

# Consultation: Review of the Scopes of Practice for Medical Laboratory Science Practitioners

This document sets out a number of proposed changes to the scopes of practice for medical laboratory science practitioners. The proposals have been developed in collaboration with representatives from the New Zealand Institute of Medical Laboratory Science to gauge their expert insights into issues facing the profession.

We look forward to getting your thoughts and ideas.





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# Scopes of Practice Review: An Overview

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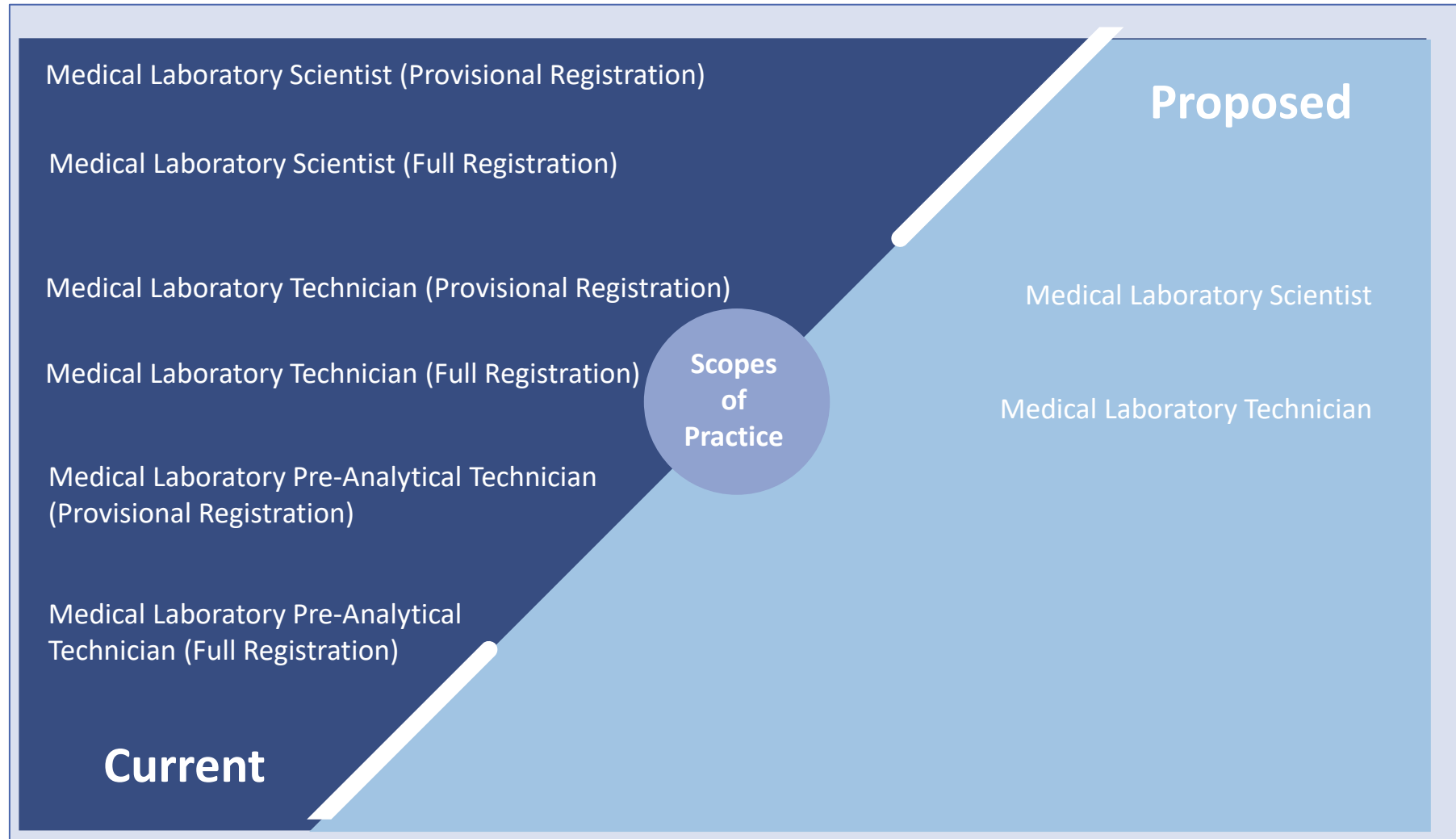
The Medical Sciences Council is appointed under the Health Practitioners Competence Assurance Act 2003 to regulate the practice of medical laboratory science practitioners. They are responsible for setting the scopes and standards of practice required of practitioners to protect the health and safety of the public of Aotearoa New Zealand.

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The Council has a regular programme of review to ensure the regulatory frameworks in place for medical laboratory science practitioners continues to be fit for purpose. This review has been undertaken as a component of the Council's regulatory frameworks review programme.

