Auckland Radiation Oncology Limited

A Report by the

Health and Disability Commissioner

(Case 16HDC00650)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

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Executive summary

1. Mr A had a medical history of adenocarcinoma of the prostate. Following consultations with Dr B, a radiation oncologist at Auckland Radiation Oncology (ARO), in March 2014, Mr A consented to receiving radiation treatment.

2. Dr B calculated and prescribed the radiation dosage required. Various staff at ARO were involved with the planning, checking, and delivery of the radiation treatment. At some stage prior to administration, the prescribed wedge monitor units (MUs), which lessen the dose of radiation received, were removed from the posterior treatment field. It is unclear whether this occurred as a result of human or technical error. ARO's pre-treatment checking policy did not include a requirement for MUs or other beam parameters to be re-checked, and the error was not picked up prior to treatment.

3. Mr A received radiation treatment at ARO between 21 August 2014 and 3 September 2014. Mr A incorrectly received significantly higher doses of radiation treatment than intended.

Findings

4. ARO delivered the wrong radiation doses, which were significantly higher than were prescribed. In addition, ARO did not have an appropriate policy for the pre-treatment check of beam parameters. Accordingly, ARO did not provide services to Mr A with reasonable care and skill, and breached Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code).[1]

Recommendations

5. In the provisional opinion, it was recommended ARO report back to HDC on the implementation of its proposed electronic portal imaging devices dosimetry to allow for a further electronic check of parameters between the planning system and the delivery system. ARO has since confirmed, and provided evidence of, the implementation of this check.

6. It is recommended that ARO provide a written apology to Mr A's family for its breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A's family.

7. It is recommended that the Office of Radiation Safety share the anonymised details of this incident with the other radiation oncology departments in New Zealand, to ensure that they have adequate policies in place to prevent this incident occurring at another centre.

[1] Right 4(1) of the Code states: "Every consumer has the right to have services provided with reasonable care and skill."

Complaint and investigation

8. In May 2016 the Commissioner received a complaint from Mrs A about the services provided by Auckland Radiation Oncology Limited to her husband, Mr A. The following issue was identified for investigation:

Whether Auckland Radiation Oncology Limited provided Mr A with an appropriate standard of care between 2014 and 2015.

9. The parties directly involved in the investigation were:

Mr A (deceased)	Consumer
Mrs A	Complainant
Auckland Radiation Oncology Limited	Provider

Also mentioned in this report:

Dr B	Radiation oncologist
Dr C	General practitioner

10. Information from the Accident Compensation Corporation (ACC) was also reviewed.

11. Independent expert advice was obtained from a radiation oncologist, Dr Claire Hardie **(Appendix A).**

Information gathered during investigation

Mr A

12. In 1999, Mr A was diagnosed with adenocarcinoma[2] of the prostate. In 2000, Mr A was treated with a radical prostatectomy.[3] Following this operation, Mr A's prostate-specific antigen (PSA) levels[4] were undetectable,[5] and the surgery was believed to have been successful. In 2008, Mr A's PSA levels became detectable and were monitored consistently.[6] In 2014, Mr A developed pain in his left groin, left hip, and right lower leg. On 24 February 2014, Mr A consulted an orthopaedic surgeon. The orthopaedic surgeon performed a bone scan,[7] which identified multiple skeletal metastases.[8] The orthopaedic surgeon recommended that Mr A consult with a

[2] A type of cancer that forms in mucus-secreting glands throughout the body.
[3] An operation to remove the prostate gland.
[4] Prostate-specific antigen (PSA) is a protein produced by cells of the prostate gland. The PSA test measures the level of PSA in a man's blood.
[5] Following a radical prostatectomy, PSA levels should drop to undetectable levels.
[6] It was thought at this stage that the testosterone treatment Mr A was receiving was causing his PSA levels to rise. The testosterone treatment was discontinued for this reason.
[7] An imaging procedure to view the bones.
[8] Metastatic cancer is cancer that has spread from the part of the body where it started (the primary site) to other parts of the body.

radiation oncologist, Dr B, at Auckland Radiation Oncology (ARO),[9] for treatment options. ARO is a private radiation therapy centre that provides radiation treatment to individuals with cancer.

Consultations with Dr B at ARO

13. On 7 March 2014, Dr B reviewed Mr A in his clinic and provided his findings to Mr A's general practitioner (GP). Dr B reported: "I think his left hip pain is likely coming from his lower thoracic[10] upper lumbar[11] spine metastases." Dr B advised that he discussed the option of palliative radiation therapy with Mr A, and he was of the opinion that such treatment would benefit him.

14. Dr B also documented that he recommended that Mr A receive antiandrogen treatment.[12] Dr B noted: "[Mr A] wished to start on an antiandrogen and I will get a Special Authority for Bicalutamide,[13] and let him know about that … I have made tentative arrangements for his thoracic and lumbar spine irradiation[14] at [ARO]."

Initial orientation

15. On 12 March 2014, Mr A attended an orientation session at ARO with a registered nurse (RN). During this session, Mr A signed a consent form to receive radiation therapy. During the appointment, Dr B also organised for Mr A to receive antiandrogen treatment.

16. On 18 March 2014, Mr A attended a further appointment with Dr B. Dr B wrote to Mr A's new GP, Dr C, with his findings. Dr B documented: "[Mr A] proceeded with a CT scan of the chest, abdomen and pelvis. This has shown bone metastases in the thoracic and lumbar spine and sacrum."[15] Dr B also documented that Mr A was responding well to his antiandrogen treatment and had identified an improvement in his pain levels, and noted that he would be reviewed again in three months' time.

17. On 19 March 2014, Dr B advised ARO that Mr A would not be proceeding with radiation therapy at this time as the pain in his spine had improved.

18. In August 2014, Mr A contacted ARO because of ongoing spinal pain. On 13 August 2014, he was reviewed again by Dr B and consented to receiving radiation treatment to his spine.

[9] Auckland Radiation Oncology Limited is a joint venture, owned and operated by two private hospitals.
[10] Upper and middle back.
[11] Lower back.
[12] Medication that lowers the levels of androgens (testosterone) in the body and can slow the growth of prostate cancer.
[13] A brand of antiandrogen medication.
[14] Irradiation involves the person being exposed to radiation.
[15] A bone at the base of the spine.

Communication with Dr C

19. On 14 August 2014, Dr B wrote to Dr C and documented that he had reviewed Mr A and recommended restaging[16] to determine the staging of his prostate cancer. Dr B documented: "Regardless based on the previous CT and bone scan, I think he would benefit from palliative radiotherapy and discussed this with him."

