# *The role of the medical laboratory assistant, the law and the need for reform*

Philip Edward Culbert*

*This paper is an analysis of the role of the medical laboratory assistant (MLA) in New Zealand's medical pathology laboratories. The paper begins with a description of the occupational and legislative background to the practice of medical laboratory technology in New Zealand and proceeds to identify some current issues. In particular the role of the MLA is analysed. Attention is focused on the scope of the MLA's role in the laboratory and the issue of supervision. The paper then discusses a possible conflict between the Medical Auxiliaries Act 1966 and the Medical Laboratory Technologists Regulations 1989. It is argued that the Regulations are, if not ultra vires, then at least in need of reform in order to reflect the intention of the Act. Some appropriate reforms are suggested.*

## I INTRODUCTION

It is vital for patient safety that medical pathology laboratory tests be performed to a high standard. Recognising this need Parliament has legislated to ensure that laboratory tests are performed by properly trained and qualified people. The practice of medical laboratory technology in New Zealand is governed by the Medical Auxiliaries Act 1966 (the Act) and the Medical Laboratory Technologists Regulations 1989 (the Regulations). Unfortunately the current Regulations can be interpreted as allowing inexperienced and unqualified Medical Laboratory Assistants (MLAs) to practise medical laboratory technology without supervision. It is essential that these Regulations be amended to limit the role of MLAs and thereby to give effect to the true intention of the Act.

Medical laboratory technology has been defined as "the examination in a medical pathology laboratory, for fee or reward, of human tissue, fluids, and excretions for medical purposes".[1] The main subspecialisations within medical laboratory technology are histology, cytology, microbiology, virology, biochemistry, cytogenetics, haematology, immunology and blood transfusion science.

Medical pathology laboratories are responsible for analysing specimens of human tissue, body fluids and excretions. Specimens are usually sent to the laboratory by the patient's doctor. The purpose of this laboratory analysis is to extract as much useful information as possible from the specimen about the patient's condition. A report

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1 The Medical Laboratory Technologists Regulations 1989, reg 2.

containing the results of this analysis is returned to the patient's doctor (or sometimes directly to the patient) who will use it to help determine the appropriate treatment. The medical pathology laboratories in New Zealand can be divided into two broad categories, public laboratories (usually attached to public hospitals) and privately owned laboratories.[2] There are currently 19 private laboratories in New Zealand and considerably more public laboratories.

Medical pathology laboratories are staffed by the following occupational groups: medical laboratory technologists (MLTs), MLAs, scientific officers, pathologists, medical registrars, secretarial and administrative staff. According to the New Zealand Institute of Medical Laboratory Science (NZIMLS) annual staffing survey there were 915 MLTs and 802 MLAs "currently employed" in New Zealand in 1992.[3] Generally speaking, MLTs are responsible for the day to day management of laboratories and the performance of technical procedures. Typically an MLT will complete four years' training which incorporates a mixture of time spent in the laboratory and time at a technical institute such as the Central Institute of Technology. University degree courses in medical laboratory science have recently become available in New Zealand.

MLAs were first employed in the Auckland area in the early 1960s. They provided laboratories with a stable group of basic laboratory workers allowing trainee MLTs to be released to take part in a formal training programme being run by the Auckland Hospital Board.[4] MLAs are now employed throughout New Zealand and form an employment group almost as large as MLTs. MLAs may, after completing two years training, sit the Qualified Technical Assistants (QTA) examination in their discipline (eg haematology, histology etc) organised by the NZIMLS. However, there is no requirement that MLAs sit this examination. There are no qualification prerequisites for a person to use the title MLA.

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2 C McKendry, D Muthumala *Health Expenditure Trends in New Zealand 1980-1992* (Department of Health, Wellington, 1993). The private laboratories claim for tests performed under the Social Security (Laboratory Diagnostic Services) Regulations 1981, made under sections 116 and 132 of the Social Security Act 1964. In 1992 $103,528,000 was paid out under these Regulations.

3 "NZIMLS Annual Staffing Survey" (1993) 47(1) NZJ Med Lab Science 11. There are currently 2,261 individuals registered as MLTs with the Medical Laboratory Technologists Board (MLTB), of which 1,200 have current licences to practise: Personal communication, The Secretary, MLTB, 11 May 1993. In 1990, 81% of MLTs were employed by area health boards, 17% by private medical laboratories, and 2% by universities, technical institutes, government departments and commercial firms: *The New Zealand Health Workforce 1990* (Department of Health, Wellington, 1991) 36.

4 "Medical Laboratory Assistants - A report on their role in clinical laboratories, their relationship with the NZIMLS and their concerns" (1992) 46(1) NZJ Med Lab Science.

The boundary between the work of an MLA and an MLT is not clear:[5]

> There is no doubt that some [MLAs] in NZ clinical laboratories are doing the same work as MLTs and they are being employed as a cheap labour force. [MLAs] have not received the same training as MLTs and should not be doing technologists' work or assuming the same responsibility ... . The fundamental cause of this problem is the lack of a definition of what the role of a laboratory assistant is and what the role of a medical laboratory technologist is (what work each should be performing).

A survey of MLAs[6] has indicated that 100% worked without direct supervision, and 90% felt that they had the same responsibility as a staff technologist (the basic grade MLT). Also, 88% of MLAs performed shift and/or on-call work unsupervised.

