KPMG

Australian Radiation Protection and Nuclear Safety Agency

Independent review of Yttrium-90 contamination on 3 September 2007

Date: 19 June 2012
This report contains 23 pages

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1 Executive summary

1.1 Background

In February 2011 the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) sought the assistance of the Department of Health and Ageing (DoHA) to undertake an investigation into ARPANSA's handling of a number of contamination incidents which occurred in 2007 and 2008 at the Australian Nuclear Science and Technology Organisation's (ANSTO) radiopharmaceuticals production facility in Lucas Heights, NSW. The DoHA investigation concluded that further examination was required of an allegation made by [redacted] a former ANSTO employee, regarding a contamination incident on the morning of 3 September 2007.

In October 2011, ARPANSA engaged KPMG Forensic (KPMG) to conduct an independent review of [redacted] allegation and to comment on its handling of the contamination incidents. The review, which was completed on 19 June 2012, required KPMG to examine documents provided by ARPANSA and ANSTO, conduct meetings with ANSTO senior management, interview current and former ANSTO personnel, and conduct a site visit of ANSTO's production facilities at Lucas Heights.

1.2 Key findings of the review

Based on the scope of our review, as set out in Section 3, we make the following findings with respect to [redacted] allegations of a Y-90 contamination on the morning of 3 September 2007:

- The recollection of events by existing and former ANSTO employees is imprecise at best. It is apparent that many of the witnesses had difficulty discerning between the alleged and reported contamination events that occurred on 3 September 2007, and other minor contamination events around the same period.
- On the four occasions that [redacted] has provided his recollection of events on the morning of 3 September 2007 (i.e. in two interviews, an email to ARPANSA and a written submission to DoHA) his recollection has been largely consistent.
- KPMG and ARPANSA interviews with [redacted] one of the individuals allegedly contaminated with Y-90 on the morning of 3 September 2007, revealed considerable inconsistencies between his recollection of events, ANSTO records and the recollection of other witnesses. This establishes doubts as to his reliability as a witness.
- The recollection of events by [redacted] another of the individuals allegedly contaminated, suggested he had difficulty discerning between the alleged and reported contamination events that occurred on 3 September 2007. However, he consistently stated, both to ARPANSA Inspectors and KPMG, that [redacted] was contaminated sometime on 3 September 2007. [redacted] also appeared to have a strong recollection that he, [redacted] and [redacted] were contaminated as a result of his handling of a Y-90 batch, as he moved it by hand between the glove box service port and the autoclave.
- On examination of records and consideration of interviews, we find it likely that [redacted] was contaminated during the autoclaving of the first run of the first Y-90

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batch, at approximately 9:00am on 3 September 2007. We note this would therefore be consistent with [redacted] allegation of encountering [redacted] and [redacted] at the barrier at approximately 9:40am with contamination on their clothing, and on [redacted] face. It would also be consistent with [redacted] response at 10:48am to a report of contamination on the floor around the Y-90 production glove box.

- In summary, we find it possible that the version of events in [redacted] allegations did occur.

Based on the scope of our review, as set out on Section 3, we make the following findings with respect to ARPANSA's handling of [redacted] allegations and the events of 3 September 2007 associated with Y-90 contamination:

- Neither the interim nor the final Inspections Reports sufficiently examined [redacted] allegations that a contamination incident involving [redacted] and [redacted] occurred during the morning of 3 September 2007.

1.3 Warranties and Disclaimers

We refer to the warranties and disclaimers in Section 8 of this report.

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2 Background to the review

2.1 Legislative context

The production of radioisotopes for medical and industrial purposes is regulated in Australia by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). ARPANSA is a Commonwealth Government agency charged under the *Australian Radiation Protection and Nuclear Safety Act 1998* (ARPANS Act) with protecting the health and safety of people and the environment from the harmful effects of radiation. ARPANSA uses its licensing powers and works with Commonwealth entities such as the Australian Nuclear Science and Technology Organisation (ANSTO) to ensure the safety of the radiation facilities and sources operated and controlled by licence holders. ARPANSA has the power to inspect and make determinations under Part 7 of the ARPANS Act. Determinations can have consequences for the status of the licence holder.

ANSTO, through ANSTO Radiopharmaceuticals and Industrials (ARI) (now ANSTO Health), manufactures a number of radioisotopes which are used for medical and other purposes in its Building 23A (B23A) Production Facility at Lucas Heights. One of the radioisotopes manufactured is yttrium-90 (Y-90). Y-90 is a beta emitter primarily used in the treatment of liver cancer. ANSTO is an ARPANSA licence holder and is regulated by ARPANSA.

One of the requirements placed upon ANSTO as a condition of holding an ARPANS licence is to report incidents which are rated or have the potential to be rated as Level 2 on the International and Radiological Event Scale. ARPANSA may then inspect the matter.

A relevant Level 2 Event includes:

- People and environment:
  - Exposure of a member of the public in excess of 10mSv; and
  - Exposure of a worker in excess of the statutory annual limits (500mSv).
- Radiological barriers and control:
  - Radiation levels in an operating area of more than 50mSv/hour; and
  - Significant contamination within the facility to an area not expected by design.

Events that would be rated as a level 1 or level 0 are not required to be reported to ARPANSA though ANSTO would ordinarily internally record, and where necessary, investigate these incidents.

2.2 Summary of events

On 3 September 2007, during routine radiopharmaceutical production operations in B23A, two personal contamination events were reported and responded to in accordance with ANSTO's internal procedures. The first event involved [redacted] and [redacted] who identified Y-90 contamination during routine monitoring at the B23A barrier at approximately 1:24pm. The second event involved [redacted] who was detected with Y-90 contamination a second time at approximately 2:37pm.

