

UNDER

The Health And Disability Services Act 1993

IN THE MATTER OF

The Ministerial Inquiry into the Under-Reporting
of Cervical Smear Abnormalities

STATEMENT OF EVIDENCE OF DR IAN D BEER

I, **IAN D BEER** of Tauranga, Pathologist, state:

1. I am the Chairman of the Association of Community Laboratories Incorporated (“ACL”). I have been Chairman of ACL since 1999, and prior to that was a member of the ACL Management Committee. I became a member of the ACL Management Committee in 1994.
2. My qualifications are BSc (1974) and MBChB (1977). In 1984 I became a Fellow of the Royal College of Pathologists of Australasia.
3. For the past 15 years I have practised as a general pathologist in Tauranga, reporting cervical cytology and histology.
4. The other representative of ACL accompanying me before the Inquiry is Mr Michael Fitzgerald (MVO, BA, CISI). Mr Fitzgerald has been the Executive Officer of ACL since March 1997. Mr Fitzgerald is experienced in business and management consulting. His career experience over 25 years includes senior management positions in the public sector (Department of Social Welfare, State Services Commission and Department of Internal Affairs).

Constitution of ACL

5. ACL is a voluntary association of community laboratories. It was incorporated on 22 October 1991 under the Incorporated Societies Act 1908. I produce a copy of the ACL Constitution as exhibit **IDB/ACL/001**.
6. ACL is concerned with developments, practices and interests relevant to community laboratories. The objects of ACL are set out in its Constitution.
7. Applications for membership of ACL are considered by the Management Committee which is elected at the annual general meetings of ACL. Membership is confined to sole practitioners, bodies corporate or representatives of a partnership involved in the private practice of pathology in community laboratories in New Zealand. Members are the community laboratories themselves, not individual staff of the business. That is to say individual pathologists, technologists and laboratory assistants are not members of ACL (they may however be registered by and/or be members of their own professional regulatory bodies and associations).
8. All privately owned community pathology laboratories in New Zealand are currently members of ACL. They and their contact details are produced as exhibit **IDB/ACL/002**. There are currently 14 members of ACL. This number has reduced from 19 over the last five years as a result of market evolution.
9. Gisborne Laboratories Limited, which was jointly owned by Dr Michael Bottrill and Mr Graham Reeve, was a member of ACL from 1991 until March 1996 when Dr Bottrill retired.

10. ACL does not have access to or hold records of particular laboratories. Nor does ACL exercise any 'policing' role over members. Rather ACL acts as a focal point for bringing together the collective views of its members, to facilitate policies on a consensus basis, and to represent the collective views of its members. ACL also provides information and advice to its members. This flow of information usually relates to the development of policy by government agencies which affect the interests of ACL's members. By far the greatest portion of ACL work for and on behalf of its members relates to the content of contracts for services entered into by the HFA (and its predecessors) with ACL members.

11. Members of ACL provide support to general practitioners, midwives, cervical smear takers and specialist practitioners to diagnose, manage and prevent patients' illnesses. This support is ongoing on a day-to-day basis and involves frequent and close associations between laboratory and health professionals. ACL members:
 - 11.1. Provide specialist pathology advice to medical practitioners and their staff in a variety of circumstances, for example: observation and training of health professionals to take specimens at their practices; educational seminars for practice staff; advice about in/appropriateness of diagnostic tests; and advice about the results of tests.

 - 11.2. Take patient specimens, collect specimens from medical centres and transport them to laboratories for testing.

 - 11.3. Carry out the tests requested by the patient's health professional (15 million tests a year across 170 different kinds of tests). These include cytological examination of cervical

smears ordered by registered medical practitioners, registered midwives and (lay) certified smear takers.

