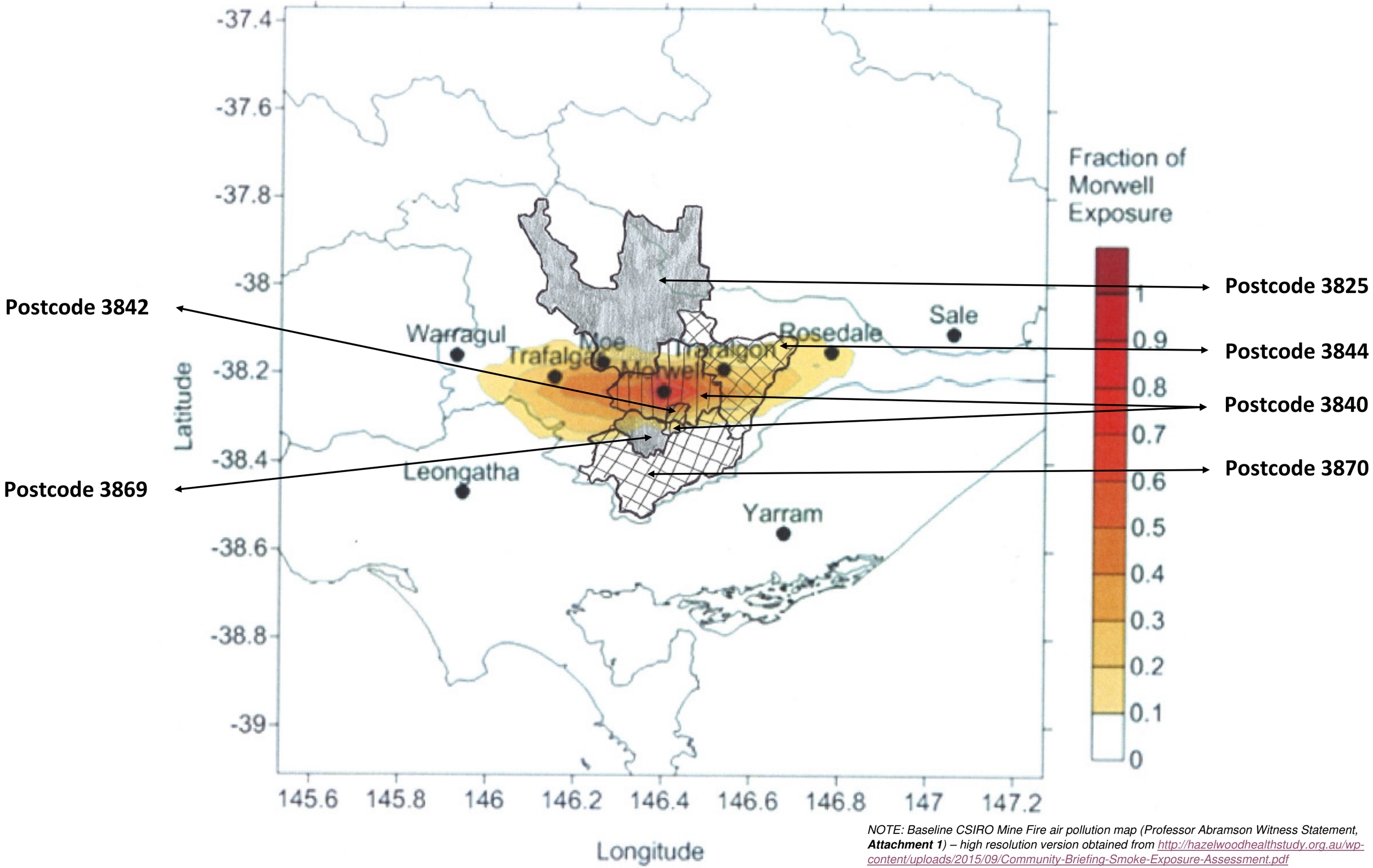
The highest indicative recording of PM_{10} in Figure 4.31 is just below 1,600 µg/m^3 (on around 15–16 February 2014). This is approximately 30 times the National Ambient Air Quality standard.