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ANSTO subsequently investigated the causes of the two separate contamination events in accordance with internal procedures. The events were recorded in the ANSTO Business Management System on 4 March 2008.

On 17 June 2009 ARPANSA conducted an unannounced inspection to obtain information about safety issues raised by ANSTO staff during an inspection on 10 June 2009. In the course of the 17 June 2009 inspection the then ANSTO [redacted] raised concerns regarding the Y-90 events of 3 September 2007 and an event relating to molybdenum 99 (Mo-99) production on 28 August 2008.

Between 25 January and 23 February 2010, in response to [redacted] allegations, ARPANSA Inspectors [redacted] and [redacted] conducted a series of inspections in regards to alleged and reported contamination events on 3 September 2007. The inspections consisted of a site visit to B23A, twelve interviews with ANSTO staff and a review of numerous ANSTO records.

On 8 February 2010, during an interview as part of the inspections, [redacted] made specific allegations that ANSTO staff [redacted] and [redacted] were contaminated with Y-90 on the morning of 3 September 2007.

A preliminary inspection report was completed by ARPANSA Inspectors on 28 May 2010. The report concluded, amongst other things, that:

- After interviews with ANSTO staff and a review of ANSTO records, the Inspectors were not able to piece together the full events of the day.
- While statements from two ANSTO staff suggest that [redacted] was contaminated, there was no substantive evidence to support those claims.
- Contrary to these statements, the balance of statements from other staff suggest [redacted] was not contaminated.
- [redacted] and [redacted] were detected with Y-90 contamination on their personal protective equipment at approximately 13:00 hrs.
- [redacted] was detected with Y-90 contamination on his face at approximately 2:37pm.
- The contamination incidents were most likely caused by escape of materials through the service port of the 'glove box' used to manufacture Y-90, not through a pinhole in the glove as the internal ANSTO review had found.

On 18 May 2010, ARPANSA provided ANSTO with a copy of the preliminary inspection report, in order to provide any corrections to factual errors for consideration by ARPANSA. As the basis of the complaints related to information supplied in interviews with certain ANSTO staff, ANSTO was also supplied with the transcripts of interviews.

On 2 July 2010 ANSTO provided ARPANSA with a report consisting of general comments on the preliminary inspection report, a timeline of events and a summary of improvements made to the Y-90 production process. The following comments were made in the report:

- The transcript of interview given by [redacted] contained many factual errors including the timing of events when compared with records of building access and production.
- The interview reflected [redacted] prejudice towards [redacted]

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- ANSTO supported the Inspector's decision to place little weight on [redacted] allegations, which appeared to be personally targeted at [redacted] and [redacted]

On 10 July 2010, [redacted] emailed [redacted] at ARPANSA, expressing his concerns with regards to the accuracy of ARPANSA's preliminary inspection report, and that information he provided in the course of the inspection had been misunderstood and/or misinterpreted. The email provided a version of events on the morning of 3 September 2007, which is largely consistent with the version provided by [redacted] in his interview with ARPANSA inspectors on 8 February 2008.

On 10 September 2010, ARPANSA issued ANSTO with a final inspection report. The report took into account all comments and additional information provided by ANSTO on 2 July 2010.

On 20 February 2011, [redacted] emailed the CEO of ARPANSA, Dr Carl-Magnus Larsson, alleging a lack of impartiality on the part of ARPANSA owing to a 'close family relationship' between a member of ARPANSA management and a member of ANSTO management. This email further requested additional scrutiny to be placed upon all investigative reports overseen by the ARPANSA employee in question.

On 23 February 2011, the CEO of ARPANSA sought assistance from the Department of Health and Ageing (DoHA) to undertake an investigation into the handling of the radioactive contamination incidents of ANSTO employees relating to Y-90 in September 2007 and Mo-99 in August 2008.

On 20 April 2011, in the course of the DoHA investigation [redacted] provided the chief investigator, [redacted] with a written statement consisting of [redacted] version of events on the morning of 3 September 2007. The statement was signed by [redacted] on 15 October 2010, as an adoption of [redacted] version of events. The version of events in the statement is largely consistent with the version provided by [redacted] in his interview with ARPANSA inspectors on 8 February 2008, and in his email to [redacted] on 10 July 2010.

On 10 June 2011 the DoHA investigation concluded, amongst other things, that the allegations made by [redacted] regarding a reportable incident involving [redacted] and [redacted] on the morning of 3 September 2007 had not been adequately tested. Accordingly, DoHA recommended that an independent reviewer be engaged to re-investigate this allegation. That recommendation resulted in KPMG being engaged by ARPANSA as the independent reviewer.

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3 Scope and objective of our work

The objective of our work, as documented in our engagement letter signed by ARPANSA on 21 October 2011, is to provide ARPANSA with an independent report into its handling of the contamination incidents which occurred at ANSTO on 3 September 2007. The purpose of this report is to provide ARPANSA with our understanding of any contamination incident(s) that might have occurred on the morning of 3 September 2007, based on the scope of worked outlined below.