20. On 16 August 2014, following his review of Mr A and Mr A's second orientation at ARO, Dr B wrote to Dr C and documented that, on review of the scan, there was quite extensive disease. Dr B documented: "I think [Mr A] would benefit from palliative radiotherapy as I have discussed with him, and have arranged for his planning and treatment at [ARO]."

Second orientation

21. On 14 August 2014, Mr A attended a second orientation session with an RN at ARO.

Radiation treatment plan — 15 August 2014 to 20 August 2014

22. On 15 August 2014, Dr B calculated the volumes of radiation required. Dr B prescribed Mr A a radiation dosage of 30 Gray[17] (Gy) at the isocentre,[18] and 32Gy at the maximum dose point,[19] in 10 fractions.[20]

23. Between 15 August 2014 and 19 August 2014, a student therapist completed the treatment plan, as calculated by Dr B, in the planning system,[21] under the supervision of a senior planner.

24. The "Peer Review Guidelines for [the Planning System]" in place at ARO required a peer review of the treatment plan to be performed. The guidelines stated: "The peer review is a thorough check of all of the plan parameters in [the planning system]."

25. The treatment plan included a three-dimensional conformal radiation therapy technique[22] composed of four beams. This included one anterior beam,[23] one posterior beam,[24] and two posterior oblique beams. The two posterior oblique beams included 60 degree wedges,[25] which would deliver 300 wedge monitor units (MUs).[26] This treatment plan was consistent with the volumes of treatment Dr B intended Mr A to receive, and had the correct wedge MUs in place.

[16] Staging is the process of determining how much cancer is in the body and where it is located.
[17] Gray is the unit used to measure the total amount of radiation the patient is exposed to.
[18] Central intersection point of the radiation beams directed at the target area.
[19] The maximum dose point of radiation to an organ or tumour target in radiotherapy cancer treatment.
[20] When the full dose of radiation is divided into a number of smaller daily doses.
[21] A treatment planning computer system.
[22] The utilisation of 3D images for treatment planning, aimed at creating a dose distribution to the tumour whilst sparing surrounding normal structures.
[23] Nearer the front of the body.
[24] Nearer the back of the body.
[25] A beam-modifying device used to optimise the volume dose distribution.
[26] A monitor unit is a measurement of radiation. A wedge is used to reduce the effect of the radiation beam. If a wedge is used during the delivery of treatment, it lessens the dose of radiation received.

26. The "[Delivery System] Plan Entry — [The Planning System]" policy in place at ARO in August 2014 required the export and import of planning data to be performed by the radiation therapist who was responsible for generating the treatment plan. The policy stated: "This will take place after the peer review. Second checks of this data by an independent Radiation therapist will verify that the entry of data is correct."

27. On 19 August 2014 the student therapist exported the treatment plan from the planning system to the delivery system.[27] The senior planner checked the treatment plan in the planning and delivery systems. On 20 August 2014, another radiation therapist performed the second check of the treatment plan in the planning and delivery systems.

28. The "Planning Second Check" policy in place at ARO in August 2014 required the "MU, Wedge MUs and control point MUs" to be checked for each beam and compared between the planning system and the delivery system. The documentation provided by ARO to HDC indicates that both the senior planner and the radiation therapist checked the wedge MUs in the delivery system and verified them against the treatment plan in the planning system.

29. On 20 August 2014, another ARO radiation oncologist approved the prescription of radiation and the radiation plan in the delivery system for Mr A, as Dr B was on annual leave at the time.

30. On 20 August 2014, a radiation therapist completed the pre-treatment check as required by the "Patient Pre-Treatment Check" policy in place at ARO at the time. The check included confirming that a second check of the treatment plan had occurred, consent for treatment had been obtained, and that the correct treatment dose, treatment site, and fractionation[28] schedule had been recorded. The policy did not require the MUs or other beam parameters to be checked.

31. ARO told HDC:

> "Because the treatment parameters in [the delivery system] are not manually entered, the pre-treatment check in place at the time were focussed on ensuring the treatment parameters were correctly imported; and furthermore we did not imagine a scenario where the imported MUs would be changed or deleted prior to treatment delivery."

32. ARO's policy "Diodes" required diode[29] measurements to be used to verify the dose of radiation delivered to a patient compared to the radiation plan. The ARO policy stipulates that "an appropriate beam" should be chosen for this check, and that "standardly the Anterior beam is used". This verification is required to be performed prior to treatment delivery. The policy did not require a diode to be placed in the posterior treatment field.

[27] A treatment delivery computer system. The delivery system is used to record and verify the radiation treatment delivery.
[28] Where treatment is delivered in smaller doses over a period of days.
[29] A device placed in the treatment beam to verify the delivered dose at the time of treatment.

33. On 21 August 2014, prior to Mr A receiving radiation treatment, three radiation therapists performed a quality assurance check of the radiation dose being delivered. This involved a diode being placed on the patient's skin in the anterior treatment field. The radiation plan indicated that the dose would be within an acceptable range.

Delivery of treatment

34. Between 21 August 2014 and 3 September 2014, Mr A incorrectly received 71.4Gy at the isocentre instead of the prescribed 30Gy, and 93.4Gy at the maximum dose point instead of the prescribed 32Gy.

35. On 3 September 2014, Mr A received his final dose of radiation treatment. An RN documented: "[Mr A] remains well … He knows to contact ARO if he has any treatment related concerns over the next 2 weeks. [Mr A] has an appointment to see [Dr B] in 6 weeks."

Care provided post-treatment

36. ARO staff reviewed Mr A and maintained regular contact with Mr and Mrs A following the provision of radiation treatment.

37. On 7 October 2014, Dr B reviewed Mr A owing to an area of broken weeping skin in his central lower back in the radiation treatment field. Dr B noted that the skin was desquamated[30] and appeared infected, and he prescribed Mr A antibiotics.

38. Between October and December 2014, Mr A consulted with Dr B on numerous occasions for review of his wound and wound management advice. Dr B noted that wound healing was slow, and arranged for Mr A to be reviewed by a plastic and reconstructive surgeon. In February 2015, Dr B discussed hyperbaric oxygen therapy with Mr A, owing to the increasing soft tissue necrosis[31] and pain associated with the wound on his back. Dr B asked Dr C to initiate a treatment injury claim with ACC, as the radiation reaction was more severe than normally would have been expected.