- 11.4. Notify the health professionals of the results of tests and assist them to interpret the results.
 - 11.5. Report regularly to government health authorities as required, including test results related to the National Cervical Screening Programme.
12. In 1993 ACL adopted Ethical Rules, a copy of which is produced as **IDB/ACL/003**. It will be seen these rules require members to, inter alia:
- 12.1. Place the highest value on service, competence and concern for the patient. Members must accept that they have obligations that may require extra service and dedication.
 - 12.2. Uphold the reputation of ACL and not engage in practices restricted by law or the New Zealand Medical Council.
 - 12.3. Practice pathology with skill, knowledge and understanding, which their pathology peers would consider appropriate.
 - 12.4. Have registered pathologists as partners/principals/directors of their laboratory, who will take professional responsibility for pathology reports and for ethical conduct.
 - 12.5. Ensure that all analyses are carried out under the supervision of a registered pathologist.

- 12.6. Maintain their professional competence, laboratory accreditation by TELARC (now International Accreditation New Zealand (“IANZ”)) or other body approved by ACL, and ensure that other laboratories to which they refer work are similarly registered.
13. The requirement that members be accredited by TELARC/IANZ was adopted by ACL with the consent of all its members. The accreditation requirements of the Rules of ACL were fully discussed and debated before they were adopted. Gisborne Laboratories Limited, and in particular Dr Bottrill, knew of this requirement. He and all other representatives of ACL members consented to the accreditation requirement being adopted as part of the Rules of ACL.
14. ACL firmly believed all of its members had complied with the accreditation requirements of its Rules. Nothing was ever said by Dr Bottrill or any other pathologist to ACL which indicated members had not complied with ACL’s accreditation requirements. It was only when ACL received Mr Mules’ evidence in this hearing, and in particular had an opportunity to read the annexures to his evidence, that it became apparent to ACL that Gisborne Laboratories Limited had not complied with ACL’s Rules.
15. ACL can only enforce its ethical rules if it becomes aware of a breach. Because ACL is a voluntary body its only effective remedy is to censure or expel a member for breaching ACL’s Rules.
16. ACL has always recognized that contracts for service provided an effective mechanism to ensure community laboratories were TELARC/IANZ accredited. It was for this reason that ACL initiated

and insisted on accreditation provisions being incorporated into HFA purchase contracts.

Relations with Midland

17. When the RHAs were established on 1 July 1993 the Managers of three of those entities (the exception was the Central RHA) announced their intention to reduce expenditure.
18. The person at Midland primarily responsible for developing that RHA's policies and procedures for reducing expenditure in respect of laboratory services was Mr Kirk Wakem whose title was "Project Manager". Mr Wakem was the person whom ACL primarily dealt with during the period July 1993 to December 1997, although on occasions there was direct correspondence between ACL and Mr Mules.
19. Soon after taking up his position Mr Wakem advised ACL that Midland's preferred policy was to introduce a system of competition between community laboratories and CHE laboratories. Midland wanted to have this model of contestability in place by 1 October 1994.
20. ACL was not opposed to members competing with the CHE laboratories so long as any competition was on the basis of a level playing field. If there were to be outright competition between the CHE laboratories and private laboratories along the lines advocated by Midland the so called contest would have been heavily weighted in favour of CHE laboratories. The reasons for this were fundamental. Community laboratories had to purchase all their equipment, lease or purchase their premises and pay commercial rates for all their assets. Hospital laboratories could not, at that stage, even identify their actual overhead costs let alone make provision for them.

21. Of even more fundamental concern to ACL was the lack of principled objectives behind Midland's proposal. In the first letter written by ACL to Midland (31 August 1993) ACL emphasized its concerns about the lack of any principled reasons for the proposed changes. It is instructive to examine what ACL advised in its first letter to Midland:

“We have heard a great deal about the need to improve health services, and this is an objective which we fully endorse. We also agree with the statement made by the Minister of Health, which was reported in the Dominion on 30 August, that ‘its important not to loose sight of the fact that the restructuring itself wasn’t the goal of reform. The better health of New Zealanders was’.

