

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

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

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**STATEMENT OF EVIDENCE OF DR JOHN MAXWELL ROBERTSON**

**TELARC/IANZ**

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**I, JOHN MAXWELL ROBERTSON**, General Manager Accreditation Services, state:

1. I am the General Manager of Accreditation Services at International Accreditation New Zealand (“IANZ”). I took up this position in October 1995.
2. IANZ was known as Telarc New Zealand until July 1997. Therefore, during the period 1990 to 1996, in which the Inquiry is directly interest, IANZ was known as Telarc and for convenience, I will refer to it in this statement as Telarc.

### **Qualifications**

3. My qualifications are:
  - (a) BSc (Hons) in chemistry (Otago 1966)
  - (b) PhD in chemistry (Otago 1969)
  - (c) Post graduate diploma of business administration (Canterbury 1993)
1. I have been an external technical expert assessor for Telarc since 1976. I was also a member of the Chemical Registration Advisory Committee, which was established in 1984. From 1987 until 1992 I served on the Laboratory Accreditation Management Advisory Committee, and wrote the Telarc Technical Guide No. 5, “Precision and Limits of Detection for Analytical Methods” in 1987. This Guide was mainly for chemistry laboratories, rather than medical laboratories.
2. The standards for accreditation required by Telarc are comparable with the highest standards in the developed world, and Telarc is highly regarded internationally. This is in part due to the fact that individuals employed by Telarc are involved in training and assessing colleagues from accreditation agencies overseas.

3. Since 1981 Telarc has participated in the International Laboratory Accreditation Co-operation teams, as well as in the Asia-Pacific and European Laboratory Accreditation Co-operation teams, which has involved evaluation of our overseas colleagues to establish mutual recognition. These teams comprise up to 4-persons and establish if the counterpart accreditation body is operating correctly and assessing its laboratories properly. I have been involved in evaluations in Australia, Chinese Taipei, Korea, Singapore, USA and China, leading most of those teams. I have also been involved in running training courses and seminars for laboratory assessors in New Zealand, Korea, Japan, Indonesia, USA and Hong Kong.
4. I am a member of the International Standards Organisation (“ISO”) Committee that wrote the latest version of the international standard for laboratories, ISO/IEC 17025: 1999. I am also a member of the ISO Committee that is currently re-writing the standard to which Telarc and other accreditation bodies around the world conform and operate, viz. ISO/IEC 17011.

### **International Consistency of Accreditation Standards**

5. Telarc is a member of International Laboratory Accreditation Co-operation (ILAC), which has standardised laboratory accreditation practices to ensure that a Telarc accredited laboratory meets the same standards of performance as any equivalent laboratory in a country where Telarc has mutual recognition.
6. The standard laboratory accreditation criteria adopted by ILAC were published in 1978 by ISO as the international standard ISO Guide 25: 1978 “Guidelines for assessing the technical competence of testing laboratories”. The New Zealand Code of Laboratory Management Practice (“the Code of Practice”), which is the Telarc primary criteria for laboratory accreditation, includes all the elements of ISO/IEC Guide 25, 1990 plus all the elements of ISO 9002: 1987 but also includes additional explanatory information and amplifications. The Code of Practice is produced as **Exhibit JMR/IANZ/0001**. I also refer to the Telarc Specific Criteria for Registration of Medical Testing, which was developed and approved by the Medical Testing Registration Advisory Committee, a committee of practicing experts, and which is

produced as **Exhibit JMR/IANZ/0002**. From 1990 to 1996 these were the criteria documents used for the accreditation of medical laboratories in New Zealand. Where New Zealand industry standards were adopted, these were also used as accreditation guidelines during the Telarc assessments of competence and technical validity.

### **Accreditation of Medical Laboratories in New Zealand**

7. New Zealand was the second country in the world to introduce accreditation, following Australia, which introduced accreditation in 1947.

8. Telarc was constituted under the Testing Laboratory Registration Act 1972, and one of its primary functions was:

*“12(a) To promote the development and maintenance of good laboratory practice in testing and to establish and maintain a scheme for registration of testing laboratories in respect of which application is made for registration and which comply with that practice, ...”*

9. Telarc accreditation is a formal recognition by an independent authority that a laboratory has attained the minimum international standards of good laboratory practices and is competent to carry out specific tests.

10. Accreditation is available to laboratories in any field of science or technology that can demonstrate that they comply with currently accepted standards of good laboratory practice and management and are competent. The specific areas that are considered include:

(a) The technical competence of staff and the effectiveness of staff training and workload allocation.

(b) Adequacy of accommodation and equipment and reference materials.