39. On 17 February 2015, the plastic and reconstructive surgeon referred Mr A for consideration of hyperbaric oxygen treatment.[32]

Discovery of error

40. On 16 April 2015, ACC requested information from ARO. On the same day, as a result of Mr A's ongoing pain associated with the wound on his lower back, a senior planner and ARO's Radiation Therapy Manager reviewed the treatment plan for Mr A in the planning system, and identified that the dose listed in the planning system matched the dose calculated by Dr B and recorded in Mr A's treatment plan.

41. On 5 May 2015, Dr B discussed Mr A's ongoing side effects and tissue problems at a chart round,[33] to try to determine what was causing the tissue problems. The chart

[30] When the skin sheds or peels off.
[31] The death of living cells or tissues.
[32] A medical treatment that enhances the body's natural healing process by inhalation and exposure to 100% oxygen in a total body chamber.
[33] A team meeting to discuss complicated cases.

round was attended by ARO staff including Dr B, a radiation oncologist, a radiation therapist and a senior physicist.

42. The physicist reported that, following the chart round, they opened the treatment plan in the treatment planning system and were unable to identify any issues that could have caused Mr A's reaction to the radiation treatment. The physicist reported: "On review we found that the plan maximum dose was approximately 32Gy … which would have been acceptable and should not have caused a severe skin reaction."

43. On 12 May 2015, the physicist performed a simulated delivery of the treatment plan from the delivery system, and discovered that the treatment had been delivered without the wedge MUs in the posterior field. It was identified that this error had caused Mr A to receive an overdose of radiation treatment.

44. On 14 May 2015, Dr B and the Clinical Director of ARO informed Mr and Mrs A of the error. ARO apologised in writing and in person to Mr and Mrs A, and advised HDC that it maintained regular contact with them throughout the investigations set out below.

45. ARO told HDC that, following the discovery of the error, all patient plans with wedge MUs were checked and no other errors were identified.

Sentinel Event Investigation Report

46. Following the identification of the error, ARO instigated a Sentinel Event Investigation (SEI) and produced a report on the error in Mr A's treatment delivery. The investigation identified that at some stage, between when the treatment plan was exported from the treatment planning computer system to the treatment delivery program, the requirement for wedge MUs was removed. The absence of the wedge MUs resulted in Mr A receiving a significant overdose of radiation.

47. ARO documented in the Sentinel Event Investigation Report (SEIR) that a check in place, in accordance with ARO's policy "Diodes, which involved the use of in-vivo dosimetry[34]" in the treatment beam to verify the delivered dose at the time of the treatment delivery, had been carried out at the time. The check involved a diode being placed on the patient's skin in the anterior treatment field. The radiation plan indicated that the dose would be within an acceptable range. ARO documented in the SEIR that the error in the posterior oblique treatment fields was not identified at this time, as the policy did not require a diode to be placed in the posterior treatment field.

48. ARO also documented: "[The delivery system] was not set to track any manual changes to the field before approval so the specific time when the [wedge] monitor units were deleted was unable to be identified."

49. It is also recorded in the SEIR that the error likely resulted from "human error" whereby someone involved in the process accidentally removed the wedge monitor

[34] In-vivo dosimetry is a check of the dose delivered to individual patients independent of the treatment planning system.

units in the delivery system. However, as the delivery system does not record changes to the treatment plan, it has not been possible to find out for certain whether the error was caused by a computer system error or by human error.

50. The SEI also found that a root cause of the incident was a stressful working environment. It is recorded that staff were engaged in higher than normal levels of overtime, and that senior planner staffing levels were inconsistent over this time period.

External review

51. ARO organised two independent external reviews of its processes, one relating to Mr A's treatment (report dated 29 March 2016) and one relating to ARO's clinical practice (report dated 6 April 2016). The review related to Mr A's treatment found:

> "As per the findings of the sentinel investigation, it appears that human error was the root cause. However, while [the manufacturer] reported that there was no evidence or indication of a [delivery system] malfunction, technical error cannot be totally excluded, especially as any accidental human interaction would have to have occurred twice; once for each field."

Treatment following identification of the error

52. During this investigation, no concerns were identified in relation to the treatment provided to Mr A following the discovery of the error.

53. Following the incident, Mr A was unable to drive or walk up stairs. Mr A received continuous dressings to the wound on his back, often provided by his wife, Mrs A.

54. In 2017, Mr A died at home.

Changes made by ARO

55. The Sentinel Event Investigation by ARO identified recommendations that the Root Cause Analysis team[35] believed would minimise the risk of such a treatment error occurring again in the future. The recommendations that were put in practice immediately included:

> "• Pre-treatment check of all parameters now takes place on day 1 of all patient treatments as from 14/05/2015 (two days following the discovery of the error). This process was checked again on 24/07/2015 by Chief Physicist to verify that this process was being carried out.
>
> • Diode measurements now done on all 3D-CRT [three-dimensional conformal radiation therapy] treatment fields as from 26/05/2015. This was checked again on 23/07/2015 by Chief Physicist to verify that this process was being carried out.

[35] A team put in place to identify the root cause of a problem.

- From 13/05/2015 Fields are tracked from import into the delivery system — changes can still be made, but the next user will be altered by way of an electronic warning to these changes.
- All staff informed that any concerns with side effects post treatment to be escalated to the whole team including physics at first indication — any ACC enquiries need to be investigated by management and physics.
- For busy periods careful review of the staff roster will be undertaken to ensure sufficient staff are always available; to avoid any periods of significant overtime and for staff to communicate any concerns immediately.
- The dosimetry trainer will supervise only one trainee, whether radiation therapy student or registered staff, at any time.
- Patients are no longer given a start date at the time of booking, this gives the planning team the ability to manage the workload and treatment start dates.
- [The delivery system] planning guideline has been updated to state that the wedge monitor units should never be changed."

56. The SEIR also recorded the recommendations that would be implemented in the future, including:

"• An electronic programme for 2nd checking to eliminate the risk of a similar human error; the software tool is undergoing commissioning checks by the physics team and is aimed to be in place by the end of October 2015.

- Electronic portal imaging device[36] … dosimetry for patient dose verification is currently under development by [the manufacturer][37] and product release is aimed for the latter part of this year. ARO will aim to acquire this as soon as the product is available, with clinical implementation in early 2016; the physics team are responsible to get this actioned."