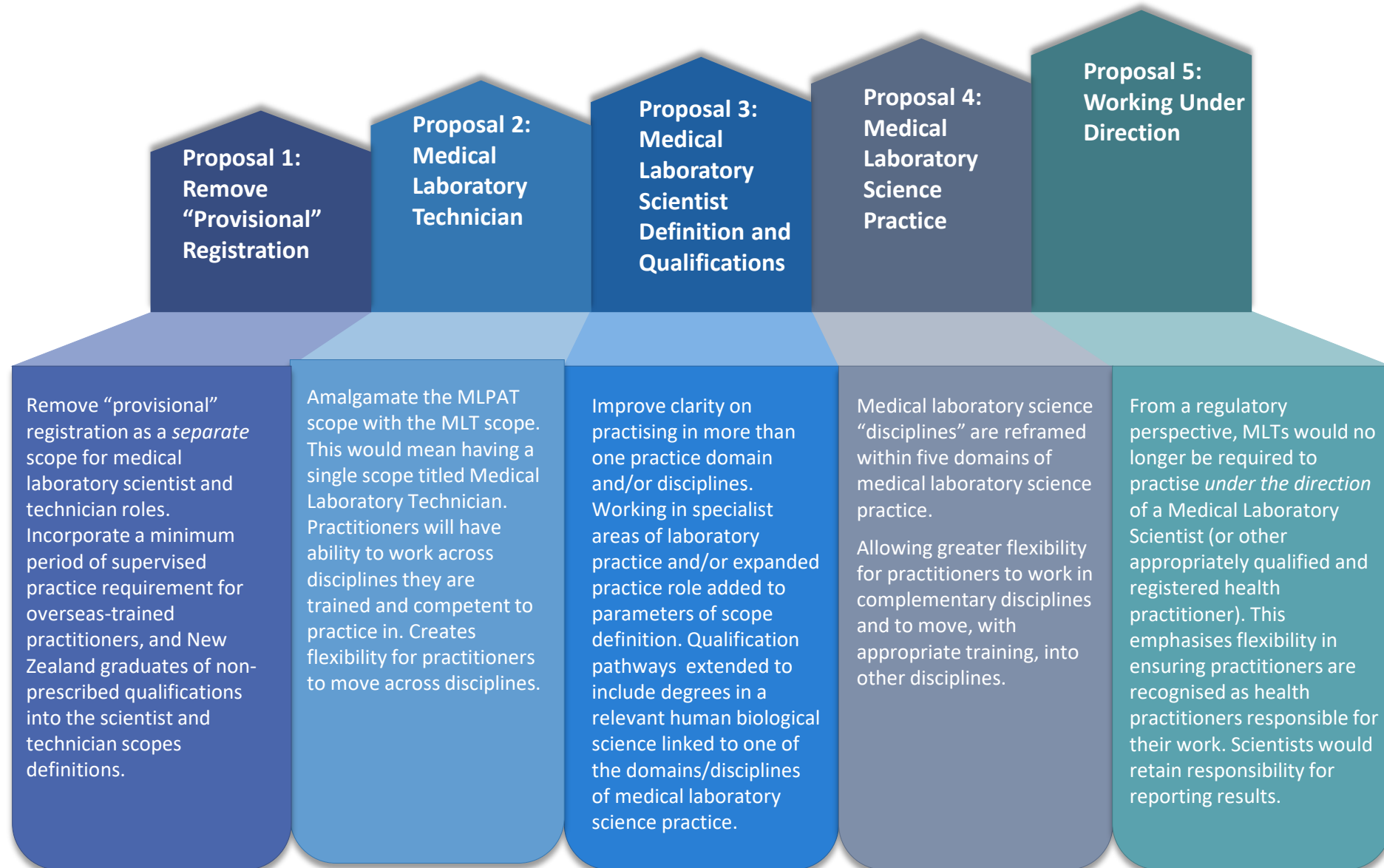


# Medical Laboratory Science Scopes of Practice Structure: From - To





# A Summary of Proposed Changes to the Medical Laboratory Science Scopes of Practice







# Proposal 1: Remove “Provisional” Registration as Separate Scopes



# From Provisional Registration to Supervised Practice

## **Background of Provisional registration:**

Provisional registration streams were introduced in 2015 as a mechanism for ensuring practitioners entering the medical laboratory science profession have appropriate monitoring and supervision in place, sufficient to protect the health and safety of the public while they gain the necessary New Zealand work-based knowledge and experience to be able to practise without supervision. Since then, provisional registration has been applied to practitioners who hold an appropriate qualification that meets the required academic standards, but who require more clinical experience to be able to practise independently within the parameters of their scope of practice.

## **Proposal to change:**

While provisional registration has met its intended purpose, eight-years on the Council is proposing to incorporate a requirement for a minimum period of supervised practice at the point of initial registration into each of the scope definitions for scientists and technicians. It is proposed that this is sufficient for continuing to meet the original and still relevant purpose – that is demonstration of competent and safe practice when beginning practice within an unfamiliar health environment.

Replacing provisional registration with a scopes-incorporated requirement of a minimum period of supervised practice will remove the additional steps practitioners need to go through to gain “full” registration and also reduce their costs.

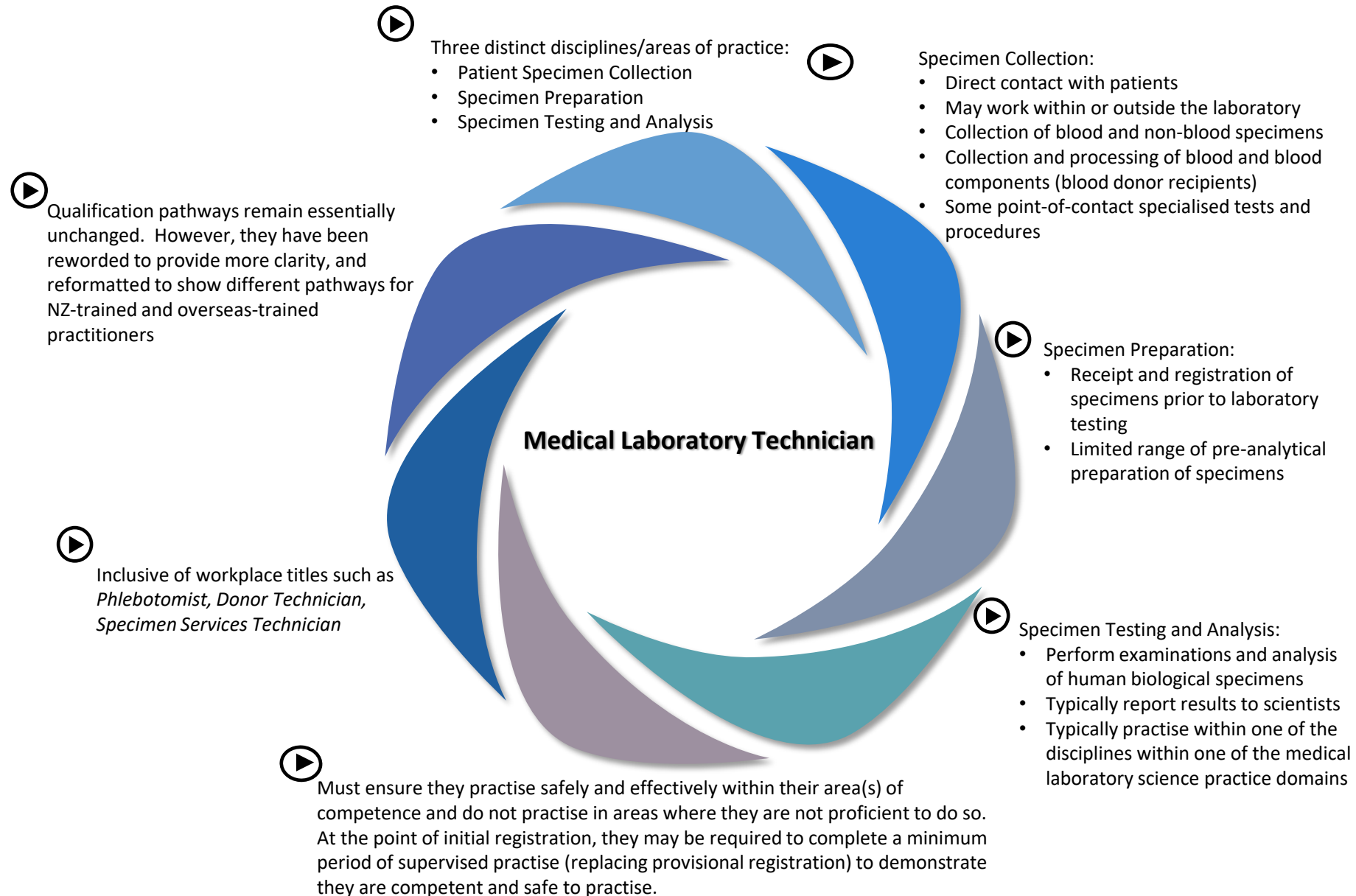


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- + . Proposal 2: Amalgamate the
  - o MLPAT and MLT Scopes of Practice