Hazelwood Mine Fire Inquiry
CSIRO Mine Fire air pollution modelling overlaid with postcode areas
Postcode boundaries determined in reference to municipal suburb boundaries



*NOTE: Baseline CSIRO Mine Fire air pollution map (Professor Abramson Witness Statement, **Attachment 1**) – high resolution version obtained from http://hazelwoodhealthstudy.org.au/wp-content/uploads/2015/09/Community-Briefing-Smoke-Exposure-Assessment.pdf*

Hazelwood Mine Fire Inquiry
CSIRO Mine Fire air pollution modelling overlaid with postcode areas
Postcode boundaries determined in reference to Australian Statistical Geography Standard (ASGS) boundaries



*NOTE: Baseline CSIRO Mine Fire air pollution map (Professor Abramson Witness Statement, **Attachment 1**) – high resolution version obtained from http://hazelwoodhealthstudy.org.au/wp-content/uploads/2015/09/Community-Briefing-Smoke-Exposure-Assessment.pdf*

McCloud Consulting Group
International Biostatistics & Data Management Specialists

Dr. Philip McCloud
[redacted]

13th October 2015

Emily Heffernan
Senior Associate
King & Wood Mallesons
[redacted]

Dear Emily,

I refer to your letter dated the 6th of October 2015 in which you requested I provide comments and observations on the enclosed expert material. I also refer to your subsequent emails dated the 8th, 9th, 10th, and 13th of October 2015.

In sundry fields of application such medical science, clinical trials, public health, and time series of death statistics the task of understanding causality is clouded because of random variation. It is well understood that unexpected peaks or troughs in time series of data are often the result of random variation.

In a number of the expert reports provided (Materials 1-12 below) the authors have noted an increase in the number of deaths during the period of the mine fire in 2014 compared to the same period for previous years, such as 2009-2013. The analyses have been based on the death statistics of 4 or more postcodes that were in the vicinity of the mine fire. The increase in the number of deaths has been shown to be of borderline statistical significance from both the frequentist and Bayesian perspective. However such an increase in the number of deaths during the period of the mine fire in 2014 compared to previous years does not prove that the pollution from the mine fire was the cause of the increase. The increase may result from changing demographic characteristics of the region, such as an aging or growing population, or it may simply be the result random variation.

I would like to make the following points.

Point 1

The absence of direct evidence such as deaths certificates that report death was caused by smoke, carbon monoxide, or other pollutants emanating from the mine fire weakens any claim that the mine fire caused an increase in deaths. I would like to offer 2 examples where such direct evidence is utilised.

1. In clinical trials that compare the safety of a new treatment to a standard treatment investigators will collect details of the adverse events that occur during the study. If a statistical analysis demonstrates an excess of adverse events in the new treatment compared to the standard treatment then the investigators or health authorities can

examine the specific reported adverse events in detail in order to assess if the increase was related to the new treatment.

2. During the influenza season an increase in the number of deaths during epidemics is often noted. However these raw numbers are supported by the death certificates reporting that the patient has died from complications arising from influenza.

It is this detailed medical assessment of the deaths during the period of the mine fire that is lacking from the current analysis. In my opinion the numbers alone are not adequate to justify a conclusion that the pollution from the mine fire caused the increase in deaths compared to previous years. A necessary additional step should be a medical assessment that attributes specific deaths to have been caused by the pollution of the mine fire.

Point 2

One of the strong indicators of cause and effect is the presence of a dose-response relationship, namely that as the dose of a stimuli is increased the response should increase. In the case of the mine fire a dose-response relationship would be in evidence if the increase in deaths during the period of the mine fire in 2014 compared to previous years was greatest in those regions that experienced the greatest impact from mine fire pollution.

