

**UNDER THE HEALTH AND DISABILITY
SERVICES ACT 1993**

**IN THE MATTER OF THE MINISTERIAL
INQUIRY INTO THE UNDER-REPORTING
OF CERVICAL SMEAR ABNORMALITIES**

EVIDENCE OF SYLVIA SAX

HEALTH FUNDING AUTHORITY

CONTENTS

BACKGROUND AND EXPERIENCE..... Page 3

ESTABLISHMENT OF JOINT RHA NATIONAL
LABORATORY STANDARDS PROJECT..... Page 3

CLARIFICATION OF TELARC's ROLE..... Page 5

THE DEVELOPMENT OF DRAFT NATIONAL
STANDARDS Page 7

NEAR PATIENT TESTING..... Page 10

FINAL WORK ON THE DRAFT NATIONAL
STANDARDS Page 12

DEVELOPMENTS AFTER 11 APRIL 1996 Page 13

EVIDENCE OF SYLVIA SAX

I, **SYLVIA SAX** of Christchurch, Senior Analyst say:

1. My full name is **SYLVIA SAX**. I reside in Christchurch.

BACKGROUND AND EXPERIENCE

2. I have been a Senior Analyst employed by the Health Funding Authority (“HFA”) and its predecessors, the Transitional Health Authority (“THA”) and the Southern Regional Health Authority (“SRHA”) since 1 April 1993. During that time I have been responsible for managing various projects.
3. Prior to commencing employment with the HFA I was employed as a Registered Nurse and Quality Assurance Co-ordinator at Mary Potter Home and Hospital in Christchurch.

ESTABLISHMENT OF JOINT RHA NATIONAL LABORATORY STANDARDS PROJECT

4. In June 1995 I was asked by the Joint RHA Pathology Laboratory Liaison Group (“RHA Group”) to act as a Liaison Person for the RHA’s in the development of National Quality and Service Standards for Medical Testing Laboratory Services.
5. The RHA Group was made up of the Project Manager for Laboratory Services within each RHA. The terms of reference for the RHA Group included:

“To provide guidelines to RHAs in establishing quality guidelines and measures for inclusion in service contracts.

To explain the options available to RHAs in relation to integration of industry sectors and the impacts policy development may have on the industry as a whole”.

6. I produce a copy of the terms of reference as **SS/HFA/0001**.

7. As a result of suggestions made by parties interested in the provision of laboratory services in the CRHA region the question was raised within the RHA Group by the CRHA representative as to whether quality and service standards could be developed on a national basis. The RHA Group agreed that this suggestion should be developed further. The suggestion was considered at a meeting of all the RHAs Health Services and Contracts Managers (“the Managers”) and the RHA Group was asked by the Managers to develop a proposal. A letter dated 6 June 1995 was sent by Geoff Wane (who was the advisor for laboratory services at Central RHA) to the members of the RHA Group advising them of this. I produce a copy of that letter and its attachments as **SS/HFA/0002**.

8. I received a copy of the letter and draft proposal for National Quality and Service Standards from Victoria Sinclair who was the SRHA’s Laboratory Services Project Manager and a member of the RHA Group. I produce a copy of that Memorandum dated 8 June 1995 and its attachments as **SS/HFA/0003**.

9. I undertook discussions with a variety of groups and persons to determine how the membership of the committee to develop the standards should be made up to ensure that it was representative of all stakeholders.

10. The proposal was put to the Managers meeting on 7 July 1995. The RHAs were concerned as to whether TELARC should be involved or whether additional accreditation bodies should also be involved in the development of the standards. This was because the RHAs did not want to inhibit competition between accreditation bodies. There was also some confusion as to what was meant by the terms “*certification*”, “*accreditation*” and “*registration*”.

CLARIFICATION OF TELARC’s ROLE

11. In order to obtain some clarification about these terms I obtained a letter dated 21 July 1995 from TELARC New Zealand. I produce a copy of that letter as **SS/HFA/0004**. This was provided to the RHA Group.
12. TELARC was established through legislation to monitor the technical competence of suppliers of goods and services including medical testing laboratories. Only TELARC had the power to formally register a laboratory although other agencies may provide accreditation.
13. The Medical Laboratory Accreditation Programme used by TELARC was developed by the Medical Registration Advisory Committee (“MedRAC”) which had been established by TELARC in 1981 and consisted of members of the New Zealand Society of Pathologists, the Royal College of Pathologists Australasia, the New Zealand Medical Laboratory Technologists Institute and the Hospital Scientists Association.
14. The information presented to me by TELARC and other information showed that TELARC had the monitoring, technical and industry knowledge, and networks essential for the development of medical testing laboratory standards.