# Key Features of a Single Medical Laboratory Technician (MLT) Scope

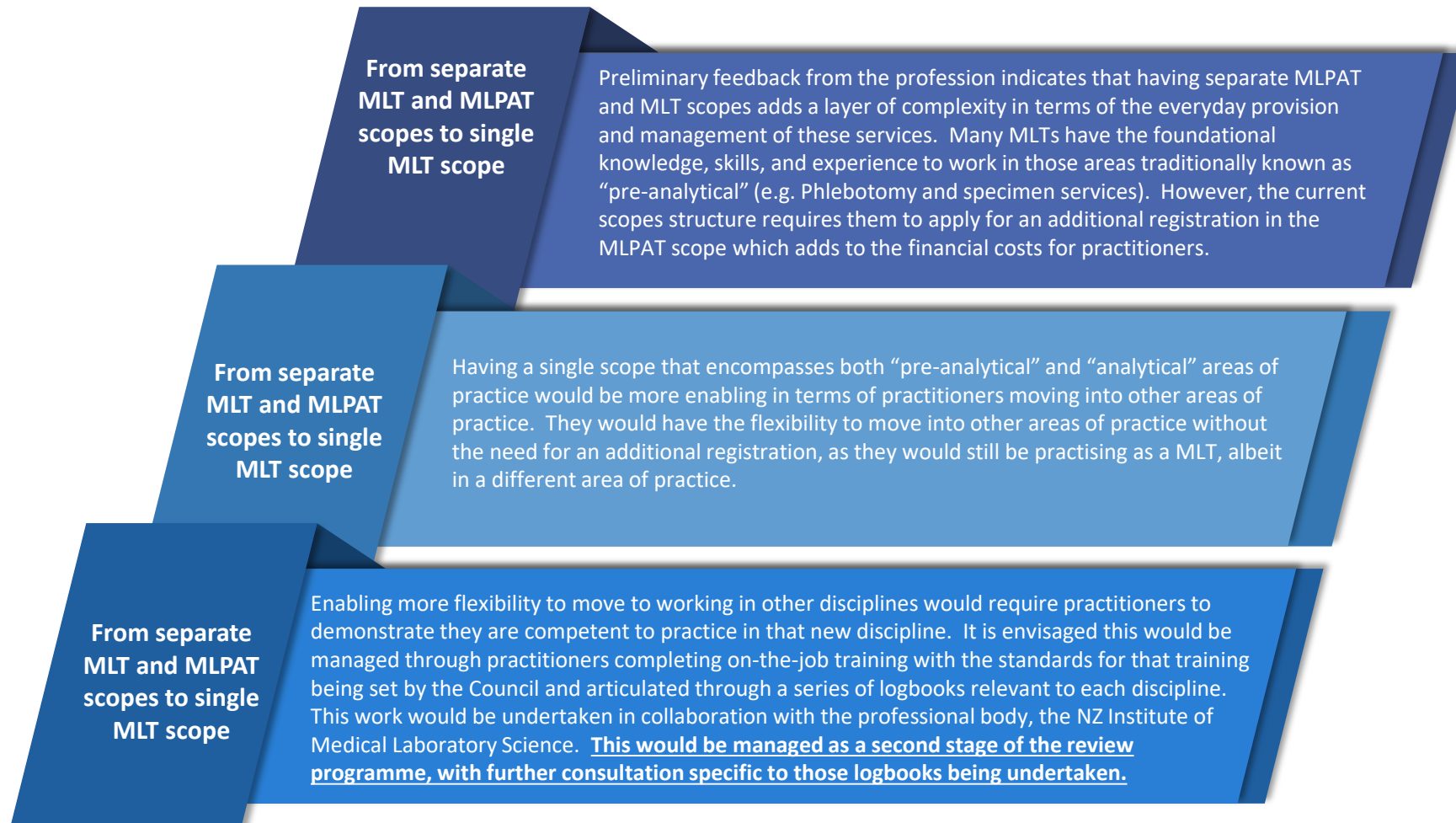
MLTs practise in a support role to medical laboratory scientists, carrying out much of the routine work within the laboratory thereby allowing scientists to concentrate on the more complex analytical processes. MLTs follow guidelines and protocols to collect, receive, prepare, test and analyse human biological material





## Why is Council Considering a Change for the MLT/MLPAT Scopes?

Within its responsibilities under the Health Practitioners Competence Act 2003, the Council is legislatively obliged to set the scopes and standards of practice for the medical laboratory science profession. As medical laboratory science is practised in an ever-changing health environment impacted by continuous medical and technological advancements, it is important the Council regularly reviews the regulatory frameworks it has in place to ensure they will continue to be fit for purpose in supporting the Council's primary function, which is to protect the health and safety of the public of Aotearoa New Zealand.





# Proposal 3: Medical Laboratory Scientist

Scope Definition and  
Qualification Pathways





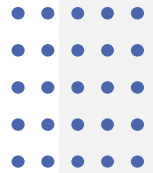
# Key Features of Revised Definition of the Medical Laboratory Scientist Scope

Scientists collaborate closely with clinicians in the diagnosing and monitoring disease processes as well as monitoring the effectiveness of treatment and therapy. They do this through testing and analysing human biological material including blood, body fluids, tissues, and cells. They are skilled in the selection of appropriate samples and preparation for testing and analysis and in the use of sophisticated laboratory equipment.