However, although there have been numerous comments about introducing various systems and procedures which are essential means of advancing goals and objectives, there has been little said about what the goals and objectives actually are. We believe that if we are to work together towards improvements in laboratory services we need to have a very clear intention of what sort of service we are trying to provide. We can then work together to introduce the best systems for providing such services.

As a basis for discussion we believe that the objectives of community laboratories, and presumably the RHA's would be along the following lines:

- (a) To maintain and improve the high quality of laboratory services in New Zealand.*
- (b) To achieve appropriate utilization rates for laboratory services and tests.*
- (c) To provide services at the lowest costs which are commensurate with the long term effectiveness and viability of the industry.*
- (d) To provide a service which operates according to high ethical standards.*
- (e) To provide a service which is accountable to users, timely in terms of geographical coverage and service.*

(f) *To allow competition within the context of ‘a level playing field’. We recognize that this is really a means of attaining an objective, rather than objective in its own right. However, it is something which is of great importance and is accepted in principle by everyone we have spoken to so we believe it is appropriate to list it here.”*

22. Members of the Inquiry panel will note that from the outset of its negotiations with Midland ACL wanted to ensure any changes promoted by Midland enhanced quality of services to ensure an improvement in the health of New Zealanders.
23. Paragraphs 19 and 20 of Mr Mules’ evidence appear to acknowledge that Midland was not focusing upon quality issues. Mr Mules offers the explanation for Midlands lack of concern about quality issues when he says:

“Arrangements for quality standards and monitoring were essentially self imposed by laboratory service providers through their professional and business representative bodies ... (20) membership of the ... ACL was available to private laboratories and ACL had ethical rules regulating the conduct of its members. A requirement of those ethical rules was that members be accredited (or have applied for accreditation) by TELARC or an equivalent accreditation body and that the accreditation body monitored the quality of the systems used by the provider.”

24. It must be said however ACL takes exception to Mr Mules’ assertion (in paragraphs 19, 20, 43 and 44 of his evidence) that Midland relied on ACL’s ethical rules to ensure community laboratories achieved appropriate quality standards in monitoring at the time they issued section 51 notices in June 1993. The copy of ACL’s ethical rules referred to by Mr Mules was not sent to Midland until September 1995. Midland did not have that document at the time it issued its section 51 notices to community laboratories in June 1993.

Community Laboratory Industry

25. Community laboratories and Hospital and Health Services' ("HHS") laboratories, in general, operate in separate markets. Community laboratories carry out specified tests contained in the Schedule to their purchase contracts with the HFA.
26. HHS laboratories carry out similar tests for hospital patients and also provide "non-scheduled" tests (potentially an additional 700 types of tests).
27. There are some overlaps between the two markets. For example, community laboratories collect specimens from General Practices or laboratory collection rooms for transportation to the laboratory for testing. If the tests are not among those on the community laboratory schedule the specimens are referred to the hospital laboratory for testing. Another example is where community laboratories undertake tests referred by hospitals for the follow-up monitoring of discharged patients.
28. Relationships between community and hospital laboratories may on occasion be competitive. This competition has essentially related to service delivery. The fees which are paid for scheduled services have been closely regulated by the HFA and its predecessors.
29. Members of the Inquiry panel will be aware the origin of the "schedule" of tests pre-dates the establishment of RHAs under the Health and Disability Services Act 1993 and relates to the time when the Department of Health purchased laboratory services under Regulations, which included a schedule of tests and fee payments.
30. The Department of Health also promoted a Laboratory Services Advisory Committee which included representatives from people who

owned or worked in community laboratories. That Committee provided input on professional matters relating to laboratory services.