57. ARO told HDC that the electronic programme for second checking has been implemented at ARO as of 1 June 2016.

58. ARO also told HDC that it intends to implement a more robust incident reporting system in early 2017. ARO told HDC:

> "This will allow earlier analysis of reports of near misses and errors and will align with the data fields of SAFRON [Safety in Radiation Oncology],[38] enabling improved communication of potential and actual errors worldwide."

[36] Used for the comparison of the treatment image against the reference planning image to remove any patient set-up errors prior to treatment.
[37] A company that provides radiation software and equipment.
[38] Allows radiotherapy centres to contribute incidents and near misses to an international learning system.

Response to provisional opinion

59. Mrs A was provided with a copy of the "information gathered" section of my provisional report. Mrs A had no further information to add.

60. In response to the provisional report, ARO told HDC that it "acknowledges the very serious complications suffered by [Mr A] as a result of incident, and [is] deeply sorry for the error that occurred. ARO submitted that it did "everything [it] could do to respond openly and in a timely manner following discovery of this error and to support [Mr A] through his recovery following the incident".

61. ARO offered its condolences to Mr A's family.

Opinion: Introduction

62. For the avoidance of doubt, my role does not extend to determining the cause of Mr A's death. My role is to assess the quality of care provided to him in light of the information that was known at the time that care was provided. Accordingly, my opinion should not be interpreted as having any implication as to the cause of Mr A's death.

Opinion: Auckland Radiation Oncology Limited — breach

First and second checks and removal of MUs

63. Between 21 August 2014 and 3 September 2014, Mr A received a course of radiation therapy. At some stage prior to the administration of the radiation treatment, the prescribed MUs in the posterior treatment field were removed. Due to the absence of the prescribed MUs, Mr A received a significant overdose of radiation.

64. It has not been possible to determine at what point the MUs were deleted. Documentation provided by ARO indicates that both the radiation therapists checking the treatment plan checked the wedge MUs and verified them against the treatment plan in the delivery system, in accordance with ARO's "Peer Review Guidelines for [the Planning System]" and "Planning Second Check" policies.

65. Expert advice was obtained from a radiation oncologist, Dr Claire Hardie. Dr Hardie advised that the system at ARO (in place at the time of these events) of a first and a second plan check would be seen as consistent with standard practice, and noted that the documentation indicated that the first and second checks were conducted.

66. ARO completed a Sentinel Event Investigation Report (SIR) in relation to the incident, which found that the error likely resulted from "human error", whereby someone accidentally removed the wedge MUs in the delivery system, and found that

a root cause of the incident was a stressful working environment. An independent external review organised by ARO found that it appeared that human error was the root cause, but the review team considered that a technical error could not be excluded totally, especially as any accidental human interaction would have to have occurred twice — once for each field.

67. Taking into consideration the information available, I am unable to make a finding as to whether the error occurred as a result of human or technical error. In light of this, I am unable to determine whether a stressful working environment contributed to the error.

Diode policy

68. ARO's policy "Diodes" required diode measurements to be used to verify the dose of radiation delivered to a patient compared to the radiation plan. The ARO policy stipulates that "an appropriate beam" should be chosen for this check, and that "[s]tandardly, the anterior beam is used". In Mr A's case, the diode was placed in the anterior beam in accordance with the policy. The MUs error was located in the posterior beams, and therefore was undetected during this check.

69. Dr Hardie advised: "In my opinion, the use of diodes for in-vivo dosimetry is a standard of care as a method of quality assurance for treatment delivery." Dr Hardie did not identify a departure from an accepted standard of care in relation to ARO's "Diode" policy.

70. I am satisfied that ARO's policy relating to diodes was adequate at the time. Following discovery of the error in Mr A's radiation treatment, ARO revised its "Diode" policy to require diodes to be placed in all treatment fields/beams, which provides a further safeguard for detecting errors in the future.

Pre-treatment check

71. The pre-treatment check policy in place at the time of these events required confirmation that the second check had been undertaken, consent for treatment had been obtained, and that the correct treatment dose, treatment site, and fractionation schedule was recorded. It did not require the MUs or other beam parameters to be checked prior to the first delivery of radiation treatment.

72. Dr Hardie advised that, in her opinion, the pre-treatment check policy in use at the time of the incident was inadequate. Dr Hardie stated that not specifically ensuring that MUs and other beam parameters were checked prior to first treatment delivery was a moderate deviation from standard practice, as these should be checked prior to at least the first treatment delivery to ensure that they match the treatment planning system.

73. I am critical that ARO's pre-treatment policy did not include a requirement for beam parameters to be re-checked. Appropriate pre-treatment check policies provide an additional opportunity for picking up any errors.

Conclusion

74. ARO delivered the wrong radiation doses, which were significantly higher than were prescribed. In addition, ARO did not have an appropriate policy for the pre-treatment check of beam parameters. Accordingly, ARO did not provide services to Mr A with reasonable care and skill, and breached Right 4(1) of the Code.

75. Dr Hardie has advised that the current systems and policies in place at ARO are adequate and consistent with standard practice.

ARO radiation oncologist care

76. Dr Hardie advised:

> "Following treatment, [Mr A] was assessed regularly at ARO by radiation oncologist [Dr B]. In view of the persistence and severity of [Mr A's] radiation reaction, [Dr B] organised a plastic surgery opinion and requested the initiation of an ACC treatment injury claim. In my opinion, this shows [Dr B] was providing ongoing care and doing his best to support [Mr A] in the circumstances."

77. I agree that Dr B provided appropriate on-going support and care to Mr A. Dr B was proactive in his attempts to investigate and understand the cause of Mr A's severe radiation reaction. This led to the error being identified following a chart round held at ARO.

Recommendations

78. I recommend that Auckland Radiation Oncology Limited provide a written apology to Mr A's family for its breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Mr A's family.

79. In my provisional opinion, I recommended that ARO report back to HDC on the implementation of its proposed electronic portal imaging devices dosimetry to allow for a further electronic check of parameters between the planning system and the delivery system. ARO has since confirmed, and provided evidence of, the implementation of this check.

80. I recommend that the Office of Radiation Safety share the anonymised details of this incident with the other radiation oncology departments in New Zealand, to ensure that they have adequate policies in place to prevent this incident occurring at another centre.

Follow-up actions

81. A copy of this report with details identifying the parties removed, except Auckland Radiation Oncology Limited and the expert who advised on this case, will be sent to the Health Quality & Safety Commission and the Office of Radiation Safety.

82. A copy of this report with details identifying the parties removed, except Auckland Radiation Oncology Limited and the expert who advised on this case, will be placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from a radiation oncologist, Dr Claire Hardie:

"I have been asked to provide an opinion to the Commissioner on case number 16HDC00650, and I have read and agree to the follow the Commissioner's Guidelines for Independent Advisors.

