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**THURSDAY 11 MAY 2000**  
**THE HEARING RESUMED AT 8.30 A.M.**

**MR MULES** (On former oath)

CHAIR: Mr Mules, could you go to paragraph 61 of your brief of evidence, please. The exhibit you've referred to Exhibit 67 is contained in exhibit 40 isn't it ..... its in both.

We will use exhibit 40 because that has the page numbers. Yesterday I asked you to turn to p25, the Midland document, headed cervical screening. What exactly was that document ..... this is a description of a broad description of the cervical screening programme for which we were buying local co-ordination from Tairawhiti Health Care.

So does it set out your understanding of the service that Midland was purchasing from Tairawhiti ..... no I would say its one level up from that, it's a way of describing for the locally based provided what the National Cervical Screening Programme was abnormal.

I note at p25 the document is described as dated 96/97. when you go to p37, headed characteristics of high quality service ..... that is part of it.

I notice under the heading "laboratory" in terms of TELARC registration it stated that the laboratories should be registered rather than must be registered. Have you any comment why it was still described in that way ..... no.

In order to reflect the contracts you had entered into, signed in March 97, backdated to December 96 by that time TELARC registration was mandatory ..... it was, it went out with a contract effective July 96.

1 Would you turn to p42. in the second paragraph it refers to a quality  
2 improvement grid which actually has been left out of this document but it  
3 appears in exhibit 37, the very last page. .... yes.

4 The reference there to stage 1 reflecting where most of Midland's providers  
5 were placed on the grid that would apply to the laboratories would it not ....  
6 probably a variable picture.

7 Turning over the page of exhibit 40 to p43, under the heading "monitoring  
8 quality', could you read that paragraph and tell me what it means, please,  
9 starting with "the emphasis". .... what it is referring to is the fact Midland  
10 Health itself needed over time to develop its own quality improvement plan  
11 and quality processes.

12 So the first sentence is referring to the need for quality for providers and the  
13 second is referring to Midland also being committed to quality .... yes.

14 Is it correct to conclude that Midland had no chance to put this plan into  
15 action effectively because of the health changes which occurred in 97 .... its  
16 fair to conclude we were at an early stage in the journey described here. I  
17 gave an example of exhibit 41, through the collection of data, this is an  
18 assembly of those facts and basing decision making on that.

19 Have the various health changes that have occurred with the move from the  
20 Department of Health and hospital boards to Area Health Boards and from  
21 there to CHEs and RHAs and from there to the HFA and the hospital  
22 services had a detrimental impact on delivery to the cervical screening  
23 programme in the sense that any long term planning for quality is quite often  
24 interrupted by new structural changes in the health system .... I haven't got  
25 any specific evidence of that but generally what any restructuring or  
26 organisation means is some turnover of people, the ending of some systems,  
27 time taken to develop new systems, loss of corporate history and memory,

1 the need for new people to build up new relationships every strictly change  
2 has significant effect.

3 Looking at the cervical screening programme in 91 policy then was to have  
4 laboratories TELARC accredited within 2 years, that was dropped out of the  
5 9e policy and when you move to CHEs and RHAs you moved away from  
6 requiring change through any direct control to a contracts based system so  
7 you then became dependent on negotiating those contracts and including  
8 quality requirements within the contract ..... yes

9 Those changes in the mechanisms by which TELARC accreditation could be  
10 achieved would contribute to the delay `in actually achieving TELARC  
11 accreditation as a mandatory requirement would they not ..... they could  
12 have. One can only speculate about what process the Department of Health  
13 would have taken to get mandatory TELARC accreditation in place in  
14 laboratories if it carried on under the Social Security Act. Presumably some  
15 sort of regulation would be introduced to give effect to that.

16 Turning back to the grid which is shown in exhibit 37, and applying this to  
17 the cervical screening programme, for example the heading decisions based  
18 on information, stage one it is said there will be financial information  
19 systems in place, data collected but not used .. rather than hard data. Would  
20 you agree that in terms of information availability the cervical screening  
21 programme had not moved beyond stage 1 if this quality improvement grid  
22 were being applied to the programme ..... what period are you talking about

23 93 to 96, which would be the period – right up until the RHAs abandonment  
24 which would e 97 ..... I think as far as Midland is concerned I think we were  
25 probably more into stage 2, we were collecting regular data about  
26 enrolments and colposcopy, everybody understood the reason for collection  
27 of that data and it was followed up and as we've seen with this sort of  
28 document there was an evaluative process going on, assessment of data

1 available, and my impression is that nationally the data from the register was  
2 beginning to be used to a decision making. I would say it was more into  
3 stage 2.

4 The document you referred to what exhibit number is that ..... 41.

5 That document came out either immediately before or just after the RHAs  
6 were abandoned ..... yes, it was printed in August 97 but all work on it had  
7 been done in the latter days of RHA.

8 In terms of use of data rather than collection of data in this one specific area  
9 of assessing laboratory performance and smear reading there doesn't seem to  
10 be any clear utilisation of data to be able to evaluate whether or not  
11 laboratories were performing the tasks of smear-reading competently .....  
12 that was the case at the RHA level, I can't speak what the Ministry was  
13 doing.

14 If you would then turn to paragraph 65 of your brief of evidence, you've  
15 referred there to the ACL interposing itself between providers and Midland.  
16 Did Midland ever attempt to approach the laboratories directly and obtain  
17 individual data from the laboratories ..... not individual data. Dr Malpass  
18 wrote to all the laboratories and we got some information out of that and we  
19 got

20 That was the letter triggered by Good Health Wanganui ..... Yes and we got  
21 comments from individual laboratories about proposals we were making, we  
22 did not get data , it was sought by deloittes and Health Benefits Ltd got a lot  
23 of data related to claims and we were given regular reports on that.

24 That's financial data ..... yes, it is, but claims volumes as well. not broken  
25 down by individual test – we had no way of knowing how much cervical  
26 cytology work each individual laboratory was doing at that stage.

1 Paragraph 67 of your brief of evidence the difficulties you've set out there in  
2 the protracted period of ?, does this illustrate one of the weaknesses of a  
3 contract based model when attempting to deliver health services ..... it  
4 certainly points to the implications of our statutory obligation to consult.  
5 There was plenty of case law emerging through toe about the requirement to  
6 consult meant and it was the consultation process that was the time  
7 consuming part, contract negotiations as such didn't start until a significant  
8 time down the line, not until we agreed on fundamentals.

9 You were aware consultation is not the same as negotiation ..... absolutely.  
10 We had a lot of legal advice about what consultation meant.

11 Paragraph 68 you said the providers were not .. standards. Would it  
12 therefore have been possible to have reached agreement on the imposition of  
13 quality standards and introduced those through the s51 Notices with the  
14 agreement of the laboratories ..... it may have been. The advice I was getting  
15 from Kirk Wakeham was that his impression was that for the community  
16 laboratories issues of quality were tied up with issues of price. Hence any  
17 agreed change to s51 would have probably required a review of fees as well.

18 Were they concerned that if quality control was introduced in a mandatory  
19 fashion and TELARC registration that the costs to meet those standards  
20 should be passed on in terms of the benefits they received ..... that's one  
21 possible interpretation, the other is that if s51 or a contract was to be  
22 renegotiated it was an opportunity to renegotiate price as well.

23 S51 of your volume 9 exhibit 1, I understand your evidence from yesterday  
24 you say this notice was drafted by the body that predated the RHAs ..... no  
25 what I said yesterday I was not sure about that. I was not personally  
26 involved in this. I think work on it was probably initiated by the health  
27 reforms directorate but as the RHAs emerged representatives of each RHA

1 would be involved, the process was led by representatives from north health  
2 who had a legal background.

3 The form of the notices were the same for each RHA ..... yes.

4 If you would turn to the third page in, paragraph 3.2, if you would read that  
5 please. .... yes.

6 You will see there that paragraph does give notice to pathologists that there  
7 may well be some changes taking place ..... yes. this was in an environment  
8 of 2 years of publicity about the health reforms coming, everybody knew  
9 government policy was to effect some change.

10 Turning over the page 67.1 you will; see the notice could be varied or  
11 terminated on giving of 3 months notice ..... yes.

12 And at paragraph 7 which deals with consultation you will see there from  
13 7.2 at the bottom of this page turning over it sets out the consultation process  
14 which in fact puts a time frame on how long consultation would take .....  
15 that's consultation in change e to s51, not on the change on the basis of  
16 contracting.

17 So you are saying if s51 Notice changed – 7.1 says “where variation ..  
18 consultation” and the variation under 6.1 is the variation allowing the RHA  
19 to vary or terminate the notice ..... yes. what this describe is a change to the  
20 s51 Notice. If we wish to continue our relationship based on s51 Notice and  
21 wanted to change them this is the process we would follow. If we wish to  
22 move from s5t1n we needed to follow a different process.

23 Looking at the consultation you will see at the bullet points there was initial  
24 comments to be received within 14 days of the proposed variation; there  
25 was to be meetings to agree a timeframe for discussion of the proposed  
26 variation and failing agreement there was a timeframe of 12 week. By my  
27 reckoning after a period of 14 weeks if the RHA had wanted to change the

1 s51 Notice by varying it to require a pathologist to be TELARC accredited  
2 in respect of cervical cytology it could have done so within that type of  
3 timeframe ..... yes.

4 Sticking with p20 of your brief of evidence I note at paragraph 19 you have  
5 said that you've referred to the quality standards and monitoring being  
6 essentially self imposed at the time when the Department of Health was in  
7 force. Given that the RHA was knowing inheriting a system whereby there  
8 had been no quality practices other than self imposed practices in force do  
9 you consider it good business practice to accept those services as being  
10 quality services without first attempting to audit those services or make any  
11 type of enquiry into the quality aspects of the service ..... in an ideal world  
12 the answer is clearly not, however the same argument applied to 800M  
13 worth of business Midland inherited on day one. We had no idea what it  
14 was we were buying on day one anywhere.

15 In business there is a due diligence before you buy anything ..... we weren't  
16 buying them we were talking on risk without much ability to mitigate that  
17 risk.

18 When you say Midland had no reason to question the quality of services –  
19 paragraph 69 – that was brought about by circumstance in that you couldn't  
20 audit all the services you were inheriting ..... that and also it was not the  
21 prevailing attitude of the time that laboratory services were substandard we  
22 did not we were not created in an environment where there was high level of  
23 concern about laboratory services.

24 Turning to paragraph 88 of your brief of evidence where there is reference to  
25 Dr Bottrill informing Midland that Gisborne Laboratories had applied for  
26 TELARC registration was there any attempt in respect of any laboratory,  
27 including Dr Bottrill who gave you notice he was applying for accreditation  
28 to see when accreditation was given or any steps were taken to pursue

1 obtaining accreditation other than making an application for it ..... I did  
2 address that yesterday but it was described as hearsay

3 From your knowledge of the RHA records you know nothing about that .....  
4 my evidence and the information I bring was abased on review of files and  
5 conversations with staff members. My evidence is based on the former  
6 rather than the latter – I was given a verbal understanding.

7 So without saying what you were told based on your knowledge, from which  
8 you obtained f staff members you have reason to believe some follow up  
9 occurred ..... yes.

10 Could you turn to paragraph 90 of your brief of evidence. You've referred at  
11 paragraph 90 to this division of responsibility for between RHAs for quality  
12 standards .. what practical impact did this division have on delivery of  
13 services under the programme ..... I think its practical impact is that we  
14 approached laboratory services in a general sense – when we were thinking  
15 of contracting with laboratories w e were not thinking of cervical cytology in  
16 isolation but all laboratory services.

17 PROFESSOR DUGGAN: I did note in exhibit 40 there were consumer  
18 surveys carried out. .... we required contracted providers to serve  
19 consumers.

20 And laboratory was one of those consumers ..... I'm not sure. You are  
21 talking Tairawhiti Health Care quality plan.

22 Yes. page 8 of the survey. .... yes

23 Consumers laboratories and smear-takers ..... yes.

24 I'm unclear with relation to laboratories are the laboratories surveying their  
25 clients or are the clients surveying the laboratories ..... question for  
26 Tairawhiti Health Care. This is in their plan.

1 When this plan was presented wasn't explanation requested ..... I personally  
2 didn't review this plan myself, I can't answer that question. I'm sure it would  
3 have been I was not involved in that.

4 There may be a document surveying the laboratory from Tairawhiti ..... there  
5 may well be.

6 CHAIR: if you would go to paragraph 91 of your brief of evidence, you've  
7 said Midland had "no reason to believe .. s51 Notice .. service quality " on  
8 my reading of the s51 Notice I couldn't see anything that specifically related  
9 to service quality other than the requirement that the practitioner be  
10 registered pathologist and have certain apparatus in the laboratory .....  
11 exactly.

12 That's what you are limiting it to ..... in other words we had very limited  
13 scope within the s51 Notice , service quality was defined in a very limited  
14 way, and the response from Dr Bottrill in his letter to Dr Malpass there was  
15 nothing in that in my view that allowed us to act in terms of s51.