The 4 postcodes included in nearly all analyses contained the towns of Morwell, Churchill, Moe, and Traralgon. Because of its relatively close proximity to the mine, Morwell would have been expected to have experienced the greatest impact from mine fire pollution. Therefore the presence of a dose-response relationship would be established if the greatest increase in deaths occurred in Morwell. In fact the opposite occurred.

Emeritus Professor Bruce Armstrong calculated that the rate ratio of deaths in 2009-13 compared to 2014 was 0.80 (95% CI: 0.51, 1.26, P = 0.34) for Morwell, and 1.36 (95% CI: 1.07, 1.71, P = 0.01) for Churchill, Moe, and Traralgon (Page 5, Table 1).

Emeritus Professor Bruce Armstrong commented (page 5, last paragraph),

"These results suggest that mortality rate ratios in Morwell in 2014 were different from those in Churchill, Moe and Traralgon. For each period, the ratio of the rate ratios (Morwell compared with Churchill, Moe and Traralgon) can be estimated, giving 0.59 (=0.80/1.36) *(95% CI 0.35-0.98) for the February-March comparisons and 0.86* (=1.05/1.22) *(95% CI 0.63-1.17) for the February-June comparisons[5]. That the upper bound of the 95% CI of the February-March comparison is very close to 1 and that the 95% CI of the February-June comparison includes 1 indicates that statistical evidence for this difference is quite weak."* Note the correction of 0.80 to 0.59.

The estimated ratio of rate ratios for the February-March period of 0.59 with a 95% CI: 0.35, 0.98 is significantly less than 1.0, because the 95% CI does not contain 1.0. Therefore the decrease in the rate of deaths in Morwell in 2014 compared to 2009-2013 was significantly less than the increase in the rate of deaths in Churchill, Moe, and Traralgon for the same period. In fact, for February-March, the most intense period of the mine fire, the estimated rate ratio of 0.80 in Morwell was 41% less than the estimated rate ratio of 1.36 for Churchill, Moe, and Traralgon. This result is diametrically opposed to the required dose-response relationship if mine fire pollution caused the increase in

deaths. The greatest impact of mine fire pollution was probably in Morwell rather than Churchill, Moe, and Traralgon, therefore, we would have expected the rate ratio in Morwell to be greater than the rate ratio of Churchill, Morwell, and Traralgon not less. The failure to demonstrate a dose – response relationship is a weakness in the claim that the increase in deaths during the period of the mine fire in 2014 compared to previous years was caused by the mine fire pollution.

Point 3

The Final Rapid Health Assessment Report of Professor Michael Abramson et al modelled the relationship between the exposure of residents to the air pollution during the time of the mine fire, and the expected increase in deaths. The report of Professor Abramson goes beyond the simple assessment of the observed number of deaths to consider the expected number of deaths given the exposure. The expected number of deaths was estimated with an epidemiological model.

Prof Abramson at el (pg 5, 2014) wrote,

"Based on these findings about the types of health outcomes related to air pollutants, epidemiological modelling undertaken as part of this review found that for combined $PM_{2.5}$ exposures around 250 µg/m^3 in Morwell South and for exposures around the National Environment Protection Measure {NEPM) in the rest of Morwell, no additional deaths would be expected even if the exposure continues for 6 weeks. However, if this level of exposure had persisted for 3 months this level of $PM_{2.5}$ might be expected to result in some additional deaths from IHD {0.5 additional deaths), Stroke {0.2), COPD {0.1), Lung Cancer {0.1) and Acute Lower Respiratory Infection {ALRI) {0.2)."

Professor Abramson et al have estimated no additional deaths if the exposure from the mine fire continued for 6 weeks, and 1.1 additional deaths if the mine fire continued for 3 months; both of these figures are much less than the 23 increased deaths estimated from the latest analysis of Associate Professor Barnett (dated 25 September 2015).