The scope of our review included the following:

- Discussions with the independent ARPANSA Inspector, [redacted] to obtain his understanding of the incident and the recommendations made;
- A review of ANSTO supplied documents and records compiled by ARPANSA to determine the sufficiency of this documentation and the location of necessary outstanding records (both physical and electronic), which were acquired in an independent and forensically sound manner. This included outstanding ANSTO swipe access records of 3 September 2007 for relevant ANSTO employees, and outstanding Therapeutic Goods Administration (TGA) batch records for Building 23A radiopharmaceutical production processes;
- A review of all relevant ARPANSA supplied documentation, including previously documented information such as ARPANSA inspection reports, ARPANSA's transcripts of interviews with ANSTO employees, and the allegations and information supplied to the DoHA review;
- A site visit of ANSTO – in particular B23A;
- A review of ANSTO's timeline of the contamination incidents of 3 September 2007, which was corroborated with our factual interrogation of documents, logs and other records;
- The identification of key witnesses and the conduct of preliminary interviews commencing with the whistleblower, [redacted] and key ANSTO personnel;
- Preparation of a report on our findings as to what may have happened, who was present when it happened and how accurately this was captured by the ARPANSA investigation; and
- A meeting with ARPANSA to present and discuss findings and recommendations.

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4 Abbreviations

The following terms are used throughout this report:

ANSTO – Australian Nuclear Science and Technology Organisation
ARI - ANSTO Radiopharmaceuticals and Industrials
ARPANSA - Australian Radiation Protection and Nuclear Safety Authority
ARPANS Act - *Australian Radiation Protection and Nuclear Safety Act 1998*
B23A - Building 23A Production Facility
cps – counts per second
DoHA - Department of Health and Ageing
I-123 – Iodine-123
Mo-99 - Molybdenum 99
mSv - millisieverts
TGA - Therapeutic Goods Administration
Y-90 – Yttrium 90

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5 The allegations

[redacted] presented his allegations on four separate occasions:

- On 8 February 2010 during an interview as part of ARPANSA's inspection.
- On 10 July 2010 in an email from [redacted] to [redacted]
- On 20 April 2011 in a statement produced during an interview as part of DoHA's investigation.
- On 31 January 2012 during an interview as part of KPMG's independent review.

The following is a synopsis of the allegations made on each of these occasions:

8 February 2010 interview

In this account of his allegations, [redacted] states he was approaching the barrier in B23A around morning teatime on 3 September 2007 when he encountered [redacted] and [redacted] They allegedly stated they were "covered in yttrium" and the radiation monitor at the barrier was sounding alarms when [redacted] breathed on it. [redacted] and [redacted] then went into the change room where [redacted] attempted to wash the contamination from his face and remove his contaminated clothing.

[redacted] recalled [redacted] saying "don't tell anyone, don't tell anyone", and he challenged [redacted] by saying "don't be stupid you gotta inform them, you gotta inform Health Physics".

When asked "when and what" was reported regarding the contamination, [redacted] stated that "some people started coming up to the lab...and I moved on to do my job". He further stated that [redacted] the [redacted] on duty, was quite concerned about [redacted] having contamination in his mouth, and [redacted] placed a call to [redacted] another [redacted] on duty, who attended 20 minutes later.

10 July 2010 email

In his email to [redacted] on 10 July 2010, a section titled "*First issue: exchange at the barrier*" describes [redacted] allegations. [redacted] states he was approaching the barrier in B23A around 09:00 hrs to 10:00 hrs when he overheard [redacted] and [redacted] talking about contamination being on their clothes, and [redacted] saying that contamination was also on his face. [redacted] heard the radiation monitor "screeching" at the same time.

[redacted] then observed [redacted] remove his coat and run it past the monitor, which then screeched. He also observed [redacted] hold his face a few inches from the monitor, whereby it screeched. [redacted] also blew on the monitor and it screeched again.

[redacted] then followed [redacted] and [redacted] into the change room, during which time they were talking about a "massive" Y-90 spill from the port. He stated that [redacted] appeared agitated and said to [redacted] "don't tell anyone, don't tell anyone". [redacted] eplied "don't be stupid, you have to report the incident."

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Inside the change room [redacted] began removing his clothes, and [redacted] then left the change room as he assumed [redacted] was about to have a shower.

[redacted] stated that "no one else was present at the time", with the words "no one **else**" highlighted in bold in the email.

20 April 2011 document

The document produced by [redacted] when interviewed by [redacted] on 20 April 2011 is an exact duplicate of the text provided in the section titled "*First issue: exchange at the barrier*" in [redacted] email to [redacted] on 10 July 2010. The document was signed by [redacted] as confirmation that [redacted] "did say and do, what he says he did". A sentence has been crossed out and initialled by [redacted] The sentence is: "[redacted] *had been hanging around waiting for his Iodine 123 to arrive from the NMC, which normally arrives between 9:30-10:00am depending on* ***traffic.***"

31 January 2012 interview

This account of [redacted] allegations is consistent with the two written versions above and includes additional information, specifically:

- [redacted] stated that, some time after the alleged event on the morning of 3 September 2007, he questioned [redacted] about the events and [redacted] claimed to have a poor recollection of the alleged incident. [redacted] said to [redacted] "[redacted] this is what I think happened. You were contaminated in the morning, [redacted] talked you out of reporting it then and there and when you found you were still contaminated in the afternoon that's when you reported it." [redacted] allegedly replied "That may have happened, I was very scared of him at the time." [redacted] then asked if [redacted] would sign a statement to that effect and [redacted] declined.

- When [redacted] was questioned about the attendance of [redacted] and [redacted] after the alleged morning contamination incident - which he recalled in his interview with ARPANSA Inspectors on 8 February 2010 – [redacted] clarified that he had heard about their attendance from [redacted]

Prior to the interview commencing [redacted] provided KPMG with a written submission consisting of a covering letter and a number of attachments.