16 Except that the terms of s51 itself and the terms of s19 and the Health and  
17 Disability Services Act didn't limit you in the way that you read clause 3 of  
18 schedule 2 to s51 did it ..... no as I recollection there is a catchall phrase in  
19 there, something about public interest

20 Yes, s19 requires the RHA to purchase services only from persons who  
21 maintain standards that the purchaser consider . for the services, and s51  
22 gives power to change the notice if you are going to revoke any of the terms  
23 and conditions you have to give 4 weeks notice but there doesn't seem to be  
24 any limiting factors in the language of s51 itself ..... no there don't. I think  
25 the prevailing attitude amongst RHAs generally was that the emphasis  
26 should be on moving to more substantive contacts and that was where we  
27 directed our energies.

1 You've actually quoted clause 3 of schedule 2 of the s51 Notice in paragraph  
2 47 of your brief and there is that clause 3.1.2 which allowed the RHA to take  
3 into account, to refuse recognition where it would be contrary to the public  
4 interest ..... yes.

5 Turning back to paragraph 91, on what basis did Midland assume that  
6 Gisborne Laboratories was operating within the terms of the s51 Notice .....  
7 in the absence of any specific audit or in the absence of any specific  
8 complaints and I've talked about some of the mechanisms through which  
9 complaints came and we received a lot of them really it was by default, we  
10 assumed they were operating unless we had some reason to understand that  
11 they were not.

12 At the bottom of paragraph 91 you deal with complaints and say there had  
13 been no complaints about Dr Bottrill. In terms of smear-reading given that  
14 CIN III is not a condition visible to the naked eye its unlikely there are going  
15 to be any complaints about false negative smear-reading until the condition  
16 advances to the point of invasive carcinoma is there ..... could assume them  
17 except as I've heard here there were concerns expressed to the Department of  
18 Health through the 80s under different circumstances, a person commenting  
19 they had never had a positive finding. That goes against the comment you  
20 just made.

21 But unless a medical practitioner was thinking in that global sense of why  
22 am I not getting an positive findings there wouldn't be anything in any  
23 individual case to trigger a complaint would there ..... complaints by  
24 practitioners about other practitioners were not restricted to individual  
25 complaints or cases, we had many observations of systematic failure.

26 PROFESSOR DUGGAN: what do you mean by that ..... by that I mean –  
27 I'm not talking about Dr Bottrill, providers observing this other provider is

1 operating in a substandard way, making generalised observations rather than  
2 about specific cases.

3 And there was a mechanism within the RHA to lodge these observations and  
4 investigate or were these anecdotal ..... they usually came to us as anecdotal  
5 but we had a senior staff member who had responsibility for investigating  
6 complaints and he would conduct initial assessment to gauge the severity of  
7 it and then in conjunction with the board make a decision about what course  
8 of action should be followed

9 Were there any complaints about laboratories in Gisborne ..... no.

10 CHAIR: how were women to know if their smears were being misread .....  
11 I think that's a very difficult question, they would really on the practitioner  
12 who took the smear given they had no personal contact with the laboratory.

13 In terms of the practitioner until the condition had progressed beyond CIN  
14 III the practitioner conducting a physical examination of the women would  
15 have no reason to think the smear had been misread ..... that's right about the  
16 individual smears but the referring practitioners would have a long  
17 association and relationship with Dr Bottrill as an individual and also in a  
18 professional relationship with him. Presumably practitioners in the Gisborne  
19 area formed a view individually about his skills.

20 Did Midland canvass the practitioners about their views on other health  
21 professionals such as the laboratory and Dr Bottrill ..... no we didn't  
22 specifically ask practitioners in Gisborne what they thought of Dr Bottrill or  
23 other laboratory providers. Other than we consulted with practitioners in  
24 Gisborne in the course of developing our laboratory contracting approach so  
25 they were involved in a general consultative process and I think there was  
26 evidence produced of a letter written to a general practitioner in Gisborne  
27 seeking his views in the approach Midland was proposing to take. So during  
28 that consultative process we would have received feedback on how they saw

1 the future of laboratories service. my recollection of that, have not  
2 researched for this, my overriding feeling is that is that general practitioners  
3 in particular wanted choice.

4 PROFESSOR DUGGAN: did Midland have a mechanism whereby it  
5 surveyed its clients and customers to determine their level of satisfaction .....  
6 yes, we did.

7 And who did you survey ..... randomly selected people from the community,  
8 we did quantitative surveys plus ran many consultation exercises through the  
9 various communities of the region in the form of small meetings and public  
10 meetings and meetings with particular community groups.

11 Were there any comments re the screening programme and the laboratories  
12 ..... I'm sure there were many comments re the screening programme.

13 Were these positive/negative comments ..... I don't recall.. there was  
14 generally a high level of support for the screening programme, that is  
15 reflected in the enrolment. Seen as positive thing by the mid 90s there were  
16 high levels of enrolment and good support.

17 If there were negative you acted on those and investigated ..... any  
18 complaints were referred to this particular senior member of staff  
19 responsible for them. As well as that we had staff members based in each  
20 locality, field managers,. We had one based in Gisborne, and they were our  
21 eyes and ears on the ground and they received often received observations,  
22 complaints, comments about what was going on, they produced weekly  
23 reports to their manager and their manager at midlands offices referred those  
24 throughout the organisation for follow-up. I can't I haven't been through  
25 those weekly sheets to see whether there were any observations of laboratory  
26 services but if they were significant they would have been escalated inside  
27 the organisation.

1 Some complaints would have gone directly to the pathologist in charge of  
2 the laboratory and may not have been copied to this key individual ..... that is  
3 possible, yes.

4 How would you know about these ..... in respect of s51 n we would not have  
5 known where we had contracts in place it was necessary for the provider to  
6 have a complaints system and for unresolved complaints to be notified.  
7 Emerging at this time was the Health and Disability Commissioner and the  
8 complaints officers that that commissioner had around the country, this was  
9 a climate in which there was a lot of awareness of the consumer's ability to  
10 complain and some confidence that those complaints would be followed up.

11 Laboratories stratified the incidence of complaints broadly into major and  
12 minor generally there is a process whereby major complaints are forwarded  
13 to a regional body such as your body ..... yes.

14 Was such a process in place in the Midland RHA ..... generally it was but no  
15 provision under s51 for that to be done. During Midland's term of existence  
16 I'm not aware of any complaints about laboratory services. Apart from the  
17 one I have included in the evidence which was that at Lakeland Health that  
18 I've described the follow-up process

19 If a laboratory had a major incident you would not know about it ..... a s51  
20 laboratory, they were not there was nothing in the s51 Notice as I recall that  
21 required them to notify us of it. I expect commonsense would prevail in  
22 those circumstances, I would hope so.

23 CHAIR: in terms of the public meetings you have spoken about where  
24 consumers met and were given opportunity to bring our complaints that may  
25 have assisted complaints re smear-taking where the consumer may have felt  
26 that she was not getting the service she desired but in terms of smear-reading  
27 you would agree the consumer be in no position to determine the quality of  
28 the services ..... yes.

1 You said at paragraph 92 that the local doctors were in the best position to  
2 consider the appropriateness of Dr Bottrill's work. What do you base that  
3 statement on ..... I base that on the observation you've made before that  
4 women were really not in a position to know and therefore the people on the  
5 ground that had the relationship with Dr Bottrill, were referring the work to  
6 him and getting his interpretation back, were the ones best placed. They  
7 were able to observe Dr Bottrill's work.

8 In terms of smear-takers, either nurse or medical practitioners, they don't go  
9 to the laboratory do they ..... generally no.

10 The smear is sent off and they receive a report in the mail saying what the  
11 reading is ..... yes.

12 How would a smear-taker for example a smear-taker who was nurse, how  
13 would that smear-taker be in a position to doubt that the test that she was  
14 reading was correct ..... generally they would need to rely on the competence  
15 of the person interpreting the test, this comment in 92 is made in the context  
16 of given the nature of the s51 Notice, the nature of our complaints system  
17 and women did not have personal contact with Dr Bottrill, generally  
18 speaking the people in the best position were ordering tests from him. There  
19 is limitation .

20 That was limited. Really all they could do would be to really on the fact that  
21 Dr Bottrill was a qualified pathologist and assume he would carry out his  
22 work competently ..... yes.

23 Would you turn to p28 ..... if I could make one other comment. The other  
24 person I haven't mentioned who would be in a strong position to get a  
25 general sense of any views there were of laboratory services in Gisborne was  
26 the cervical screening manager who had the on the ground co-ordinating role  
27 that encompassed liaison with laboratories.

1 Was this person employed by Gisborne or Tairawhiti ..... Tairawhiti. We  
2 never received any comments from the people in that position about the  
3 competence of Dr Bottrill.

4 Who was Programme Manager at the time ..... there were a number of  
5 people, the correspondence in exhibit 40 is from the person who was the  
6 Queenie Puketapu.

7 No doubt Tairawhiti would be able to inform us when they give evidence .....  
8 yes.

9 Turning to paragraph 100 of your brief of evidence you refer to the policy  
10 group which was developed as a result of the Malpass memo. That first met  
11 on 12 April 95 and I note the Malpass memo to you was 18 October 94. do  
12 you consider that was sufficient time in which to respond ..... as you would  
13 see from other exhibits the process followed from there was we got the  
14 response to the Malpass letter, I wrote to all laboratories suggesting we were  
15 considering implementing mandatory internal external peer review, we got  
16 the responses from those people, they were considered, a paper was put to  
17 the Midland board as I recall in October, a decision was made at that stage to  
18 establish a group, there was then consultation with all the bodies about what  
19 that group should compromise and what terms of reference should be and  
20 Christmas intervened, and then it first met in April. From my perspective  
21 the timeframe is understandable.

22 At paragraph 101 where you referred to the letter from TELARC, that letter  
23 appears on its face to be limited to histology accreditation and not cytology  
24 ..... it was because the correspondence with initiated by Good Health  
25 Wanganui was about histology, as I recall that letter says that through 95  
26 specific requirements were going to be defined for each branch of laboratory  
27 services which would have included specific cytology requirements.

1 Paragraph 105 where you refer to the small market for laboratory services,  
2 choice of laboratory was determined by the primary caregiver who took the  
3 smear ..... yes

4 The only influence Midland could have would by refusing to pay a  
5 laboratory or requiring the primary caregiver to go to a laboratory of  
6 midlands choice ..... yes, that latter choice of action my impression that has  
7 never been done in New Zealand for any service.

8 P109 which deals with the National Cervical Screening Programme, you  
9 were an assistant g with the Bay of Plenty Area Health Board. Where you've  
10 said each "... co-ordination" to your knowledge were there variations in  
11 terms of how Area Health Boards delivered the programme and managed the  
12 registers ..... my impression was that the variation was in the strategies used  
13 to promote the programme and in the method of delivering health education  
14 and health promotion services around the programme and in the extent to  
15 which non-medical smeatakers were recruited. That was driven by the  
16 nature of the population being served.

17 At paragraph 112 you said "there were challenges .. and laboratories". Can  
18 you outline what was the Area Health Boards source of authority to deal  
19 with laboratories ..... I'm not sure we had any authority, this was the point  
20 I'm referring to here. We were charged with co-ordination but we had no  
21 authority to apply to general practitioners or laboratories. It was  
22 encouragement.

23 In a practical sense how did that impact on your ability to bring about any  
24 change you might want to bring about in respect of delivery of the  
25 programme ..... severe impact., the relationship of laboratories was with the  
26 Department of Health, similarly the relationship of general practitioners was  
27 with the Department of Health. so and in both cases those were payment  
28 relationships. Through this time the department was working with national

1 bodies through Cytology Advisory Liaison Committee and the other  
2 Cervical Screening Advisory Committee but there was no – a lot of the role  
3 of the Area Health Board Programme Manager was to try and communicate  
4 what was going on nationally at the local level.

5 And did the Programme Manager have any authority or was she simply  
6 performing the role of passing on information flowing to her ..... it was the  
7 latter – she had no authority nor over general practitioners. In Bay of Plenty  
8 case it was similar to the others, the only management authority and control  
9 she had was over health education and health promotion services and the  
10 register.

11 In terms of there being 14 different registers and taking what you've said at  
12 the bottom paragraph 113 of your brief of evidence, we talked about Area  
13 Health Board manager .. programs, did this lead to duplication .....  
14 duplication of what

15 Just in terms of if there are 14 separate registers, 14 separate programmes  
16 running, were there overlaps – was it an efficient way to run the programme  
17 ..... I think it was efficient in effective in one way and the operating  
18 environment was that of devolved responsibility to Area Health Boards and  
19 the rationale was local responsiveness being able to respond to the  
20 idiosyncrasies of the local environment. I think that was a positive element  
21 of it as opposed to a one size fits all nationally imposed framework. We've  
22 heard from other witnesses there was a downside to having 14 separate stand  
23 alone registers. I think one observation with hindsight one could have had a  
24 locally responsive programme but a single register, that was moved to over  
25 time. This was in an environment where it was opt on, the emphasis had to  
26 be on promotion of the programme in a way locally responsive to encourage  
27 women to enrol.

1 From the management perspective in terms of delivering efficient service  
2 given that screening programme is a discreet issue, New Zealand has a small  
3 population, would it be more effective to be run from a national unit with a  
4 body who had executive decision making power and funding allocation  
5 powers ..... with hindsight one can say that. that was not the prevailing  
6 environment at the time and I was not party to any discussion or decision  
7 making on that – I can't make an observation, in hindsight.