Point 4

Associate Professor Barnett has described a new analysis based on the number of *"daily deaths from 1 January 2009 to 31 December 2014, which is 2191 days. The deaths were split by four postcodes (3840-Morwell, 3842-Churchill, 3825-Moe, 3844-Traralgon) according to usual place of residence. There were 3,414 deaths in total."*

In designing scientific studies one method to control for systematic bias is the selection of the control group. In earlier analyses of the Hazelwood mine fire the analysts generally used the period of the mine fire (February-March) from previous years 2009-2013 as the control group. In my opinion restricting the control group to the period of the mine fire may well provide a better control group than using all days of the year.

The control group restricted to the period of the mine fire excludes those days of the year not in the period of the mine fire, and therefore excludes many potential confounders associated with the autumn, winter, and spring months of the year. It can be difficult to model satisfactorily all such potential confounders with a statistical model. In the report dated 25th September 2015 Associate Professor Barnett commented that,

"This latest analyses gives a 99% probability of an increase in deaths during the 45 days of the fire, with an estimated 23 additional deaths."

However, the 23 additional deaths is compared to the expected number of deaths based on the statistical model of deaths across the over 2,100 days in the control group. If the statistical model does not adequately account for all the potential confounders then the estimate of 23 additional deaths may be called into question.

In correspondence between Emeritus Professor Bruce Armstrong and Justine Stansen, Emeritus Professor Bruce Armstrong made a similar point when he commented,

"Barnett now describes how the numbers of additional deaths due to the fire in each postcode were calculated. This explanation, however, is not clear to me. There are two variables in the expression that Barnett offers on page 2, 4th line up from the bottom of the page:

1. *The mean number of deaths per day for each postcode. The period over which this average has been calculated is not stated; It should be. As I see it, the period should (a) be relatively recent so that it can provide a reasonably unbiased estimate of the expected number of deaths in the four postcode areas over the period of the fire, (b) not include the observed deaths during the period of the mine fire and (c) be based on a period long enough to remove most of the effect of day to day variation in daily numbers on the calculated mean numbers. All these may be true, but it is not clear that they are.*

2. *Exp (α_{20}), the relative risk of death during the fire. As far as I can tell this is the relative risk across all four postcodes. If this is true, postcode specific relative risks have not been used when estimating the excess deaths and, therefore, previously apparent variation between postcodes in relative risk of death during the period of the mine fire is not taken into account when calculating the numbers of excess deaths. If this is correct, a deficit of deaths in Morwell during the period of the mine fire would be obscured in this analysis."*

In my opinion the better control group for estimating the increased number of deaths in 2014 compared earlier years is that restricted to the period of the mine fire rather than using all days of the year.

Point 5

In correspondence on the 10th of October Emily Heffernan provided a summary of the deaths recorded by Births Deaths & Marriages for the period 9 February – 25 March for the years 2014, and 2015 for the postcodes most impacted by the mine including postcodes 3840, 3842, 3825, and 3844 which have been included in nearly all analyses. The numbers are summarised below. The data show that for the 4 most analysed postcodes the number of deaths for the period of the mine fire for 2015 (77 deaths) was similar to the number of deaths for 2014 (83 deaths), which is a difference of only 6 deaths. Therefore for the period of the mine fire the number of deaths in 2015 would also be high relative to the years 2009-2013. However, the increase in deaths in 2015 relative to the years of 2009-2013 cannot be explained by the impact of pollution from a mine fire. Therefore the increase in the number of deaths in 2015 relative to the years of 2009-2013 must be the result of demographic changes in the region such as an aging or growing population, or the result of random

variation. Both the demographic changes in the region, and random variation are likely explanations for the increase in deaths in 2014 relative to the previous years of 2009-2013.