## II THE EXISTING LEGAL FRAMEWORK

### *A The Medical Auxiliaries Act 1966*

The purpose of the Act is "to make provision for the registration and discipline of persons engaged in occupations auxiliary to medicine."[7] The Act lists medical laboratory technology, medical radiation technology and podiatry as registrable occupations. Medical laboratory technology was brought under the Act in 1973. These occupations have associated Boards, the functions of which include exercising a general supervision over the registrable occupation, the promotion of high standards and the exercise of disciplinary powers.[8] Each Board must maintain a register of those persons that have the required qualifications and have applied for registration. A Board has the power to inquire into a complaint made against a registered person and may remove a person's name from the register or suspend registration for up to 12 months.

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5 Above n 4.

6 S Smith "Survey of Laboratory Assistants" 1990 (unpublished, results reproduced in n 4 above).

7 Long Title to the Medical Auxiliaries Act 1966.

8 **5. Function of Boards-** The functions of a Board shall be to exercise a general supervision of the registrable occupation for which it is constituted, and in particular-

(a) To advise and make recommendations to the Minister in respect of any matter affecting the education and registration of persons engaged or intending to become engaged in that registrable occupation:

(b) To promote high standards of education and conduct among those persons:

(c) To exercise disciplinary powers in accordance with the provisions of this Act in respect of registered persons engaged in that registrable occupation:

(d) To conduct or direct the conducting of such examinations as may be prescribed, in relation to entry into that registrable occupation, as examinations to be conducted under this Act:

(e) To consider applications for registration in respect of that registrable occupation:

(f) To carry out such other functions and to exercise such other powers as may be prescribed or conferred on it by any other enactment.

Section 32 of the Act makes it an offence for an unregistered person to engage in a registrable occupation, unless they are authorised to do so by regulations made under the Act:

> **32. Offences by unregistered persons**-(1) Except as expressly provided in regulations made under this Act, no person shall, on or after the material date, engage in a registrable occupation or hold himself out, whether directly or by implication, as being entitled to engage in that occupation, or use or permit to be used in connection with his business or work any written words, titles, or initials implying that he is registered in respect of that occupation or that he is qualified to engage in that occupation, unless he is registered in respect of that occupation.
> (2) Any person who acts in contravention of subsection (1) of this section commits an offence and is liable on summary conviction to a fine not exceeding $400, and, if the offence is a continuing one, to a further fine not exceeding $10 for every day on which the offence continues.

Registered persons must obtain an annual licence issued by the Board if they intend to engage in the registrable occupation.[9]

*B The Medical Laboratory Technologists Regulations 1989*

The Regulations define an MLT:[10]

> "Medical laboratory technologist" means a person who is a registered medical laboratory technologist under these regulations and is qualified to engage in medical laboratory technology:

An MLA is defined as:[11]

> a person who, being *responsible to* and *under the supervision of* a medical laboratory technologist, scientific officer, or registered medical practitioner, is employed in a medical pathology laboratory and engaged in manual or technical work *ancillary* to medical laboratory technology; but does not include a medical laboratory technologist or trainee:(emphasis added)

The Council of the NZIMLS has produced its own definition of an MLA, it presumably not being prepared to accept the definition given in the Regulations or else not finding it helpful or clear. The NZIMLS definition is:[12]

> A Medical Laboratory Assistant is a person employed to perform routine tasks by following established protocols under the supervision of a Medical Laboratory Technologist.

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9 Section 34, Medical Auxiliaries Act 1966.
10 Above n 1.
11 Above n 1.
12 "Medical Laboratory Assistants Report" Institute News, Newsletter of the New Zealand Institute of Medical Laboratory Science Inc, December 1992.

This definition was approved by a remit passed at the 1992 Annual General Meeting of the NZIMLS. The NZIMLS convened a workshop to produce lists of the tasks that MLAs might be allowed to perform by following established protocols. The workshop participants felt that they could not produce these lists and agreed instead to clarify what MLAs should not be required to do.[13] The following recommendations from the workshop have been adopted by the Council of the NZIMLS:[14]

- Medical Laboratory Assistants may perform tasks as required by their laboratory after suitable training.
- Registered medical laboratory technologists or registered medical practitioners should maintain individual task work records for medical laboratory assistants under their supervision. This record should comprise a list of tasks in which the medical laboratory assistant has demonstrated competency.
- Medical laboratory assistants should not be required to evaluate or institute new methods or technology. They should not offer clinical advice or unauthorised result interpretation and should know when to ask for assistance or refer to a higher authority.

The definition of an MLA contained in the Regulations is inconsistent with the definition adopted by the NZIMLS. The reasons for this inconsistency are discussed in this article.

The Regulations establish the Medical Laboratory Technologists Board (MLTB) as required by section 4 of the Act. Regulation 3 prescribes the following composition for the MLTB: one person from the Department of Health; two medical practitioners nominated by the New Zealand Society of Pathologists (NZSP); three MLTs nominated by the NZIMLS; two MLTs appointed by the Minister of Health after consultation with the NZIMLS and the NZSP; and the Director-General of Education, or his or her nominee. Contrary to regulation 3, neither the Director-General of Education, nor a nominee, currently sits on the MLTB.[15]

To gain registration as a medical laboratory technologist, applicants must complete a course of training as outlined in the MLTB manual issued under regulation 4 of the Regulations.