I trained as a Clinical Oncologist at the Royal Marsden Hospital, London and the Nottingham University Hospitals, Nottingham in the UK between 2002 and 2007, obtaining my Fellowship of the Royal College of Radiologists in 2005. I have worked as a Consultant Radiation Oncologist at the Regional Cancer Treatment Service, Palmerston North Hospital since April 2007. I received Fellowship of the Royal Australian and New Zealand College of Radiologists in 2015. I have 14 years experience (as a registrar and consultant) treating patients with radiation therapy.

My referral instructions from the Commissioner are:

1. To review the documentation provided to me and advise whether I consider the care provided to [Mr A] at Auckland Radiation Oncology (ARO) was reasonable in the circumstances, and why.

2. In particular (and without limiting the scope of this request) to comment on:
    a. The adequacy of the systems in place at ARO at the time of [Mr A's] treatment.
    b. The adequacy of the relevant policies and procedures in place at the times of the events complained of.
    c. The adequacy of the systems in place at ARO currently.
    d. The adequacy of the relevant policies and procedures currently in place, including any further changes that you consider may be appropriate.
3. To comment on any other aspects of the care provided to [Mr A] that I consider warrants such comment.

4. For each issue listed above, to advise:
    a. What the standard of care/accepted practice is.
    b. If there has been a departure from the standard of care or accepted practice, how significant a departure I consider it is.
    c. How the care provided would be viewed by my peers.

Sources of information reviewed:

1. Complaint dated […].
2. Information provided by ARO:

a. Response to HDC dated 1 June 2016.
b. Internal Sentinel Investigation Report dated 7 August 2015.
c. Radiation Incident External Review Report dated 29 March 2016.
d. [Mr A's] radiation chart and clinical notes.
e. Protocols in place at ARO in 2014.
f. Current protocols in place at ARO.
g. Radiation therapy student training report — Radiation Therapy Practice III.
h. Planning training guideline for radiation therapy students.
i. [The] Manufacturer's report into incident — not dated but noted to have been received by ARO on 10 July 2015.
j. [The manufacturer's] response to requested changes to software — [the delivery system] dated 7 August 2015.
k. Report on physics involvement in days around discovery of [Mr A] mis-treatment dated 27 July 2015.
l. External Review of Clinical Practice at ARO report dated 6 April 2016
m. Letter of apology to [Mr A] from ARO dated 25 May 2015.
n. Letter to [Mr and Mrs A] from ARO outlining findings of the internal root cause analysis report dated 28 August 2015.
o. Diodes memo dated 25 April 2015.

3. HDC's Guidelines for Independent Advisors.

4. CODE OF SAFE PRACTICE FOR THE USE OF IRRADIATING APPARATUS IN MEDICAL THERAPY. Office of Radiation Safety, PO Box 3877, Christchurch 8140, NEW ZEALAND June 1992. Revised December 2004. Revised February 2010.

5. The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. *Towards Safer Radiotherapy*. London: The Royal College of Radiologists, 2008.

6. Radiation Oncology Practice Standards, a Tripartite Initiative, Royal Australian and New Zealand College of Radiologists, Australian Institute of Radiography and the Australasian College of Physical Scientists and Engineers in Medicine, 2011.

7. File from Office of Radiation Safety regarding the incident at ARO in September 2014.

Summary of events

[Mr A] has metastatic prostate cancer to the bone and was referred in March 2014 to [Dr B] at ARO for consideration of radiation therapy to the site of painful bone metastases in the spine.

[Mr A] attended an orientation and CT simulation session at ARO on 12 March 2014 for treatment to T5–L2 (5th thoracic vertebra to 2nd lumbar vertebra). This

treatment was cancelled on 19 March 2014 prior to any radiation treatment being administered as [Mr A's] pain in the spine had improved.

On 13 August 2014, [Mr A] consented to radiation therapy to his spine and he underwent orientation and CT simulation at ARO on 14 August 2014. The patient was simulated in the treatment position, lying on his back. The prescribed dose was 30Gy in 10 fractions treating once daily to T11–L2 (11th thoracic vertebra to 2nd lumbar vertebra).

On 15 August 2014, [Dr B] contoured the volume to be treated on the CT slices obtained at CT simulation. Between 15 August 2014 and 19 August 2014 a student radiation therapist, under the supervision of a senior radiation therapist, created a radiation treatment plan for the contoured volume on [the treatment planning system].

The treatment plan created was a 3D conformal radiation technique composed of 4 beams:

- An anterior beam (open field), gantry angle 0°, delivering 85 monitor units (MUs) per fraction.
- A posterior beam (open field), gantry angle 180°, delivering 100 MUs per fraction.
- 2 posterior oblique beams both with 60° wedges, gantry angles 150° and 210°, each delivering 330 MUs per fraction (the wedge was to be present throughout the treatment delivery and therefore the wedge MUs were also 330 MUs).

On 19 August 2014, the treatment plan was exported from [the planning system] to [the delivery system], (the system used to record and verify radiation treatment delivery by the linear accelerators), by the student radiation therapist. On the same day, a check of the export to [the delivery system] and a first check of the radiation plan were performed by the supervising radiation therapist.

On 20 August 2014 a second check of the radiation plan in [the delivery system] was performed by a second radiation therapist.

As [Dr B] was on leave, another radiation oncologist approved the radiation plan and prescription in [the delivery system].

On 20 August 2014, a pre-treatment check was performed by a 3rd radiation therapist who would be one of the team treating [Mr A]. This included confirming a second check of the treatment plan had occurred, consent for treatment had been obtained from the patient and that the correct treatment dose, treatment site and fractionation schedule was recorded.

On the first day of treatment, 21 August 2014, a quality assurance check of the radiation dose being delivered was performed. This was in the form of placing a diode on the patent's skin in the anterior treatment field. The radiation plan indicated that the dose measured by the diode would be 1.392Gy and the actual measured result was 1.45Gy (a difference of 4.17%). This difference was less than

7%, within the tolerance for in-vivo dosimetry using diode measurements according to ARO's protocol at the time).

Radiation treatment was completed to T11–L2 on 3 September 2014.

[Mr A] attended ARO for review on 7 October 2014 due to an area of broken weeping skin in the central lower back in the radiation treatment field. [Dr B] reviewed [Mr A] and noted the skin was desquamated and appeared infected and he prescribed antibiotics.