15. I completed a paper setting out the results of my discussions which was provided to the RHA Group in July 1995. I produce a copy of that paper as **SS/HFA/0005**.
16. A discussion of my paper of 21 July (SS/HFA/0005) clarified for the RHA Group the functions of registration by TELARC, accreditation, and standards setting.
17. Geoff Wane prepared a further Memorandum dated 2 August 1995 for the Managers regarding the National Quality and Service Standards and outlining the resolution of the concerns regarding the involvement of TELARC. I produce a copy of that Memorandum as **SS/HFA/0006**.
18. On 10 August 1995 I met with Tony Barker (Royal College of Pathologists of Australasia), Brian Linehan, (MedRAC), Dr Jack Garside (CEO of TELARC) and Graham Walker (Programme Manager of TELARC) to discuss a proposal for the development of the standards. I produce a copy of the notes from that meeting as **SS/HFA/0007**.
19. It was agreed by those groups that:
- “There are already two bodies who are responsible for developing and monitoring service and quality standards for laboratories in New Zealand. Professional standards are developed and monitored through the College of Pathologists; technical and other standards are developed and monitored through TELARC.”*
20. But it was also noted in Section D of the notes that:
- “4. The NZ Society of Pathologists and the College of Pathologists have different responsibilities in setting and monitoring standards for pathologists. The NZ Society of Pathologists continues to be the body recognised by the Medical Council to*

do formal assessments of pathologists while the College has established the accreditation process for pathologists. They are having a workshop in November and hope to amalgamate.

5. *There appears to be a lot of stress in the industry due to lack of time to train (is this due to a lack of pathologists?).”*

21. A recommendation from the meeting was that the proposal for the development of standards be carried out by the RCPA with assistance from TELARC (MedRAC):

THE DEVELOPMENT OF DRAFT NATIONAL STANDARDS

22. The initial draft standard was to be developed by Graham Walker (a representative of TELARC) and Tony Barker (the President of the New Zealand Regional Committee of the Royal College of Pathologists in Australasia (“RCPA”)) for consultation with stakeholders.

23. A schedule for the development of the standards was also proposed at the meeting. The schedule anticipated further identification of indicative issues, development of draft standards, obtaining comments and holding consultation meetings with recommendations being made to the RHAs in late November/early December.

24. The issue of costs was also discussed and the group estimated that the total cost of the project (including the face to face meetings in November) would be no more than \$5,000.00.

25. This budget reflected the willingness of the parties involved to contribute their time and resources freely. This approach was in line with the Policy Guidelines for Regional Health Authorities which were issued by the Minister of Health annually.

26. The 1994/95 Policy Guidelines stated at page 36:

“RHAs are to encourage the Providers they enter into purchase arrangements with to participate in quality improvement processes which are culturally effective. This may include accreditation. Quality improvement processes should include encouraging healthcare professionals to work within guidelines for treatment for specified conditions under usual circumstances and to promote the effective use of services for outcomes.”

27. I was a liaison person for the RHAs but the development of the standards was industry based.

28. Following the RHA Group’s approval of the proposals for the project (which I have described) I wrote to interested stakeholders on 22 August 1995 advising them of the proposal and inviting submissions on issues to be considered. I produce a copy of that letter as **SS/HFA/0008**.

29. The letter exhibited is the one which was sent to the Association of Community Laboratories (“ACL”). The ACL represents the interests of Community or private laboratories. By community or private laboratories I mean the laboratories that are not publicly owned. Significantly the ACL had obtained “*in principle agreement*” from all its members nation wide to the development of standards on a national basis. The CHE laboratories were also involved in the project although they were not represented by an association.

30. I developed a list of interested stakeholders which I used to address communication regarding the standards. There were over 100 interested stakeholders on that list. I produce a copy of that list as **SS/HFA/0009**.