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6 KPMG review

6.1 Meetings

KPMG participated in the following meetings in relation to this review:

Date	Attendees	Purpose
13 Dec 11	[redacted] ARPANSA [redacted] Operation Services; [redacted] ARPANSA [redacted] KPMG; [redacted] KPMG	• KPMG provided a Phase One progress report. • Parties agreed on the draft Investigation Plan, including interviewees, meetings, site visit and request for information.
30 Jan 12	[redacted] ANSTO Health; [redacted] Environmental and Radiological Assurance; [redacted] ANSTO Health; [redacted] ANSTO [redacted] ARPANSA [redacted] KPMG; [redacted] KPMG	• Formal meeting to discuss the scope of the review with ANSTO senior management. • [redacted] were provided with a familiarisation of manufacturing processes in B23A.
16 Feb 12	[redacted] ANSTO Health; [redacted] Environmental and Radiological Assurance; [redacted] ANSTO Health; [redacted] Radiological Assurance, ANSTO; [redacted] ANSTO Health; [redacted] ARPANSA [redacted] KPMG; [redacted] KPMG	• Provided ANSTO senior management with an update on progress with regards to the review. • [redacted] ANSTO Health, provided an overview on safety improvements since 2007. • [redacted] provided KPMG with a document titled *'Review of Alternative Hypothesis Regarding Yttrium-90 Contamination Event at ANSTO Radiopharmaceuticals and Industrials (ARI) on 3 September 2007'*

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6.2 Interviews

KPMG conducted electronically recorded interviews with the following current and former ANSTO employees in relation to this review:

Date	Interviewee	Role at ANSTO (on 3 September 2007)
31 Jan 12	[redacted]	[redacted]
15 Feb 12	[redacted]	[redacted]
15 Feb 12	[redacted]	[redacted]
15 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]
16 Feb 12	[redacted]	[redacted]

In the course of these interviews it was noted that the recollection of events by existing and former ANSTO employees was imprecise at best. It was also apparent that many of the witnesses had difficulty discerning between the various contamination events that occurred on 3 September 2007, and other minor contamination events around the same period. There is a high likelihood that individuals' personal recollection of events have been diluted through discussing the events numerous times with colleagues over the last four and a half years.

6.2.1 Synopsis of interviews

[redacted]

- Overall, [redacted] had a poor recollection of the events on 3 September 2007.
- He denied the [redacted] allegations that he and [redacted] had been contaminated in the morning, and that he had urged [redacted] not to report the contamination.
- [redacted] did not think [redacted] was making Y-90 on the day in question.
- He had a vague recollection of [redacted] and possibly [redacted] being contaminated during the day but could not say whether it was in the morning or the afternoon, or whether there had been more than one contamination incident.

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[redacted]

- [redacted] recollection of events on 3 September 2007 was not clear and his version of events became somewhat confused during the interview.
- When presented with [redacted] written statement, which he had signed on 15 October 2010, [redacted] agreed the events described in the statement would have likely occurred. However, he was not sure whether the events occurred in the morning or the afternoon. He explained that he did not read the statement carefully before signing it, and the reason he crossed out paragraph 11 was because it suggested the discussion at the barrier had occurred between 9:30am and 10:00am, and that he believed it had occurred later in the day.
- [redacted] recalled that he, [redacted] and [redacted] were contaminated "at some point, the three of us together."
- [redacted] recalled [redacted] being present at the barrier when he and [redacted] detected contamination on themselves: "He was definitely there for one of them 'cause I remember him being there.". He also recalled [redacted] being surprised when he learned that he had received contamination on his face.
- [redacted] believed he may have been contaminated by the "second batch" of Y-90 that he was not involved in producing.
- [redacted] stated he would have been contaminated by the Y-90 batch when he was asked to put it in the autoclave: "...so I had to grab the actual product and put it in. That was the only time I had contact with it, to get it on my face, otherwise I would have just had it on my shoes, like if it was on the floor or something."
- [redacted] stated he had opened up the Y-90 port and his face was close to it and "that's probably how it got contaminated...it went everywhere and [redacted] got it on his pants and [redacted] got it on his pants as well, and I had it on my pants as well."
- [redacted] stated "the whole area was contaminated not just me". He also stated that afterwards he "had to go and wipe out the whole yttrium area."
- When asked if [redacted] had challenged [redacted] regarding an urging not to report the contamination, [redacted] stated it seemed "likely or definitely possible".
- When asked if he recalled [redacted] following himself and [redacted] into the change room after the contamination, [redacted] agreed and also recalled [redacted] being present with them, but then stated "or maybe he wasn't." When it was pointed out that [redacted] was not at work that day, [redacted] stated "Okay, it might have been a different incident then. There's been a few, it's hard not to get them mixed up."
- [redacted] suggested he may have been contaminated only once on the day in question (on his clothes and face when moving the Y-90 batch into the autoclave) and that the contamination on his face was not detected when Health Physics first responded at 1:24pm because only his clothing was checked for contamination. He recalls the contamination on his face was first detected when he was crossing the barrier at 2:37pm and he put his head close to the monitor.

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[redacted]

- [redacted] recalled [redacted] telling him about the contamination which involved [redacted] and [redacted] at 1:24pm on 3 September 2007. He also recalled attending the second contamination incident involving [redacted] at approximately 2:37pm the same day.
- [redacted] assumed that [redacted] must have still had contamination on his face after the 1:24pm incident, which was then picked up at 2:37pm.
- When asked if it would be common for staff to assist with Y-90 production, even though they might be rostered to perform other duties, [redacted] stated "I wouldn't rule that out and that's ... that's common."
- When asked about the possibility of a contamination of clothes and face not being reported in 2007, [redacted] stated: "It could have happened. I can't say it wouldn't have because it wasn't as strict a reporting back then. And now with the training we've got now that may have happened. I can't rule that out."
- When further asked about the possibility of staff having a shower as a result of a contamination incident and not reporting the event, [redacted] stated: "No, that shouldn't happen because you've lost containment then...once you've lost containment and it's all over your PPE, oh, no way."

