MEASUREMENT STANDARDS LABORATORY OF NEW ZEALAND

QUALITY MANUAL

October 18, 2023

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Measurement Quality Council
Measurement Standards Laboratory of New Zealand

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Quality policy statement

This signed statement is stored in the central files system.

MSL Quality Policy Statement

The Measurement Standards Laboratory (MSL) is New Zealand's National Metrology Institute (NMI). MSL is responsible for developing and disseminating the physical measurement standards needed in New Zealand, and ensuring that they are accepted nationally and internationally. MSL's activities support measurement capabilities that underpin New Zealand's prosperity and quality of life.

We aim to provide the services that our customers need and, through a process of continuous improvement, to anticipate those needs and exceed our customers' expectations. We are committed to providing a quality service in a safe and healthy working environment.

MSL's calibration and testing services are accredited by International Accreditation New Zealand (IANZ), against the ISO 17025 standard for testing and calibration laboratories, using internationally recognised technical experts in each area. The capability of these services is documented in the MSL Scope of Accreditation schedule issued by IANZ.

As an NMI, MSL:

- participates in international activities that ensure mutual recognition of New Zealand's and other nations measurement capabilities;
- provides technical measurement services for the public and private sectors;
- engages in research and development activities that support the scientific and technical foundation
 of the international measurement system;
- provides scientific leadership to New Zealand's National Quality Infrastructure in the form of authoritative and independent scientific advice on measurement;
- provides knowledge transfer and advice for industry, Government and academia.

MSL is committed to the level of quality expected from a national centre of excellence in metrology. MSL management and staff are committed to complying with ISO 17025 and to seeking continual improvement in the effectiveness of the management system. MSL staff and individuals qualified to carry out test and calibration activities adhere to the policies and procedures documented in the quality management system.

The quality of services and other activities are monitored and regularly reviewed, using information collected from:

- client satisfaction surveys and customer feedback;
- MSL's performance in international measurement comparisons;
- international peer-reviews of calibration and measurement services;
- management reviews of the Quality Management System;
- IANZ audits of the Quality Management System;
- MSL audits of calibration and measurement services and the Quality Management System;
- MSL reviews of technical areas;
- health and safety audits of work areas.

Paul Linton, General Manager Commercial Business Callaghan Innovation

1 Introduction

The Measurement Standards Laboratory of New Zealand (MSL) is New Zealand's National Measurement Institute (NMI). MSL is designated as the verifying authority of New Zealand's national measurement standards by act of parliament. All results quoted in measurement, calibration and test reports issued by MSL are directly traceable to the national measurement standards held by the laboratory.

New Zealand is a signatory to the international Meter Convention [?], which establishes a world-wide system of measurement units. MSL plays a key role in ensuring international recognition of New Zealand's measurement system.

MSL is a signatory of an international Mutual Recognition Agreement (MRA) [?] that provides a framework for NMIs to demonstrate the performance of measurement capabilities that support calibration and measurement services. One of the MRA requirements for mutual recognition is that each NMI implement a suitable system for ensuring quality. MSL has implemented a quality management system (QMS) that is accredited, by International Accreditation New Zealand (IANZ), against the ISO 17025 standard for testing and calibration laboratories [?].

For the purpose of accreditation against ISO/IEC 17025, the scope of the QMS covers all MSL activities that relate to the provision of traceable calibration and measurement services within MSL's scope of accreditation. This includes realisation and maintenance of standards, calibration, and product testing.

This Quality Manual also covers activities that are related to MSL's role as an NMI but are not part of ISO 17025. Such activities include research, training and dissemination and consultancy.

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2 Organisational structure

MSL operates as a group within Callaghan Innovation. The structure of Callaghan Innovation and the structure of MSL are summarised below.

2.1 Callaghan Innovation

Callaghan Innovation is a Crown Agent of the New Zealand government.

Callaghan Innovation is led by a Chief Executive Officer and divided into a number of Hapū, each managed by a Chief reporting to the Chief Executive. Innovation Expertise is one of these Hapū, within which MSL is a Hapū team. A Director manages MSL.

Inside the MSL group, the role of Team Manager is recognised as someone who reports to the MSL Director and supervises staff.

Callaghan Innovation also maintains a register of designated Work Area Managers. The role of Work Area Manager is important to the organisation in meeting statutory Health and Safety requirements. Work Area Managers report on Health and Safety issues to their respective Team Managers.

2.2 Measurement Standards Laboratory

MSL identifies the following roles:

- Director
- Chief Metrologist
- Quality Manager
- · Team Manager
- Member
- · Quality Council Member

The appointment of staff in relation to MSL's role as New Zealand's National Metrology Institute (NMI) is described in section 2.2.3 below.