Regulation 9 exempts certain persons from the operation of section 32 of the Act:

> **9. Section 32 of principal Act not to apply to certain persons-** Nothing in section 32 of the Act shall prevent the performance of medical laboratory technology by-
> (a) A registered medical practitioner:
> (b) A scientific officer:

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13 "Medical Laboratory Assistants Report" Institute News, Newsletter of the New Zealand Institute of Medical Laboratory Science Inc, June 1993.

14 Above n 13.

15 Personal communication, The Secretary MLTB, 19 July 1993.

(c) A medical laboratory assistant:
(d) A trainee while he or she is responsible to and under the supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner.

The meaning and implications of regulation 9(c) will be explored in this article. It will be argued that regulation 9(c) authorises unqualified persons to engage in medical laboratory technology without supervision.

## III ISSUES ARISING

### A *What is the Meaning of "Supervision" as Used in the Definition of an MLA in Regulation 2?*

#### 1 *Supervision*

According to regulation 2, an MLA is a person who is "responsible to and under the supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner." An MLA is to be both "responsible to" and "under the supervision of" the appropriate person. These two phrases appear to mean different things. Presumably it is possible to be responsible to one person (eg the Charge Technologist) but be working under the supervision of another person (eg a Staff Technologist). Clearly it is still possible for an MLA to remain responsible to a Charge Technologist who is not physically present if "responsible to" means the person's immediate manager. If that is the relationship envisaged by the words "responsible to", then to what do the words "under the supervision of" refer? Clearly they cannot refer to the immediate managerial relationship covered by "responsible to" and must have a different meaning. Does "supervision" require the actual physical presence of the supervisor at all times or is something less acceptable?

The Concise Oxford Dictionary defines "supervise":[16]

> **supervise** ...v.tr. **1** superintend, oversee the execution of (a task etc.). 2 oversee the actions or work of (a person)... **supervision** n. **supervisor** n. **supervisory** adj...

This definition is not very helpful in determining what regulation 2 means by its use of the word "supervision". The meaning of the word "oversee" would appear to be central to the meaning of "supervision". Looking up "oversee" in the dictionary is of no help as the Concise Oxford Dictionary defines this word as "officially supervise", bringing us back to the question what does supervise, and hence supervision, mean?

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16 *The Concise Oxford Dictionary of Current English* (8 ed, Clarendon Press, Oxford, 1990).

In *Roberts* v *Littlewood's Mail Order Stores, Limited*[17] the court had to decide whether a provision of the Pharmacy and Poisons Act 1933, which required that certain poisons be sold only if the sale "is effected by, or under the supervision of, a registered pharmacist", had been breached. A customer had purchased a bottle containing poison covered by the Act from a saleswoman in the shop. At the time of the sale the registered pharmacist employed to supervise the sale of poisons was in another room, out of sight and hearing of the sale and was unaware that it was taking place. Had the sale been effected under the supervision of the registered pharmacist?

Viscount Caldecote CJ observed that the object of the Act was "beyond all other considerations to provide for the safety of the public", as a mistake could result in "disastrous consequences" (some similarity here may be noted with the Medical Auxiliaries Act[18]). He decided that the sale had not been effected under the supervision of the registered pharmacist:[19]

> It has been suggested that a man can supervise a sale without being bodily present. I do not accept that contention unless some further facts are proved which do not appear in this case. It is conceivable, with the mechanical assistance of a telephone or something of that sort, that a person might be supervising something although he was not on the spot, but in the present case the person who is vouched for as supervising this particular sale was in the stock room upstairs and only appeared if and when he was asked for. I think there was a complete lack of evidence that this sale was effected under the supervision of a registered pharmacist.

In *Maloney* v *Cameron Ltd*[20] the English Court of Appeal had to decide on the meaning of regulation 6 of the Building (Safety, Health and Welfare) Regulations 1948. Regulation 6 provided that scaffolding should only be substantially altered "under the immediate supervision of a competent person". Holroyd Pearce LJ said that the word "immediate" was directed to the relationship between the workmen and a supervisor who was "immediately responsible", and did not require that every act of the workmen must be closely supervised. Furthermore, the extent of supervision was a question of degree:[21]

> In some cases the supervision may have to be constant and relate to every act that is done - where, for instance, great danger and difficulty is involved. In other cases, where there is no risk and the men are competent, the supervision may be less intensive.

In *Owen* v *Evans & Owen (Builders) Ltd*[22] the English Court of Appeal again had to decide on the meaning of the words "immediate supervision", this time as used in regulation 79 of the Building (Safety, Health and Welfare) Regulations 1948. A foreman

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17 [1943] 1 KB 269.
18 See Part III D 1 below.
19 Above n 17, 272.
20 [1961] 1 WLR 1087.
21 Above n 20, 1090.
22 [1962] 1 WLR 933.

had issued instructions to two workmen regarding the safe way to remove a beam during the demolition of a building. Regulation 79 required that this procedure be carried out under the "immediate supervision" of the foreman. The foreman was called away to the telephone while the workmen continued with removing the beam. While the foreman was away the workmen decided to ignore their instructions with regard to the procedure to follow for removing the beam. They adopted an easier but more dangerous method. One of the workmen fell from the building and was injured. The injured workman sued the foreman's employers for a breach of statutory duty in failing to observe the requirement for "immediate supervision" under regulation 79.