[redacted]

- [redacted] stated he was not involved with the alleged contamination incident on the morning of 3 September 2007.
- [redacted] confirmed he had attended the reported incidents on the afternoon of 3 September 2007.
- [redacted] stated that when he attended any contamination incident he would conduct a "head to toe" contamination check.
- [redacted] agreed he had made an entry on page 155 of the Health Physics Log Book, for 10:30am Monday 3 September 2007, which had been a response to a reported contamination on the floor around the Y-90 glove box. He could not recall the circumstances around why he had been asked to respond. He stated that he would normally check the benches, floor and ports around the Y-90 production are, and commented that a reading of less than 5cps was "a very good reading".
- When asked if it was possible for a significant contamination to be cleaned up using a vacuum cleaner, to a degree that gives a reading of less than 5cps, [redacted] agreed that it was possible.

[redacted]

- [redacted] confirmed he was not on site for either of the two afternoon contamination incidents involving [redacted] and [redacted]
- [redacted] explained it was good work practice for Production staff to clean up small contamination events themselves, to reduce the chance of the contamination spreading. It was advisable for staff to then call a Health Physics Surveyor to check that the contamination had been contained.

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- [redacted] confirmed that it was general practice to check around the face when responding to a contamination incident. However, he stated that there was a "potential you wouldn't see the beta if the probe's to the back of the head or the side of the head. You could miss. Plus an EP15, if that's what was used, is relatively directional."

[redacted]

- [redacted] confirmed he was on long service leave on 3 September 2007.
- [redacted] stated that in the course of a Y-90 process improvement meeting in October 2007, [redacted] raised an issue in regards to a contamination incident. [redacted] could not recall the specific details of the incident.
- After the meeting, [redacted] and [redacted] remained in the room and [redacted] became aggressive towards [redacted] accusing [redacted] of calling him a liar. [redacted] stepped between [redacted] and [redacted] to "break the interaction".
- [redacted] stated the events occurred during either the 11 October 2007 meeting or 14 October 2007 meeting. He confirmed that [redacted] recorded minutes for each meeting, which were then circulated to attendees via email.

[redacted]

- [redacted] confirmed he had attended the contamination incident involving [redacted] and [redacted] at approximately 1:24pm on 3 September 2007.
- With regards to the alleged contamination incident on the morning of 3 September 2007, when asked if it would seem out of character for [redacted] to cover up the alleged contamination incident, [redacted] stated: "I suppose it's something that could have happened because it's...like trying to save face...and I suppose at the time we weren't as big on reporting." He further stated that at the time there may have been a perception amongst staff that "if we say something we'll get in trouble."

[redacted]

- [redacted] recollection of the events of 3 September 2007 was somewhat vague. He confirmed he detected contamination on his clothing at the barrier, along with [redacted] at approximately 1:24pm. He left for the day soon after.
- He did not recall any events relating to the alleged contamination in the morning.

[redacted]

- [redacted] stated that around 10:00am on 3 September 2007 he was changing out of his 'scrubs' in the change room when [redacted] entered the change room. He asked [redacted] if he was contaminated and [redacted] replied "Bloody shut up...just be quiet [redacted]".
- [redacted] did not recall anyone else being in the change room at the time.
- [redacted] stated he left the change room before [redacted] and as he exited B23A he overheard [redacted] and [redacted] talking at the barrier [redacted] was asking [redacted]

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[redacted] to breath into the monitor, and he heard the monitor activating. He did not see either [redacted] or [redacted] before leaving.

- When it was pointed out to [redacted] that the roster for 3 September 2007 showed he was rostered off for the day, and that there were no swipe access records for him that day, [redacted] suggested checking the overtime roster. He also stated that the swipe access records can be inaccurate due to 'tailgating', and that an investigation into overtime between June 2009 and April 2010 showed inaccuracies in the swipe access records.

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6.3 Timeline of events

The following is a sequence of relevant events on 3 September 2007 identified from documentary evidence and interviews:

- On 3 September 2007 [redacted] and [redacted] were rostered on Y-90 production, with the first batch scheduled between approximately 6:30am and 10:00am, and the second batch between 12:00pm and 3:30pm. [redacted] was rostered on generator production, [redacted] was rostered on Mo-99 production and [redacted] was rostered on Iodine-123 (I-123) production.
- Because [redacted] did not arrive at B23A until 8:27am, [redacted] assisted [redacted] in Y-90 production as the second batch operator. His role was to record and sign off production entries in the Y-90 batch record (Batch Number 113593). He commenced assisting [redacted] sometime between 7:10am (when he entered B23A) and 7:20am when he initialled the completion of step 14 of the production process in the batch record.
- At 9:00am the Record of Autoclave Sterilisation indicated that the Y-90 batch was transferred from the production glove box to the autoclave. The operator initials bear a resemblance to [redacted] initials, but he did not identify the entry as his own initials when interviewed by KPMG.
- At 9:09am the Label Account Report attached to the I-123 batch record (Batch Number 113597) indicated that [redacted] commenced printing batch labels as part of the I-123 production process.
- At 9:19am [redacted] exited B23A and returned at 9:40am.
- At 9:44am [redacted] exited B23A and entered the Radiopharmaceuticals Administration building. [redacted] returned to B23A one minute later, at 9:45am.
- At 10:00am [redacted] and [redacted] exited B23A and entered the Radiopharmaceuticals Administration building. [redacted] returned to B23A at 10:20am, followed by [redacted] two minutes later.
- At 10:26am [redacted] printed the I-123 Manufacturing record for batch number 113597. It was subsequently completed.
- At 10:28am the Label Account Report attached to the I-123 batch record (Batch Number 113597) indicated that [redacted] commenced printing a second set of 2 batch labels as part of the I-123 production process.
- At 10:32am the Intermediate and Finished Good Product Label Account on the I-123 batch record showed that [redacted] produced a further 2 labels.
- Sometime after 10:45am, when the quality control TPA ion chamber measurement was completed, [redacted] re-dispensed, re-measured and re-autoclaved the quality control sample and part numbers 2 and 10 because a measuring error had resulted in the quality control sample failing the pH test. The Record of Autoclave Sterilisation indicates that the second run of Y-90 Batch Number 113593 was transferred from the production glove box to the autoclave at 11:18am. [redacted] initialled the Record of Autoclave Sterilisation Record as the operator. There are no batch records for the re-dispensing and re-measuring of the second run of Batch Number 113593.