2.2.1 Responsibilities

 All staff in the MSL group at Callaghan Innovation and any other individuals authorised to carry out test and calibration work (i.e., individuals named in the Technical Competency Matrix) operate under the terms of this Quality Manual.

- The Chief Metrologist acts as a verifying authority in relation to the verification of any standard or standards of measurement in New Zealand. The role of the Chief Metrologist shall be given to the Quality Manager or to another MSL Member.
- The role of Director is of particular relevance to the Metre Convention. The Director also makes
 the necessary delegations to implement the QMS. The MSL Group Manager is currently the
 Director of MSL.
- The Quality Manager ensures that the QMS is implemented and followed, oversees the management and improvement of the QMS and ensures that MSL's scope of accreditation, and its Calibration and Measurement Capabilities (CMCs) in Appendix C of the MRA, are consistent with each other.
- Members of the Quality Council (MQC) maintain the QMS, and the Quality Manual.

Impartiality All staff shall act impartially.

Teams shall be responsible for identifying and documenting potential risks to impartiality. Team managers will take account of these records when assigning tasks to staff.

Potential risks to impartiality may be identified by the process described in the corporate document "Declaring Interests and Managing Conflict Policy.docx". Individuals' declarations will not be available to other staff, but team Managers will have access to this information and can manage the associated risks. The accreditation body will not be able to access this private information.

The Risks and Opportunities register will be used to record potential risks to impartiality that are not subject to privacy constraints. The Risks and Opportunities register is part of the central file system (see ??).

The Quality Manager A Quality Manager is required by ISO 17025.

Although the title Quality Manager need not be used, someone must be assigned the Quality Manager functions.

A senior metrologist is usually appointed as Quality Manager. So, that person occupies a line management position under the MSL Director and Team managers. This should not present a problem provided that, on matters of quality, the Quality Manager has direct access to the highest level of management in the organisation at which policy and resourcing decisions are made affecting the laboratory.

The Quality Manager is responsible for implementing and operating the quality system on a day-to-day basis. He or she is normally responsible for administering the quality management system, for compiling the quality manual and for organising reviews and audits of the quality system.

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While the role has a large administrative component, the Quality Manager is ultimately responsible for effective enforcement of quality policy.

The Quality Manager is distinct from the MSL Director and Team manager roles. The responsibility is discharged through monitoring and advising not by managing technical activities directly.

The Quality Manager will advise management on quality issues and also has a responsibility to report to the APMP Technical Committee on Quality Systems on matters of quality relating to MSL. The Quality Manager role requires familiarity with ISO 17025 and knowledge of the MSL quality system. Suitable experience could be acquired, for example, by acting as an IANZ Technical Expert to assess commercial calibration laboratories, and by serving on the MSL Quality Council.

2.2.2 MSL Sections

MSL is organised into three technical teams, each comprised of sections aligned with different technical areas of the SI (see figure ??).

The sections are:

- Length
- · Time and Frequency
- Electrical
- · Temperature and Humidity
- · Photometry and Radiometry
- · Mass and Pressure

Sections are involved in:

- maintenance and development of measurement standards;
- · calibration and measurement services:
- · scientific research;
- · liaison with international metrology groups and networks of peers;
- dissemination of knowledge and technical services within New Zealand.

Third-party accreditation of MSL by IANZ is organised by section, and sometimes by sub-section (e.g., Pressure, Mass and related quantities, Temperature, and Humidity are typically treated as distinct disciplines for technical reviews).

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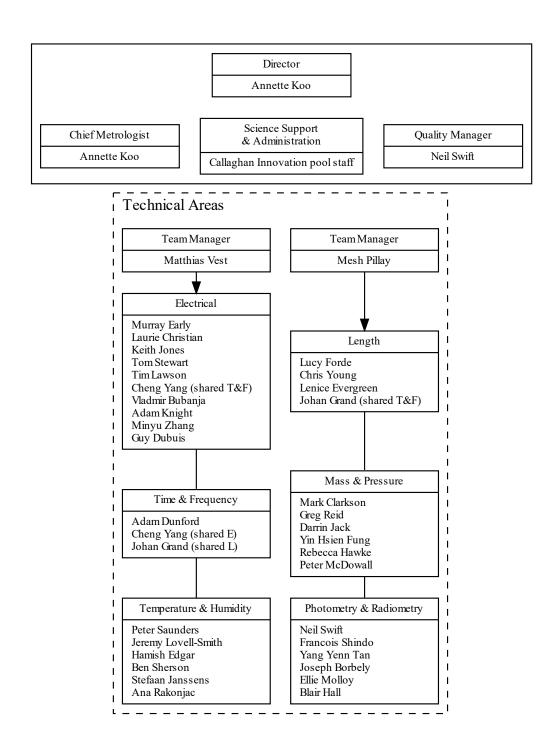