8 I am asking from your perspective what the Area Health Board structure had  
9 on the management of the programme ..... it was set up in that environment,  
10 in that environment that was all we knew. Its only with hindsight one can  
11 look back and take lessons from it. I described the thinking of the RHAs on  
12 the breast screening programme which gives evidence of the lessons learnt  
13 of trying to operate a national programme inside a devolved structure.

14 Did the concept of a cervical screening programme get caught up in the  
15 greater momentum of the devolution of health delivery to the regions ..... I  
16 really only became aware of the detail of the cervical screening programme  
17 when it arrived on Bay of Plenty Area Health Boards door. I can't make  
18 observations what happened prior to that

19 To whom was the local Area Health Board Programme Manager  
20 accountable ..... to me

21 Did she have accountability to the Department of Health ..... a dotted line  
22 accountability to the national co-ordinator

23 What does that mean ..... as opposed to a managerial accountability there  
24 was a less formal line of accountability, but that was given that it was less  
25 formal it was still very strong. There was a very effective working  
26 relationship between Bay of Plenty programme manager during this time.

1 At paragraph 115 you've referred to the aim of the programme and you've  
2 quoted from the 91 policy under heading laboratories. You then go over the  
3 page at 116 to say to your knowledge .. standards .. unclear. Was it therefore  
4 unclear to you in your role as an Area Health Board assist manager that  
5 there was no accountability structure built in to implementing these quality  
6 standards ..... I was aware that the laboratories were paid by the Department  
7 of Health under the Social Security act. I wasn't aware of the detail of the  
8 Social Security Act but I was broadly aware from reading the policy  
9 guidelines and the literature that came to the Area Health Board at the time  
10 that this is what the Department of Health was working on. And I knew that  
11 there was a Social Security Act that really governed terms of payment and I  
12 had no knowledge of what was being envisaged in the department as a way  
13 of ensuring that it was able to implement quality standards in laboratories.  
14 As I said the assumption I now make is they must have been thinking of  
15 doing that by regulation .

16 Do you know who had authority in 91 to 93 to ensure the 91 policy of  
17 accreditation in 4.1.2 was said to take up to 2 years was actually carried out  
18 ..... no, it would be someone inside the Department of Health. ultimately the  
19 Director-General I guess.

20 And you've then later at paragraph 120 referred to the 93 policy which of  
21 course imposed the responsibility on the Ministry of Health to monitor  
22 whether or not the standards were being carried out ..... it rolled over the  
23 responsibility from the department to the Ministry. So in that sense it was  
24 really just a name change

25 We've learnt through evidence and you dealt with this yesterday that you  
26 now know the Ministry of Health considered it wasn't capable of carrying  
27 out the role under the 93 policy dealing with laboratories. It would seem,  
28 taking your evidence as set out at 116, when the policy was first published in

1 91 the Department of Health had a responsibility under it to ensure that  
2 laboratories to monitor laboratories to see whether they conformed with  
3 certain criteria but your evidence is it was unclear how this would be  
4 achieved ..... yes

5 By the time we move to the 93 policy where the Ministry of Health was  
6 going to carry out this responsibility it didn't have the means to do so as we  
7 heard from Ms Glackin ..... it could have done it in 2 ways, presumably  
8 regulations could have been introduced and the RHAs could have been  
9 instructed. It could have been done through the RHAs or done through  
10 regulation.

11 Accepting Ms Glackin's evidence the Ministry wasn't doing it, she says in  
12 paragraph 291 of her brief of evidence it was clearly not possible ..  
13 arrangements. It would seem the upshot is since 91 there has been a policy  
14 document which sets out good criteria for requiring laboratory quality  
15 controls to be in place and no-one has been effectively carrying it out nor  
16 does it seem has there been any clear authority by which it could be carried  
17 out do you agree ..... I would certainly the evidence would support the  
18 former. I think there are ways in which it could have been carried out.; the  
19 impression that one gets from the 93 policy is that the Ministry was working  
20 with Cytology Advisory Liaison Committee and with other bodies on these  
21 sort of things and that in time the RHAs would have been instructed to  
22 implement them through contracts.

23 But you accept under the policy the policy document states it will be the  
24 Ministry of Health who carries these matters out ..... yes

25 [you thought the Ministry of Health was doing it therefore the RHA wasn't  
26 doing it ..... yes.

27 at paragraph 122 you dealt with the change from Area Health Boards to  
28 CHEs and RHAs. Do you agree after the reforms the accountability

1 structure for the cervical screening programme in effect became split  
2 between funding agreements between Ministry of Health; secondly and the  
3 RHA and the RHA and laboratories and then thirdly the RHA and CHEs .....  
4 yes, that's right. I think operationally on the ground as far as the transition  
5 from Area Health Boards into CHEs were concerned very little changed.  
6 The nature of the programme didn't change at all, their line of accountability  
7 was, in contract terms, to a RHA instead of the Department of Health  
8 because there were contracts between Area Health Boards and the  
9 Department of Health. so operationally nothing changed. And the CHEs  
10 continued to have the dotted line relationship to the national co-ordinator in  
11 the Ministry of Health. this is why as I described yesterday It was a struggle  
12 for the RHAs to see how much value they were adding in the programme.

13 At paragraph 124 you referred to the 93 policy and referred to the  
14 monitoring and evaluation of the programme remaining with the Ministry of  
15 Health. you said the Ministry had access to information to allow monitoring.  
16 What did that mean to Midland ..... I meant the only information we had  
17 routinely about laboratory services was that from Health Benefits Ltd

18 That was to do with payment wasn't it ..... correct.

19 Could Midland have got any other information about the register if it had  
20 sought it ..... yes we could and I'm aware of one request for register  
21 information that one ad hoc request we made on behalf of the Programme  
22 Managers from the CHEs which was made through the Kaitiaki Group for  
23 information about enrolment of Maori women. And I think that is actually  
24 mentioned in some of the evidence that's been presented by other people.  
25 There was discussion amongst Programme Managers with the national co-  
26 ordinator how useful it was to get that information – an ad hoc report.

27 Did you have any systems set in place to receive other information from the  
28 Ministry of Health concerning the programme other than the information

1 from health benefits ..... Jane Hudson used to meet with the national co-  
2 ordinator – clause 135 – annually but that the RHA Programme Manager  
3 used to go to the regular national meeting and anything of significance for  
4 RHAs was fed back at that time through the central RHA representative.

5 You've referred at paragraph 125 “monitor .. purchased”. Given that under  
6 the 93 policy the responsibility was out of the Ministry of Health to monitor  
7 and evaluate laboratory services did this more general requirement to  
8 monitor and evaluate under your funding agreement with the Crown create a  
9 tension in terms of who had responsibility to do what under the screening  
10 programme ..... the information that we had access to that allowed us to  
11 monitor and evaluate quality was through our contracts with CHEs that is  
12 why I included the relationship with Tairawhiti Health Care which was  
13 through regular reporting of the indicators plus development of quality  
14 improvement plan and reporting against milestones in that. I think as far as  
15 other routine monitoring and evaluation that depended on the information  
16 from the register and I think in time if the RHA had remained in the role it  
17 had we would have sought to significantly improve the information from the  
18 register as you would see from exhibit 41. the next stage from that was to  
19 look at what were the operational implications of this kind of document and  
20 its very clear from that that there were significant operational implications to  
21 be followed up and information from the register would be important part of  
22 that.

23 In practice then was there any ambiguity or not in terms of balancing the  
24 general requirement under the funding agreement to monitor and evaluate  
25 quality of services including laboratory services and the 91 policy which was  
26 incorporated into your funding agreement which placed specifically the  
27 responsibility for monitoring and evaluating laboratories on the Ministry of  
28 Health ..... it was a 93 policy included in the funding agreement both of

1       them said the same things. It is that ambiguity I am attempting to point out  
2       in paragraph 125 here.

3       At paragraph 126 of your brief of evidence you say there that “although you  
4       had responsibility .. such quality issues.” Is it correct that on the face of it  
5       you appeared to have contractual obligations to monitor quality which you  
6       had no means of fulfilling in a full sense but all you could do was respond to  
7       ad hoc complaints when they arose, so that these monitoring and evaluating  
8       responsibilities may have created a false sense of comfort. .... I'm not sure  
9       who they created comfort with.

10       How did you find them in terms of carrying out the role given you had no  
11       means of identifying quality issues and obtaining information ..... it was a  
12       major concern, it explains why – it applies not just to laboratory services but  
13       across all services, we were created to effect change and as I've said in my  
14       evidence to install a system, wide sector, wide chain of accountability for  
15       quality as well as other matters, we inherited a system that had very little of  
16       that kind of accountability and we need to take a staged approach to  
17       introducing it. We were part way through that task when we ceased to exist.

18       The limitations on the RHA's ability to discharge its responsibilities in terms  
19       of monitoring and evaluating, was that inability acknowledge by the  
20       Ministry of Health at the time ..... yes. it was commonly understood and you  
21       would see from the policy guidelines that there is a lot of discussion there  
22       about the need to move from s51 to contracts and the need to install quality  
23       systems; there was an acceptance that they didn't exist and a process needed  
24       to be followed to introduce them.

25       From the perspective of the onlooker reading documents such as the funding  
26       agreement and the 93 cervical smear policy agreement and not having the  
27       benefit of the background information that someone working within the  
28       RHA or Ministry of Health would have had that these documents with their

1 provision for m/evaluation may have been falsely reassuring in terms of  
2 those activities being delivered ..... I think the cervical screening programme  
3 policy made it clear that there was a lot of work to be done, the clauses  
4 we've talked about in paragraph 120, that these describe some processes that  
5 were to be done – it would clear from the 93 policy that there was work to be  
6 done, work in train, that system was not fully implemented but broadly  
7 speaking the Health and Disability Services Act with some the clauses we  
8 talked about made broad statements about the responsibilities that RHAs had  
9 for example to purchase quality services that it would not have been clear  
10 from reading that Act that it would take a considerable period of time and  
11 resources to make it happen.

12 Turning to paragraph 127 of your brief of evidence you have said the  
13 specific laboratory component of the programme .. responsible. Did the  
14 Ministry know that the RHA took this view of their responsibility ..... the  
15 Ministry of Health set the performance indicators and they were focused on  
16 enrolment numbers of smears and access to colposcopy and they were aware  
17 of the approach that we were taking to laboratory contracting. It was  
18 commonly understood amongst all parties that the RHA focus was on  
19 enrolment and colposcopy in respect of the programme.

20 Is your evidence then that the Ministry knew that the RHA believed that the  
21 Ministry was responsible for the what you've described as the specific  
22 laboratory component of the National Cervical Screening Programme ..... it  
23 was documented in the funding agreement in that way as we have seen. This  
24 is in respect of the clauses that were carried forward from the cervical smear  
25 policy

26 4.12 to 4.15 clauses ..... yes. I don't recall any discussion to the contrary  
27 either during funding agreement discussions or at other times during the year  
28 that the Ministry had a different view of that and they were kept fully

1 informed of the process we were following to move from s51 to laboratory  
2 contracts.

3 I want to be clear then, you can only give evidence of your experience of  
4 dealings with the Ministry during this time, but from your dealings with the  
5 Ministry did you gain the impression that the Ministry was aware Midland  
6 Regional Health Authority believed because of the cervical screening policy  
7 in 4.1.2 and 4.1.4 that the laboratory component of the programme was the  
8 responsibility of the Ministry ..... if you are referring to those aspects of the  
9 laboratory components as described in 4.1.2 to 4.1.5 ..... yes, I was never  
10 party to any discussions that would have made people think otherwise. We  
11 were responsible in the context of moving from s51 to laboratory contracts  
12 that would have introduced TELARC region but that was in a generic sense.

13 As I read your evidence in paragraph 1.2.7 you are saying the RHA believed  
14 Ministry responsible for the laboratory component of the screening  
15 programme ..... yes, as laid out in policy guidelines.

16 The point is if that was the understanding of the RHA then whether or not  
17 there was any monitoring and evaluation of the laboratory component of the  
18 programme would depend very much on whether the Ministry recognised  
19 that it was responsible for that part of the programme wouldn't it ..... yes it  
20 would depend on their interpretation of the cervical screening policy and the  
21 funding agreement.

22 What I am trying to find out from your knowledge is whether or not the  
23 Ministry was aware of the RHA view ..... I've got no reason to believe that  
24 they weren't, and Jane Hudson was in frequent communication with the  
25 national co-ordinator and as you've seen from the service requirement  
26 definition Jane has carried forward the policy into those documents. I would  
27 have thought she would not have done that if she had a contrary view.

1 The outcome would be if the RHA relying on the documentation believed  
2 the Ministry was responsible for the laboratory component of the programme  
3 in terms of monitoring and evaluation but if the Ministry itself believed that  
4 it couldn't carry that out, as heard from Ms Glackin, it would really mean no-  
5 one was doing the job wouldn't It ..... one can assume that.

6 Would it be correct to conclude that ..... if I could add one comment to that.  
7 my understanding was that as far as use of the information from the register  
8 there was some m/evaluation being carried out by the Ministry so I don't  
9 think it is fair to say nothing was happening.