31. The schedule of tests were “inherited” by the four RHAs set up under the 1993 Act and were incorporated into RHA contracts with community laboratories for pathology services.
32. The Inquiry Panel will be aware that initially laboratories operated under RHA notices issued in 1993 under section 51 of the Health and Disability Services Act 1993.
33. The National Laboratory Services Advisory Committee fell by the wayside during this change-over (although the four RHAs did create four regional Laboratory Advisory groups). These groups met infrequently. The meetings which were held did provide an opportunity to inform RHA’s about the clinical value of laboratory testing and evidence based medical practice, but the main focus of the meetings was fiscal (ie expenditure containment)
34. ACL has consistently suggested to successive Governments and the HFA that the Laboratory Services Advisory Committee be re-established. If re-established the Committee should comprise representatives from the Ministry of Health, HFA and hospital and community laboratories. Its objectives should be to address and advise government authorities on policy and professional matters concerning laboratory services.

Rates of Remuneration

35. Three of the four RHAs entered into purchase agreements with community laboratories in 1996/97. Laboratories in the Northern Region have never moved beyond section 51 notices.

36. The substantive purchase agreements/section 51 notices under which community laboratories operate expired on:
- Northern Region:.....30 June 1997
 - Midland Region:31 October 1999
 - Central Region:31 December 1997
 - Southern Region:.....30 June 1997
37. Since then, the contracts/section 51 notices have been rolled over for various periods. It is ACL's understanding that these roll-overs have taken place because the HFA (and its predecessor RHAs) wanted to revise the purchasing strategy for laboratory services. The latest strategy intentions were issued in May 1998 and have yet to be finalised.
38. Ninety-six percent of community laboratory revenue derives from the HFA for the provision of the "scheduled" tests and associated pathology services under the contracts mentioned above.
39. RHAs and the HFA entered into the contracts with community laboratories on the basis that the laboratory services are free of charge to consumers. Laboratories cannot recover the costs of the services from parties other than the HFA, and the services purchased by the HFA are thus fully funded by the Government.
40. Over the decade of the 1990s, however, the average unit costs of services provided by community laboratories have increased by 30.6%. Over the same period, fees paid by Department of Health/RHAs/HFA have increased by only 5% to 8%.
41. A 1998 study by PriceWaterhouseCoopers, commissioned by ACL, found that revenue received by New Zealand community laboratories

is in a range of 32% to 55% of the equivalent fees in Australia, Canada and South Africa. A copy of this study is produced as exhibit **IDB/ACL/004**.

42. The fees, exclusive of GST, paid by the HFA for cytological examination of cervical smears until recently was:
- Northern Region:.....\$14.67
 - Midland Region:\$15.03
 - Central Region:\$15.11
 - Southern Region:.....\$14.96 - \$15.03
43. The equivalent prices paid in Australia and South Africa are \$21.17 and \$18.36 respectively, in equivalent New Zealand dollars.
44. The HFA recently (March/April 2000) offered increases to the cervical smear test to bring it to a level of \$21, exclusive of GST, which has been accepted by all community laboratories.
45. ACL is concerned that reductions in revenue will impact on the ability to retain and attract sufficient numbers of competent and suitably qualified pathologists and technologists. It is important that the viability of community laboratories is assured so that qualified pathologists and technologists can be recruited into the histology/cytology speciality and retained in New Zealand. If there is insufficient incentive for professionals to enter into laboratory practice this branch of medicine will deteriorate and ultimately fail.

Quality of Services

46. The quality of pathology services needs to be under-pinned by sound planning, investment and resource management. In the view of ACL,

the ability of community laboratories to do this has been continually threatened by:

- 46.1. A series of inconclusive purchasing strategies by ever-changing personnel in the RHAs, THA and HFA.
 - 46.2. The failure of the HFA to define and implement a proper balance between the service levels which are required and the funding levels to achieve these services.
 - 46.3. The absence of proper purchase agreements for the medium term which enable community laboratories to plan, invest and manage with confidence and certainty.
 - 46.4. The absence of any formal mechanisms enabling community laboratories and the HFA to properly review performance, anticipate issues and address them in a preventive way.
47. ACL believes it is vital there be a regular opportunity for community service providers and purchasers to communicate in a systematic way. There is currently no mechanism, equivalent to the previous national Laboratory Services Advisory Committee or the regional Laboratory Advisory groups, to provide professional advice to the HFA on matters affecting pathology services.
48. ACL would strongly advocate and endorse the re-establishment of a Laboratory Services Advisory Committee. The HFA has taken some initiatives to set up an advisory committee to advise it on revisions of the schedule of tests. However ACL believes any such advisory committee should address the wider field of professional and policy advice relating to the provision of laboratory services by both community and hospital laboratories.