Figure 1: MSL Organisational Structure (September 4, 2023)

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2.2.3 Approvals

Chief Metrologist The appointment of the Chief Metrologist in relation to MSL's role as the New Zealand NMI is done in the context of the Measurement Standards Act 1992 [?] and the National Standards Regulations 2019 [?]. The National Standards Regulations 2019 (as at 20 May 2019) has the definition:

Measurement Standards Laboratory of New Zealand means the laboratory of Callaghan Innovation (established under section 7 of the Callaghan Innovation Act 2012) that maintains the principal standard measures for New Zealand.

This is interpreted as being the responsibility of Callaghan Innovation to define (effectively delegated from the Minister, through the regulation). Under this interpretation, the Chief Executive Officer shall appoint, in writing, the Chief Metrologist. The Chief Metrologist shall be a senior metrologist with knowledge of and familiarity with the New Zealand and international measurement infrastructure. The roles of Director and Chief Metrologist may be combined. Under the National Standards Regulations, the Chief Metrologist may delegate, in writing, to any other person who is an MSL Member.

Team Manager Technical activities are organised into three teams, each with a manger who has overall responsibility for technical operations, including provision of the resources needed to ensure the required quality of laboratory operations.

Quality Manager The Director appoints the Quality Manager. Appointments are for a period of two years, which may be extended.

The Quality Manager has the responsibility and authority to ensure that the quality management system is implemented and adhered to at all times; the Quality Manager has direct access to the highest levels of management at which decisions are made on laboratory policy or resources (currently the Chief of Innovation Expertise).

The Quality Manager may delegate, in writing, to any MSL Member.

When the Quality Manager is absent, the Chief Metrologist automatically assumes the relevant responsibilities. The Chief Metrologist may re-delegate such responsibilities.

Member Members are qualified for particular roles in relation to specific technical procedures. Members are listed in the Technical Competency Matrix (TCM, the TCM is part of the central files system described in section 4.2). Note, some individuals in the TCM may be under contract to MSL or be employees of Callaghan Innovation outside MSL.

An MSL Member who has been approved as a signatory by IANZ for particular items in the scope of

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accreditation is authorised to sign IANZ endorsed certificates and reports for these items.

Note that in clause 8(2)(a) of the National Standards Regulations 2019, in relation to delegation of the power of a verifying authority, the reference to 'a person working in the Measurement Standards Laboratory of New Zealand' is interpreted as an MSL Member.

Quality Council After consultation with the Director, the Quality Manager appoints, in writing, the members of the MSL Quality Council (MQC). Membership tends to be for periods of several months, so that representation can be shared across MSL over time.

Leadership Team The MSL Leadership Team includes the Director, the Chief Metrologist, the Quality Manager, the Team Managers and the Science Support Coordinator.

2.2.4 MSL Affiliations

- MSL is accredited, by IANZ, as an accredited Metrology and Calibration Laboratory complying with NZS/ISO/IEC 17025 (original date of accreditation, 30 July 2004).
- The Chief Metrologist is authorised by the Minister of Science and Innovation, under the Measurement Standards Regulations, to act as a verifying authority in relation to the verification of any standard or standards of measurement in New Zealand.
- New Zealand is a signatory to the Metric Treaty of 1875 and hence is a member state of the Metre Convention. New Zealand (through the Ministry of Business, Innovation and Employment) subscribes annually to the Comité International des Poids et Mesures (CIPM) which administers the Metre Convention, provides technical coordination, and is the owner of the Système International d'Unités (SI). The Ministry of Business, Innovation and Employment handles the administrative aspects of New Zealand relationship with the CIPM, while MSL handles the technical aspects, and provides a New Zealand representative (normally the MSL Director) to the Conférence Générale des Poids et Mesures (CGPM).
- MSL is a signatory to the Mutual Recognition Arrangement on National Measurement Standards and Calibration Measurement Certificates Issued by National Metrology Institutes (MRA) drawn up by the CIPM under the authority given to it under the Metric Treaty.
- MSL is a permanent member of four of the Consultative Committees (CCs) that assist the BIPM with its scientific work: CCT (Thermometry), CCEM (Electricity and Magnetism), CCPR (Photometry and Radiometry) and CCM (Mass and related units).
- MSL and IANZ have signed a Memorandum of Understanding (MOU) formalising the relationship between the national metrology institute and the national laboratory registration agency, as required for recognition by the European Union (EU), of New Zealand testing and certification.
 The Measurement and Calibration Professional Advisory Committee, chaired by the Chief Metrologist, provides the vehicle for operating the MOU.