10 I'm referring specifically to the criteria set out in the cervical screening  
11 policy 91 and 93. when you say in paragraph 127 that the RHA believed the  
12 Ministry was responsibility for the laboratory component of the programme  
13 are you speaking more broadly than simply the criteria set out from 4.1.2 to  
14 4.1.4 of the policy ..... no, I'm speaking specifically about that. we were  
15 responsible in the sense that we were purchasing laboratory services across  
16 the board but in respect of the detail of the programme that is what is  
17 described in 4.1.2 to 4.1.5.

18 And I note from paragraph 133 of your evidence that the 96 screening  
19 programme also provides the Ministry of Health – “is to develop processes ..  
20 practice” - that responsibility remained with the Ministry when the 96 policy  
21 was developed ..... yes. because this information would be obtained from  
22 the register.

23 Turning to paragraph 140 you have referred to TELARC and the limitations  
24 of TELARC. In the correspondence that was replying to Dr Malpass' letter  
25 there is a letter from Medlab Hamilton which sets out their views in  
26 TELARC, dated November 94, tab 11. if you turn to the second page you  
27 will see firstly at paragraph 4 the writer refers to the main focus of TELARC  
28 .. of work” but goes on to say “... personnel”. Then in the next paragraph

1 the reference to TELARC “ ... quality assurance programme”. Paragraph 8  
2 “.. internal audits .. for histology will be required .. cytology”. TELARC  
3 accreditation would in itself bring with it the requirement to participate in  
4 both the external quality assurance programmes and internal audits ..... that’s  
5 my impression from this. This was pointing out to me yesterday. I think its  
6 fair to say, you would see this from Dr Malpass memo to me there was – the  
7 prevailing view at this time was that TELARC focus primarily on systems  
8 and processes and there was ongoing reliance on the College’s to do with the  
9 competence of individuals.

10 In paragraph 142 you've referred to period 91 to 96 with the  
11 department/Ministry of Health being responsible for laboratory quality in the  
12 programme, that is a reference back to the 91 and 93 cervical screening  
13 policy isn’t it ..... yes.

14 You then said the Ministry controlled the data from the screening register ..  
15 laboratory activity .. Midland did not have access to such data. In terms of  
16 wanting to generally evaluate whether it was getting value for money from  
17 the laboratories it was funding could Midland have gained access to that data  
18 ..... I have described one episode in which we did so. It was possible to get  
19 ad hoc reports but we didn't have routine access to it and the sort of  
20 information we would have needed regularly was the analysed data rather  
21 than raw data otherwise we would need do all analysis ourselves again.

22 Did Midland have any other cause to approach the register to see if it could  
23 get data ..... I'm not sure about that.

24 Between the time that Midland was in existence between 93 and 97 would a  
25 correct summary of its dealings with the laboratories have been that it was  
26 funding laboratories, including Dr Bottrill’s in circumstances where there  
27 were no quality assurance requirements in place and it had no means of

1 monitoring the laboratories work practices ..... broadly speaking yes, the  
2 only provisions there were extremely limited ones in the s51 Notice.

3 PROFESSOR DUGGAN: One final question. In exhibit 18 at the back of  
4 this contract there is a draft national quality service standards for medical  
5 testing standards ..... yes

6 This is an earlier draft of this document ..... yes this was the draft that existed  
7 in early 97. I think it went through after this a whole consultation rounds  
8 and various other forms. I had left the RHA by this stage.

9 Do you know if this document is in final form ..... no I don't know

10 Was it in final form when you left RHA ..... no, still in draft form

11 When did you leave ..... late 97.

12 So that would have been a year later ..... yes, this was attached to the  
13 contracts signed February/March 97 – at the end of that year. This was a  
14 process that I was not involved in.

15 However you have the skills and expertise to comment on my next question,  
16 which is how long does it take to develop such a document from draft stage  
17 to final stage ..... the length of time it takes is directly proportional to the  
18 number of parties involved and complexity of the content. And also what  
19 process is being followed to develop the content and how much resource is  
20 dedicated to it. And I'm not aware of the detail of any of those things other  
21 there was a gigantic number of parties to be consulted in the development of  
22 these standards but one would expect that a year max would be a reasonable  
23 amount of time I would have thought but I don't know the detail of how  
24 much resource, what process was followed and how contentious the content  
25 was.

26 Were you developing similar documents for other professional groups such  
27 as radiology ..... no we weren't. this was the first area in which the RHAs

1 decided to work jointly on national standards, it was a test case. The general  
2 approach at the time was for each RHA to act regionally in developing its  
3 approach to quality and as you have seen from the documentation Midland's  
4 approach generally was around having quality implementation plans for each  
5 provider. This approach was not typical of the time and was really agreed to  
6 be necessary in the absence of any appropriate standard national standard to  
7 call on as a backdrop for individual quality improvement plans.

8 Thank you.

9

10 MR KIRTON:

11 The chair this morning prior to 9a.m. asked you issues relating to s51 notices  
12 and is It correct that your response was the Kirk Wakeham gave you advice  
13 that a mandatory change to s51 in quality would create an opportunity to  
14 renegotiate price as well ..... yes the advice from Kirk was that in terms of  
15 the parties he was working with he believed issues of price and quality were  
16 intimately related

17 He gave you that advice when you were considering the responses that you'd  
18 received from the various laboratories in relation to the Wanganui and  
19 Malpass letters ..... no I wouldn't categorise it that way. It was a major  
20 reason as to why we decided to move down the path of introducing contracts  
21 as opposed to any specific revision of a s51 Notice to apply to cervical  
22 cytology. That was the context in which I answered the question

23 K/wakeham did give you advice at the time Dr Malpass was similarly  
24 advising you on his concerns in respect of some of the practices going in  
25 Midland – 18 October 94 memo from Dr Malpass which was c.c. to  
26 k/Wakeham. Did he give you similar advice at that point ..... I can't  
27 remember specifically but the memo presented to the Midland board that

1 recommends a course of action would have been drafted by k/Wakeham.  
2 And it was that course of action that was ultimately recommended to the  
3 board, yes.

4 Can I ask you then in terms of Dr Malpass' memo in October 94 where he  
5 has clearly become concerned and he says "it is recognised that this  
6 prescriptive advice .. however it is of utmost importance to ensure ..  
7 services." Was it Dr Malpass concern that he was aware of the Wakeham  
8 advice and no action was likely to be taken in specific in Gisborne ..... no I  
9 don't think you can connect it in that way. I think what he was saying was  
10 that he was aware, Dr Malpass was aware of the nature of the s51 Notice  
11 and the nature of the contracts with CHEs and he was just making the  
12 observation that mandatory imposition of internal and external quality  
13 review practice would be awkward given the nature of our current contracts  
14 – what he is saying is obvious.

15 You made an active decision not to invoke s51 at that time didn't you ..... yes  
16 we made the decision to press ahead, to continue our efforts with relation to  
17 laboratory contracts.

18

19

20

21 RE-EXAMINED BY MR MURRAY:

22 You were asked a question by madam chair about reasonable endeavours,  
23 the question is at p1269 of the inquiry's transcript, line 26, madam chair  
24 said this "The fact that the Crown used that phrase reasonable endeavours in  
25 the ... the Crown" and your answer was yes. do you remember that  
26 evidence ..... yes.

1 Is it also a possibility that the RHAs persuaded the Crown that there were  
2 practical difficulties if it was made mandatory, if TELARC accreditation  
3 was made mandatory ..... there would discussion certainly of the reasons  
4 why there were practical difficulties in making anything happen in a hurry.  
5 There would be discussion about the appropriateness of the process Midland  
6 was following and acceptance on the part of the Ministry and the Minister  
7 that that was an appropriate process to be following.

8 So it may have been a high priority for the Crown but there may have been  
9 practical problems. Do you personally know of any practical dfclt8es that  
10 were brought to the Crown's attention about TELARC accreditation being  
11 made absolute in the funding agreements ..... I don't personally recall the  
12 detail of any discussions. I can remember extremely general issues of the  
13 discussions but the extent to which it was entered into I don't recall.

14 You earlier referred to the possibility that laboratories would have to cease  
15 providing a cervical screening service if mandatory TELARC accreditation  
16 was introduced. Do you know if that came up in this context ..... I'm sure it  
17 would have, I don't recall specific instances of it.

18 You were asked a question I think by Professor Duggan about the viability  
19 of laboratories and your evidence was you had a problem in Midland  
20 because you didn't know the costs. Looking at the period 90 to 96 can you  
21 say what your impression of the laboratory business was – in other words  
22 were laboratories proliferating in number or were they stable business or  
23 being wound up and being closed down at that time ..... I would comment  
24 separately on public and private laboratories. The prevailing view was that  
25 private laboratories must be a very viable business, there was no evidence of  
26 them being in trouble financially. And there was the development in  
27 Hamilton of a new laboratory during this time, that focused on the Waikato  
28 market and during this time it grew to be a significant business and the

1 anecdotal information that I received was that it had had no impact on the  
2 volume of work going through the existing laboratory but that the new  
3 laboratory had been able to establish a significant business base to make it  
4 viable. Public laboratories during this time, particularly in smaller hospitals,  
5 were struggling to maintain themselves. I had previously worked at Thames  
6 hospital prior to the Bay of Plenty and I was involved in laboratory services  
7 there and it was very much struggling to maintain a critical volume of work  
8 as the private laboratories came in and captured general work. Hospitals  
9 like Thames like Whakatane, like Te Kuiti and a lesser extent Gisborne,  
10 were struggling during this time to have sufficient volume of work going  
11 through the laboratories to maintain critical staffing. They reason they were  
12 struggling to do that was that the private laboratories were capturing general  
13 practitioner rfgrs. this was a particular problem for these hospitals who  
14 needed to maintain an on site laboratory to support their surgical medical  
15 inpatient activities so the smaller public hospitals were really struggling with  
16 their laboratories.

17 If you could turn to exhibit 41, I know you can't deal with this document in  
18 any substantive way, but if you look at p13, does that set out midlands  
19 geographic area of responsibility ..... yes.

20 Tairawhiti being only one sub region of the Midland Regional Health  
21 Authority ..... yes.

22 So that care would be required in using this document if we are only talking  
23 about Tairawhiti area is that correct ..... yes as this document makes clear  
24 this is a comparison of Midland health's data with national data, it does not  
25 get into sub-regional analysis.

26 Thank you. I would now propose to put the funding agreements in through  
27 this witness:

1 Exhibits: 93/94 funding agreement Exhibit CM/HFA/ 0051; 94/95 funding  
2 agreement CM/HFA/ 0052; 95/96 funding agreement CM/HFA/ 0053;  
3 96/97 funding agreement CM/HFA/ 0054; 97/98 funding agreement  
4 CM/HFA/ 0055.

1 MR MURRAY called –

2 SYLVIA SAX (Sworn)

3 Could you confirm a few details. Is it correct that in 70 you qualified as a  
4 registered obstetric nurse in British Columbia, Canada ..... yes

5 And in 83 you also qualified with a BSc in nursing with honours from .....  
6 University of Illinois in Chicago

7 And you in New Zealand qualified in 94 obtaining a dip in public health .....  
8 yes

9 You are just finishing off the masters for public health degree at university  
10 Otago ..... yes, that is correct

11 And I think you have other additional qualifications in relation to quality  
12 assessment and audit in the health sector, ..... that is correct.

13 A certificate in clinical training from Christchurch College of education, and  
14 qualified by SGS New Zealand ..... yes

15 What does SGS stand for ..... it is a Swiss word, it's basically an ISO 9000  
16 accreditation body that provides training around that model of accreditation.

17 You have been a guest lecturer to the profession at Christchurch College of  
18 Education over 2 or 3 years ..... that is correct.

19

20 **XXD MS KAYE:**

21 Ms Sax, I wonder if I could ask you some questions first of all about the  
22 various drafts and redrafts of the national standards. In your volume of  
23 exhibits you have annexed several drafts of the standards ..... yes.

24 I think there are four, there's one under tab 14 isn't there ..... yes there is.

1 And there's an ACL redrafted version under tab 17, is that right ..... yes there  
2 is.

3 And then there's another draft under tab 21 ..... the one under 17 is actually  
4 comments received back from ACL on a draft we have sent them.

5 And then there's one under 21 ..... yes there is

6 And then there's one under 26 ..... yes.

7 You refer to that in paragraph 46 of your brief of evidence. .... yes.

8 As the further and final draft which Tony Barker sent to you on 26/2/96, is  
9 that right ..... yes, that's right.

10 In paragraph 50 of your brief of evidence you say that after the final  
11 consultation a version of the standards then went to the Royal College of  
12 Pathologists for final approval on 29 May 1997. you have produced the  
13 letters that accompany that but not the version that was sent. Is there a  
14 reason for that ..... no I don't think there was a reason. It was basically the  
15 same draft, that 29 May draft.

16 Are you certain of that ..... no I'm not certain of that actually.

17 Can this witness be shown Mr Mules exhibits, volume 1, tab 18, the final  
18 document in those exhibits to which I refer. There's a document at the end  
19 as appendix 5 headed draft national quality and service standards for medical  
20 testing laboratories dated 6 November 1996. .... yes.