The court applied the decision in *Maloney* v *Cameron*.[23] Ormerod LJ said that "immediate" meant "direct" so that "[t]here must not be any intermediary between the person supervising and the person being supervised." The court rejected the plaintiff's argument that regulation 79 required constant and unremitting supervision.

Ormerod LJ then considered the word "supervision":[24]

> [I]t may be that the term "constant" is a quality connoted in the term "supervision." I do not think that is so. I think that the supervision, in certain circumstances which will demand it, may have to be constant, whereas in other circumstances a much more intermittent supervision will be a compliance with the regulation.

The court decided that there had been adequate supervision to comply with regulation 79.

Do these cases help us to interpret the meaning of "supervision" as used in regulation 2? As none of these cases had to interpret the same phrase which concerns us (ie "responsible to and under the supervision of") they must be used with caution. Also, regulations intended to cover work on a building site in England 40 years ago may appear irrelevant to the modern day practice of medical laboratory technology in New Zealand. *Roberts* involving the Pharmacy and Poisons Act 1933 is closer to the field of medical laboratory technology.

The following points can be extracted from these cases. First, according to *Roberts*, if an MLA is in the laboratory on his or her own, with a supervisor in another room or at another location but available by telephone, then this would not constitute "supervision". Viscount Caldecote CJ accepted that supervision may be possible by a person not on the spot, possibly over the telephone, but only if some undefined "further facts" are proved.[25] In that case he considered it important that the registered pharmacist only appeared "if and when he was asked for"[26] but was otherwise in the stockroom. It follows that an MLT in another room, or available by telephone at another location, who was only involved by an MLA working alone "if and when he was asked for",

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23 Above n 20.
24 Above n 22, 937.
25 Above n 17, 272.
26 Above n 17, 272.

could not meet the "supervision" requirement of the Regulations. However, an MLT who regularly telephoned or looked in on an MLA otherwise working alone, to check on him or her, might satisfy the test for supervision.

Secondly, in *Maloney* v *Cameron Ltd*[27] the court said that the amount of supervision required was a matter of degree. For some procedures supervision should be constant while for others less intensive supervision would be adequate. This concept can easily be applied to the work of MLAs. Some procedures might require constant supervision, while for others intermittent supervision would be adequate. The degree of supervision required might logically be related to the seriousness of the consequences of an error for the patient. This approach is also supported by *Owen*.[28]

2 *The supervisor*

It is implicit in the concept of supervision that the supervisor has the necessary skills to fulfil that function. A supervisor should be able to identify whether a procedure is being performed correctly and suggest the appropriate corrective action should an error or difficulty arise. Regulation 2 restricts the supervision of MLAs to three groups of people: MLTs, scientific officers, and registered medical practitioners. Does it follow that any person belonging to one of these three groups is competent to supervise an MLA performing any task? For example, can a registered medical practitioner with no training in the performance of a particular haematology procedure (while having a thorough understanding of the significance of the results of the procedure) supervise that procedure being performed by an MLA? Surely the answer must be no. The regulation 2 definition should be read as if it said "...under the supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner, *competent in the area being supervised...*". It is reasonable to infer the presence of these words in order to give effect to the true intention of the Regulations. Parliament could not have intended, under legislation intended to regulate the practice of medical laboratory technology, to allow an incompetent supervisor to supervise an inexperienced MLA (truly the blind leading the blind!). It follows that an MLT, trained in haematology but ignorant of histology, cannot supervise an MLA working in histology. Likewise a pathologist cannot supervise an MLA unless they are technically competent in the area they are purporting to supervise.

An alternative, although less satisfactory, view on the word "supervision" might be put forward in the following terms. It is possible to supervise a procedure which one does not understand in sufficient technical detail to perform it oneself. The supervisor may only be skilled at interpreting the results of a particular procedure. The supervisor can ensure the employment of competent staff to carry out the procedure. They can also carefully monitor the results of the test being performed. If the results are not what one would expect then the supervisor can reject them and require a repeat test. If the results continue to arouse suspicion then the supervisor can organise retraining for the operator involved. The danger in this situation is that errors may not be detected unless they are

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27 Above n 20.
28 Above n 22.

either large or frequent. Under this alternative the supervisor cannot retrain the operator themselves as they do not possess the necessary skills.

### *B What Is the Meaning of "Ancillary" As Used in the Definition of an MLA in Regulation 2?*

Regulation 2 defines MLAs as performing work "ancillary" to medical laboratory technology. What work does this allow MLAs to perform? This limitation has never been translated into clear guidelines for laboratories and, as already stated, the boundary between the role of an MLA and an MLT is not clear.[29]

The Concise Oxford Dictionary defines "ancillary":[30]

> **ancillary**...adj. & n. - adj. **1** (of a person, activity, or service) providing essential support to a central service or industry, esp. the medical service. 2 (often foll. by to) subordinate, subservient. -n. (pl. **-ies**) **1** an ancillary worker. **2** something which is ancillary; an auxiliary or accessory...