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- MSL and the National Measurement Institute, Australia (NMIA), have signed seven agreements
 recognising the equivalence of the following units: metre, kilogram, volt, ohm, farad, second,
 kelvin.
- MSL is a full member of the Asia-Pacific Metrology Programme (APMP). This Regional Metrology
 Organisation (RMO) is a member of the Joint Committee of Regional Metrology Bodies and the
 BIPM (JCRB) that plays a key role in operating the MRA.

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3 Quality Assurance

3.1 Policy on the Quality Assurance of Measurement Capabilities

MSL sections will monitor the performance of all measurement capabilities.

Monitoring must be planned and will include both internal and external activities.

The results of quality assurance activities will be continuously reviewed within the section so that appropriate action can be taken to prevent unsatisfactory measurement capabilities from being used.

Any results that suggest the performance of a measurement capability is inferior to the current accredited scope must be documented and investigated by the section. The MQC must be notified immediately about any discrepant results. The MQC will maintain a record of such instances, including a report about the corrective actions taken.

Internal quality assurance activities shall be used to monitor the performance of measurement procedures. For example,

- regular use of certified reference materials and/or reference material and/or quality control material;
- regular use of alternative metrologically traceable instrumentation;
- · functional checks of measuring and testing equipment;
- use of check-standards with control charts and/or control limits;
- · periodic intermediate checks on measuring equipment;
- replicate tests or calibrations using the same or different methods;
- re-testing or recalibration of retained items; inter-operator comparisons;

External quality assurance activities within the accredited scope should be planned, if possible, to occur over the usual accreditation cycle. These activities generally involve participation in international measurement comparisons with other NMIs.

A central register of all MSL participation in international comparisons will be maintained in the QMS and will include a copy of comparison reports, which will be reviewed.

3.2 Metrological traceability

The metrological traceability policies in the CIPM MRA [?] and ILAC MRA [?] are different. The CIPM MRA is more restrictive, requiring external measurements to be obtained from other NMIs or DIs.

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The only permitted exception is for 'auxiliary influence quantities, not part of the main traceability path to the SI for a particular measurand' if the contribution to uncertainty is 'minor' (a definition of minor is not given). In such cases, 'measurement services provided by laboratories accredited by a signatory to the ILAC Arrangement' may be used.

A CMC published in the BIPM KCDB must conform to the CIPM MRA policy.

3.2.1 Traceability policy

The CIPM MRA traceability policy is preferred for all MSL measurement capabilities.

The criterion for being an 'auxiliary influence' is interpreted as follows. If $u_{\rm cmc}$ is the nominal *standard* uncertainty associated with a measurement capability, then the maximum acceptable standard uncertainty of an auxiliary influence factor shall not exceed $u_{\rm cmc}/10$.

Exceptions: If a measurement capability is not published in the BIPM KCDB, then compliance with the ILAC MRA traceability policy will be sufficient for entries in our IANZ scope of accreditation. However, the status of MSL as an NMI and a party to the CIPM MRA means that the most, if not all, measurement capabilities should strive to meet the CIPM requirements. A justification for any exception should be recorded (for example, as a note in the technical procedure).

Quality assurance: Whenever traceability is sourced externally, MSL must take steps to assure the quality of all external measurement services incorporated in our measurement processes; section 6.6 of ISO 17025 applies [?].

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4 Documents and document control

4.1 File systems

The QMS file system comprises a central file system and a number of section file systems. Central files contain documents and information relating to MSL as a whole, including the functions of the Quality Manager and Quality Council. Section file systems contain documents more specifically related to the activities and capabilities of the section.

4.2 Central file system

The central file system is the 'MSL Quality Management System' library within the Callaghan Innovation document management system. This is a AODocs secured folder library with access limited to staff working at MSL and certain key members of the organisation who need access.

The secured folder library type stores data within a folder structure. In a change from the prior document management system (edi), key information such as the Technical Competency Matrix is now stored within files instead of as meta data. The following table summarises the type of information stored.