- (c) Validity and documentation of test methodology.
  - (d) Use of quality control procedures, including proficiency testing.
  - (e) Recording of test data and reporting results.
1. An applicant for accreditation must satisfy Telarc of their technical competence in specific tasks within each specific area, as illustrated in **Exhibit JMR/IANZ/0003**.
  2. It must be stressed that Telarc accreditation is predominantly concerned with ensuring that a laboratory's procedures are technically valid, that staff are technically competent, and that the results are technically valid. The quality management system or "paper trail" requirements, are not the focus of accreditation procedures. Accreditation should not be confused with certification, such as ISO-9000 certification, which is more concerned with compliance of processes and procedures with the standard. The onus of proof is on each individual laboratory to satisfy the Telarc technical expert assessors that their personnel are competent and that their procedures are technically valid. Assessments are not merely checks to ensure compliance with the various written criteria, they are thorough evaluations to determine competence. Competence cannot be defined in written criteria. It can only be judged by experts questioning and observing and making professional judgements.
  3. Telarc divides testing laboratories into broad categories, including medical testing.
  4. The medical testing field is divided further into various sub-fields, including cytology and histopathology. Registration is generally granted only for work that is performed regularly and for which the laboratory is properly equipped and has demonstrated its competence and capability.
  5. Application for accreditation is voluntary. While the Health Funding Authority, approximately four years ago, drafted "National Quality and Service Standards for Medical Laboratories", with a requirement for medical laboratories to be accredited, to the best of my knowledge the standards have never been adopted. I also understand

that cervical screening programme contract documents in 1996 stated accreditation as being a requirement for reimbursement of laboratories.

6. In some other sectors such as the dairy industry, dairy testing laboratories have been required by MAF to be accredited since 1990. Also, the Accident Compensation Corporation has recently instituted a policy requiring high technology radiology services to be accredited before they are entitled to receive payment. This has resulted in a significant increase in the applications for accreditation from radiology services.
7. Accreditation is very thorough and therefore requires a significant effort by the applicant laboratory. Typically, it would take a medical laboratory one to two years to raise its standards to the level required for accreditation to be granted. This often involves a significant cost to the laboratory, both in time and money. It has not been unusual for large, multi-discipline laboratories to seek accreditation department by department, because of the effort compliance with Telarc standards requires.

### **Process of Accreditation**

8. The Telarc “Procedures and Conditions of Accreditation” are annexed as **Exhibit JMR/IANZ/0004**.
9. The accreditation of a laboratory involves three important steps:
  - (a) An evaluation of the technical competence of the key laboratory staff by practising laboratory professionals from other similar laboratories. These professionals also assess the technical validity of all the work that is to be accredited. This is the most important aspect of the process.
  - (b) A check to ensure that the laboratory is actively participating in proficiency testing programmes (inter-laboratory comparisons) and addressing performance problems that are identified by these proficiency testing programmes. It is a requirement of accreditation that the medical laboratory must be enrolled in the appropriate Royal College (“RCPA”) or comparable

proficiency testing programmes of equivalent inter-laboratory proficiency testing programmes.

- (c) An evaluation of the laboratory's quality system to ensure that laboratory management is effective and fulfils the requirements of the New Zealand Code of Laboratory Management Practice which incorporates ISO/IEC Guide 25: 1990.
1. Accreditation requires ongoing assessments and evaluations, rather than being one process. Flow diagrams illustrating the series of "gates" to be gotten through, and the extent of the on-site assessment are annexed as **Exhibit JMR/IANZ/0005**.
  2. Accreditation is granted by the Testing Laboratory Registration Council, which comprises five people appointed by the Government and four appointed by those first five and based on technical expertise. The Council then appoints the Chief Executive, who is currently Dr Llewellyn Richards.
  3. It must be emphasised that accreditation takes substantial commitment to achieve by any laboratory. However the independent recognition of competence, which accreditation provides, is highly valued because it confirms to clients and regulators and the public that laboratories meet their requirements and expectations and are performing to international standards.

### **Management System of Applicant Laboratory**

4. The first step towards accreditation, albeit not the most important, is to ensure that the laboratory has adequate and appropriate documentation of all its policies, management practices and operational procedures, including;
  - (a) sampling, sub-sampling and sample identification procedures
  - (b) test procedures

- (c) quality control procedures
- (d) test recording and reporting procedures
- (e) corrective action and complaints procedures

plus other elements relating to the quality system.