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- At 10:48am [redacted] responded to a report of contamination on the floor around the Y-90 production glove box. He took smears which produced a reading of less than 5 counts per second (cps), which he considered "a very good reading".
- At 11:07am the I-123 batch record for Batch Number 113597 indicated that [redacted] commenced stage one of the production process, with MIBG ion chamber measurements. [redacted] stated that he would have remained in the I-123 production area until he completed stage one at approximately 1:20pm, when he again conducted MIBG measurements at the ion chamber.
- At approximately 12:30pm, step 14 of the production process in the Y-90 batch record for Batch Number 113615 indicated that [redacted] and [redacted] commenced the second Y-90 batch for the day. [redacted] was the main operator, with [redacted] as the second batch operator. It is noted that the batch sheet was not printed before 1:27pm that day.
- At 1:20pm [redacted] completed stage one of the I-123 production process, and headed to the barrier.
- At 1:24pm, [redacted] and [redacted] detected contamination on their clothing at the barrier during routine exit procedures.
- At 1:27pm [redacted] entered B23A in response to the reported contamination on [redacted] and [redacted]. He took smears which suggested possible Y-90 contamination on [redacted] trousers and [redacted] trousers and shirt.
- At 1:46pm [redacted] exited B23A and proceeded to exit the ANSTO site. He did not return.
- At 2:05pm [redacted] commenced the second part of the I-123 batch process for Batch Number 113597.
- At 2:10pm the Record of Autoclave Sterilisation indicated that Y-90 Batch Number 113593 was transferred from the production glove box to the autoclave. [redacted] initialled the Record of Autoclave Sterilisation Record as the operator.
- At 2:17pm [redacted] completed the final measurement in the ion chamber for the second part of the I-123 batch process.
- At 2:35pm [redacted] entered B23A in response to a call from [redacted] about a second contamination on the face and clothing of [redacted] The HP Log Book recorded that the isotope was determined to be a Beta emitter through use of a Series 900 mini-monitor and decontamination procedures including a shower and use of barrier cream were effected on [redacted] face, reducing the contamination from over 500cps to 5cps.
- At 2:59pm [redacted] entered B23A for the first and only time in response to a call from [redacted] He left at 3:19pm.
- At 3:19pm [redacted] exited B23A and entered the Radiopharmaceuticals Administration building. [redacted] returned to B23A at 3:41pm. [redacted] again left B23A six minutes later at 3:47pm, entering the Radiopharmaceuticals Administration building. [redacted] returned to B23A at 4:07pm.
- At 4:28pm [redacted] left for the site for the day via 38 VB08 Exit NE, twelve seconds after [redacted]

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6.4 Analysis of evidence surrounding [redacted] allegations

6.4.1 Allegations made by [redacted]

On the four occasions that [redacted] provided his recollection of events on the morning of 3 September 2007 (i.e. in two interviews, an email to ARPANSA and a written submission to DoHA) his recollection has been largely consistent. However, it is noted that the two written versions are exact duplicates.

A potential inconsistency in [redacted] recollection of events was during his interview with ARPANSA Inspectors on 8 February 2010, when he recalled the attendance of [redacted] and [redacted] after the alleged morning contamination incident. When questioned about this in his interview with KPMG on 31 January 2012, [redacted] clarified that he had heard about their attendance from [redacted] and had mistakenly assumed this was in response to the morning incident. He explained that it was not until much later that he learnt there had been two reported contamination incidents in the afternoon.

6.4.2 Evidence provided by [redacted]

When compared to the other persons interviewed as part of ARPANSA's inspections and KPMG's review, [redacted] appeared to have a very poor recollection of the events on 3 September 2007. In interviews with ARPANSA and KPMG he strongly denied [redacted] having a role in Y-90 production, even though he personally provided ARPANSA with the batch records for Y-90 production, and these records clearly showed [redacted] as the second operator assisting [redacted] on the first Y-90 batch for the day.

6.4.3 Evidence provided by [redacted]

When presented with [redacted] written statement, which he had signed on 15 October 2010, [redacted] agreed the events described in the statement would have likely occurred. He was, however, not entirely sure whether the events occurred in the morning or the afternoon.

[redacted] explained that he did not read the statement carefully before signing it, and the reason he crossed out paragraph 11 was because it suggested the discussion at the barrier had occurred between 9:30am and 10:00am, and that he believed it had occurred later in the day. This does not seem entirely plausible given the statement contains three other direct references, and one indirect reference, to the event being in the morning, and these were not identified and corrected by [redacted]

- Paragraph 1: "*It was around the morning break.*"
- Paragraph 9: "*...this incident would have been around 9-10am...*"
- Paragraph 13: "*Note the Y-90 production is generally completed by 9:30am...*"
- Paragraph 14: "*...the first occasion of* [redacted] *and* [redacted] *fully appreciating they were contaminated was mid morning at the barrier...and not in the afternoon, as the Report's timeline suggests.*"

[redacted] recalled that he, [redacted] and [redacted] were all contaminated when he was handling a Y-90 batch, which he was not involved in producing, as he moved it by hand between the glove box port and the autoclave. It should be noted that in his interview with ARPANSA Inspectors on 18 February 2010, [redacted] also recalled himself, [redacted] and [redacted] being contaminated.