Hazelwood Mine Fire Inquiry - Term of Reference 6

Summary of deaths recorded by Births Deaths & Marriages in the period 9 February – 25 March (Postcode of Usual Place of Residence)

	Year	
Postcode	**2014**	**2015**
3840	18	22
3842	6	6
3825	32	29
3844	27	20
4 postcode total	83	77
3869	0	3
3870	0	1
6 postcode total	83	81
3854	1	0
3856	2	0
8 postcode total	86	81

Point 6

Associate Professor Adrian Barnett reported an analysis of the number of deaths during the mine fire compared to other months and previous years in September 2014. I would like to make the following observations. All the parameters included in the statistical model are appropriate, and on face value may play a role in predicting the number of deaths in each year, month, and postcode. However the credible intervals of all risk ratios except Intercept, and Postcode include one (Tables 1 and 2). Therefore we do not have strong evidence that the parameters: Trend, Season cos, Season sin, and Fire have a strong impact on the predicted number of deaths. In particular, the estimate of the Fire risk ratio was 1.14 with a credible interval of (0.92, 1.41) (Table 1), which includes the possibility that the effect of the Fire was "negative" so that less people died during the period of the fire than the average. In the analysis that included Temperature (Table 2), the estimate of the Fire risk ratio was 1.11 with a credibility interval of (0.87, 1.37), which again includes the possibility that the effect of the Fire was "negative" so that less people died during the period of the fire than the average. The common scientific thinking is that a parameter is important or significant if the credible interval or confidence interval does not contain one or zero depending on the key statistic. The relevance of the model is called into question because most of the parameter estimates are not significant.

I hope that the discussion above will be of assistance.

Yours sincerely,

Philip McCloud, PhD, AStat

Statistical reports before the Board for the purposes of the hearings on Term of Reference 6 conducted on 1, 2, 3 and 9 September 2015

1. Final Report – Rapid Health Risk Assessment dated 12 March 2014. Authors: Professor Michael Abramson, Dr. Martine Dennekamp, Professor Malcolm Sim, Associate Professor Manoj Gambhir, Professor Brian Priestly, Dr. Fay Johnston, Dr. Lisa Demos, and Professor John McNeil.
2. Report of Associate Professor Barnett dated September 2014 entitled Analysis of death data during the Morwell mine fire.
3. Report of Associate Professor Barnett dated December 2014 entitled An updated analysis of death data during the Morwell mine fire.
4. Report of Emeritus Professor Bruce Armstrong dated August 2015 entitled *Expert Assessment and Advice Regarding Mortality information as it relates to the Hazelwood Mine Fire lnquiry Terms of Reference - Final Report.*
5. Report of Professor lan Gordon dated 11 August 2015 entitled *Commentary on the Hazelwood Mine Fire and Possible Contribution to Deaths*.
6. Report of Dr Louisa Flander and others dated 28 April 2015 entitled Review of "*Analysis of death data during the Morwell mine fire*," A. Barnett, working paper, unpublished (2014, Queensland University of Technology) and "*An updated analysis of death data during the Morwell mine fire*," A. Barnett, working paper, unpublished (2015, Queensland University of Technology)"
7. Report of Dr Louisa Flander and others dated 4 June 2015 entitled Age-Standardised Mortality and Cause of Death in the Latrobe Valley at the Time of (and Five Years Prior to) the Hazelwood Coal Mine Fire in Morwell, Victoria.
8. Joint Report of Emeritus Professor Bruce Armstrong, Associate Professor Adrian Barnett, Professor lan Gordon and Dr Louisa Flander dated 31 August 2015, entitled "*Consultations relating to Term of Reference 6: Whether the Hazelwood Mine Coal Mine Fire contributed to an increase in deaths, heaving regard to any relevant evidence for the period 2009 to 2014*."
9. Report of Associate Professor Barnett dated 25 September 2015 entitled *Analysis of daily death data during the Hazelwood mine fire.*
10. Email of Emeritus Professor Bruce Armstrong dated 18 September 2015.
11. Report of Associate Professor Barnett dated 25 September 2015 entitled *Analysis of daily death data during the Hazelwood mine fire*.
12. Report of Associate Professor Barnett dated 7 October 2015 entitled *Analysis of daily death data during the Hazelwood mine fire*.