### **Assessment of Technical Competence**

1. The second step is an evaluation of the laboratory personnel's technical competence. Telarc's external technical expert peer assessors are chosen for their personal knowledge and expertise relevant to the work of the applicant laboratory. The peers doing the assessments are normally selected from equivalent or larger laboratories.
2. The assessment of a small general medical laboratory often takes up to three days with up to six volunteer technical/professional experts from other equivalent laboratories. For a larger laboratory, it can involve a team of up to 12 experts spending 5-7 days at the applicant laboratory. For a medical laboratory with, say, three assessment departments the Telarc lead assessor would be accompanied by a series of medical laboratory experts including one pathologist and one technologist for each major discipline in the laboratory. It is important to emphasise that these experts are not Telarc personnel, apart from the lead assessor, but are independent experts in the field of practice of the laboratory being assessed for accreditation.
3. The aspects of technical competence evaluated by the assessment team include:
  - (a) The qualifications, experience and ongoing professional development of the key professional/technical staff.
  - (b) The technical validity of test procedures, equipment and materials.

- (c) Whether the laboratory has a quality control system sufficient to demonstrate that accurate, reliable test results are produced. This is to identify potential sources of error in the laboratory's operations by detecting any errors that have occurred. The quality control system should include:
    - (i) Participation in formal proficiency tests and other inter-laboratory comparisons.
    - (ii) Regular use of certified standard reference materials or in-house quality controls using secondary or sub-reference materials.
    - (iii) Testing of multiple samples (eg duplicates and triplicates).
    - (iv) Repeat testing of samples by a second analyst (second opinion).
    - (v) The identification of known samples for subsequent re-testing.
  - (a) Whether the laboratory has procedures to ensure that any substandard testing work is stopped until the problem is resolved.
  - (b) Whether the laboratory has a test record system to ensure, among other things, that reports contain sufficient information to allow identification of possible sources of error and, where necessary, satisfactory repetition of the test under the original conditions.
1. Once accredited, the medical laboratory is audited and assessed every year by Telarc staff. A full team of independent outside expert pathologists and technologists carries out a full technical competence re-assessment every 4 years.

## Proficiency Testing Programmes

2. The third component of the assessment is to ensure that the laboratory is participating in sufficient and appropriate proficiency testing programmes and other inter-laboratory trials and studies to validate its testing operations.
3. Competence in cytology is essentially related to correct calibration of the pathologist's "eye" rather than of specific equipment.

It is therefore extremely important, particularly for a sole pathologist in a geographically isolated area, to regularly test his or her competence internally against known reference slides in the laboratory and in textbooks, and externally through proficiency testing programmes. In addition, attendance at professional development meetings and seminars and contact with other pathologists is crucial.

4. In cytology, the Royal College of Pathologists of Australasia ("RCPA") operates a very well established and internationally recognised proficiency testing programme.
5. Proficiency testing for cytology involves a series of cervical smear slides being sent to all the participating laboratories. The laboratories then independently report their results and they are advised of their results and where they fall within the range of results from all of the laboratories.
6. Telarc requires cytology laboratories to actively participate in these programmes. In addition, each pathologist making diagnoses in cytology would be expected to participate in the RCPA's Continuing Professional Development Programme. If these programmes reveal deficiencies in performance, urgent corrective action would be expected.
7. The results from the RCPA proficiency testing programme for accredited cytology/histology laboratories are checked by Telarc during the next assessment.

8. There is no deterrent to participate in inter-laboratory proficiency testing. If a laboratory submits a number of incorrect results, there is no immediate sanction, but the onus is on the laboratory to take immediate action to remedy the deficiencies identified by the results. If there is no corrective action taken by the time of the next Telarc visit, however, the laboratory will receive an urgent correct action request from Telarc (see paragraphs 44, 45 and 46).
9. Telarc also has a Medical Testing Professional Advisory Committee. This consists mostly of pathologists, and is currently chaired by Dr Brian Linehan.
10. The Committee is responsible for agreeing to the specific criteria for accreditation of medical laboratories and, following assessment and laboratory corrective action, for signing off on new accreditations before they proceed to the Chief Executive who grants accreditation. The Committee also approves the list of external technical experts Telarc draws on for the initial and four-yearly medical laboratory competence assessments, and liaises with the laboratory community as a source of technical information on relevant pathology.

### **Numbers of Registered Medical Laboratories**

11. The Telarc medical laboratory programme began in 1976 with the accreditation of the first applicant, Waikato Hospital on 21 October 1977. The programme grew slowly at first because it was, and still is as far as Telarc is concerned, a voluntary programme. Making programmes mandatory is a regulatory function and not a function of Telarc. By 1990 there were 23 accreditations, 9 of which were private medical laboratories and the rest were hospital laboratories. Amongst these were 15 cytology departments.
12. As at January 2000, there were 67 accredited medical laboratories in New Zealand with about 27 cytology departments accredited.
13. To the best of my knowledge, there are about 5 small medical laboratories in New Zealand that are not yet accredited, none of which are involved in cytology. Some of

these are actively working towards accreditation while one or two have yet to approach Telarc.