49. While ACL recognises that evolving changes in the health sector are to be expected, the contractual and fiscal environment referred to has created and exacerbated the instability and uncertainty within community laboratories.
50. It is ACL's view that the HFA/Ministry must address these contract, fiscal and communication issues in order to stabilise the histology/cytology services provided by laboratories.

Qualifications for Pathology

51. The cytological examination of cervical smears is difficult and time consuming. It typically involves the primary and secondary examination of smears by two different people trained in cytological screening, with abnormal cases being referred to a third person, the pathologist.
52. The route to registration for medical scientists (technologists) to work in cytology (or other laboratory departments) is by way of a four-year degree course, namely the Bachelor of Medical Laboratory Science, offered by Otago, Massey and Auckland Universities. Cytology is one component of the course. If cytology is chosen as a major discipline in the fourth year, the student spends one semester (16 weeks) working in a laboratory focusing on cytology.
53. Laboratory assistants can study through a correspondence course in cytology offered by National Women's Hospital.
54. Students usually go on to sit a theory and practical examination, offered by the NZ Institute of Medical Laboratory Science, to become a Qualified Technical Assistant.

55. Continuing education includes:
 - 55.1. A three-day refresher course offered by National Women's Hospital laboratory;
 - 55.2. Teaching programmes and annual meetings and workshops held by the NZ Society of Cytology;
 - 55.3. Short-term opportunities for training offered by some laboratories to cytologists from other areas; and
 - 55.4. A theory and practical examination offered every two years by the International Academy of Cytology.
 - 55.5. Courses are also available from overseas institutions.

56. By now the Inquiry Panel will be aware that the validity of results of cytology (and other) laboratory tests may be influenced by a number of factors:
 - 56.1. Prior to testing (physiological factors/the preparation of the patient/how the patient specimen is collected or transported).
 - 56.2. During testing (the test method/patient medications affecting test assay).
 - 56.3. After testing (data entry/interpretation of results/data transfer).

57. These factors are controlled as far as practicable by each individual laboratory's:

- 57.1. Internal quality assurance procedures. For example double screening of cervical smear slides and comparison of the histology of cervical biopsies with any preceding screening cytology so that any discordance is reviewed.
- 57.2. Participation in external quality assurance programmes run by the Royal College of Pathologists of Australasia whereby sets of carefully selected cervical smear slides are provided four times a year to participating laboratories for reporting and comparative analysis, as well as other surveys of laboratory's practices.
58. A laboratories' internal quality measures include:
- Laboratory staff and their management, training and performance.
 - Management responsibilities.
 - Quality systems.
 - Documentation control and maintenance of manuals.
 - Review of work.
 - Procurement of goods and services.
 - Test reporting, certificates and records.
 - Management and calibration of testing equipment.
 - Identification, handling and storage of test items.
 - Complaint handling.
 - Statistical techniques.
 - Internal audits.

TELARC/IANZ

59. IANZ's liaison with accreditation bodies in other countries ensures that accredited laboratories in New Zealand meet comparable

standards of performance of laboratories in Australia, the UK, USA, France and other western countries.