In regulation 2 "ancillary" is used as an adjective to medical laboratory technology. MLAs are thus to perform work that provides essential support to medical laboratory technology. Where does essential support end and medical laboratory technology begin? Do these two activities overlap? In some laboratories in New Zealand only MLAs are to be found, while in many laboratories MLAs are performing on-call work (where they may find themselves in the laboratory alone outside normal working hours performing urgent tests).[31]

"Ancillary" could be interpreted to cover everything from cleaning the laboratory floor to performing some or most of the work of MLTs. Logic requires that it be given a meaning less than performing all medical laboratory technology, otherwise it would have no meaning in this context (ie "medical laboratory technology" cannot logically have the same meaning as "ancillary to medical laboratory technology"). The wide definition given to medical laboratory technology in regulation 2 does not help clarify the situation.[32] If "ancillary" were given a very narrow definition, limiting the role of MLAs to procedures with minimal impact on the reliability of laboratory results, it might seem odd that these procedures should only be carried out "under the supervision of a medical laboratory technologist...".[33] Why would supervision by an MLT be required unless it was envisaged that MLAs would be performing medical laboratory technology as a part of their "ancillary" role? The answer might be that although MLAs are not meant to perform medical laboratory technology, they are envisaged as performing important work in support of MLTs, work which must be done correctly if

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29 Above n 4.
30 Above n 16.
31 Above n 6.
32 Above n 1.
33 Above n 1.

MLTs are to be able to maintain their standards. Hence supervision does not appear anomalous.

A definition of "ancillary" which envisages MLAs performing some medical laboratory technology under supervision is to be preferred. This would accord with common sense and actual laboratory practice, and the word "ancillary" can naturally be given this meaning.

### C *Does An MLA Performing Medical Laboratory Technology Under Regulation 9(c)[34] Have to be Supervised?*

An argument for requiring supervision, in relation to regulation 9(c), could be based on the regulation 2 definition of an MLA. This definition describes an MLA as a person performing work ancillary to medical laboratory technology under supervision. It therefore follows, according to this argument, that an MLA performing medical laboratory technology under regulation 9(c) would also have to be working under supervision. The regulation 2 requirement for supervision also applies in the case of an MLA working under regulation 9(c). Regulation 9(c) does not, either explicitly or implicitly, remove the requirement for supervision.

Another argument in favour of interpreting regulation 9(c) as requiring supervision is that it would be contrary to the spirit and intent of the Act to allow the unsupervised performance of medical laboratory technology by unqualified people. This view is bolstered by looking at the other groups authorised to perform medical laboratory technology by regulation 9. Registered medical practitioners (regulation 9(a)) and scientific officers (regulation 9(b)) are both qualified people. Although registered medical practitioners are not qualified in medical laboratory technology they are capable of making competent decisions regarding their limitations. Trainees (regulation 9(d)) are allowed to perform medical laboratory technology only if supervised.

Another possibility is that regulation 9(c) is not intended to modify the meaning of the regulation 2 definition of an MLA at all. Its purpose is merely to render an MLA working in accordance with the regulation 2 definition immune from prosecution should his or her ancillary work include the performance of medical laboratory technology. Therefore the supervision requirement still attaches to an MLA working under the authorisation of regulation 9(c).

At least three arguments against the requirement of supervision may be identified. First, regulation 9(d) explicitly says that a trainee performing medical laboratory technology must be under supervision. If the same limitation is to apply to MLAs under regulation 9(c) why does it not say so? The implication is that MLAs do not have to be supervised when performing medical laboratory technology under regulation 9(c). A counter argument to this is that the regulation 2 definition of an MLA includes the requirement for supervision, while the regulation 2 definition of a trainee does not. Therefore it is necessary to explicitly state the requirement that trainees be supervised

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34 See Part II B above.

under regulation 9(d), but it is not necessary to do this for MLAs, since by the regulation 2 definition MLAs must already be supervised.

Secondly, regulation 9 lists groups exempted from the scope of section 32 of the Act. MLAs are to be allowed to perform medical laboratory technology and thereby engage in a registrable occupation without the risk of conviction under section 32 of the Act. The work of MLAs is no longer restricted by the word "ancillary". This is inconsistent with the regulation 2 definition of an MLA. The regulation 2 definition is therefore not appropriate in the context of regulation 9(c). The regulation 2 definition of an MLA as a person engaging in work ancillary to medical laboratory technology under supervision applies to the usual role of an MLA. It cannot apply to an MLA performing medical laboratory technology under the authority of regulation 9(c).

Finally, the regulation 2 definition of an MLA is prefaced by the words "unless the context otherwise requires". Arguably the context of regulation 9 requires a different definition of the role of an MLA because here MLAs are to be allowed to perform medical laboratory technology, and not merely work ancillary to it. In this context supervision is not required and is not consistent with the natural interpretation of regulation 9(c).