21 This document differs in material respects from what you have produced as  
22 the final draft under your tab 26. could you have both documents before you  
23 so that you can have a look at the differences that I would like you to  
24 consider. .... would it be helpful if I explain why they are different. When I  
25 mention in my brief it was the final draft that I covered it means it was the  
26 final draft not of the whole project it was - I left the project on 11 April 1996  
27 to manage another project and I passed responsibility for the project on to

1 Victoria Sinclair who was also working with the Southern RHA ,. At that  
2 point we had sent out this document of 26 February for further consultation  
3 to various parties and it was reviewed and revised based on the information  
4 that was received through that consultation into this I believe the 6  
5 November 1996, but I wasn't part of that process.

6 But we do not know what 29 May 97 version was ..... 29 May?

7 That is the one to which you refer in paragraph 50 of your brief. .... no, they  
8 are not attached here.

9 CHAIR: Ms Sax, does this mean what you have said in your evidence at  
10 paragraph 46 was a final draft of the standards ..... yes.

11 is really no more than the final draft of the standards which came to you and  
12 there are subsequent drafts of these standards

13 MR MURRAY: the person who took over the project is no longer in New  
14 Zealand. There is a gap in the evidence and we are hopeful that TELARC  
15 and the Royal College will fill it. What I would propose is Ms Sax take the  
16 evidence as far as she can, we may be left with some gaps.

17 CHAIR: what we have in Ms Sax evidence is half the picture. I wonder  
18 how relevant is it for us to be looking at drafts which have been superseded  
19 by other drafts.

20 MR MURRAY: the document in the Mules evidence is labelled "draft  
21 national standards" which is what they were at that stage.

22 Ms KAYE: Ms Sax can I ask you first to look at paragraph 2.4 of each of  
23 the draft standards, i.e. the one that you have produced under tab 26 and the  
24 one dated November 96 which I understand was attached to Dr Bottrill's  
25 contract. The final sentence in the earlier draft that you have produced states  
26 that freedom of consultation between pathologists including that necessary  
27 to gain a second opinion or between pathologists and clinicians should not

1 be excluded by commercial or financial considerations; the word should is  
2 replaced with the word shall in the document annexed to Mr Mules evidence  
3 isn't it ..... yes.

4 Can I ask you to turn to paragraph 5.2, under the paragraph beginning "the  
5 accompanying request forms should include" there are two items in the  
6 document that you have produced and 3 in the document that Mr Mules has  
7 produced ..... yes there is.

8 In paragraph 5.3 headed : "informed consent from patients" the document  
9 that you have produced says in the final sentence "the laboratory should  
10 comply with current legal requirements in obtaining patient consent for  
11 additional tests"; in the document that Mr Mules" produced the phrase is  
12 "the laboratory shall use their best endeavours to comply with current legal  
13 requirements", is that correct ..... yes, that is correct.

14 In paragraph 6.1,

15 CHAIR: why isn't it that the laboratory must comply with current legal  
16 requirements ..... I think it would be best I comment on how the documents  
17 were developed rather than the actual wording. These were developed in  
18 consultation with the pathologists, the community of pathologists and also  
19 the medical testing laboratories and HFA staff.

20 How does that explain a dilution of obligations to comply with legal  
21 requirements with a best endeavours rather than a must ..... in our contract  
22 with providers we would have that the providers must comply with legal  
23 requirements, these were standards that were included within the contract  
24 that the different that would have been consulted on with the various groups  
25 and I suppose that the contract would be the document that would have the  
26 must meeting legal requirements within it.

1 What is the status of these standards ..... the standards were developed so  
2 that TELARC would have a document that they could accreditation  
3 organisations against. It was an agreement between all the bodies that this  
4 was the standard that would be required of the various laboratories both the  
5 private and the public.

6 This is the standard TELARC would be enforcing ..... yes, that was my  
7 understanding of the intent of developing the standards, it was so that  
8 TELARC would have a tool when they went to the medical testing  
9 laboratories.

10 Ms KAYE; Please refer to paragraph 6.1. in the document that you have  
11 produced the final sentence of paragraph 6.1 reads “where testing volumes  
12 are below the min guidelines the laboratory may be asked to demonstrate  
13 competency.” That sentence is not included in the document that Mr Mules  
14 produced is it ..... no, it’s not.

15 CHAIR: where is this leading to, it doesn't directly cover the period we are  
16 looking at – Dr Bottrill had retired. It is clear there had been changes in the  
17 draft process of the standards. We don't know what the final version is.  
18 This witness is not in a position to advise how the final version has come to  
19 be.

20 MS JANES: Mr Graham Walker who was involved in the drafting of these  
21 standards will be giving evidence.

22 CHAIR: we are better to look at what the final version is with a more  
23 informative witness than this one.

24 Ms KAYE: I am happy to leave it there. you've said in paragraph 10 of  
25 your brief, Ms Sax, that there was concern as to whether TELARC should be  
26 involved. You've stated the reason as follows “this was because the RHAs  
27 did not want to inhibit competition between accreditation bodies”. You've

1 then gone on in the subsequent paragraphs to explain the process by which  
2 you did eventually reach the decision that TELARC would be the principal  
3 accreditation body. But can I ask you to refer to the letter from TELARC,  
4 under your tab 4, dated 21 July 1995. on p2 there's a paragraph that begins  
5 "TELARC is a not for profit statutory body." Have you got that ..... yes, I  
6 have that.

7 That paragraph contains a statement that around the world it is widely  
8 recognised that accreditation bodies should not be profit motivated, it refers  
9 to a direction of the European commission that laboratory accreditation in  
10 the union should not be subject to commercial competition, and to a recent  
11 review of accreditation structures in Australia which has come to the same  
12 conclusion. Did the RHAs accept this proposition in principle ..... yes I  
13 would say this was one piece of information that we used in our decision  
14 making to include TELARC in the consultation process around the standards  
15 Did you specifically adopt the principle that there should not be competition  
16 in accreditation ..... no I don't think you could read that into this, no.

17 No further questions.

18 CHAIR: are you saying you can't read into this document in exhibit 4 that  
19 that is what it is saying ..... no, but when we made the decision around who  
20 should be involved in the development of the standards. We looked at the  
21 various bodies and there is evidence I phoned Australia and several other  
22 organisations and had discussions and what we basically in looking at just  
23 the development of the standards we used this as one piece of information in  
24 deciding TELARC should be the body, it didn't fall into it per se

25 You took this issue about accreditation should not be profit motivated, you  
26 took that to mean TELARC was the body of choice ..... that was just  
27 basically around the development of the stands, not who would accredit in  
28 the end. It was some question about whether TELARC because they were

1 developing the standards would have a conflict of interest in turning around  
2 the organisations.

3

4

5

6 MR CORKILL:

7 At tab 8 you produce a letter which at paragraph 28 of your brief you say  
8 was a copy of the group's letter or a letter on behalf of the group to all  
9 interested stakeholders ..... yes, that is right.

10 And at tab 9 you show the addressees of that letter, yes, that is right.

11 Which includes, on the last page of that exhibit, - sorry, the third page, third  
12 last entry, Gisborne Laboratories Limited. In the materials you have  
13 produced there is no record of a response from Gisborne Laboratories  
14 Limited do I take it that there was not one ..... I'm not sure if there was. I  
15 don't think I have produced the list of the people we received submissions  
16 from.

17 Given the focus of this inquiry on Gisborne laboratories Limited had there  
18 been one you would have noticed it ..... I can't say. We went through a lot of  
19 documentation so that could be something we could relook at I'm not sure.

20 In the schedules of persons who subsequently attended the various meetings  
21 which you conducted, which we see at tab 18, I think there were 4 meetings  
22 4 interested stakeholders, 4 matters throughout the country, and analysis of  
23 those schedules does not show any representative from Gisborne  
24 Laboratories Limited is that correct ..... I would have to look at the list

25 You can take it from me that I have not been able to discover a person from  
26 Gisborne Laboratories Limited particularly at the Hamilton one which is the

1 second of those shown. To your knowledge is it correct that Gisborne  
2 Laboratories Limited took no part in this consultative process ..... I couldn't  
3 say because I didn't go through and match the list to all the people within  
4 New Zealand who worked at laboratories.

5 Certainly these lists are a complete schedule of those who attended those  
6 meetings ..... yes they are.

7 On another matter, paragraph 26 of your brief you refer to the 94 95 policy  
8 guidelines and you refer to a particular clause which deals with an issue of  
9 accreditation . I would like you to take up Mr Mules volume 1, tab 7 and the  
10 last page of that document. I take it you are familiar with this document,  
11 having referred to it ..... yes I would have been – I haven't looked at it for  
12 some time.

13 You will see that the last page contains a schedule dealing with issues  
14 relating to cervical screening ..... yes, I see that.

15 In sub paragraph c deals with safety and quality standards and the  
16 requirement that RHAs were to ensure that their purchase arrangements  
17 reflected the requirement that all lbs servicing the programme should be  
18 TELARC registered, see that ..... yes I see that

19 The general clause which you have referred to in your brief needs to be read  
20 with the specific clause at the end of the document that we've just looked at  
21 correct ..... yes I suppose that is correct.

22 Now if you go to p2 in the same document we see a statement by the  
23 Ministry of Health the Hon Jenny Shipley at the time, 1 march 94, correct  
24 ..... yes, that is correct.

25 So this obligation was known to the RHAs as from 1 march 94 at the latest,  
26 correct ..... yes,..... I suppose so.

1 And was directed presumably to the upcoming funding year 94/95 correct  
2 ..... yes and would have been translated into the funding agreement.

3 Now, just really dealing with a couple of contextual matters for your  
4 process. The second contextual matter is the Good Health Wanganui events  
5 which surfaced in mid 94, correct ..... yes, I suppose.

6 We've seen a document earlier in evidence which suggests that those matters  
7 were current in June 94. Was the Good Health Wanganui incident one of  
8 the triggers for the process you have described as far as the RHA was  
9 concerned given the Good Health Wanganui limited was within its region  
10 ..... I think you'd have to put that to someone from the RHA laboratory  
11 liaison group who basically asked me to manage this project. I'm not sure  
12 what all the issues that arose that brought this project

13 You were contacted in June 95 ..... yes.

14 Which was certainly well after those Good Health Wanganui events ..... yes,  
15 a year later.

16 Given the direction we see in the policy guidelines which dated from March  
17 94, and given the Wanganui events of June 94 also, and given that this  
18 process eventually got underway in June 95, that's when you were  
19 contracted ..... yes

20 Was there any sense of urgency in relation to the advancing of this process  
21 or project concerning standards ..... well yes a sense that this was a project  
22 that definitely needed to occur and there needed to be standards that  
23 TELARC could use to audit laboratories against because they currently did  
24 not have standards that covered the wide range of areas that needed to be  
25 covered.

26 The project in which you were involved at least as far as you personally  
27 were concerned began in June 95, you left it in April 96 ..... yes.

1 And we've seen evidence earlier that there was a further draft in November  
2 96 . from your perspective as an expert in quality matters do you have any  
3 concerns about the length of time that it took to develop these standards  
4 particularly given the two triggers that I mentioned in mid 94 ..... well, no I  
5 don't because I know of the process and the industry , the contentious issues  
6 that were in the industry at the time that they were developed. I suppose  
7 because I have the personal experience, if I was someone external to the  
8 process and didn't understand all the issues that needed to be discussed and  
9 resolved as part of this process then I might have concern and ask some  
10 questions about that, but because I was involved and knew the extent of  
11 consultation required with so many groups for the standards to be developed  
12 I don't have a concern about the process.

13 You are speaking of the period of your involvement from June 95 to April  
14 96 ..... unfortunately I didn't see the project through.

15 Do you have any concerns that it took a year from the two triggers that  
16 imented to start the project ..... I only know about the issues that from being  
17 involved in this inquiry and reading that I know there were some  
18 relationship issues with the industry and so forth

19 Do you have concerns ..... no.

20 Notwithstanding the mandatory obligation expressed in the policy guidelines  
21 in march 94 ..... I must say when I took on the project I knew that there was  
22 that the Ministry of Health was covering cervical screening and therefore I  
23 think if I looked at those policy guidelines I would then believe that the  
24 Ministry had some processes in place – no I wasn't concerned.

25 Had any work been done on this matter before you got involved to your  
26 knowledge ..... I know that Tony barker who I eventually worked with and  
27 graham Walker had done work on them Mr barker is a pathologist from the  
28 College and Graham Walker is from TELARC.

1 They had done some work you think. Had any work been done within the  
2 RHAs ..... are we talking about screening ]

3 On this project that you became involved in ..... my project was developing  
4 standards for medical testing laboratories (generic standards) and was not  
5 focused on cervical screening

6 It wasn't limited to cervical screening ..... it encompassed some aspects of  
7 cervical screening but there are many standards within that are relevant for  
8 medical testing laboratories that go into the detail of various aspects. And I  
9 think in my evidence there is a letter from someone from the Ministry saying  
10 they were developing standards for cervical screening so that there were  
11 many processes going on for that detail in various aspects of the medical  
12 testing laboratory. We were looking at the broader picture of setting  
13 establishing standards.