31. Throughout the process the ACL provided input on behalf of its members (the privately owned laboratories). I produce a copy of the

initial submissions from ACL dated 14 September 1995 as **SS/HFA/00010**. The submissions enclosed the ACL's Ethical Rules. These Rules required all members to be accredited by TELARC or an equivalent body or be in the process of achieving accreditation and stated that members may not offer tests until they have applied for accreditation and continue to comply with the requirements of the accrediting body.

32. Following the receipt of submissions I prepared a progress report to the RHA Group dated 24 September 1995 updating the timeline for the project and annexing my notes from the meeting of 10 August 1995 (SS/HFA/0007). The new timeline provided for full submissions to be made by 16 October, consultant meetings to take place in November. I produce a copy of that report as **SS/HFA/00011**.

33. I received as a submission a letter dated 9 October 1995 from Di Best at Health Care Otago Limited regarding the issues relating to laboratories that had concerned Local Managers of the National Cervical Screening Programme. I produce a copy of that letter and its attachments as **SS/HFA/00012**. The letter from Di Best was provided to Graham Walker and Tony Barker along with other correspondence from interested parties.

34. On 3 November 1995 the initial draft National Quality Standards for Medical Testing Laboratories prepared by Graham Walker and Tony Barker were provided to me. I produce a copy of the covering letter as **SS/HFA/00013**. I produce a copy of the draft National Quality Standards as **SS/HFA/00014**.

35. On 8 November 1995 a copy of the draft standards was sent to stakeholders together with an invitation to attend a consultation meeting (to take place in Dunedin, Christchurch, Wellington, Hamilton and

Auckland) in November to discuss the draft standards. I produce a copy of the covering letter as **SS/HFA/0015**. I produce a copy of the address list showing the interested stakeholders who received the covering letter and draft standards as **SS/HFA/0016**.

36. I received a number of comments on the draft standards from interested parties. As an example of the comments I received, I produce a copy of the comments from ACL as **SS/HFA/0017**.
37. The consultation meetings were well attended and revealed a desire on the part of the attendees to be involved in the development of the standards. I produce copies of the lists of participants who indicated they would like to receive follow up information as **SS/HFA/0018**.
38. Tony Barker and Graham Walker developed the standards as the consultation meetings took place receiving the dictated comments after each consultation meeting. The suggested amendments were then discussed at the next meeting.

NEAR PATIENT TESTING

39. A key issue which arose during the consultation was Near Patient Testing (“NPT”).
40. NPT refers to any type of diagnostic testing that can be performed in close proximity to the patient's location. An example of NPT is the use of a glucometer machine in a general practitioner's office to test a diabetic's blood glucose or the use of cholesterol testing strips within a pharmacy. NPT does not refer to tests performed by patients themselves (thus a diabetic patient using a glucometer to test his own blood would not be included). NPT results are available more quickly

than laboratory testing results and it is my understanding that many of them were developed to indicate to a diagnostician (doctor, nurse etc.) whether the results indicated that they should carry out the more detailed (time-consuming and expensive) tests. The results of NPT are generally not as accurate as the more detailed tests carried out in medical testing laboratories. Over the years, and in particular in the last five years, these NPT results have become more accurate and there has been a push by many diagnosticians (particularly in the primary care setting) for these to be used more extensively.

41. There are many issues around these tests, my understanding is that the two major ones were:
 - a. Practices such as poor training of those undertaking the tests and inadequate calibration of testing equipment would impact on the accuracy of the results.
 - b. Commercial impact on medical testing laboratories if their services are replaced by these types of tests.
42. The issue of NPT remained at the forefront of discussion throughout the development of the standard. We sought to resolve the issue by indicating in the standards that a separate working group be set up to address the issues of NPT.

FINAL WORK ON THE DRAFT NATIONAL STANDARDS

43. Following the consultation the standards were further amended and a list of comments on discussion topics for which standards would not be developed through this project was prepared. I produce a copy of the comments as **SS/HFA/0019**. There were 8 topics which were not

covered for various reasons. A further draft amended standard was provided to the RHA Group on 8 January 1996. I produce a copy of the covering letter as **SS/HFA/0020** and a further draft standard as **SS/HFA/0021**.