Between October and December 2014, [Mr A] had multiple attendances at ARO for review of his wound and wound management advice. Wound healing was slow and an appointment was arranged for him to see [a plastic surgeon] in December 2014.

In February 2015, [Dr B] discussed hyperbaric oxygen therapy with [Mr A] due to increasing soft tissue necrosis and pain associated with the wound in the radiation field. [Dr B] asked the GP to initiate a treatment injury claim as the radiation reaction was more severe than would have been normally expected.

On 16 April 2015, ACC requested further information on [Mr A's] case in light of the treatment injury claim. At that time [Mr A's] radiation plan was reviewed in [the planning system] by a senior radiation planner and the radiation therapy manager, with no concerns raised.

On 5 May 2015, at the end of a chart round at ARO, [Dr B] discussed [Mr A's] case due to the ongoing wound issues in the radiation treatment field. [Mr A's] plan was opened in [the treatment planning system] for review. The plan was thought to be acceptable and should not have caused the degree of skin reaction seen in [Mr A's] case. [The physicist present at the chart round] suggested that measurements should be done to check the dose in the radiation plan was the dose that was actually delivered according to the plan parameters in [the delivery system].

The measurement of the actual radiation dose delivered according to the radiation plan in [the delivery system] was performed by [the physicist] during the evening of 12 May 2015.

The review identified that the radiation plan in [the delivery system] had no wedge MUs in the 2 posterior oblique fields and the radiation treatment had been delivered as open fields. This indicated that the patient received an estimated 7.5Gy per fraction at the plan isocentre (the intended dose on the plan at this point was 3.28Gy per fraction). At the site of maximum dose, the patient received an estimated 9.25Gy per fraction (the intended dose on the plan at this point was 3.42Gy per fraction).

On 13 May 2015, [Dr B], the CEO of ARO and the ARO board were made aware of the treatment error.

Actions taken by ARO on being alerted to the error:

- 13 May 2015: Settings on [the delivery system] altered so that any manual changes to radiation plans were tracked.
- 13 May 2015: All plans using wedges were checked to ensure all plans had wedge MUs for treatment delivery. This was completed on 17 May 2015 and no other errors were found.
- 14 May 2015: Pre-treatment checks extended to include checking beam parameters, including MUs, on [the delivery system] compared to the intended radiation plan on [the planning system].
- 14 May 2015: [Mr and Mrs A] informed of the treatment error.
- 18 May 2015: Treatment error reported to Office of Radiation Safety, Ministry of Health, New Zealand and [the manufacturer], the equipment manufacturer of [the delivery system].
- 18 May 2015: Implementation of revised Pre-Treatment Plan Export and Data Import Guidelines.
- 20 May 2015: First meeting of the internal root cause analysis team set up to investigate the error.
- 26 May 2015: In-vivo dosimetry on first day of treatment expanded so that diodes placed in all treatment fields for 3D conformal radiation treatments.
- 26 May 2015: Letter of apology (dated 25 May 2015) given to [Mr and Mrs A] by [the Clinical Director] and [the Manager] at a meeting held at ARO. Information on HDC procedures was provided to the [Mr and Mrs A] at this meeting.

On 10 July 2015, [the manufacturer's] report into the incident was received. It indicated they had not identified a malfunction in [the delivery system] and they attributed the incident to human error.

On 3 August 2015, ARO implemented the Treatment Checks Master Guideline and revised Diode Protocol.

The internal root cause analysis team provided their report on 7 August 2015. They identified that the wedge monitor units had been deleted from the 2 posterior oblique fields following transfer of the treatment plan from [the planning system] to [the delivery system]. It was not possible to identify who made the changes to the treatment fields as [the delivery system] was not set to track any manual changes to treatment fields at that time. The team attributed the root cause of the incident as a combination of human error and a stressful working environment at the time the incident occurred.

On 28 August 2015, ARO wrote to [Mr and Mrs A], providing them with a copy of the internal root cause analysis report.

The Office of Radiation Safety for the Ministry of Health visited ARO on 28 August 2015.

On 18 September 2015, [Mr and Mrs A] met with [Dr B] and the [manager of ARO] to discuss the findings of the root cause analysis report. ARO again apologised to [Mr and Mrs A].

At the request of ARO, an external review of the incident [was performed], including a site visit between 7 and 8 December 2015. Their final report was published on 29 March 2016. [The reviewers] also provided a report on clinical practice at ARO published on 6 April 2016.

On 4 May 2016, [Mr and Mrs A] lodged their complaint with the HDC.

Review of the case:

As has been determined by the internal root cause analysis performed by ARO and [the external review], there was an error in the radiation treatment delivered to [Mr A] in August/September 2014. The nature of this error was the absence of the planned wedges in the 2 posterior oblique fields used to treat [Mr A] and the radiation in these beams was delivered using open fields. The plan created in [the planning system] had the wedges correctly in place and the correct wedge MUs. It has not been definitely determined whether there was an error in the plan transfer from [the planning system] to [the delivery system] or if at some point after the export of the plan from [the planning system] to [the delivery system], there was an accidental deletion of the wedge MUs in the beam parameters. The error was not detected prior to or during treatment delivery to [Mr A], but came to light after a review of his case several months later due to the ongoing severity of his radiation reaction.

1. In response to the request 'to review the documentation provided to me and advise whether I consider the care provided to [Mr A] at Auckland Radiation Oncology (ARO) was reasonable in the circumstances, and why'.

On my review of this case, I believe the care provided to [Mr A] and the error that occurred are 2 separate issues. My comments in this section are therefore in reference to patient care alone. As such I consider the care provided to [Mr A] at ARO was reasonable in the circumstances and would be viewed in this way by my peers.

The documents show that [Mr A] was assessed prior to treatment delivery in August 2014 and consent for treatment was obtained. Throughout [Mr A's] radiation treatment no concerns were raised related to side effects with a formal review by the Radiation Therapy Patient Care Specialist on the 25 August 2014. It would not be anticipated that any skin side effects would be evident during radiation treatment as these effects usually become apparent 3–4 weeks after the commencement of radiation treatment.

Following treatment, [Mr A] was assessed regularly at ARO by [Dr B]. In view of the persistence and severity of [Mr A's] radiation reaction, [Dr B] organised a plastic surgery opinion and requested the initiation of an ACC treatment injury claim. In my opinion, this shows [Dr B] was providing ongoing care and doing his

best to support [Mr A] in the circumstances. The treatment error was detected due to [Dr B] requesting [Mr A's] case be reviewed in a chart round, in spite of no concern being raised regarding the treatment plan a month earlier when the case had been reviewed at the request of ACC. Again I feel this shows [Dr B] was persistent in doing his best to understand why the radiation reaction was so severe and to determine if this was related to the treatment plan.