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[redacted] was certain that [redacted] was present at the barrier when they detected contamination on themselves. He also believed it was "likely or definitely possible" that [redacted] had urged him not to report the contamination, and that [redacted] had challenged [redacted] over this when he followed both of them into the change room. It should be noted, however, that in his interview with ARPANSA Inspectors on 18 February 2010, [redacted] was unsure as to whether [redacted] had urged him not to report the contamination.

6.4.4 ANSTO's culture of reporting and managing contamination incidents in 2007

When asked about the probability of a contamination of clothes and face not being reported in 2007, [redacted] stated it could have happened because reporting was not as strict at the time. This supposition was supported by [redacted] confirmation that it would not have been out of character for [redacted] to cover up the alleged contamination incident as he may have been trying to "save face", and that there may have been a perception amongst staff in 2007 that reporting contamination incidents might lead to disciplinary action.

[redacted] explained it was good work practice for Production staff to clean up small contamination events themselves, to reduce the chance of the contamination spreading.

Whilst [redacted] account of events on 3 September 2007 can be discounted because there is no record of him being on duty that day, he does appear to have a strong recollection of confronting [redacted] in the change room, where [redacted] appeared to be denying a contamination incident.

6.4.5 Source of Y-90 contamination

Examination of records and interviews with personnel have determined that two Y-90 batches were produced on 3 September 2007, with the first batch originally scheduled between approximately 6:30am and 10:00am, and the second batch between 12:00pm and 3:30pm.

Because [redacted] was late to start his shift, [redacted] assisted [redacted] in Y-90 production as the 'second' batch operator on the first Y-90 batch. The second batch operator records and signs off production entries in the Y-90 batch record.

This Y-90 batch was transferred from the production glove box to the autoclave at approximately 9:00am. The operator initials bear a resemblance to [redacted] initials, but he did not identify the entry as his own initials when asked by KPMG in the course of his interview.

After 10:45am [redacted] was required to do a second run on the first batch (i.e. re-dispense, re-measure and re-autoclave the batch) because of a measuring error. The autoclaving was done at 11:18am, and [redacted] initialled the Record of Autoclave Sterilisation Record as the operator. It is not clear whether [redacted] assisted [redacted] on this second run, as there is no batch record for the re-dispensing and re-measuring.

[redacted] and [redacted] commenced the second Y-90 batch for the day at approximately 12:30pm. [redacted] was the main operator, with [redacted] the second batch operator. The second batch was autoclaved at 2:10pm.

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From the evidence provided by [redacted] it appears the contamination he received occurred during the autoclaving stage in the Y-90 production process, when a batch is transferred from the glove box port to the autoclave. This is consistent with the preliminary and final ARPANSA Inspection Reports, which concluded that the reported contamination to [redacted] and [redacted] was likely to have occurred via the service port in the glove box, and not via the glove box gloves, as originally reported by ANSTO.

[redacted] is unlikely to have been contaminated during the autoclaving of the second run on the first batch, as this occurred at 11:18am whilst [redacted] was measuring the first part of the I-123 batch between 11:07am and 1:20pm in Room 115 of B23A, a room spatially isolated from the Y-90 production area in Room 99. [redacted] confirmed he would not have left Room 115 during this part of the I-123 batch process.

Similarly, [redacted] could not have been contaminated by the second batch, as he was in Room 115 performing the second part of the I-123 Batch production process when the second batch was autoclaved at 2:10pm.

It appears more likely that [redacted] would have been contaminated during the autoclaving of the first run of the first Y-90 batch, at approximately 9:00am. This would then be consistent with [redacted] allegation of encountering [redacted] and [redacted] at the barrier at approximately 9:40am with contamination on their clothing and on [redacted] face.

If [redacted] subsequently wiped out the whole Y-90 production area, as stated by [redacted] it is possible that he was able to reduce the level of contamination to less than 5cps, as was measured by [redacted] at 10:48am. This is supported by [redacted] confirmation that it would be possible for a significant contamination to be cleaned up using a vacuum cleaner, to a degree that gives a reading of less than 5cps.

6.4.6 Potential level of Y-90 contamination

To assist in understanding the potential level of exposure to ANSTO employees as a result of the alleged contamination incident on the morning of 3 September 2007, ARPANSA used the contamination levels recorded on [redacted] face between 2:44 and 3:19pm to estimate a potential skin dose. ARPANSA concluded that if the alleged contamination incident had occurred at approximately 9:00am, the potential skin dose would have been approximately 7.24mSv. This is a relatively small dose, and only constitutes 1.45 percent of the statutory annual limit of 500mSv.

6.5 Review of ARPANSA inspections

Between 25 January and 23 February 2010, in response to [redacted] allegations in the course of the 17 June 2009 inspection, ARPANSA Inspectors [redacted] and [redacted] conducted a number of inspections with regards to alleged and reported contamination events on 3 September 2007. The purpose of the inspections were to assist the CEO of ARPANSA in determining ANSTO's compliance with the ARPANS Act and the *Australian Radiation Protection and Nuclear Safety Regulations 1999*.