14 You said it encompassed some aspects of cervical screening but not all of it.  
15 What was the bit it didn't encompass ..... I could talk more about the part it  
16 did encompass would be the general training

17 Let's go to the document in Mr Mules affidavit in exhibits, tab 18, 6  
18 November 196 one ..... what I could say is this document covers medical  
19 testing laboratories including any facility performing medical tests. For  
20 instance it does not include self testing by patients, so that general aspect.  
21 Next point is that in this document 1.1 accreditation criteria that it outlines  
22 criteria for accreditation shall include the quality management system  
23 requirements of ISO guide 25 and ISO 9002 and the technical requirements  
24 as defined in the specific criteria documents presented by the approved  
25 accreditation body. For instance at 1.4 it states that in some disciplines  
26 additional technical criteria will also need to be considered.

27 To your knowledge were there any technical or any other criteria outside this  
28 document that were necessary for cervical screening ..... I think that's

1 something you would have to put to Tony Barker and graham m walker –  
2 I'm not a specialist in laboratory services.

3 CHAIR: you can't say whether there was anything addition for cervical  
4 screening ..... no. I was the project manager working with the professional  
5 group and the industry who had the technical knowledge and the  
6 professional knowledge of what should be included in the standards.

7 Was the Ministry to your knowledge working with this group at all to have  
8 included specific criteria for TELARC accreditation of laboratories doing  
9 cytology for the screening programme ..... was the

10 To the best of your knowledge was the Ministry of Health working with the  
11 group you were Project Manager of to develop criteria for TELARC  
12 accreditation of laboratories doing cytology screening for the National  
13 Cervical Screening Programme ..... the project group that I worked with was  
14 basically Tony Barker and Graham Walker – just the three of us running a  
15 consultation process throughout the country. The information around the  
16 standards that would be included within this document were distributed to  
17 the Ministry of Health as part as one group being consulted with. They  
18 would have received our documentation, they would have sent us  
19 submissions and if they believed that their documents should be included in  
20 this standard that would have come through the submissions.

21 Did you receive any such submissions from the Ministry of Health ..... we  
22 received one letter which I see was received after I left the project and I  
23 believe the letter is in my – can we look at it?

24 Yes. this is the letter at tab 28. .... the letter states that they have enclosed  
25 a copy of the standards they were developing for the National Cervical  
26 Screening Programme laboratory advisory committee – the committee has  
27 developed standards – the National Cervical Screening Programme  
28 laboratory advisory committee has developed standards for laboratories

1 providing cervical screening services. And then goes on to say “I have  
2 enclosed a copy of the standards .. similar agency for accreditation purposes  
3 DO YOU HAVE the standards that accompanied the letter as part of your  
4 exhibits ..... I did not find the standards in the file. I'm not sure. Victoria  
5 would have been given this letter rather than myself

6 Even though it is addressed to you ..... even though it is addressed to me.

7 Do you know what the group that you were the Project Manager of did in  
8 response to this letter and the standards which accompanied it ..... the  
9 process that we had was that all submissions were sent to Tony Barker and  
10 Graham Walker. They reviewed them and we had a discussion around  
11 revision of the standards based on the comments made so Victoria would  
12 have met with them, this would one submission included in a number of  
13 submissions we received.

14 Were you aware that the 93 as also the 91 National Cervical Screening  
15 policy made specific provision for the Ministry of Health to be responsible  
16 for confirming that laboratories were carrying out requirements which are  
17 set out in 4.1.4 of that policy – there were specific criteria to be taken into  
18 account for TELARC registration ..... it was not a detail that I would have  
19 been aware of as part of this project.

20 The other members of the group would they be aware of it ..... the laboratory  
21 liaison group would be aware of it and they would have comment on the  
22 draft standards

23 That would be Graham Walker ..... within the HFA. I'm not sure if Graham  
24 and Tony would be aware of that. within the RHA there was a laboratory  
25 liaison group and they would have been aware of that, the 4.1.

26 The screening policy specifically provided criteria for TELARC registration  
27 .. in consultation with the Ministry of Health and the policy says that the

1 criteria will include specific criteria - who can tell the committee whether  
2 when developing the broader national standards for TELARC accreditation  
3 these specific criteria set out in the cervical screening programme were  
4 included within the broader standards for the purposes of cervical cytology  
5 screening ..... I would say that would be Kirk Wakeham, part of the  
6 laboratory liaison group and would have taken the specific knowledge about  
7 laboratories and ensured they were included in the standards. If it was  
8 relevant that they would be included in the standards.

9 MR CORKILL: I suspect the document in question is found at tab 25 of  
10 Boyd volume 5. I don't think this witness can necessarily help because she  
11 said she didn't see the letter. The evidence I think from the Ministry  
12 witnesses was that Cervical Screening laboratory Advisory Committee had  
13 developed those standards – you may recall some evidence about that – and  
14 drawing an inference the timing of that document that we see at tab 25  
15 would be consistent with the timing of Ms Handisides letter of 15 April 96.  
16 I take it there is no point in your looking at this document Ms Sax, you  
17 wouldn't know it in any event ..... no, I wouldn't.

18 Ms Sax, in your own volume at tab 12, it is a letter written to you by the  
19 manager of the Dunedin screening programme Di Best she says in her letter  
20 that there were some issues that had concerned local managers of the  
21 programme, she sets that out in the next page. One of the issues there,  
22 number 3, was tighter quality assurance measures for reporting that use  
23 international laboratories as the standard. She gives a footnote, 3, and  
24 refers to what she terms a wide range of reporting over the country,  
25 especially with regard to less than optimal smears and gives the range of  
26 those, and later says the Programme Managers had been assured this was an  
27 internationally accepted range but the managers had reservations about the  
28 difference. In your brief you say you gave this letter to Mr Walker and Mr

1 Barker. To your knowledge what did they do with that information ..... this  
2 information would have been included along with a lot of other information  
3 we received as submissions and they would have discussed this amongst  
4 themselves in developing the standards and those standards developed were  
5 taken throughout the country and also sent back to Di Best,..... the draft  
6 standards, the various drafts of the standards.

7 So this response was part of the mix of information that they considered in  
8 dealing with the overall standards which they were concerned about. Are  
9 you saying they would not have become involved in an operational issue in  
10 connection with the programme itself ..... I don't think they were – I don't  
11 understand

12 What I mean by that is that clearly the Programme Managers had some  
13 concern the word reservations, also their word. They were operational  
14 issues about which they were concerned. Would Mr barker and Mr Walker  
15 have become involved in those operational matters ..... I'm not sure if this is  
16 an operational matter. They would have seen this and probably read tighter  
17 quality assurance measures for reporting that use internationally accepted  
18 laboratories as the standard and seen the footnote and I can only assume if I  
19 had read this I would say that is exactly the process were going through in  
20 developing the standards, that there were quality assurance standards being  
21 put in place.

22 This wasn't a process involved in establishing standards with regard to  
23 particular issues such as less than optimal smears ..... that had been discussed  
24 with Cervical Screening laboratory Advisory Committee and they had said  
25 we were assured this was an internationally accepted range.

26

27 MS JANES: .

1 If we can perhaps continue from where my friend Mr Corkill left off in  
2 terms of the reporting structure relating to your project and the liaison group.  
3 are you aware of that other projects the laboratory liaison group were  
4 involved with apart from the standards ..... none that I can think of right  
5 now.

6 So there were no discussions between yourself in areas other than this draft  
7 national standards ..... I would expect if there were other projects they would  
8 have informed me of that – I don't recall.

9 Looking at the terms of reference they were in existence from August 93  
10 weren't they ..... yes.

11 When you first came on board , if I can show you this email, obviously one  
12 of our first concerns also was the Ministry involved in this issue ..... yes.

13 And again because of the national focus do you recall that the reason for  
14 your concern was because of an understanding the Ministry of Health was  
15 involved in the national co-ordination of the programme and therefore it was  
16 important that they be kept involved ..... no looking at this I think that my  
17 why I would think the Ministry should be involved is because of their role at  
18 strategic policy level and would not be looking the cervical screening level.

19 Do you recall what response you received as a consequence of this email  
20 trying to determine what the Ministry's involvement was ..... I don't  
21 remember any specific discussions but I think the outcome obviously was  
22 that they were included in the consultation that they received all documents.  
23 I think we sent several sets to various parts of the Ministry to ensure they  
24 were kept informed.

25 Are you able to outline which parts of the Ministry would have been kept in  
26 touch with the project ..... that would be in the list of those that received the  
27 consultation documents

1 Under tab 9 that is the complete list ..... yes.

2 Can you explain the lines of reporting of this project ..... I was responsible,  
3 the lines of reporting for the project itself was I responsible to the laboratory  
4 liaison group for the 4 RHAs but I must admit because there was 4 different  
5 organisations at times that proved it was a challenge.

6 And apart from your personal challenge are you aware of the next level of  
7 reporting of the actual committee ..... well I am aware that Victoria St Clair  
8 reported who was on the group for Southern RHA reported to Conway  
9 Powell, I can't remember his title, but there were direct lines of reporting.

10 If I can briefly summarise you were involved on a day to day basis working  
11 on the project with Dr Tony Barker and Graham Walker ..... I wouldn't say a  
12 day to day basis, this project was a small part of my work over the period of  
13 that 10 months I was actually at that time establishing an audit programme  
14 of rest homes throughout the sthn region, that was the main focus of my  
15 work, this was a project I was doing in addition to that. I did not have daily  
16 contact with Tony and Graham.

17 PROFESSOR DUGGAN: was the length of time to dvlp0 the standards  
18 compromised by your other commitments ..... I would say it was a challenge,  
19 I think because we had determined at the beginning we required extensive  
20 consultation and that the RHAs were constantly being challenged when we  
21 did consult we didn't give enough time for feedback, wed made a decision at  
22 the beginning to consult extensively and do it slowly, we really wanted buy  
23 in by the pathologists and the in the technicians and the rest of the industry  
24 into this process, this was also affecting both the private laboratories and the  
25 public laboratories which in the past had actually had different requirements.

26 MS JANES: if I can take you to tab 2 of your materials, third page in,  
27 fourth paragraph, it indicates that the ACL has obtained ... nationwide. ACL  
28 .. community laboratory standards". So as of June 95, I assume, there were

1 certainly in principle agreement from the community laboratories to  
2 nationwide standards is that correct ..... yes that's what this says. I would  
3 say those who that the managers of the laboratories would have agreed.

4 And if we can turn to tab 3, p4, which is actually p2 at the top, it indicates  
5 that a full proposal in the final paragraph will be submitted to the ACL for  
6 comment before being finalised by the College and then distributed . is it  
7 fair to say that given the ACLs appears to have been fully involved in the  
8 process from the very early stages and is assumed to be representing the  
9 views of its members, at that that may have been an indication that the  
10 consultation process could have been speeded up ..... I have to go from my  
11 recollection, I recall at the beginning of the process of the whole  
12 consultation that I had some communication – I can't remember in letters or  
13 telephone calls with Peter Jones from ACL and I found the process quite  
14 frustrating, I remember being frustrated because I didn't feel that he was  
15 responding very rapidly to the documents I was sending him or my telephone  
16 calls and so forth, so I just remember that at that point we made the decision  
17 we rely needed to have a full consultation process to included people  
18 throughout the laboratories and not just go through ACL.

19 And also in one of your documents there was also in principle agreement  
20 from the CHE laboratories to national standards, ..... to the standards but not  
21 the contents. There's in principle that there should be a standards process  
22 but to the contents of the standards it was very contentious and required a  
23 lot of discussion and changes. That was why we decided we need to have a  
24 very thorough consultation process so that in the end when the laboratories  
25 were accredited that they basically would have bought into the standards and  
26 wouldn't feel that it was something being placed upon them.

27 Where was the decision on the extent of the consultation derived from – was  
28 I operational decision, the RHA management line, from legal opinions – are

1 you able to comment why It was decided and one would be as a legally  
2 acceptable, from the documents it appears to have been an 8 month process  
3 ..... it was a very thorough process

4 Where was the decision taken, at what level, for embarking on such  
5 extensive consultation ..... from my memory, and there is documentation that  
6 would support that, once we had decided to go ahead and involve TELARC  
7 in the process, that was the initial hurdle to get over, I had a meeting with  
8 the Chief Executive Officer of TELARC and with Graham Walker and I  
9 believe Brian Linehan I can't remember who else but the minutes are in my  
10 evidence here, and it was at that meeting that we first started talking about  
11 how extensive the consultation process should be and some basic agreement  
12 on how that should occur. I took that back to the laboratory liaison group  
13 and they agreed with that approach that it should be an extensive  
14 consultation and so forth.

15 Are you aware whether there was any consideration about such extensive  
16 consultation process being in conflict with the requirements under the  
17 funding agreements for quality particularly in relation to cervical screening  
18 and reasonable endeavours ..... no I think that we wanted something that  
19 would be around for a long time, we were going from the principles of  
20 continuous quality improvement , we wanted something agreed upon by the  
21 industry and the professionals and the HFA so we could come to an  
22 agreement that would last for a long period of time and not be something  
23 that would become contentious in the long term.

24 I understand and obviously evidence will need to come in about it, but if it  
25 were the case that the draft standards were still not promulgated in any  
26 formal sense would that strike you as being reasonable given it is 5 years  
27 since the initiation of this particular project ..... I would think 5 years would

1 be a long period of time, yes. but that's not my understanding of what has  
2 happened to the standards.