**The changes to the definition of the medical laboratory scientist scope of practice are intended to provide more clarity as to the extent of a scientist's practice parameters.**





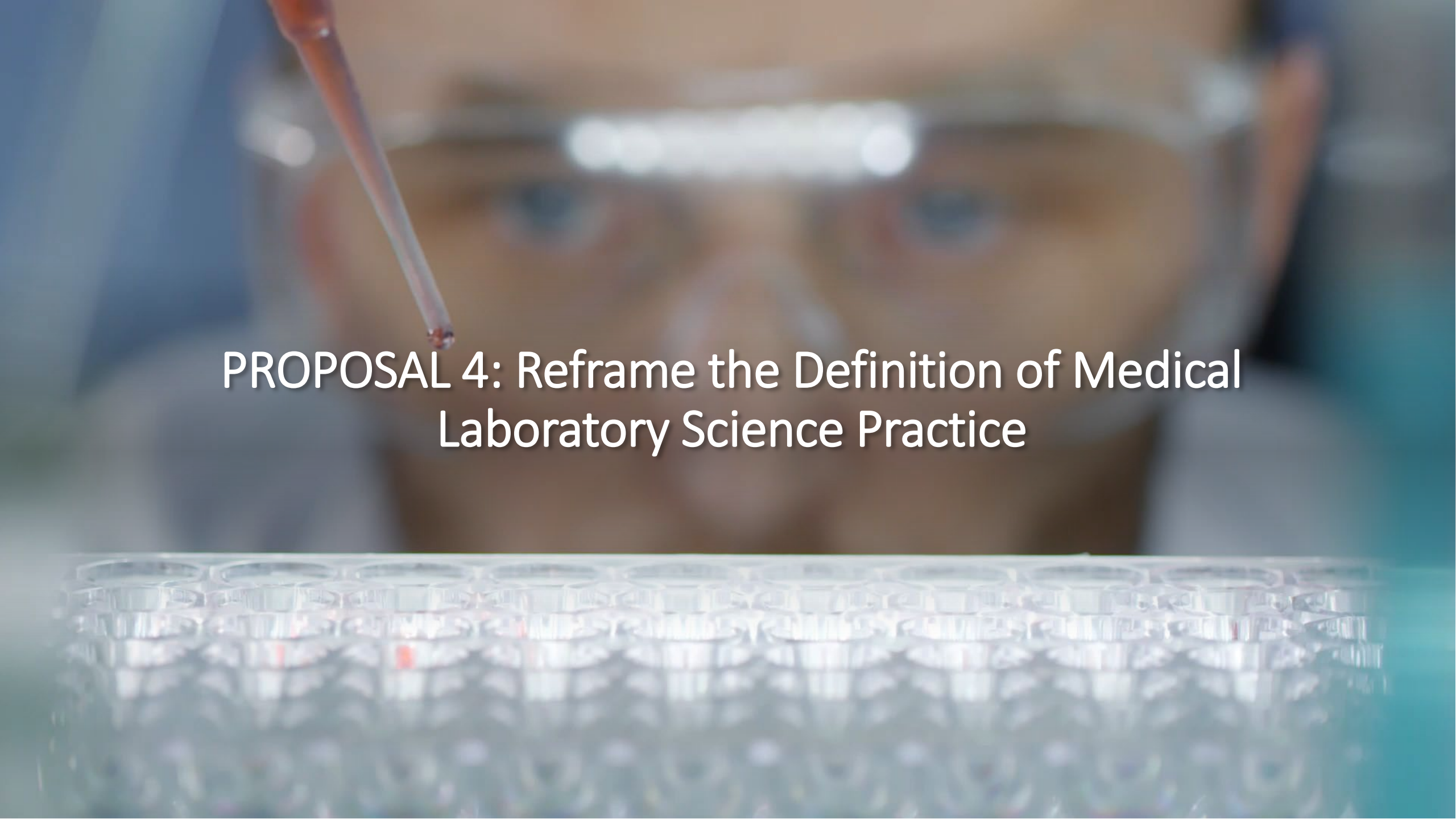


# Proposed Changes to the Qualification Pathways for Scientists

The qualification pathways available to practitioners seeking registration as a medical laboratory scientist will be extended to include undergraduate degrees in a relevant human biological science linked to one of the domains and/or disciplines of medical laboratory science practice. While this pathway is included in the current gazetted qualifications requirements, it is inclusive of the practitioner also passing a Council examination. In the proposed scenario, a practitioner with an undergraduate degree in a relevant human biological science may be registered without having to sit an examination, and instead have a condition placed on their practice limiting them to working within a specified medical laboratory science area of practice/discipline.

The revised qualification statements will also be reformatted to more clearly show the different pathways for NZ-trained and overseas-trained practitioners. An example of the proposed changes to the different registration pathways is shown on page 25.