60. The international standards applied in New Zealand are reflected in IANZ's "New Zealand Code of Laboratory Management Practice", which sets out standards in the following areas:

- Laboratory management responsibility.
- Quality systems.
- Documentation control.
- Review of new work.
- Procurement of equipment, consumables and sub-contract services.
- Test methods and procedures.
- Accommodation and environment.
- Test equipment management.
- Calibration of test equipment.
- Identification of items for tests.
- Handling and storage of items for tests.
- Laboratory quality control procedures.
- Control of sub-standard testing work.
- Complaints.
- Corrective action procedures.
- Test records.
- Test reports and certificates.
- Quality records.
- Management of laboratory staff.
- Training of laboratory staff.
- Statistical techniques.
- Laboratory audits.
- Computers and automated test equipment.

61. IANZ carries out a major assessment of laboratories every four years, with annual visits in the interim to assess the effectiveness of the laboratory's quality system, including its performance in external quality programmes.

National Cervical Screening Programme

62. In 1994 ACL, in consultation with the NCSP and professional bodies, initiated a panel to review cervical smears where there was a complaint or question about the diagnosis. The procedures for this Review Panel are produced as exhibit **IDB/ACL/005**.

63. At the same time, ACL recommended to the NSCP that a suitable statement be issued to inform the public about the incidence of "false negative" results, notwithstanding rigid controls applied in laboratories carrying out cytology screening. This recommendation is produced as exhibit **IDB/ACL/006**.

Quality Requirements of Health Funding Authority Contracts

64. In 1996 the RHAs issued draft "National Medical Laboratory Quality and Service Standards". A copy of the draft standards and ACL's comments on this document are produced as exhibits **IDB/ACL/007** and **IDB/ACL/008**. The draft standards have not been finalised by the HFA. We do not know why. We observe that they are still being issued by the HFA in the draft form. The draft standards cover:
 - 64.1. Accreditation of laboratories.

 - 64.2. Pathologist staff (qualifications/professional development/staffing/clinical liaison).

 - 64.3. Scientific, technical and support staff (qualifications/professional development/clinical advice and interpretation).

- 64.4. Quality control programmes (external quality controls/ sharing materials/internal quality control/responsibility for quality control).
 - 64.5. Specimen management collection facilities: labelling and request-form requirements, patient informed consent.
 - 64.6. Testing capabilities of laboratories (criteria for testing competence).
 - 64.7. Test records and reports: authorisation of results, consistency of reporting, electronic transfer of results, retention of patient records, reporting on material referred to other laboratories, confidentiality.
 - 64.8. Test procedures and equipment: relevance of methods, equipment maintenance and replacement.
 - 64.9. Near-patient testing (equipment management/staff training/ responsibility for results).
65. While each community laboratory has developed its own quality standards members of ACL are open to adopting national standards developed in consultation with ACL if the health authorities wish and if this will enhance performance in a consistent manner.

Management of HFA Contracts

- 66. The HFA purchases services for the cytological examination of cervical smears, under its contracts for services with community laboratories.

67. There is no active management of the contract by the HFA, in the sense of regular, pro-active discussion between the parties over utilisation of laboratory services and management of potential issues which arise. Instead, dialogue over contract requirements tends to happen in a reactive way when issues arise, thus, all annual reviews of tests and prices under the contracts have been initiated by ACL. The scheduled expiration of community laboratory contracts are typically dealt with by the HFA by short term 'roll-overs' because strategies are being reviewed; the few new contract negotiations that have commenced have been aborted by the HFA before completion because of changes in its organisation. Regrettably laboratories have had no other option but to pursue litigation in some instances to ensure HFAs contractual obligations are met.
68. The absence of dialogue over professional issues is compounded by the absence of a laboratory services advisory group such as operated under the Department of Health or of laboratory advisory groups mooted by the previous RHAs.
69. This vacuum in conventional contract management practice breeds an atmosphere of distance and distrust between the parties, and this is exacerbated by an absence of any mechanism for assisting the HFA with the routine provision of pathological advice on technical and policy issues.
70. The ACL would recommend that there should be regular contract management meetings between parties, in order to share data about performance, to anticipate and manage potential issues which arise and to support the HFA's responsibilities by providing pathology and professional advice. Much, if not all, of this contact could be at a national level with ACL.