3 What do you understand to have happened to the standards ..... my  
4 understanding TELARC has been using the standards for some time but they  
5 are included in the contracts with the laboratories.

6 You may have heard Mr Mules give evidence and accept that participation  
7 in the Royal College is voluntary, accreditation up until 96/97 was voluntary,  
8 does that appear to be undue reliance on TELARC where they have no  
9 control over any laboratory who isn't accredited – in other words they  
10 cannot impose standards unless someone has allied and been granted  
11 registration and therefore reliance on TELARC is perhaps unreasonable in  
12 terms of national standards under the funding agreements ..... I would say no  
13 because the process that was set up that I managed included the programme  
14 - included the College and TELARC and the standards were to be used by  
15 the accreditation organisation to be used by TELARC so that was the  
16 collaborative approach between the funder, the professionals and the  
17 accreditation organisation.

18 Can you accept that that only works as long as a laboratory is accredited  
19 otherwise there are no standards imposed on that laboratory ..... it was my  
20 understanding that the contracts were being negotiated with the laboratories  
21 and developed at the time we were developing the stands, the contracts were  
22 being developed and would be signed with the laboratories and they would  
23 be required TO BE ACCREDITED WITH TELARC, that's what it states in  
24 the standards.

25 Had those contracts and that requirement for accreditation applied at the  
26 time you left the project ..... I don't believe so, we were working towards it  
27 at the point I left.

1 In April 96 that was still an unfulfilled expectation ..... it was becoming  
2 fulfilled, we were part of that process that we were developing standards  
3 included in the contract .

4 If you can turn to tab 2, at the back, there is a proposal for national quality  
5 and service standards. And in fact the final page is the draft indicative  
6 issues for consideration ..... yes.

7 Where were they derived from ..... I'm not sure. I was given that list and I  
8 believe that was the basis upon which Tony Barker and Graham Walker first  
9 started to develop the first draft of the standards.

10 Is it likely that that came from the 4 regional managers ..... it could be the  
11 collation of what their thoughts were after discussions with the industry

12 You are clear that predates TELARC and the Royal College involvement .....  
13 I think it does, yes. I would say yes It does.

14 In that email which I will produce - SS/HFA/ 0032 – at paragraph 6 of that  
15 email you've asked if there was information ... quality assurance in other  
16 countries and you've specifically mentioned Great Britain. Are you aware  
17 whether either the committee or Mr Walker or Dr Barker took account of  
18 accreditation or other quality standards from overseas ..... I definitely  
19 would have expected them to do that, I believe Graham Walker – in my  
20 discussions with him he has extensive knowledge and contacts with  
21 accreditation organisations in other countries specialising in accreditation of  
22 laboratories.

23 A previous exhibit from Dr McGoogan number 6, table 1, which is about  
24 halfway through on p9: this goes in part to Mr Corkill's question in relation  
25 to your tab 12 where the screening managers indicated a concern about the  
26 wide range of reporting of less than optimal smears. Are you aware whether  
27 any consideration was given to quality standards of a similar qualitative

1 nature as seen in that table before you ..... as I said, what we were looking at  
2 was generic standards not service specific standards. I would say the stands  
3 for cervical screening would be quite specific to that service, we were  
4 looking at the broader general standards.

5 Are you aware what international generic standards were allied in the  
6 development of New Zealand's national draft standards ..... I can remember  
7 from recollection having discussion with Graham Walker about this and he  
8 actually had looked at standards from other countries and was very aware of  
9 them, so I had confidence in his knowledge about laboratories which I'm not  
10 a specialist in them and he was so he was aware of those standards.

11 Is it fair to say essentially you had no involvement into the input what the  
12 standards contained but were project managing the assimilation of those in  
13 the consultation process ..... yes.

14 Just on that consultation process, if we can cover ACL's involvement in that  
15 process. Would it be your recollection that they had fully co-operated with  
16 the project team in order to ensure that there were going to be national  
17 standards which would include compulsory accreditation ..... yes I would say  
18 as the consultation process emerged that we got a very high level of co-  
19 operation from everyone within the industry and the professional groups,  
20 who were all very pleased at the turnouts and the meetings and the number  
21 of submissions we received.

22 When you spoke previously about contentious issues relating to the  
23 standards they were the actual substance of the standards rather than co-  
24 operation to seeing the project coming to fruition ..... yes, in the final draft  
25 that I was involved in of the standards the issue arose around near patient  
26 testing and I think it's quite interesting that my email to Victoria Sinclair  
27 mentions general practitioners who carry out laboratory tests in their  
28 practices - contentious issue - and that is exactly what did occur in the end.

1 There is a document that actually indicates the potential to separate out  
2 standards into three different categories, one being generic

3 CHAIR: what year is it?

4 MS JANES: it is in the 95 year and it sets out the fact that there is  
5 recognition that the consultation process is going to be extensive. Do you  
6 recall that ..... yes.

7 Given that that was recognised very early on was consideration given at the  
8 point that the mere patient testing became very contentious to actually taking  
9 out that particular segment and promulgating the other standards which had  
10 generally been agreed upon ..... that was the intent. When I left the project  
11 that was what we were working on, we had put that recommendation  
12 through that we remove the standard for near patient testing from the generic  
13 standards and establish a separate working group.

14 In your discussions with Victoria Sinclair subsequent to your departure did  
15 that occur to the best of your knowledge ..... my understanding, from my  
16 discussions with Victoria Sinclair is that this recommendation was made to  
17 the College of pathologists and I believe also to MedRAC, which was the  
18 committee overseeing the TELARC accreditation and that I believe the  
19 College was not did not agree with this and wanted the standard to be left in.  
20 but because that standard would have major implications on general  
21 practitioners or could potentially have implications for general practitioners  
22 we felt that I believe that the liaison committee felt that they couldn't leave it  
23 in and put it in the contracts with the laboratories in that way with that  
24 standard in there. but that they would need to consult with the general  
25 practitioners and so forth – no that they couldn't put it in the contracts.

26 From a layperson's point of view given that these were national standards  
27 for laboratories and as you've described near patient testing is related more  
28 to the general practitioners and given it was a very contentious issue, why

1 was it not separated out as soon as it arise in order to able to progress the  
2 laboratory standards and work to - separately work on the near patient  
3 testing which related to a different group altogether. .... it does relate to a  
4 different group but it impacts upon the laboratory industry. So by taking it  
5 out I believe the pathologist, there's documentation in here which describes  
6 this, they believed it would have a potential commercial impact on the  
7 laboratories if the general practitioners were allowed to undertake laboratory  
8 testing under different standards. It is an important issue. There are some  
9 tests that can be undertaken within a physicians office using equipment such  
10 as when you go if you go to a general practitioner and they he may suspect  
11 you are a diabetic and he will do a test of your blood with a small instrument  
12 and get an immediate reading. That reading may not be accurate as a test if  
13 that if you take that blood sample and send it to a laboratory that would be  
14 more accurate. And then there's the issues of whether or not the instrument  
15 is being calibrated on a routine basis and whether the staff are being trained  
16 to use that eq8iupmt. So what the and if you do that test in the general  
17 practitioners office and do not send a blood sample to the laboratory then the  
18 laboratory there's a commercial impact upon the laboratory so there were  
19 those two, the standard and commercial impact are tied together, that's what  
20 they were stating nee

21 CHAIR: were the laboratories concerned about too much patient testing  
22 occurring in the general practitioners rooms .... that was an emerging issue.  
23 As soon as I took on this project I got many phone calls from industry  
24 representatives attempting to sell their equipment to general practitioner  
25 offices and were trying to encourage as part of the standards that the RHAs  
26 would accept that as being a practice.

27 MS JANES: given that you've indicated it emerged as a contentious issue  
28 immediately, is it reasonable for the process of national standards to have

1       been delayed for a period of 4 to 5 years purely so that the near patient  
2       testing issue could be addressed and as I understand it there is still no  
3       resolution on that issue even today ..... I'm not sure I said that It emerged as a  
4       contentious issue immediately, that's not true, it appeared it could be  
5       resolved through the consultation process and when I left the project I was  
6       hopeful - I believed it would establish a separate working group. but that  
7       did not eventuate, which was very sad that it didn't.

8       It was of sufficient concern to you even at the point you left in April 96 that  
9       you recommended it be split to a separate working group ..... that's right.

10       And who was that recommendation made to ..... it was made to the  
11       laboratory liaison group.

12       And the chain of communication would be that it would go from the liaison  
13       group back to the RHA individual Chief Executives ..... I'm not sure if it  
14       went to the Chief Executives but definitely have gone to Victoria would  
15       have given it to Conway Powell in the sthn region – I don't really know.

16       Would it be your understanding of the Midland region it would go to Kirk  
17       Wakeham and then his superior ..... I would expect so, yes.

18       The exhibit I was referring to earlier was exhibit 24. if I can cover tab 27.  
19       the deadlines for the project as indicated in the exhibits to your brief initially  
20       it was going to be November 95 and then it mushroomed ..... yes

21       Here you have set out a timeframe for accreditation being 31 December 96  
22       and there is a letter from TELARC in the exhibits indicating that was a  
23       feasible albeit slightly tight timeframe and in tab 31 in the second paragraph  
24       it actually indicates that the deadline for accreditation has been moved out to  
25       31 June 1997 ..... yes.

26       You have obviously left. Are you able to make any comment about the  
27       shifting deadline ..... no, I'm sorry I don't.

1 The point you left the programme it was still your understanding that  
2 December 96 deadline was being targeted ..... yes.

3

4

5 LUNCHEON ADJOURNMENT 1.00P.M., TO RESUME AT 2.00 P.M.

6

7

8 MS JANES: If I can just finish with ACL. At document 10 of your  
9 exhibits do you recall that it was the ACLs position that they supported  
10 accreditation of laboratories which is contained in this letter ..... yes, I do.

11 And that it was also part of their ethical rules that they provided as part of  
12 that document ..... yes I remember reading those

13 And was reliance placed on the fact that ? was ACL in the ethical rules .....  
14 yes.

15 And on the ACL you confirm that they sent a very detailed submission in  
16 response to the draft submission sent out ..... yes, which was included with  
17 the other submissions and included in the final drafts.

18 Did you receive more than one submission from them or was that the extent  
19 of the involvement ..... I remember we received submissions I believe from  
20 staff working in the laboratories beyond the ACL submission.

21 It would be fair to say that they had an ongoing involvement and initial. In  
22 the development of the draft standards ..... definitely.

23 Do you recall also that there were standards that were not going to be  
24 included in the draft standards raised by TELARC – tab 13 ..... yes. this list  
25 was developed from the submissions and by Tony and graham as part of the  
26 process, yes.

1 And one of the issues on the first page of that letter is laboratory workload to  
2 staff ratios. Do you recall whether anything occurred as a result of this  
3 particular document and the issues raised .... I believe that this list was  
4 included with the draft standards when they were sent out for consultation, I  
5 believe they are the last consultation we did we sent out this list so that those  
6 being consulted with would be aware that these areas were not going to be  
7 included in the draft standards.

8 Was there any particular reason that they weren't included in the draft  
9 standards, particularly issues like workload and training .... I think that there  
10 were several reasons, different reasons for different areas that were not  
11 being included. Some of them because they were already included in other  
12 standards or other guidelines or other legislation I believe.

13 So there was a feeling that they were taken care of in some other standard  
14 measurement .... they were, or I think some of them were beyond the brief  
15 of developing standards for accreditation.

16 CHAIR: would there be any document which would show that you had  
17 actually identified those issues that were either covered by other existing  
18 standards or legislation or considered to be beyond the brief .... I think that  
19 this letter from TELARC partly answers of that, for some of these it says  
20 under central database "the development .. outside the scope of laboratory  
21 accreditation" in this document generally we tried to ensure that the reasons  
22 were included

23 That's a TELARC document is it .... yes

24 I was interested. in the group in which you were Project Manager actually  
25 sat down and identified in writing those aspects of standards which fell  
26 outside your brief for the reasons already in force elsewhere or beyond the  
27 scope of your brief .... no, we didn't look at all specific standards and say  
28 these are being developed now.

1 MS JANES: did the group satisfy itself that in fact these requirements for  
2 standards as outlined were in fact taken care of in some other sphere of  
3 obligation or responsibility ..... I think as you can see, this list includes not  
4 only generally it isn't talking about service specific standards but things such  
5 as laboratory workload to staff ratios, specimen transport and so forth which  
6 are more not so much standards., we didn't sit down and look at all standards  
7 that were required by – that would be pertinent and laboratories and go  
8 through that list – no we never did that

9 Where you believed it was directly relevant to the draft standards at tab 28  
10 with the Ministry of Health ones there are h/written notes indicating they  
11 were being monitored or noted. Where it says noted does that mean it is  
12 incorporated into the staff standards ..... that's Victoria's writing. I think  
13 that she would - I'm not sure what she meant by that. I really did - I do not  
14 have expertise in accreditation and standards in laboratories, I did really on  
15 the expertise of Graham Walker and Tony Barker

16 CHAIR: if the group did not cover those areas covered by existing  
17 standards how was it in a position to know the standards went far enough .....  
18 I think that probably should be a question you put to TELARC and the  
19 College. These were very broad generic standards that we saw needed to be  
20 put in place before the next move to more specific standards.