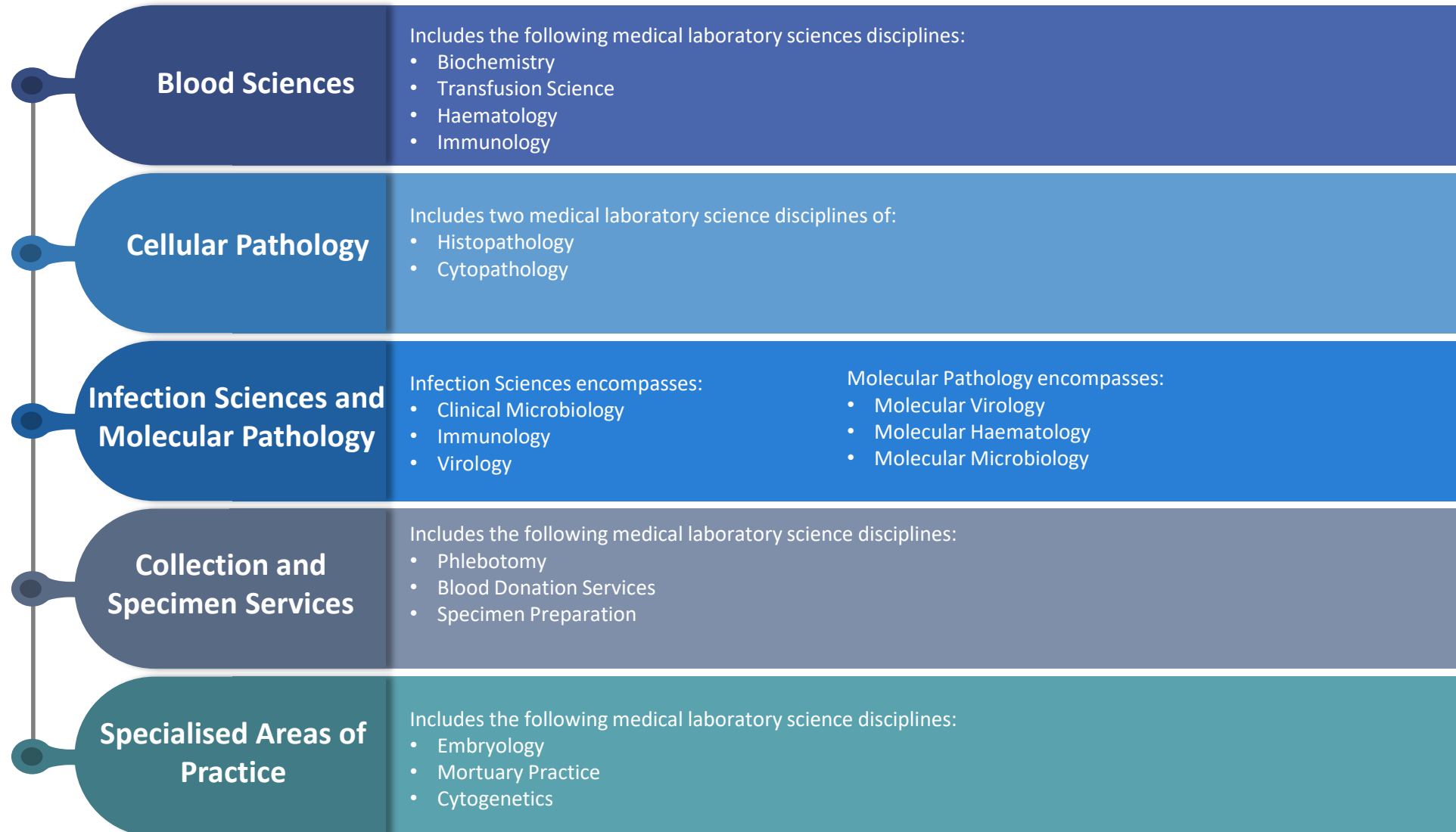


## PROPOSAL 4: Reframe the Definition of Medical Laboratory Science Practice



# Definition of Medical Laboratory Science Practice

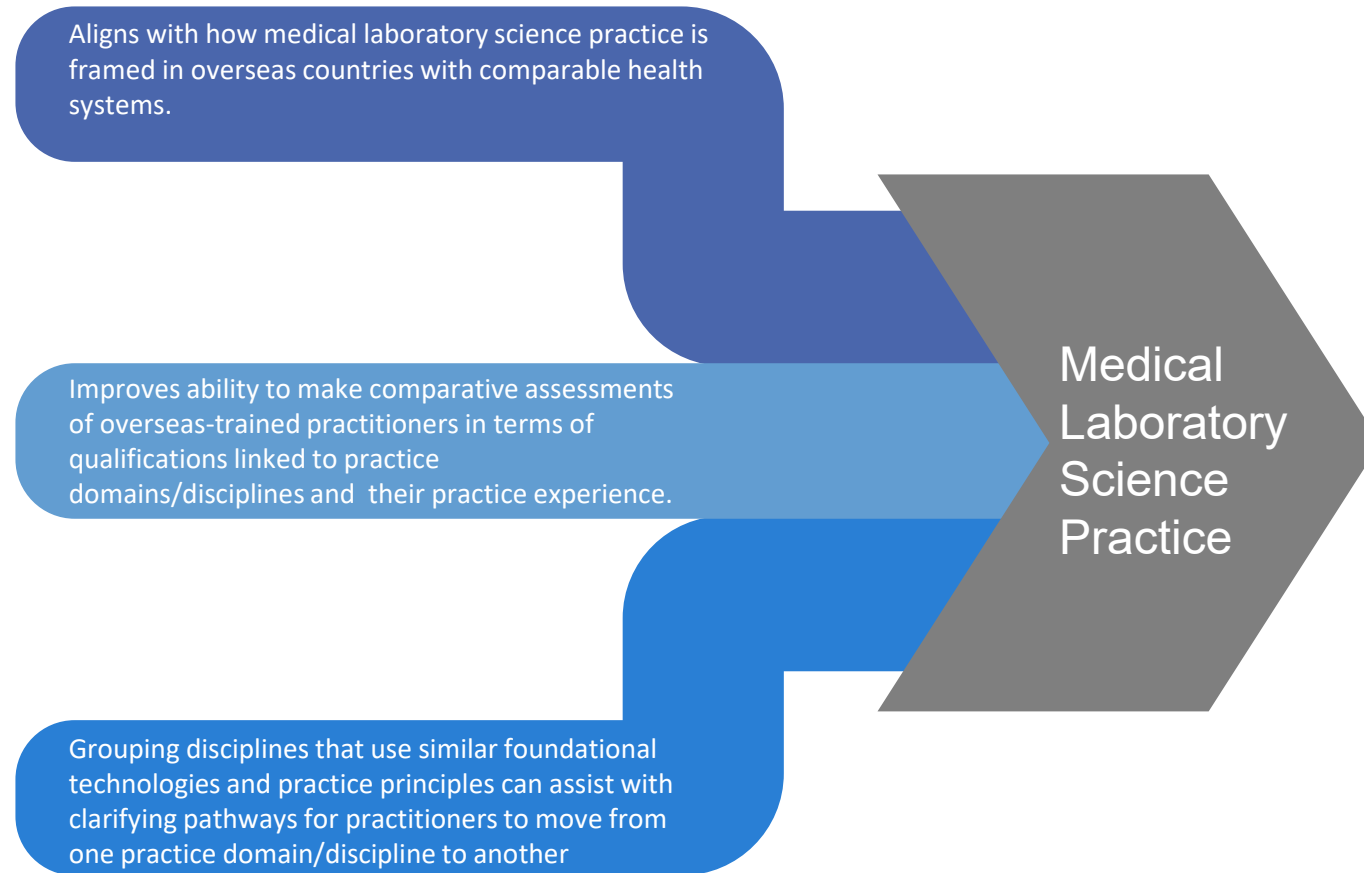
Medical laboratory science is the collection, receipt, preparation, investigation and laboratory analysis of samples of human biological material to help clinicians diagnose and treat patients and to the evaluate the effectiveness of treatment. Medical laboratory science encompasses five domains of practice, each of which contain numerous “disciplines” with practitioners typically practising in one or two disciplines.





## Why Reframe the Definition of Medical Laboratory Science Practice?

The Council's current gazetted definition of the practice of medical laboratory science lists fifteen distinct disciplines. The proposal is to re-structure those disciplines into five domains of practice, with each of those practice areas encompassing numerous disciplines. This will provide clarity and flexibility for the workforce.







# Proposal 5: Working Under Direction

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# MLTs will No Longer be Required to Work Under Direction

A requirement of the current iteration of the MLT scope is for these practitioners to work under the direction of a registered medical laboratory scientist or other appropriately qualified and registered health practitioner who holds a current practising certificate and has expertise and knowledge in the relevant discipline. This feature of the MLT scope is a historical one that was included in the original iteration of the scope definition back in 2004.

After almost 20-years of statutory regulation, the Council considers the requirement for MLTs to work under direction is redundant. From a regulatory perspective it does not offer added value in protecting the health and safety of the public when using medical laboratory science services. As registered health practitioners under the Health Practitioners Competence Assurance Act 2003, MLTs have the same responsibilities as any other registered health practitioner to ensure they comply with the Council's requirements in respect of their competence and fitness to practice. As such they take full responsibility for their practice and removal of the requirement more accurately reflects this. The scope definition clearly articulates that MLTs must ensure they practice within their area(s) of competence and do not practise in medical laboratory science practice domains/disciplines where they are not proficient to do so.