44. The RHA Group met on 24 January 1996 to discuss the draft standards. I attended that meeting by teleconference. The RHA Group had a number of queries which I addressed to Graham Walker and Tony Barker by letter dated 29 January 1996. I produce a copy of my letter to Tony Barker as **SS/HFA/0022**.
45. Those queries were answered by a letter representing the joint opinion of Graham Walker and Tony Barker dated 1 February 1996. I produce a copy of that letter as **SS/HFA/0023**. That letter was discussed at a meeting of the RHA Group in Auckland on 19 February 1996. I produce a copy of a filenote I made regarding the issues discussed at that meeting as **SS/HFA/0024**. One of the issues discussed was the cost of accreditation.
46. On 26 February 1996 Tony Barker sent a further and final draft of the standards to me. I produce a copy of the covering letter as **SS/HFA/0025**. I produce a copy of the draft standards as **SS/HFA/0026**. The key elements of the standards which are relevant to the Inquiry are:
- a. That standards will be assessed by the accreditation body.
 - b. That standards include the qualifications and continuing professional development of pathologists, as well as their responsibilities within a laboratory.

- c. That all existing labs are to be accredited or assessed by 30 June 1996, and all are to be accredited by 31 December 1996.
 - d. That all new labs are to be assessed within 6 months and accredited within 12 months.
47. After some discussion within the RHA Group the final draft was sent to interested stakeholders for final consultation. I produce a copy of the covering letter dated 1 April 1996 as **SS/HFA/0027**. The final consultation round required submissions to be made by 19 April 1996.
48. I was required to assume responsibility for a new project called "*Models of Service Delivery*" on 11 April 1996. This meant that I would be unable to continue responsibility for the final steps in the project after that date. Victoria Sinclair assumed responsibility for the final steps of the project.

DEVELOPMENTS AFTER 11 APRIL 1996

49. I am aware of a letter addressed to me dated 16 April 1996 from Teenah Handiside at the Ministry of Health ("MoH") who made a submission on the draft standards. I produce a copy of that letter as **SS/HFA/0028**. That letter would have been received after I had left the project.
50. I am aware that after the final consultation a version of the standards were sent to the Royal College of Pathologists of Australasia and MedRAC for final approval on 29 May 1997. I produce copies of the letters which were sent to MedRAC and RCPA as **SS/HFA/0029** and **SS/HFA/0030**.

51. I produce a copy of the letter which was sent by Victoria Sinclair to the National Co-ordinator of the National Cervical Screening Programme on 30 May 1997 advising that the standards had been sent to MedRAC and RCPA for endorsement as **SS/HFA/0031**.
52. Victoria Sinclair left the HFA in January 1999 and I understand that responsibility for the project was then passed to Graham Drury.
53. My understanding from information supplied by Victoria Sinclair is that the RCPA were not prepared to give final approval to the draft standards until the issues surrounding NPT were resolved due to the perceived potential quality and business risks associated with increases in NPT. The RCPA wanted the RHAs to develop national standards for NPT with all standards being given effect at the same time. The RHAs believed that it was appropriate for the industry to develop its own standards and a stalemate position developed.
54. Despite the stalemate position with the RCPA I also understood from information supplied by Victoria Sinclair that all laboratories audited at the time agreed with MedRAC to be audited against the *“Draft National Quality and Service Standards for Medical Testing Laboratories”* and that TELARC began to audit against the standards. I have also noted from the evidence of Chris Mules that the 1997 Midland RHA contracts with private laboratories required all services covered by those contracts to be in accordance with the terms of the laboratory’s TELARC (or similar) accreditation.
55. I have since had discussions with relevant people at TELARC and I understand that, in principle, TELARC includes the standards in their auditing of medical testing laboratories. The areas from the standards not included in the auditing are the ones that relate to staffing of pathologists and NPT. Some laboratories (especially smaller

laboratories) have some difficulties in complying with some areas of the standards. In particular, the requirement for quarterly visits by a pathologist to all laboratories. Laboratories can still gain accreditation even if they do not fully meet the requirements of the standards. If there is significant non-compliance with areas of the standards other than the NPT and pathologist staffing sections MedRAC would withdraw the laboratory's accreditation.