McCloud Consulting Group
International Biostatistics & Data Management Specialists

Dr. Philip McCloud
[redacted]

14th October 2015

Emily Heffernan
Senior Associate
King & Wood Mallesons
[redacted]

Dear Emily,

I refer to my letter dated the 13th of October, in which I made comments regarding the control group for comparison to the mine fire period (Point 4), and comments regarding the September 2014 analysis of Associate Professor Adrian Barnett (point 6). I would like to provide the following additional comments regarding the recent analysis of Associate Professor Barnett dated the 25th of September 2015, and dated the 7th of October 2015.

Associate Professor Barnett has described a new analysis based on the number of *"daily deaths from 1 January 2009 to 31 December 2014, which is 2,191 days. The deaths were split by four postcodes (3840-Morwell, 3842-Churchill, 3825-Moe, 3844-Traralgon) according to usual place of residence. There were 3,414 deaths in total." (Report dated 25 September 2015).*

Associate Professor Barnett commented that,

"Table 1 shows a higher mean number of daily deaths in all four postcodes during the period of the fire compared with all other times. These crude figures do not adjust for the seasonal pattern in deaths or changes over time in population size, and the regression model below should give a truer picture of any increase in death rates."

The final comment that the regression model should *"give a truer picture of any increase in death rates"* depends on whether the statistical model for the number of daily deaths spread over 2,191 days adequately captures all sources of systematic variation. If the statistical model fails in this regard then the estimate of 23 additional observed deaths compared to the expected number of deaths based on the statistical model maybe unreliable.

The statistical model contained terms for the following:

- trend over time
- season using sinusoidal functions cosine and sine
- day of the week
- maximum temperature modelled with a spline, and
- the fire period

The parameter estimates and 95% credible intervals (Table 1, Barnett Report dated 7 October 2015) show that:

- Only 1 of 2 trend effects was significantly different from zero
- The postcode effects were significantly different from zero, which reflects the different number of deaths between the postcodes
- The seasonal effects of cosine and sine were not significantly different from zero
- The effects for days of the week were not significantly different from zero, and
- 7 of the 9 parameters associated with the splines for maximum temperature were not significantly different from zero.

Therefore very few of the parameters in the statistical model demonstrate a significant effect with the number of daily deaths, and most could be removed from the statistical model without impacting the expected number of deaths per day. Therefore there is either no association between the time or temperature variables included in the statistical model or the analysis lacks power. One reason for this lack of power may be the result of dividing the 3,414 deaths across the 8,764 days of observation, which equates to 2,191 days of observations multiplied by 4 for the postcodes. This equates to an average of 0.39 deaths per day of observation, so that many days within the postcodes will record either: 0, or 1 death. The absence of a significant effect for the parameters in the statistical model and the number of daily deaths may result from these many small frequencies.

In particular the non-significant parameter estimates for the seasonal components, cosine and sine, may mean that any increase in deaths associated with the summer months is being under estimated by the statistical model. For example, the number of deaths from the period of the mine fire (February-March) for the years 2009-2013 will have relatively little impact on the statistical model compared to the other roughly 1,600 days over this 5 year period. Therefore if the number of deaths from the February-March period is relatively high compared to the remainder of the year the new statistical model may under estimate the number of deaths for the February-March period. The nett effect would be to over-estimate the true difference between the number of observed deaths and the number of expected deaths based on the statistical model.

Associate Professor Adrian Barnett commented that,

"The mean estimated number of extra deaths during the fire over the four postcodes is 23 (95% credible interval: 2 to 46)." (Page 6, report dated 25 September 2015)

I would just make the observation that the 95% credible interval is relatively wide. The upper limit of 46 deaths is double the point estimate of 23, and the lower limit is close to zero. The wide 95% credible interval means that there is considerable uncertainty about the point estimate of 23 observed deaths.

In Point 6 of my letter dated 13 October 2015, I noted that the parameter *"estimate of the Fire risk ratio was 1.14 with a credible interval of (0.92, 1.41) (Table 1), which includes the possibility that the effect of the Fire was "negative" so that less people died during the period of the fire than the average."* In the analysis of Associate Professor Barnett dated 25 September 2015 of daily death data the estimate of the Fire risk ratio was 1.324 with a 95% credible interval of (1.034, 1.656),

which does not include 1.0. However, the credible interval is relatively wide, so that considerable uncertainty remains about the point estimate for the risk ratio.