Decisions around MLTs working under the direction of someone else is ultimately an employment matter rather than a regulatory one. The Council notes newly registered MLTs may have a supervision requirement which ensures that practitioner gains the necessary familiarity before beginning independent practice.





# Revised Scopes Definitions in Detail

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# The Practice of Medical Laboratory Science

Medical laboratory science is the collection, receipt, preparation, investigation and laboratory analysis of samples of human biological material to help clinicians diagnose and treat patients and to evaluate the effectiveness of treatment. A large amount (at least 70%) of diagnoses made by clinical staff depend on laboratory tests.

In Aotearoa New Zealand medical laboratory science is performed by two groups of registered health practitioners, medical laboratory scientists (“scientists”) and medical laboratory technicians (“technicians”). While scientists and technicians both work in diagnostic medical laboratories and have similar roles in performing tests on human biological samples, a scientist normally has a higher level of education, can perform more complex laboratory work, and typically has more job responsibilities. Scientists may use their educational preparation and laboratory expertise to practise within a specialist area of laboratory practice, as well as to manage, teach, evaluate, and research medical laboratory science practice. A technician performs more of the routine laboratory work and their work may be overseen by a scientist. Collection and specimen services practice is primarily performed by technicians.

Medical laboratory science is practised in diagnostic medical laboratories within both the public and private health sectors and blood donor facilities in Aotearoa New Zealand. In a small number of circumstances medical laboratory science practitioners may work in the health sector but outside of the diagnostic medical laboratory setting.

Medical laboratory science encompasses five practice domains, each of which contain numerous “disciplines” with practitioners typically practising in one or two disciplines. Practitioners have a responsibility to ensure they only practise in those disciplines in which they have demonstrated competency.



# Domains/Disciplines of Medical Laboratory Practice

Practice Domains	Medical Laboratory Sciences Disciplines	
<b>Blood Sciences</b> <ul style="list-style-type: none"><li>In blood science practitioners test blood samples to diagnose disease or ensure a donor’s blood is matched with the patient receiving it</li></ul>	Biochemistry	The analysis of blood, serum, and other biological fluids to help diagnose disease and manage wellness, and toxicology studies.
	Transfusion Science	Determination of donor/recipient blood compatability and ensuring blood banks are sufficient.
	Haematology	The study of whole blood and coagulation proteins to diagnose specific blood coagulation disorders as well as monitor anticoagulant therapy.
	Immunology	The study of the body’s immune system and its role in infectious diseases, parasitic infestations, allergies, tumour growth, tissue grafts, and organ transplants.



# Domains/Disciplines of Medical Laboratory Practice

Practice Domains	Medical Laboratory Science Disciplines	
<b>Cellular Pathology</b> <ul style="list-style-type: none"><li>Cells form the basic building blocks for all living things and the human body is made up of trillions of cells</li></ul>	Histopathology	The preparation and staining of tissue samples taken during surgery or post mortem to establish or identify the cause of disease.
	Cytopathology	Best known for its work in screening cervical smears. It also provides a non-gynaecological service investigating cellular components in specimen samples.
<b>Infection Sciences and Molecular Pathology</b>	<p>Infection sciences focuses on the study of bacteria, fungi, parasites, and viruses that attack the human body causing infections and diseases. This may require the growth of actual pathogens or the identification of their specific genes.</p> <p>Infection sciences encompasses areas such as clinical microbiology, immunology, and virology.</p>	<p>Microbiology focuses on the identification of micro-organisms causing disease and establishment of antibiotic treatment required to treat them.</p> <p>Immunology is the study of the body’s immune system and its role in infectious diseases, parasitic infestations, allergies, tumour growth, tissue grafts, and organ transplants.</p> <p>Virology focuses on the identification of viruses and associated diseases and monitoring the effectiveness of vaccines.</p>
	<p>Molecular pathology is a scientific discipline that encompasses the development of molecular and genetic approaches to the diagnosis and classification of human diseases, the design and validation of predictive biomarkers for treatment response and disease progression, the susceptibility of individuals of different genetic constitution to develop disorders.</p> <p>Molecular pathology encompasses virology, molecular haematology, and molecular microbiology.</p>	<p>Focuses on the study and diagnosis of disease through the examination of molecules within organs, tissues, or body fluids.</p> <p>It is multidisciplinary in nature and uses numerous techniques.</p>



# Domains/Disciplines of Medical Laboratory Practice

Practice Domains	Medical Laboratory Science Disciplines	
<b>Collection and Specimen Services</b> <ul style="list-style-type: none"><li>The collection, receipt, registration, and preparation of specimen samples</li></ul>	Phlebotomy	The collection of blood and non-blood specimens.
	Blood Donation Services	Collection and pre-analytical processing of blood and blood components for the purpose of donation to blood donor recipients.
	Specimen Preparation	Receipt and registration of specimen samples. May include pre-analytical preparation of samples.
<b>Specialised Areas of Practice</b>	Embryology	Fertility treatments, specialising in the development and handling of embryos in a laboratory setting.
	Mortuary Practice	Assisting the pathologist during post mortem examinations and managing operational requirements of the mortuary facility and post mortem suite.
	Cytogenetics	Identification of changes in chromosomes associated with genetic diseases or conditions.



# Medical Laboratory Scientist

Medical Laboratory Scientists (“scientists”) collaborate closely with clinicians in diagnosing and monitoring disease processes, as well as monitoring the effectiveness of treatment and therapy. They do this through testing and analysing human biological human material including blood, body fluids, tissues, and cells. They are skilled in the selection of appropriate samples and preparation for testing and analysis, and in the use of sophisticated laboratory equipment. Establishing quality assurance programmes to monitor and ensure test result accuracy is a fundamental skill required of scientists. Scientists analyse and interpret laboratory results and report their findings to referring clinicians. They may also advise of the need for further relevant testing.

Scientists with a qualification specialising in medical laboratory science typically practise in one or two of the disciplines within the medical laboratory science profession – those disciplines may be in more than one of the practice domains. Scientists’ breadth and depth of training typically allows them to practise across all disciplines, with appropriate training and demonstrated competence as required. Scientists with a more generalist and/or discipline specific qualification in a relevant human biological science will typically have a condition imposed on their practice, limiting them to practising in a particular medical laboratory science discipline.