The stronger arguments, it is argued here, are those which indicate that an MLA performing medical laboratory technology under regulation 9(c) does not have to be supervised. However, an employer who allows a person whom they know to be incompetent to perform medical laboratory technology (whether that person is an MLT or an MLA) may be at risk of a common law action for negligence, provided that the Accident Rehabilitation and Compensation Insurance Act 1992 does not apply.[35]

### *D Ultra Vires Arguments*

#### *1 What is the purpose of the Medical Auxiliaries Act 1966?*

The Act states in its long title that it is to make provision for the registration and discipline of persons engaged in occupations auxiliary to medicine. What was the purpose which Parliament intended to achieve by providing for the registration and discipline of MLTs under the Act? It has been suggested that the driving force behind the inclusion of medical laboratory technology within the scope of the Act was the Department of Health, [36] while the New Zealand Institute of Medical Laboratory Technologists (the former title of the NZIMLS) was luke warm to the prospect. The

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35 The Accident Rehabilitation and Compensation Insurance Act 1992 raises a number of issues relevant to the practice of medical laboratory technology. For example MLAs are excluded from the definition of "registered health professional" given in section 3 of the Act. Therefore a personal injury resulting from the act or omission of an MLA may not fall within the section 5 definition of "medical misadventure" under the Act. Space limitations precludes further consideration of these issues here.

36 J Parker "Competency and Registration Issues" (1992) 46(4) NZJ Med Lab Science145.

Office Solicitor of the Department of Health is reported as having said that the Regulations "were for the protection of the patients ...[and]... for the protection of the Profession".[37] Presumably this means the protection of patients from the hazards that would result from the performance of laboratory tests by inadequately trained personnel. The protection of the profession may be a reference to protecting the high standard of practising MLTs, and not to providing MLTs with some kind of industrial monopoly. From what does the profession need to be protected? Possibly the profession needs protecting from market forces which might operate to encourage laboratories to minimise their costs by employing fewer qualified staff and reducing training and supervision requirements for other staff. In this sense protecting the profession is really about protecting the patient from falling standards.

*2 The nature of the regulation making power conferred by section 40 of the Act.*

Section 40 provides as follows:

> **40. Regulations**-(1) The Governor-General may from time to time, by Order in Council, make regulations for all or any of the following purposes:...
> .....
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> (u) Limiting the application of section 32 of this Act in relation to any particular registrable occupation, and exempting, or providing for the exemption by a Board subject to such conditions as it thinks fit, of any specified person or specified class of persons from all or any of the provisions of this Act or of any regulations made under this Act:
> (v) Providing for such matters as are contemplated by or necessary for giving full effect to the provisions of this Act and for the due administration thereof.

*3 Is the regulation 2 definition of an MLA ultra vires?*

Medical laboratory technology is a registrable occupation under the Act. If MLAs do not perform medical laboratory technology then they are not engaging in a registrable occupation. If they are not engaging in a registrable occupation, do they come within the scope of the Act? If they do not come within the scope of the Act can regulation 2 require that they be supervised by an MLT, scientific officer or registered medical practitioner while they perform their ancillary work? The practical reality is that MLAs do perform medical laboratory technology in New Zealand. However, what is the role of MLAs envisaged by the regulation 2 definition of an MLA? This largely depends on the interpretation of the word "ancillary".[38]

If "ancillary" means that MLAs do not perform medical laboratory technology itself (ie they do not perform the registrable occupation) then it could be argued that the Act does not authorise the imposition of any further restrictions, such as supervision by an MLT. The Regulations may define what medical laboratory technology is, but having defined a particular activity as being outside the realms of medical laboratory technology

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37 Above n 36.
38 See Part III B above.

they cannot then seek to impose restrictions on that activity. For example, what if the Regulations declared that the laboratory secretary was a person who did not perform medical laboratory technology but that they must have certain qualifications and be supervised by a certain class of person? It is valid for the Regulations to define the laboratory secretary as a person who does not perform medical laboratory technology. However, having done that it is beyond the authority given by the Act to seek to set requirements for that non-registrable occupation. The requirements for certain qualifications and supervision would not be valid. If Parliament wanted to regulate the work of the secretary then this occupation would be included in section 3 of the Act. The regulation 2 requirement for such supervision of MLAs is *ultra vires* and outside the powers to make regulations conferred by section 40 of the Act.

However, section 40(1)(v) of the Act also authorises the making of regulations in rather wide and non specific terms. This wide power could be used to justify the regulation 2 definition of an MLA if it is required to give full effect to, or enable the due administration of, the provisions of the Act as required by section 40(1)(v). Which provision of the Act is the regulation 2 definition of an MLA giving effect to? If the ancillary work performed by MLAs is not intended to include medical laboratory technology, then this definition does not appear to be giving effect to any provision of the Act. Under section 5 of the Act the MLTB is to exercise a general supervision of medical laboratory technology. It could be argued that the regulation 2 definition of an MLA assists the MLTB in the exercise of this general supervision of medical laboratory technology. However, it is difficult to see how requiring MLAs to be supervised while they perform their non-registrable occupation can assist the MLTB in exercising a general supervision of the registrable occupation ie medical laboratory technology. The existence of the definition makes no difference to the ability of the MLTB to exercise its general supervision. Its powers are the same whether or not the definition of an MLA in regulation 2 exists. This includes the power to initiate a prosecution under section 32 of the Act if an unregistered person, not exempted by regulation 9(c), engages in medical laboratory technology.

The New Zealand Court of Appeal has held that even a wide empowering provision such as this one may only be used to promote the policy and objects of the Act.[39] The regulations must be necessary or expedient for the general purpose of the Act.[40] The general purpose of the Act is to provide for the registration and discipline of MLTs. This purpose is not served by requiring the supervision of MLAs performing work ancillary to medical laboratory technology on the narrower meaning of "ancillary".