### **Impact of Accreditation on Standards**

14. As stated, once a medical laboratory has obtained accreditation it is audited annually, with a full assessment being carried out by an external team of experts every four years. During these audits/assessments, Telarc aims to work with the client. If they fall short in any area or Telarc perceives inadequacies in procedure or competence, then the laboratory will receive corrective action requests. The laboratory must then provide records demonstrating that the inadequacies identified have been rectified.
15. Where technical inadequacies are considered to be critical, the laboratory may have its accreditation suspended then and there. However, on most occasions inadequacies are not critical and a laboratory may take up to three months to rectify the situation.
16. Telarc does not suspend laboratories lightly as there can be significant commercial and financial penalties to being suspended. On average, 2 to 3 laboratories from the entire Telarc programmes may be suspended each year for serious technical inadequacies that threaten the validity of test results. Reinstatement occurs only after evidence is forthcoming that the problems have been fully resolved. A recent example of this was a Hospital laboratory department (not cytology) that was suspended for several months until a re-assessment confirmed satisfactory corrective action had been implemented.
17. Although Telarc does not have any regulatory enforcement ability, accreditation nevertheless does have “teeth” as a result of its ability to suspend a laboratory for non-compliance with accreditation requirements and the subsequent commercial and financial consequences.
18. It is not a function of Telarc to formally advise anyone except the laboratory itself of a suspension. If a client of a laboratory believes that they are getting results from a laboratory accredited for that work, and the laboratory is suspended but continues to deliver Telarc-endorsed results, then the laboratory will have broken one of the Telarc

rules which we will view very seriously indeed. It will also have contravened the Fair Trading Act 1986. The onus is on the laboratory to advise its clients and other interested parties such as purchasers of its accreditation status. However, if anyone enquires of Telarc whether a laboratory is accredited or not for any particular work, Telarc will advise them immediately of the accreditation status of that laboratory. I do not recall, and my staff have no records of, any such enquiries relating to medical laboratories which have been suspended.

19. It is necessary to point out that a laboratory that has been suspended, or is inoperative or withdrawn from accreditation has not necessarily attained that status because it has done something wrong. In most cases, laboratories self-suspend or withdraw one or more units from accreditation because they are no longer involved in carrying out that particular type of work, or until they have replaced a staff member with a suitably qualified replacement, or other changes are complete.

#### **Accreditation of Laboratories in Gisborne**

20. There are two testing laboratories in Gisborne. The first, Gisborne Hospital laboratory, was accredited in 1990. The second laboratory was Gisborne Laboratories Limited (“Gisborne Laboratories”). I have no record of Gisborne Laboratories being accredited. That laboratory changed ownership in 1996 and I understand that it is now called Medlab Gisborne. I understand that the new owners immediately started working towards accreditation. The laboratory obtained accreditation in December 1997.

#### **Impact of Funding on Accreditation Standards**

21. Telarc are observing a worrying trend which appears to be a result of reduced health funding to medical laboratories, which is impacting on staffing and resources. Several medical laboratories are now receiving increasing corrective action requests for deteriorations in quality management. Short cuts in quality controls, shortages of staff, staff working excessive hours, lack of key expertise and other matters are

indicating a lack of resources. This is particularly prevalent in the hospital laboratories.

## **Conclusion**

22. Telarc accreditation provides a three-fold assurance of the quality of the laboratory:
  - (a) It ensures that the laboratory is managed effectively and consistently.
  - (b) It provides a peer evaluation of the technical competence of the laboratory personnel.
  - (c) It provides an assurance that the methodology of the laboratory is technically correct and that the results of the laboratory procedures are technically valid.
1. The range of quality control measures required for accreditation should provide an early warning system for any areas where the laboratory may be falling below an acceptable standard of performance and competence.
2. Where a laboratory is not accredited it is not possible to say whether its practices, methods and results are valid or not. A pathology laboratory without the benefit of internal laboratory checks by colleagues, without participation in inter-laboratory comparative programmes and without participation by its pathologists in the on-going professional development and education programmes of the RCPA would not meet the requirements for accreditation.
3. In summary, Telarc accreditation provides recognition that a laboratory meets recognised industry expectations and international requirements and assures both patients and clinicians that the laboratory's staff is competent and its practices, methods and results, are technically valid.

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J M Robertson

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Date