Scientists may use their educational preparation and laboratory expertise to practise within a specialist area of laboratory practice, as well as to manage, teach, evaluate, and research medical laboratory science practice. Entry into these roles will be primarily gained by scientists developing their practice through continuing education, experience, and ongoing competence development.

Some scientists may practise in an expanded practice role, an example being that of a Clinical Scientist. Practising in a Clinical Scientist role would require a scientist to complete a post-graduate qualification approved by the Council. Scientists practising in an expanded practice role will typically have a condition on their practising certificate certifying they hold the necessary qualification (inclusive of experience) to practise in the specified field of expanded practice. Pathways for entry into an expanded practice role are set out in Council policy.

Scientists must ensure they practise safely and effectively within their area(s) of competence and do not practise in medical laboratory science disciplines where they are not proficient to do so. They need to exercise professional judgement by undertaking any necessary training and/or gaining experience before moving into a new area of practice.

At the point of their initial registration scientists will normally be required to complete a minimum period of 3-months of supervised practice. The period of supervised practice may be longer than 3-months and will be determined in accordance with the Council’s registration policies. Supervision is a formal process of professional support and teaching to enable the practitioner to build on their knowledge, skills, and professional attributes within the Aotearoa New Zealand medical diagnostic laboratory environment.



# Prescribed Qualifications for Medical Laboratory Scientists

For the purpose of registration, a practitioner must hold one of the following:

## **New Zealand Graduates**

A L7 bachelor's degree in medical laboratory science issued by a New Zealand university accredited by the Medical Sciences Council of New Zealand; or

A L7 graduate diploma in medical laboratory science issued by a New Zealand university accredited by the Medical Sciences Council of New Zealand; or

A New Zealand L7 bachelor's degree or L8 Honours degree, or L9 postgraduate qualification in a relevant human biological science linked to one of the domains/disciplines of medical laboratory science practice, and approved by the Medical Sciences Council of New Zealand; and

A pass in an examination for medical laboratory scientists set by the Medical Sciences Council of New Zealand; or

A condition on their practice limiting them to practise within the discipline(s) within which they have demonstrated competency.

## **Overseas Trained Practitioners**

A graduate medical laboratory science qualification assessed by the Council at level 7 of the New Zealand Qualifications Framework; or

A bachelor's or postgraduate degree in a relevant human biological science linked to one of the domains/disciplines of medical laboratory science practice, and approved by the Medical Sciences Council of New Zealand combined with appropriate laboratory experience; and

A pass in an examination for medical laboratory scientists set by the Medical Sciences Council of New Zealand; or

A condition on their practice limiting them to practise within the discipline(s) within which they have demonstrated competency.



# Medical Laboratory Technician

Medical laboratory technicians (“technicians”) practise in a support role to medical laboratory scientists, carrying out much of the routine work within the laboratory thereby allowing scientists to concentrate on the more complex analytical processes. Technicians follow guidelines and protocols to collect, receive, prepare, test and analyse human biological material.

Technicians practise within three distinct areas of medical laboratory science – patient specimen collection, specimen preparation, (both are disciplines within the Collection and Specimen Services practice domain) and specimen testing and analysis (this may be in disciplines in any of the four practice domains outside of Collection and Specimen Services).

Technicians may practise under different workplace titles including but not limited to *medical laboratory technician*, *phlebotomist*, *donor technician*, and *specimen services technician*. The scope of practice of Medical Laboratory Technician is inclusive of these workplace titles.

Technicians practising in **specimen collection** have direct contact with patients and must have a good foundational knowledge of human anatomy and pathology. They may work both within or outside of the laboratory environment. Specimen collection includes collection of blood and non-blood specimens, and the collection and processing of blood and blood components for the purpose of donations to blood donation recipients. It may also involve some specialised tests and procedures that are performed at the point of contact with patients.

Technicians practising in **specimen preparation** are responsible for the receipt and registration of samples prior to laboratory testing. They may perform a limited range of pre-analytical preparation of samples within the parameters of approved guidelines and protocols.

Technicians practising in the area of **specimen testing and analysis** work in a diagnostic medical laboratory to perform examinations and analysis of human biological samples including blood, body fluids, tissues, and cells. They will typically report test results to a medical laboratory scientist who is responsible for interpretation of those results and reporting the findings to referring clinicians. Technicians working in this area of medical laboratory science typically practise within one of the disciplines within one of the following practice areas: blood sciences, cellular pathology, infection sciences and molecular pathology, or the specialised area of mortuary practice.

Technicians must ensure they practise safely and effectively within their area(s) of competence and do not practise in medical laboratory science practice domains/disciplines where they are not proficient to do so. They may move to practising in another domain and/or discipline of medical laboratory science while remaining within the technician scope of practice, providing they have undertaken any necessary training and/or experience requirements as approved by the Council. Pathways for technicians to move to another practice domain/discipline within the medical laboratory technician scope of practice are set out in Council policy.

At the point of their initial registration technicians who have not previously worked within the New Zealand diagnostic medical laboratory environment will normally be required to complete a minimum period of 3-months of supervised practice. The period of supervised practice may be longer than 3-months and will be determined in accordance with the Council’s registration policies. Supervision is a formal process of professional support and teaching to enable the practitioner to build on their knowledge, skills, and professional attributes within the Aotearoa New Zealand medical diagnostic laboratory environment.



# Prescribed Qualifications for Medical Laboratory Technicians

For the purpose of registration, a practitioner must hold one of the following:

## New Zealand Graduates

A New Zealand bachelor's degree in a relevant biological science linked to one of the domains/disciplines of medical laboratory science practice and approved by the Medical Sciences Council of New Zealand; or

A certificate in a relevant area of medical laboratory science practice issued by a New Zealand qualification provider accredited by the Medical Sciences Council of New Zealand; or

A level 6 (New Zealand Qualifications Framework) New Zealand Certificate in Science in a relevant human biological science; **or**

**A relevant biological science qualification assessed as suitable by the Council and a** pass in an examination for medical laboratory technicians set by the Medical Sciences Council of New Zealand; or

A New Zealand registered nurse with post-qualification medical laboratory science experience in specimen collection (phlebotomy or blood donation services); or

**For registration restricted to collection and specimen services, a level 5 New Zealand Diploma in Applied Science (PAT pathway).**

## Overseas Trained Practitioners

A graduate medical laboratory science qualification assessed by the Medical Sciences Council as at least level 6 of the New Zealand Qualifications Framework combined with appropriate laboratory experience; or

A degree in a relevant biological science linked to one of the domains/disciplines of medical laboratory science practice, and assessed by the Council at level 7 of the New Zealand Qualifications Framework combined with appropriate laboratory experience; or

**A relevant biological science qualification and a** pass in an examination for medical laboratory technicians set by the Medical Sciences Council of New Zealand; or

A registered nurse with current registration with an overseas regulatory authority and 2-years of post-registration medical laboratory experience (within the immediately preceding 5-years) in specimen collection (phlebotomy or blood donation services).