The inspections required Inspectors to conduct a site visit to B23A, conduct several interviews with ANSTO staff, and to review a large number of ANSTO records. In drawing conclusions and making recommendations from the inspections, the ARPANSA Inspectors were required to take into consideration a broad range of factors, including:

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- the sequence of events on 3 September 2007;
- the cause of the contamination;
- whether ANSTO policies and procedures to respond to, investigate and report the contamination were followed correctly;
- whether these policies and procedures were adequate for such incidents;
- the adequacy of training provided to staff in how to follow these procedures;
- the suitability of equipment used in the manufacture of Y-90; and
- the sufficiency of incident record keeping in ANSTO.

After careful examination of the interim and final Inspection Reports and the transcripts of interviews between ARPANSA Inspectors and ANSTO personnel, we found that neither the interim nor the final Inspections Reports sufficiently examined [redacted] allegations that a contamination incident involving [redacted] and [redacted] occurred during the morning of 3 September 2007.

Further to this, we made the following observations with regards to the inspections and reports:

- It is apparent from the transcript of the interview with [redacted] that the temporal inconsistency between [redacted] account of events (morning) and those reported within ANSTO (afternoon) was not sufficiently examined by ARPANSA in the course of the interview with [redacted]
- Whilst [redacted] was clearly a key witness and could also be considered a whistleblower with regards to the Y-90 events of 3 September 2007, he was not interviewed at the commencement of the investigation. Had he been interviewed at the outset, ARPANSA would have been in a better position to effectively test his allegations against the recollection of the other key witnesses. This appears to be the reason [redacted] was required to be interviewed a second time, after [redacted] interview.
- In the interview with [redacted] ARPANSA failed to sufficiently question [redacted] as to whether [redacted] had assisted with Y-90 process. It also appears ARPANSA did not conduct sufficient prior examination of records provided by ANSTO to assist in planning for the interviews with witnesses. In the transcript of interview with [redacted] he stated that if he had access to the batch records he would have been in a better position to answer the Inspectors' questions. It is also apparent in the interview that [redacted] had previously sent these records to the Inspectors, but no attempt was made to produce them in the interview to assist [redacted] recollection of events. ARPANSA has informed KPMG that they had requested the batch records prior to the commencement of interviews but these had not been made available[1].
- A careful pre-examination of documents such as swipe access, batch and roster records would have assisted ARPANSA in better planning their interviews with ANSTO personnel.

[1] ARPANSA further submits that evidence in support of this claim can be found the Department of Health and Ageing's review undertaken by [redacted]

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7 Findings

Based on the scope of our review, as set out on Section 3, we make the following findings with respect to [redacted] allegations of a Y-90 contamination on the morning of 3 September 2007:

- The recollection of events by existing and former ANSTO employees is imprecise at best. It is apparent that many of the witnesses had difficulty discerning between the alleged and reported contamination events that occurred on 3 September 2007, and other minor contamination events around the same period.
- On the four occasions that [redacted] has provided his recollection of events on the morning of 3 September 2007 (i.e. in two interviews, an email to ARPANSA and a written submission to DoHA) his recollection has been largely consistent.
- KPMG and ARPANSA interviews with [redacted] one of the individuals allegedly contaminated with Y-90 on the morning of 3 September 2007, revealed considerable inconsistencies between his recollection of events, ANSTO records and the recollection of other witnesses. This establishes doubts as to his reliability as a witness.
- The recollection of events by [redacted] another of the individuals allegedly contaminated, suggested he had difficulty discerning between the alleged and reported contamination events that occurred on 3 September 2007. However, he consistently stated, both to ARPANSA Inspectors and KPMG, that [redacted] was contaminated sometime on 3 September 2007. [redacted] also appeared to have a strong recollection that he, [redacted] and [redacted], were contaminated as a result of his handling of a Y-90 batch, as he moved it by hand between the glove box service port and the autoclave.
- On examination of records and consideration of interviews, we find it likely that [redacted] was contaminated during the autoclaving of the first run of the first Y-90 batch, at approximately 9:00am on 3 September 2007. We note this would therefore be consistent with [redacted] allegation of encountering [redacted] and [redacted] at the barrier at approximately 9:40am with contamination on their clothing, and on [redacted] face. It would also be consistent with [redacted] response at 10:48am to a report of contamination on the floor around the Y-90 production glove box.
- On examination of records and consideration of interviews, we find it possible that the version of events in [redacted] allegations did occur.

Based on the scope of our review, as set out in Section 3, we make the following findings with respect to ARPANSA's handling of [redacted] allegations and the events of 3 September 2007 associated with Y-90 contamination:

- Neither the interim nor the final Inspections Reports sufficiently examined [redacted] allegations that a contamination incident involving [redacted] and [redacted] occurred during the morning of 3 September 2007.

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8 Warranties and disclaimers

This report is issued to ARPANSA in accordance with our Engagement Letter, signed by ARPANSA on 21 October 2011. It represents the findings from our work up to 12 April 2012.

We have prepared this report for the purpose set out in Section 3, and it is not to be used for any other purpose without prior written consent. Accordingly, KPMG accepts no responsibility in any way whatsoever for the use of this report for any purpose other than that for which it has been prepared.

We have prepared this report for the benefit of ARPANSA only. Whilst we have consented to the distribution of this report beyond ARPANSA, it should not be regarded as suitable for use by any party other than ARPANSA. If you are in possession of this report and you are a party other than ARPANSA, KPMG:

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We have considered and relied upon information provided to us in both document form and in interviews. Nothing is this report should be taken to imply that we have verified any information supplied to us, or have in any way carried out an audit of any information supplied to us other than as expressly stated in this letter. The findings and conclusions included in this letter are given in good faith, and in the belief that such findings and conclusions are not false or misleading.

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