21 I was interested in the process, in the sense if you design new standards I  
22 would have thought you would want to identify what standards were in place  
23 so you weren't duplicating those standards. Did you have a process in place  
24 to check out what was in existence and to avoid duplication ..... I would have  
25 relied on graham and Tony to have actually done that aspect, they were  
26 experts in that field.

27 MS JANES: did you see your role merely as the conduit of liasing between  
28 the industry groups and the interested parties and Dr barker and graham

1 Walker with the expectation that they would make sure that the standards  
2 were in accordance with the guidelines ..... yes, and I would include in that  
3 the laboratory liaison group because they had service specific knowledge  
4 about the laboratories, that's why they were in the positions they were in  
5 within the HFA, they had the policy development and contracting  
6 responsibility with the laboratories because of their knowledge in that area.

7 Did you receive any feedback from that liaison committee as to what was  
8 actually happening with the standards subsequent to Dr Barker and Graham  
9 Walker ..... sorry.

10 We've established that you were essentially the conduit between the industry  
11 and Dr and Graham Walker to the liaison committee. Is the level of  
12 communication between the I/committee and yourself in terms of the next  
13 stage and where those ideas were being taken to, whether there was  
14 feedback the other way ..... I was really the liaison – generally I brought the  
15 information from the project which was with Tony and Graham and on a  
16 regular basis and I believe they had monthly meetings so I would feed back  
17 to them at each monthly meeting on the progress of the project and the time  
18 recourses and so forth. There were times when Tony and Graham met with  
19 the liaison group.

20 Essentially the question is did they make a contribution as well to the  
21 development of the stands ..... they also put in submissions themselves to our  
22 group and commented on the draft standards as they were being developed.

23 They are not contained in the exhibits ..... not their particular submissions,  
24 no.

25 Are they available ..... probably.

26 PROFESSOR DUGGAN: did you use a template from another organisation  
27 ..... no, we didn't use a template from another country or organisation. They

1 were developed from scratch. TELARC already had standards the ISO  
2 guide 25, this was actually to address the gaps in the standards that were  
3 already existing, the broad standards they already had. That should be clear  
4 from the standards.

5 I understand ISO 900 ..... 9902. there's two documents that TELARC used  
6 in the accreditation of laboratories, one the ISO 9002 broad management  
7 types of standards which you could use for any type of industry be it tooth  
8 picks, cars or health industry you could use.

9 Could you explain exactly what this approach measures in the laboratory .....  
10 basically it manages the management processes and training of staff and so  
11 forth. The broad parts of running a business and ensuring that the outcome  
12 is a quality product

13 MS JANES: we can go to tab 4 which is a letter from TELARC setting out  
14 the difference between certification and accreditation.

15 PROFESSOR DUGGAN: nevertheless I feel we need a bit more  
16 explanation.

17 MS JANES: are you able to give that explanation or is it better to come  
18 from TELARC ..... I don't know whether I can make an explanation which  
19 goes beyond this letter.

20 PROFESSOR DUGGAN: can we put these processes in PAP smear  
21 reading in the laboratory for example ..... I'm not sure I know that much  
22 about PAP smear reading. ISO 9000 you would require you to have a  
23 documented process for storage of the equipment that would be used in  
24 taking a PAP smear but that wouldn't happen in a laboratory.

25 Actually it would if the laboratory provided the materials to the smear-taker  
26 ..... so it's that part of having the documented process, that's all it would  
27 require, it wouldn't look at whether that documented process and it would

1 look at whether that was based on good practice. it would look at what you  
2 used to develop that documented process.

3 We heard evidence when Dr McGoogan was here that Dr Bottrill used a size  
4 of cover slip that was not in common use in other parts of the world at that  
5 time. Would the ISO 9000 specify the size of coverslip to be used ..... you  
6 would have to ask Graham Walker.

7 MS JANES: the second to last paragraph in that letter you have before you,  
8 is it correct that TELARC indicates that ISO 900 is no guarantee of accuracy  
9 of test results ..... yes.

10 If you turn over the page the last sentence in the first paragraph is laboratory  
11 accreditation requires that laboratories must demonstrate ... of their test  
12 procedures .. test results ..... yes that's what it says

13 Does that equate with your understanding of ISO 900 and accreditation ISO  
14 25 ..... yes, for a laboratory that's the information I have.

15 PROFESSOR DUGGAN: does ISO 25 guarantee accuracy of results ..... I  
16 think you would have to ask graham that.

17 MS JANES: do you recall that in the process of developing the standards  
18 there was a lot of discussion about where the responsibility should lie in  
19 terms of responsibilities advising the RHA about accreditation or any  
20 suspension /withdrawal of accreditation ..... yes there was quite a bit of  
21 discussion about that.

22 If I may show you this document I understand this says draft minutes, are  
23 you able to confirm whether they turned out in fact to be final minutes or  
24 truly represent the minutes of meeting of 19 February. If you would refer to  
25 tab 24 of your document, your file note following that meeting. .... they  
26 look like – it looks like the issues we discussed at the meeting, I'm not sure  
27 if this is the final, it would be a fair representation.

1 The two issues are on the first page, the first one the agreement which is  
2 documented about “concerns or complaints about individual pathologists  
3 should be referred to the College, concerns ... must be in writing and  
4 substantiated and referred to the accreditation body.” Are you able to recall  
5 what was contemplated in the term “substantiated” when referring a  
6 complaint about a laboratory or individual pathologist ..... no I can't recall  
7 what the discussion around that would have been.

8 So no recollection of what would be required before somebody would act on  
9 a complaint or concern ..... no, not at that particular time, I can't remember  
10 the discussions at that meeting.

11 From your involvement with the project are you able to provide some clues  
12 ..... I would say substantiated. You would want some kind of evidence that  
13 something had happened, like a letter of complaint from a consumer that  
14 they had been mistreated by somebody or technologist with evidence that a  
15 pathologist had not done something properly. That is the type of evidence.

16 So as far as you can recall it wasn't necessary that the substantiation be  
17 directly related to one of the standards in the draft standard document .....  
18 well, I think you would infer yes it would, it is basically compliance with the  
19 standards will be assessed. I really can't remember any particular  
20 discussion.

21 The second issue is the agreement at the bottom of the page you've indicated  
22 in your brief of evidence that there were concerns by TELARC because of  
23 the contractual relationship that they had with laboratories that it would not  
24 be an appropriate role for them to play to be the reporting or non complaint  
25 notifying body ..... hmm

26 So your recollection is that this agreement that it would be TELARC  
27 notifying the RHA only if there was a proven in the contracts (provision) .....  
28 this was a very we did talk about this issue quite a bit. And TELARC was

1 very clear that it would be beyond their brief to inform the RHAs about  
2 suspension or non accreditation of a laboratory. That the RHA would need  
3 to put a requirement in the contract requiring the laboratory to notify the  
4 RHA about their status.

5 CHAIR: why wouldn't TELARC agree to notify the RHA of either a  
6 suspension of accreditation or refusal ..... I think you best put that question  
7 to TELARC I'm sorry.

8 Given that you were representing the RHA at the time did the RHA consider  
9 it might be prudent to ensure that it was receiving this communication from  
10 a body like TELARC rather than relying on a laboratory that had found itself  
11 suspended from TELARC accreditation ..... my memory of the reasons were  
12 that TELARC was a body that had no responsibility or accountability to the  
13 RHA and therefore it would influence their relationship as an accreditation  
14 body if they were notifying the RHA about suspension

15 Is that the view they took ..... that's my memory, that it would affect their  
16 ability to accredit organisations.

17 MS JANES: SS/HFA/ 0033. at document 24 of your exhibits on the  
18 second page, under the heading resources, you've set out in your file note the  
19 costs of accreditation . do you recall where you got that information from  
20 ..... I got this information from Graham Walker and we also have more  
21 detailed information on this. Do you recall this letter you received ..... I  
22 definitely recall it, I couldn't find it in the files.

23 I want to clarify one particular issue. In your exhibit you've indicated the  
24 approximate direct costs of a small facility being accredited as 6 to 7,000  
25 plus GST. On the document from TELARC can I confirm a small laboratory  
26 which they classify as 3 to 4 units it 6 to 8,000 ..... yes.

1 Do you recall individual units are able to be accredited, a cytology unit of a  
2 laboratory for instance ..... I'm not sure that's what unit means.

3 So what is your understanding of 3 to 4 units being 6y to 8,000 ..... I really  
4 didn't have an understanding of that. different services have different ways  
5 of units, a rest home would have a totally different way of quantifying their  
6 size.

7 That was the reason for you extrapolating that figure into your file note ..... I  
8 don't think I extrapolated this from this letter into my f/note, my f/note is  
9 from a discussion, the notes I took at the meeting, that's why it is probably  
10 different. This f/note occurred before I got the letter and I asked graham to  
11 go and do more research and give me a more accurate account, and that's  
12 what I think this document is.- SS/HFA/ 0034

13 Continuing on with the resourcing issue of this particular project. What do  
14 you recall the commitment being to the development of the national  
15 standards project of the RHAs jointly. Was it very important, medium  
16 important ..... I think it was actually very – well, it depends on who you ask  
17 in the RHA. I think it was seen as quite important because it was the first  
18 time they brought the 4 RHAs together to develop a set of standards and I  
19 think it was seen as very necessary and quite important.

20 And one of the terms of reference under tab 1, number 2, and one assumes  
21 therefore reasonably important in the hierarchy in their terms of reference is  
22 to advise RHAs on significant issues which affected development and which  
23 may be resolved at an RHA level ..... yes

24 Would that fit in the context of a national focus and quality being an  
25 important standard to be introduced ..... yes, I think that the development of  
26 the standards was down on no. 6 and 7, but you could see that it was  
27 recognised that the lack of standards was a significant issue, so yes I suppose  
28 you could move that one up.

1 Given it was an important project to be involved in, can I take you to tab 2  
2 paragraph 4 in the first page where it indicates that we need to control the  
3 revenue implications – i.e. .. costs of meeting the standards. What were the  
4 concerns about the financial implications . was it an indication the RHAs  
5 did not wish to meet the cost of the standards or the laboratories would have  
6 to absorb those costs themselves ..... no I don't think it was either of those.  
7 There are always revenue implications when you introduce new standards.  
8 Introduction of standards can decrease the cost of a service by making it  
9 more efficient by putting systems in place that assist the service to work  
10 more efficiently but at the same time new standards can cost such as  
11 requiring new equipment, so I think this is just saying as part of the process  
12 we need to be aware of the financial implications for the public dollar.

13 And was that one of the reasons for seeking that letter to TELARC to  
14 quantify those costs ..... to make an attempt to quantify the costs, definitely.

15 Was similar information sought from any other bodies in relation to the other  
16 quality standards contained in the draft national standards, external the  
17 Royal College external participation for example ..... no. we didn't, we were  
18 simply looking at the actual cost of the accreditation process.

19 And you've indicated that this was an important project and at paragraph 24  
20 of your brief you've indicated that the issue of costs was discussed and that  
21 the total cost of the project should be no more than \$5,000 ..... yes.

22 In our view does that equate with an important project. If I could turn you to  
23 tab 2, 4 pages in, at the very bottom of that the budget for 95/96 exclusive of  
24 GST was set per RHA which would have made it \$24,000 and at tab 3 the  
25 second to last page, the budget appears to have increased to \$7,500/RHA,  
26 which is \$30,000. are you able to explain why it dropped from \$30,000  
27 which reflect an important project to \$5,000 which was eventually agreed  
28 on. .... first of all the \$5,000 came out of the meeting between Graham

1 Walker Tony Barker I think it was jack – the Chief Executive Officer of  
2 TELARC, that figure was actually an agreement by the group that Tony  
3 Barker and Graham Walker would participate in the project and their  
4 organisations would pay for them. The RHA would pay for me – the 4  
5 RHAs, and TELARC would pay for graham. That's where that \$5,000 came  
6 from. The RHAs were willing to spend \$30,000 but the group said it  
7 wouldn't cost more than \$7,000.

8 So through the goodwill of TELARC and the Royal College it was able to be  
9 done by a significantly reduced budget ..... totally, they gave a lot of their  
10 time freely.

11 The intellectual property rights in those standards, do you recall how that  
12 was resolved or if It was resolved ..... I think the discussion was probably  
13 from TELARC because I believe they put a lot of time/effort into the guide  
14 25 standards and that in a sense they were concerned if they were going to  
15 put a lot of time /effort into these standards and there was another  
16 accreditation body the other accreditation body could use the standards., it  
17 didn't come up as issue once we made it clear TELARC was the only  
18 organisation within New Zealand that had the skill and expertise to carry out  
19 the accreditation process.

20 And can I just clarify to the best of your knowledge TELARC are  
21 accrediting against one of the final drafts ..... yes I believe they are.

22 But that the drafts are as yet not promulgated within the RHA or now HFA  
23 ..... what do you mean by promulgated

24 They haven't been entrenched in contracts, apart from accreditation ..... I  
25 don't know that, its not part of my brief.

26 CHAIR: thank you Ms Sax.

27

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4 THE HEARING ADJOURNED AT 2.45 P.M., TO RESUME AT  
5 10.00A.M. ON 3 JULY 2000 IN GISBORNE