The period of 8 months after treatment delivery to the time the treatment error was detected may in part be due to the presence of infection when the skin wound in the radiation field first developed. Infection is known to delay wound healing. The focus on eradicating the infection and managing the wound may therefore have delayed the recognition of a more serious radiation reaction than would be usually anticipated.

Following the discovery of the treatment error, the documentation I have been provided with shows that ARO were in regular contact with [Mr and Mrs A], ARO formally apologised to [Mr and Mrs A] and provided them with a copy of the root cause analysis report when it was available. In my opinion, this was reasonable in the circumstances and shows a willingness by ARO to continue to support and care for [Mr A].

2. In response to the request 'to in particular (and without limiting the scope of this request) to comment on:

- **The adequacy of the systems in place at ARO at the time of [Mr A's] treatment.**
- **The adequacy of the relevant policies and procedures in place at the times of the events complained of.**
- **The adequacy of the systems in place at ARO currently.**
- **The adequacy of the relevant policies and procedures currently in place, including any further changes that you consider may be appropriate.'**

Radiation Plan Checks:

In radiation treatment planning it is standard practice for a radiation plan to be independently reviewed by a second radiation therapist or radiation oncology medical physicist. As outlined in section 10 of the Royal Australian College of Radiologists Radiation Oncology Practice Standards, a tripartite initiative published in 2011:

> *Calculation of MU, exposure times or dwell times required to deliver each prescribed dose are independently checked.*
>
> ***COMMENTARY 10.4***
>
> *All calculations of dose to a patient are performed and independently checked by, or under the supervision of ROMPs or RTs trained and experienced in specific planning calculation methods.*

> *Where independent monitor unit calculation is impractical (e.g. IMRT), due to the complexity of some dose-delivery techniques and associated calculation methods, measurement may replace an independent check.*
>
> *An independent check is a check performed by a suitably authorised person who did not perform the original task being checked and is not influenced by the person who performed the original task or any of that person's workings. Ideally the check process should utilise a different method to the original method used.*

Similarly, the Code of Safe Practice for the Use of Irradiating Apparatus in Medical Therapy published by the Office of Radiation Safety, Ministry of Health stipulates:

> *6.6.6 Each stage of the treatment planning documentation shall be initialled by the individual primarily involved. It shall be checked and counterinitialled by a second staff member of at least equivalent seniority.*

A system of second independent checks of radiation plans was in place at ARO at the time of the incident, consistent with standard practice. The ARO policy, 'Planning Second Check Protocol TM-03.20', effective from 02.08.11, clearly outlines that 'MU, wedge MUs and control point MUs' should be checked for each beam and compared between the treatment planning system and [the delivery system].

The documentation provided by ARO relating to the first and second check of [Mr A's] radiation plan on 19 and 20 August 2014 indicates that in both checks the MUs were checked in [the delivery system] and verified against the treatment planning system. As such, it is unclear why the MUs error was not detected during the first or second plan check, as the policy appears to have been followed. However, it has not been possible to determine at what point the wedge MUs were deleted prior to the plan approval in [the delivery system]. It is therefore not clear if both radiation planners missed the MU error or only one and as was noted by the root cause analysis they were working in a stressful environment that potentially contributed to the error being missed.

The settings on [the delivery system] at ARO at the time of the incident did not track any manual changes to the treatment plan or provide alerts that beam parameters had been altered. The ability to change parameters in [the delivery system] is recognized amongst the users of this system and the onus is on the user to put in place checks and/or modify the settings to reduce the risk of beam parameters being changed inadvertently. There is no 'standard' for settings on [the delivery system] and it is for an individual centre to modify the settings to their needs.

The system at ARO of a first and a second plan check and the ARO policy of second plan checking would be seen as adequate and consistent with standard practice.

Since the error in [Mr A's] treatment was detected, ARO have implemented an electronic programme for second checking radiation plans, to avoid human error during this checking process. In addition to this, ARO have modified the settings on [the delivery system] such that any manual changes to beam parameters are tracked and an alert on this change is visible to the next person reviewing the plan. This reduces the potential risk of human error during the plan checking process.

As I have previously indicated, I would consider the plan checking process at the time of [Mr A's] treatment as adequate, with other factors, particularly the stressful working environment at the time, potentially contributing to the MUs error being missed. The new electronic programme therefore has the potential to further reduce the risk of errors at this stage of the planning process, but I would caution that electronic programmes are not always error free. As noted in the document 'Towards Safer Radiotherapy' published by the Royal College of Radiologists in 2008:

> *It is important to recognise that automated systems can go wrong, particularly in complex circumstances that the programmer cannot predict or for which a programmed system may be inappropriate. Without experience, it is difficult to recognise that an error has been made because the system has been seen to be safe and reliable in the past. Over-reliance on such technology tends to impair individuals' expertise if they no longer have to exercise their skills on a regular basis.*

The manufacturer of [the delivery system] has been contacted by ARO to review if changes in the software programme can be put in place to prevent modification of beam parameters after a radiation plan has been approved. If this can be achieved, it would be of benefit to all users of [the delivery system] in New Zealand.

Pre-Treatment Checks:

As has occurred in this case, an error can be missed at plan checking and therefore there is a further quality assurance check of the radiation plan prior to treatment delivery. In the document 'Towards Safer Radiotherapy' published in 2008 by the Royal College of Radiologists, section 5.10 notes:

> ***5.10 Treatment checks and verifications***
>
> *Radiographers undertaking final verification of treatment immediately prior to irradiation act as operators under IR(ME)R. The employer should maintain a list of entitled operators and specify precise responsibilities in written procedures.*
>
> *Setting the patient up accurately on the treatment machine is crucial to the delivery of the prescribed treatment. This process can conveniently be considered in two parts:*
>
> 1. *The physical position and orientation of the patient in relation to the isocentre and direction of the treatment beams*

2. The setting of the treatment machine, including monitor units, and any beam modification devices, such as wedges or compensators.