## Summary of proposed changes:

### **Proposal One - Move from six scopes of practice to two:**

- |                                                                                                                                                                                                                                                                                                                                                                                    |    |                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Medical Laboratory Scientist (Provisional)</li><li>• Medical Laboratory Scientist (Full)</li><li>• Medical Laboratory Technician (Provisional)</li><li>• Medical Laboratory Technician (Full)</li><li>• Medical Laboratory Pre-Analytical Technician (Provisional)</li><li>• Medical Laboratory Pre-Analytical Technician (Full)</li></ul> | to | <ul style="list-style-type: none"><li>• Medical Laboratory Scientist</li><li>• Medical Laboratory Technician</li></ul> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|------------------------------------------------------------------------------------------------------------------------|

As part of the move to two scopes, provisional registration will be replaced with a minimum period of supervised practice at the point of initial registration (overseas trained and NZ graduates) into each of the scope definitions for scientists and technicians.

### **Proposal Two - Amalgamating the MLPAT scope with the MLT scope:**

This would mean having a single scope titled Medical Laboratory Technician. Practitioners will have ability to work across disciplines they are trained and competent to practice in. This creates flexibility for practitioners to move across disciplines.

### **Proposal Three – Defining the Medical Laboratory Scientist Definition and Qualifications**

This will improve clarity on Scientists practising in more than one practice domain and/or disciplines. Working in specialist areas of laboratory practice and/or an expanded practice role would be added to the parameters of the scope definition. Qualification pathways would be extended to include degrees in a relevant human biological science linked to one of the domains/disciplines of medical laboratory science practice.



## Summary of proposed changes continued

### **Proposal Four - Reframing the definition of Medical Laboratory Science Practice**

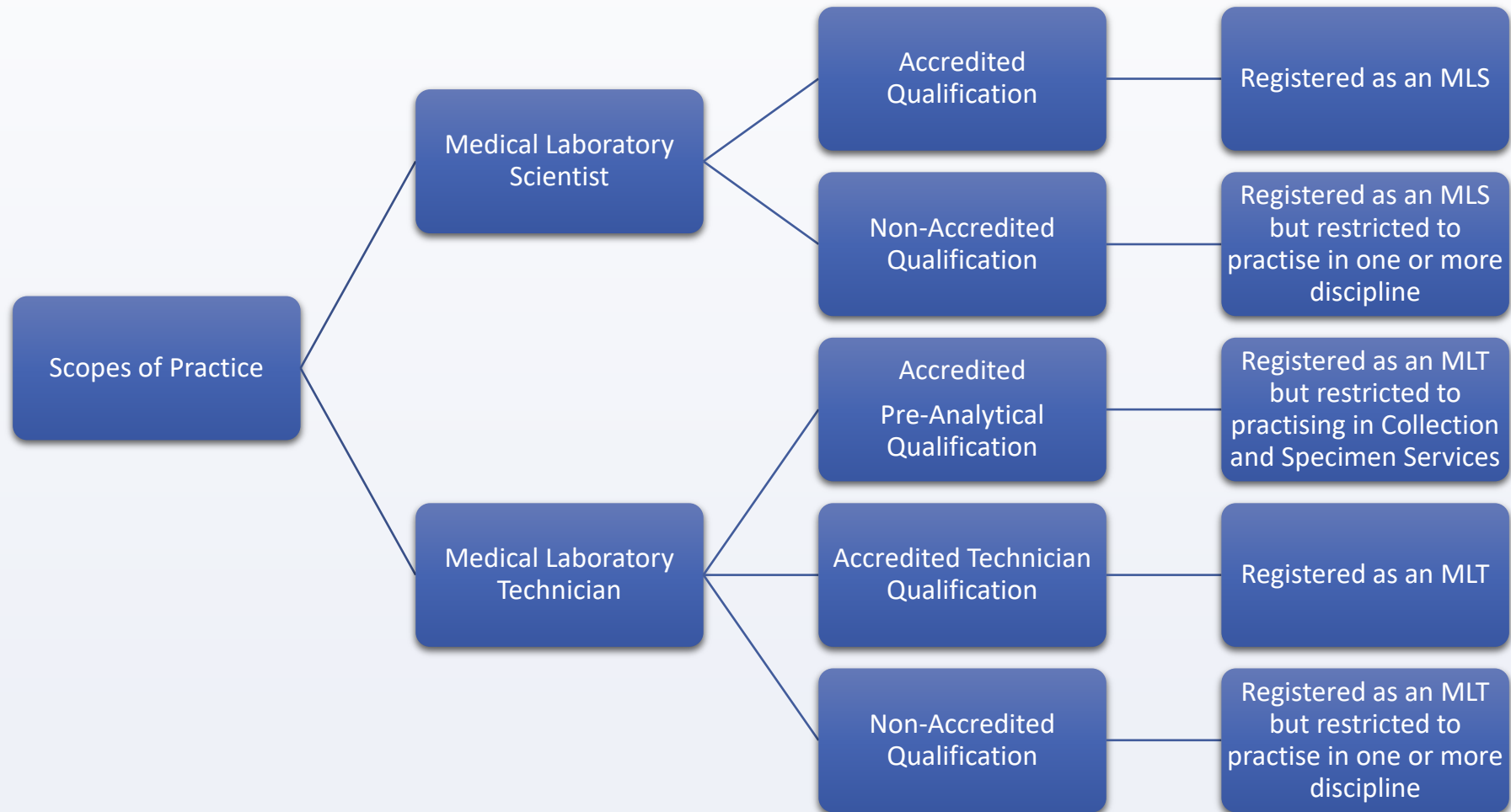
The Council's current gazetted definition of the practice of Medical Laboratory Science lists fifteen distinct disciplines. The proposal is to re-structure those disciplines into five domains of practice, with each of those practice areas encompassing numerous disciplines. This will provide clarity and flexibility for the workforce.

### **Proposal Five - Working under Direction**

The concept of working under 'direction' is outdated and no longer fit for purpose. Scientists will retain the responsibility to report results. MLTs have the same responsibilities as any other registered health practitioner to ensure they comply with the Council's requirements in respect of their competence and fitness to practice.



## Proposed Scopes and Pathways to Registration







Your Informed and Constructive Feedback is  
Welcomed



# Online Questionnaire

1

We ask that you provide your feedback through an online questionnaire.

2

Please complete the questionnaire by no later than 4.30 pm Monday 16 January 2023.

3

The Council is aiming to have made a final decision and a revised scopes framework ready for publication circa March 2023.