Management of National Cervical Screening Programme

71. An independent Cytology Advisory Liaison Committee was established in 1989. It comprised representatives of the NZ Society of Pathologists, NZ Society of Cytology, the RCPA, and Institute of Medical Laboratory Technologists. In 1994 this committee was expanded to incorporate membership from the Ministry of Health, and was absorbed into the NCSP administration. The committee was, however, disestablished in 1996. During its existence, the committee made two sets of recommendations to TELARC/IANZ for quality assurance programmes in laboratories.

72. The Ministry of Health has issued various documents relating to the NCSP including a policy document for the NCSP in 1996 titled "*National Cervical Screening Programme - Policy*", statistical returns of data including variability of laboratory reporting, and newsletters covering progress with enrolments, incidence of cervical cancer and NCSP developments. The Ministry has also provided coding and management guidelines.

73. ACL hopes that opportunity for linking the NCSP administration with professional and technical input and feedback will be carried on, with the transfer of administration of the NCSP to the HFA. The HFA set up a new advisory committee for public health screening programmes (cervical and breast screening) in December 1998. ACL successfully nominated Dr Clinton A Teague as a personal member to that body.

74. Management of a national programme requires pro-active leadership to define the goals, identify the programme standards, ensure participating laboratories (and other parties) meet the standards, and monitor progress in the achievement of the programme's goals.

75. The NCSP's policy document requires laboratories to:
- 75.1. Provide efficient and accurate services for processing and examining cervical smears (including cytological and histological cervical smear tests) and report results to smear takers within 5 working days.
 - 75.2. Forward cytology and histology results (except where participants object) to the National Cervical Screening Register in agreed codes and electronic format, within 10 and 20 (respectively) days of receipt.
76. ACL does not have statistics on performance against the 5 and 10 day criteria - we expect the NCSP to monitor its own criteria - but our general impression is that community laboratories do meet these requirements.
77. The Policy requires laboratories to be TELARC/IANZ accredited and to have policies and procedures which assure the quality of smear reading. Laboratories are to:
- Define staff and laboratory procedures.
 - Appoint appropriately qualified and experienced staff.
 - Ensure high quality, accurate reporting systems using prescribed coding systems.
 - Have quality control systems that can identify potential sources of error in laboratory operations.
 - Implement controls to detect and minimise errors.
 - Have quality control systems to minimise the incidence of false negative and false positive results.

- Participate to a satisfactory standard in an external quality assurance programme such as the RCPA programme, or an alternative that meets TELARC/IANZ standards.
 - Meet National Quality and Service Standards for Medical Testing Laboratories (under development).
78. The HFA recently issued for comment a first draft of *“Policy and Quality Standards for the National Cervical Screening Programme”*, including a chapter on laboratory services covering:
- Training and staffing.
 - Test reading services.
 - Internal quality control.
 - Monitoring of the Programme.
 - Reporting requirements.
 - Register requirements.
 - Fail-safe arrangements.
 - Accreditation.
 - Quality assurance.
79. ACL members have been encouraged by ACL to provide comment to the HFA on that draft document.
80. While ACL is confident that community laboratory standards are of a high quality, we consider it prudent for the Programme managers to:
- 80.1. Continue with the development of national standards for screening in consultation with community laboratories. As noted earlier, ACL are open to the adoption of national standards.

80.2. Positively assure themselves of the adequacy of standards of screening operations (whether local laboratory or national standards), and by satisfying themselves explicitly about laboratory accreditation following IANZ audits, particularly for histology/cytology.

80.3. Ensure that Programme operations are satisfactorily resourced.

80.4. Ensure the provision of leadership and financial support for relevant education and development opportunities for laboratory personnel working in this field.

Dated this day of 2000.

Ian D Beer