On the other hand the word "ancillary" could be given a wider meaning extending to include the performance of some medical laboratory technology. Section 40(1)(u) of the Act provides for the making of regulations which exempt a specified class of persons from all or any of the provisions of the Act. Is the effect of the regulation 2 definition of an MLA to exempt MLAs from some of the provisions of the Act (ie registration,

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39 *Transport Ministry* v *Alexander* [1978] 1 NZLR 306.
40 Above n 39, 309.

prescribed qualifications, annual licences), and to replace them with the requirement for supervision, while allowing them to perform medical laboratory technology?

The problem with this latter interpretation of the regulation 2 definition is that it requires the acceptance of a group of people performing a registrable occupation without having to meet the requirements of the Act or coming under the control of the MLTB and not being subject to the disciplinary provisions of the Act which apply only to registered persons as in section 26 of the Act. The only sanctions that the MLTB can impose, apart from ordering the payment of costs, are suspension or removal of a name from the register. Such a sanction is not effective against a person who is not registered. This implies that the only people that the Regulations and the MLTB are intended to cover are registered. It could be argued that if "ancillary" is given this wider meaning then the regulation 2 definition of an MLA is *ultra vires*. The general purpose of the Act is to provide for the registration and discipline of MLTs. MLAs cannot be registered with or disciplined by the MLTB.

However, the Act clearly envisages that some groups of non-registered persons will be exempted from the requirements of the Act and allowed to perform medical laboratory technology. This is indicated by the existence of section 32 and section 40(1)(u). The regulation 2 definition of an MLA could be viewed as an exercise of the regulation making power conferred by section 40(1)(u) to exempt certain persons from the operation of section 32. The problem with this view is that the function of exempting certain persons from the operation of section 32 is performed explicitly by regulation 9 which starts with the words "[s]ection 32 of principal Act not to apply to certain persons...". It is the function of regulation 9 and not regulation 2, to exempt certain persons from the operation of section 32. It might also be argued that Parliament did not intend to allow exemptions from the Act which undermine the purpose of the Act. The definition of an MLA is probably not this serious in its consequences. The MLAs are to be supervised by competent people, thus safeguarding the patients.

*4 Is regulation 9(c) ultra vires?*

If the protection of patients from incompetent people performing their laboratory tests was a primary reason behind Parliament's decision to make medical laboratory technology a registrable occupation, then this may have consequences for the validity of regulation 9(c). If the correct interpretation of regulation 9(c) is that it allows the performance of medical laboratory technology by anybody, regardless of their training and whether or not they are supervised, it seems to be contrary to the purpose of the Act. In authorising the making of regulations in section 40(1)(u) of the Act, can it be believed that Parliament intended to authorise the making of regulations which are directly opposed to the purpose of the Act and are capable of completely undermining the status of medical laboratory technology as a registrable occupation? If the answer is no, then regulation 9(c) might be considered to be *ultra vires*.

The Regulations could be challenged by drawing them to the attention of the Regulations Review Committee of Parliament on the following grounds as set out in Standing Order 413 of the House of Representatives: (i.) the regulation is not in accordance with the general objects and intentions of the statute under which it is made,

and (ii.) it calls for elucidation. Alternatively the Regulations could be challenged by seeking judicial review in the High Court.

*5 Possible outcomes of the ultra vires debate.*

*(a) If the regulation 2 definition of an MLA and regulation 9(c) are both ultra vires.*

In this case both regulations should be struck out. Any person engaging in medical laboratory technology must be registered or exempted from the operation of section 32 of the Act by regulation 9(a), (b), or (d). Any MLA practising medical laboratory technology would be liable to prosecution under section 32 of the Act. Many MLAs under current laboratory practice would be committing an offence and be liable to prosecution under section 32 of the Act. This outcome is unsatisfactory because it denies the important role MLAs are capable of playing while performing medical laboratory technology under supervision.

*(b) If the regulation 2 definition of an MLA is ultra vires but regulation 9(c) is intra vires.*

In this case the regulation 2 definition should be struck out. MLAs would be free to practice medical laboratory technology unsupervised as authorised by regulation 9(c). If there is no regulation 2 definition of an MLA, there is no longer any room for debate over whether an MLA performing medical laboratory technology under regulation 9(c) must be supervised, as the supervision requirement was based on regulation 2. This outcome is unsatisfactory because it allows the unsupervised performance of medical laboratory technology by potentially unqualified and inexperienced people.

*(c) If the regulation 2 definition of an MLA is intra vires but regulation 9(c) is ultra vires.*

In this case regulation 9(c) should be struck out. Any MLA practising medical laboratory technology, supervised or not, would be liable to prosecution under section 32 of the Act. It was regulation 9(c) which protected MLAs performing medical laboratory technology from the operation of section 32 of the Act. However, if the regulation 2 definition itself can be interpreted as creating a class, ie MLAs, exempted from the operation of section 32 under the regulation making power of section 40(1)(u), then they will not be liable to prosecution as long as they are supervised. The problem with this latter view is that the function of exempting certain persons from the operation of section 32 is performed explicitly by regulation 9 which starts with the words "[s]ection 32 of principal Act not to apply to certain persons...". It is the function of regulation 9 and not regulation 2, to exempt certain persons from the operation of section 32. The performance of medical laboratory technology by MLAs was authorised by regulation 9(c). If regulation 9(c) is struck out this function cannot be fulfilled by the regulation 2 definition of an MLA. If it could be then arguably regulation 9(c) never had any function. Therefore, under current laboratory practice, many MLAs would be liable to prosecution under section 32 of the Act for performing medical laboratory technology. This outcome is unsatisfactory because it denies the

important role MLAs are capable of playing while performing medical laboratory technology under supervision.