I hope that the discussion above will be of assistance.

Yours sincerely,

Philip McCloud, PhD, AStat

Curriculum Vitae for Philip McCloud
Principal Statistician

Tertiary Education/Qualifications

- B.A. (Hons) in Mathematical Statistics with 1st Class Honours, Flinders University, 1972 – 1975
- Diploma of Computer Science, The University of Adelaide, 1976 – 77
- Ph.D. Flinders University, Title: "Some Log-Linear Models For The Analysis Of Categorical Repeated Measurements", 1983-1987

Employment History

Director and Principal Statistician **Oct 2010 –Current**
McCloud Consulting Group

- August 2015: MCG employed 12 people
- Over 50 clients in Australia, US, Asia and Europe across several therapeutic areas including oncology.

Site Head of Pharma Development, **1997 – 2010**
Roche Products Pty Ltd

Asia-Pacific Head of Biometrics/Biostatistics **1997 – 2010**
Roche Products Pty Ltd

- Commence and build the Biometrics Department in Sydney.
- Reported to the Global Head of Biometrics.
- Influential in growth of Biometrics from 1 individual in 1997 to 70 in 2006.
- Management of approximately 20 clinical trials at any one time.
- Development of Pegasys in hepatitis B, Xeloda in metastatic gastric cancer, and Herceptin in metastatic gastric cancer.

Responsibilities

- To manage the department to provide a quality and timely biometrics service.
- To liaise with Global Biometrics to secure the necessary project work and resources.
- To liaise with Global Biometrics to ensure the consistency of processes and systems across the Global Development Sites.
- To manage the budget of the department.
- To ensure that all members are trained in GCP, and are qualified and trained to do their jobs.
- To provide statistical expertise in the design, conduct, and analysis of data, in particular clinical trial data.
- To provide opportunities for staff to develop their expertise.
- To hire staff as needed.

Major Achievements at Roche

- The establishment and management of the Biometrics department in Sydney from one in 1997 to 70 people in 2006.
- Proven ability to lead a team to produce excellent results.
- Member of the Medicines Australia (then APMA) Weighted Average Monthly Treatment Cost (WAMTC) working group.
- Proven ability to successfully collaborate with people of different cultural backgrounds.
- Project Statistician for the Regional Study Program.
- Skilful ability to argue in a cogent and credible manner at the industry level. (I.e. Medicines Australia, FDA.)
- Demonstrated ability to work with industry providers in an innovative and creative way.
- Develop use of IVRS in Australia.
- Created an Asia-Pacific Regional Clinical Trial program.

- Initiated the registration for Xeloda in Metastatic gastric cancer in Switzerland.
- Demonstrated ability to communicate with upper management.
- Close liaison with Regulatory colleagues in preparation of new drug applications and addressing health authority questions.
- Represented Medicines Australia at PBPA and PBB MEETINGS.
- Assist Sales and Marketing Teams in the interpretation of data.
- Excellent rapport with investigators.

Lecturer / Senior Lecturer **1989 – 1997**
Director of the Monash University Statistical Consulting Service
Monash University

- Lecturer Department of Mathematics at Monash University.
- Supervisor of Honours, Masters and PhD Students.
- Director of the Monash University Statistical Consulting Service (MUSCS)
- Trainer of new graduates in the MUSCS.
- Grew the MUSCS from 1989 to 1997 from $5000 to $400,000 pa.

Senior Biometrician **1975 – 1989**
South Australian Department of Agriculture

- Worked across many fields of application
  - Agronomy
  - Fisheries
  - Livestock
  - Plant Pathology
  - Poultry
  - Veterinary
  - Viticulture
  - Zoology
- Applied many statistical methods
  - Generalised Linear Models
  - Categorical data analysis
  - Analysis of repeated measurements
  - Analysis of (Co) Variance

Philip McCloud
Director