Similarly the Royal Australian College of Radiologists in Section 11 of the Radiation Oncology Practice Standards, a tripartite initiative published in 2011, notes:

> *'Two major sources of error in radiation treatment are incorrect dose and incorrect geometry. It is important to check these parameters prior to the patient's first treatment.*
>
> *Verification procedures ensure monitor unit settings and all other treatment parameters are correct for every treatment fraction and radiation field delivered.'*

In the supplementary guide to this section of the document, it is outlined that:

> *treatment parameter data are crosschecked to the treatment plan and set-up at the first treatment session and whenever there is any modification of the treatment plan. These parameters include:*
>
> - *gantry angle;*
> - *collimator angle;*
> - *machine;*
> - *modality;*
> - *energy;*
> - *aperture;*
> - *beam modifiers (wedge size and direction, shielding, Multileaf Collimator (MLC), compensator, electron cut out, bolus, HVL, applicator);*
> - *monitor units/treatment time;*
> - *couch positions;*
> - *landmarks;*
> - *SSD/FSD or SAD/FAD;*
> - *accessory equipment (immobilisation devices); and*
> - *additional instructions (rectal emptying, bladder filling, pre-medication.*

The Code of Safe Practice for the Use of Irradiating Apparatus in Medical Therapy published by the Office of Radiation Safety, Ministry of Health states:

> 7.1.1 *Irrespective of automatic verification and interlocking systems used, a method of human double-checking of all machine parameters should be included as routine practice prior to every radiation exposure.*

All these codes and guidelines clearly document that the beam parameters are to be reviewed prior to delivering radiation treatment.

In [Mr A's] case, a pre-treatment check was performed on 20 August 2014. The documentation I have received on his pre-treatment checklist does not clearly indicate any review of the individual beam parameters by the radiation therapist performing this check, in particular there is no clear documentation to indicate a review of the MUs in [the delivery system] was compared to the treatment planning system. The error in MUs was not detected at this time, or at any time during [Mr A's] treatment as the pre-treatment check was only performed prior to the first radiation treatment.

It should be noted that the ARO policy 'Patient Pre-Treatment Check TM-04.10', effective from 17/1/13, had no specific stipulation that the monitor units should be checked during the pre-treatment check. It did indicate that the radiation therapist should confirm a second check of the radiation plan has been performed and all boxes on the second plan check have been acknowledged. The policy also indicated that the pre-treatment check was to be performed prior to the first treatment and prior to commencing a phase 2 or boost plan. The radiation therapist who performed the pre-treatment check therefore appears to have been correctly following the policy that was in place at that time.

In my opinion, the pre-treatment check policy in use at the time of the incident was inadequate and by not specifically ensuring MUs and other beam parameters were checked prior to first treatment delivery this was a moderate deviation from standard practice. If these checks did occur there is no documentation to support this. As I have highlighted in the guidelines and standards above, which predate this incident, it would be considered standard practice that the beam parameters, including MUs, are checked prior to at least the first treatment delivery to ensure they match the treatment planning system. If this had occurred in [Mr A's] case the error would likely have been detected.

Since the error in [Mr A's] treatment was detected, ARO quickly put steps in place to reduce the risk of this type of error occurring again and have revised their policy in relation to the pre-treatment check. In particular, the 'Treatment Check Guidelines' now stipulate Day 1 checks prior to treatment delivery that check the beam parameters including MUs in [the delivery system] compared to the treatment planning system. Reviewing the current systems and policies in place for pre-treatment checks at ARO, in my opinion these are adequate and consistent with standard practice.

In-vivo dosimetry

As is noted in section 10 of the Royal Australian College of Radiologists Radiation Oncology Practice Standards, a tripartite initiative published in 2011, there should be:

> *a system for independent verification of dose delivery to individual patients.*
>
> *COMMENTARY 10.5*
>
> *In-vivo dosimetry is a check of the dose delivered to individual patients independent of the treatment planning system. It should be provided*

according to protocol or upon the request of the RO, ROMP or RT in consultation with the planning RT.

At the time of [Mr A's] radiation treatment, the ARO policy, 'Diodes TM-04.30', effective from 29.5.12 and revised on 29.05.13 outlines diode measurements are used to verify the dose of radiation delivered to a patient compared to the radiation plan. This is a standard method to perform in-vivo dosimetry.

The ARO policy stipulates that an appropriate beam should be chosen for the diode measurement and 'standardly, the anterior beam is used, except when this is not an option, or in single energy breast tangents, when both tangent fields are measured together'. In [Mr A's] case, the diode was appropriately placed in the anterior beam, consistent with the policy. Unfortunately as this was the only beam measured, the error in the 2 posterior oblique beams could not be detected.

In my opinion, the use of diodes for in-vivo dosimetry is an accepted standard of care as a method of quality assurance for treatment delivery.

Since the error in [Mr A's] treatment was detected, ARO revised their policy on diodes so that diodes are placed in all treatment fields for 3D conformal radiation treatments. I also note a different form of in-vivo dosimetry, using electronic portal imaging, is being implemented early next year. Reviewing the current systems and policies in place for in-vivo dosimetry at ARO, in my opinion these are adequate and consistent with standard practice.

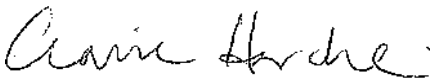
3. In response the request 'to comment on any other aspects of the care provided to [Mr A] that I consider warrants such comment'.

On my review of the documents provided, it is clear this treatment error has had a devastating effect on [Mr A] and his family and the staff of ARO. ARO have made significant changes to some of their policies after the treatment error was detected and on their own initiative sought an external review of both the incident that occurred and the processes they put in place subsequent to the treatment error being detected. The recommendations from ARO's internal root cause analysis report and the external review are either already in place or being implemented and show ARO's willingness to learn from this incident and to do their best to maximise the safety of their patients.

As I have outlined in my review of the case, although there has most likely been a human error that led to [the delivery system] plan having the incorrect MUs for 2 of the radiation beams, the quality assurance policy on pre-treatment checks was not adequate to detect this error and prevent the incorrect radiation dose being delivered. As such, I view this as an error in the systems in place at the time, rather than the error of any individual radiation therapist and would challenge comment 33 in ARO's letter to the HDC on 1 June 2016.

Finally, the Office of Radiation Safety file indicates that following their review of the incident and visit to ARO 'no further action was required from a radiation safety perspective'. This again would indicate that the current policies in place at

ARO are adequate. However, given the impact of this incident on the patient and the department, I would recommend, if it has not occurred already, that the Office of Radiation Safety anonymously share the details of this incident with the other radiation oncology departments in New Zealand to ensure they all have adequate policies in place to prevent this incident occurring again at another centre.



Dr Claire Hardie 14th October 2016"