*(d) If the regulation 2 definition of an MLA and regulation 9(c) are both intra vires.*

As already discussed MLAs do currently perform medical laboratory technology unsupervised.[41] If regulation 9(c) does not require supervision of MLAs performing medical laboratory technology then it is being complied with (it is very difficult to imagine how it could not be complied with). This outcome is unsatisfactory because it allows the unsupervised performance of medical laboratory technology by potentially unqualified and inexperienced people.

If the correct interpretation of regulation 9(c) is that MLAs must be supervised (and such an interpretation is likely to keep 9(c) *intra vires*) then the issue of exactly what does supervision mean becomes important. If the meaning argued for above[42] is correct, it is likely that some current laboratory practices do not comply with the Regulations. For example, MLAs performing on-call work[43] alone after hours may not be complying and will therefore be liable to prosecution under section 32 of the Act. If the correct interpretation of the Regulations is that MLAs may perform medical laboratory technology only under the supervision of a qualified person, and that supervision is given the meaning argued for above, [44] then this would be a satisfactory situation. This interpretation should be disseminated through the laboratories, and offenders warned that they could be prosecuted under section 32 of the Act. However, this interpretation has nowhere been stated authoritatively (eg by the MLTB or by the courts) and does not emerge clearly from the words used in the Regulations. This has led to uncertainty in laboratories with regard to what the law actually is.

Of the above scenarios none is entirely satisfactory, and reform of the Regulations is called for.

## IV LAW REFORM

### *A The Law As It Is*

It has been argued that as the law currently stands no special training, qualifications or experience are required to practise medical laboratory technology. Anybody who uses the title MLA is authorised by regulation 9(c) to perform medical laboratory technology without supervision.

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41 Above n 6.
42 See Part III A above.
43 Above n 6.
44 See Part III A above.

### B *The Law As It Ought To Be*

In 1990 The Working Group on Occupational Regulation[45] recommended that the legislation regulating medical laboratory technology be repealed. The Working Group did not consider that the practice of medical laboratory technology posed a sufficient risk to the health and safety of consumers to merit regulation. The recommendation of the Working Group has not been acted upon.

Parliament believed that medical laboratory technology should be regulated and in 1973 brought it within the scope of the Medical Auxiliaries Act 1966. The purpose of this one assumes was to protect patients from the dangers that would result from the incompetent performance of laboratory tests. The Act remains in force. However, as the Medical Laboratory Technologists Regulations 1989 stand they do not give effect to the intentions of Parliament. This situation could be corrected by making some changes to the Regulations. These changes could be so designed as to comply with the intention of the principal Act while also recognising some economic and practical realities. There is an important role for MLAs, and it is neither economically or practically feasible to insist that all medical laboratory technology be performed exclusively by MLTs. The following changes should be made to the Regulations:

1 The regulation 2 definition of an MLA should be amended to read as follows:

> "Medical laboratory assistant" means a person who performs medical laboratory technology while being responsible to and under the supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner.

If the supervision requirement is not met then an MLA will be liable to prosecution under section 32 of the Act. An MLA working within the above definition will be exempted from the operation of section 32 by an amended regulation 9(c). Supervision is to be interpreted in accordance with the earlier discussion of its meaning.[46] The amount of supervision required will be a question of degree and will vary from one procedure to another. It need not always be constant and unremitting, although sometimes it will be. The supervisor must of course be competent to supervise the task being performed. This entails the technical knowledge necessary to identify whether a procedure is being performed correctly and suggest the appropriate corrective action should an error or difficulty arise. It might be necessary to provide a separate definition of "supervision" in regulation 2.

2 Regulation 9(c) should be amended to read as follows:

> **9. Section 32 of principal Act not to apply to certain persons-** Nothing in section 32 of the Act shall prevent the performance of medical laboratory technology by-

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45 *Report of the Working Group on Occupational Regulation, Review of Health Related Occupations* (Ministry of Commerce, Wellington, 1990).

46 See Part III A above.

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(c) A medical laboratory assistant while he or she is responsible to and under the supervision of a medical laboratory technologist, scientific officer, or registered medical practitioner:

If these changes were made then laboratories would still be able to employ large numbers of MLAs to perform many routine tasks. The public would be protected because this work would always be supervised by competent people and the intention of the Act would be given effect to.

## V CONCLUSION

It has been argued that the Medical Laboratory Technologists Regulations 1989 allow the unsupervised performance of medical laboratory technology by unqualified and inexperienced MLAs. MLAs are currently performing medical laboratory technology unsupervised in New Zealand's medical pathology laboratories. This was not the intention of Parliament when it made medical laboratory technology a registrable occupation under the Medical Auxiliaries Act 1966. This situation should be rectified by amending the Regulations. Some suitable amendments have been suggested.