Name	Contains
APMP Reporting	A folder structure containing section presentations and reports to the annual APMP meetings.
Calibration reports	A folder containing copies of issued calibration and test reports.
Client Callbacks	A folder of documents related to calls to clients about work done recently by MSL.
CMCs and IANZ Scope	A folder structure containing past and present CMC documents (from the BIPM database) and IANZ scopes of accreditation for MSL.
Correspondence	A folder structure of important correspondence related to the quality system. Mostly communications to and from the Quality Manager, IANZ, Director or Chief Metrologist relating to the accredited laboratory.
IANZ Assessments	A folder structure containing reports from prior technical reassessment and surveillance audits.

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Improvement Requests Each improvement request is given a separate folder iden-

tified by number and description. The original improvement request document and any supporting information is

stored in this folder.

Internal Audits A folder structure with a folder for each round of internal

audits.

International Comparisons A folder structure containing documents related to the

participation of MSL in international measurement com-

parisons.

MQC documents A folder of MSL Quality Council working documents.

MSL Publications A folder structure containing records associated with pub-

lication of a Book, Book chapter, Conference Proceedings, MSL Consultancy Report, MSL Technical Guide, MSL Training Course, Peer-reviewed journal, Presentation, Proficiency Test, Software, Technical Publication (not peer

reviewed) or Technical Report.

Quality Manual A folder containing this document, a number of guidance

documents that supplement this manual, and some forms

used by the QMS.

Risks and Opportunities This folder contains a deprecated spreadsheet. Risks and

Opportunities are now stored in JIRA, see section 10.1 of

this Quality Manual.

Signing Delegations A folder containing a spreadsheet with a list of the people

with delegated authority to sign for the Chief Metrologist

and for the Quality Manager

Technical Competencies A folder containing subfolders for each person in MSL

within an entry in the Technical Competency Matrix. Each person's folder contains documents presented to the Quality Manager as evidence of an individual's competency. The 'Technical Competencies List' is a spreadsheet at the top level folder and is the official record of MSL technical

competencies.

Technical Procedure

Records

A folder structure containing a copy of the validation cover sheet and other supporting validation documents, such as

the change history, for each validated technical procedure.

Validated Procedures

Register

A folder containing the spreadsheet 'Validated Procedure List' of MSL Technical Procedures with information about

their validation status.

4.2.1 The MSL Quality Manual

The documents listed in this table form the MSL Quality Manual.

Full Name

Quality Policy Statement (signed)

Quality Manual (this document)

Guidelines on Measurement Uncertainty

Guidelines on Reporting and Publishing

Note, 'Guidelines' documents are considered appendices of the Quality Manual and contain detailed information on various topics.

Amendments to the Quality Manual Any MSL Member, or staff member of the MSL group, may request a change to the Quality Manual.

Requests for additions, changes, and deletions to the MSL Quality Manual shall be made using the improvement request procedure (see 10.2.1). It is the responsibility of the MQC to decide what changes shall be made.

4.3 Section file systems

Sections maintain a file system containing technical records, such as raw and processed data and records of the checking metrological reports, as well as other section-specific documents, such as: technical procedures, a software register, an equipment register, staff training records, correspondence, complaints and feedback, etc.

A document that describes the structure and operation of this file system will be available. A master document list shall be maintained. This list shall refer to, as a minimum, the following items:

- · A register of Technical Procedures.
- · A register of files other than commercial job files.
- · A register of software used.

Each item in the master document list shall identify:

• The document (name)

- The document location(s)
- · The responsibility for maintaining the document

4.3.1 Technical procedure files

Sections have a number of technical procedures that describe specific technical activities (see §??). These procedures and documents related to them are filed by the section.

Note, the validity status of all technical procedures is recorded in the 'Validated Procedure List' spreadsheet in the central file system. The report prepared by the validation team when a procedure is validated is stored in the Technical Procedures Records folder.

4.3.2 Technical records

Sections shall retain records of original measurements and derived data. The integrity of data and information in these records will be maintained; they shall be protected against tampering and loss.

Technical records provide a traceable link between the item under calibration and the issued calibration report. The records shall include sufficient information to enable identification of the factors contributing to the measurement uncertainty obtained and, if possible, allow the calibration to be repeated under equivalent conditions. The records shall identify the individuals who carried out the calibration and checked the results.

Amended technical records shall be traceable back to previous or original versions. Original and amended data files shall be retained and a record kept of the changes made, the personnel responsible and the date of changes. Technical records shall be retained indefinitely.

4.3.3 Commercial jobs

Documents related to the contractual arrangements for commercial jobs are managed within section quality systems. A job register is available for use within JIRA, though its use is not mandatory and sections are free to implement their own method instead.

4.3.4 Software register

Each section maintains the software used to carry out technical procedures. A software register will uniquely identify the software used with each technical procedure (including version numbers and its location).

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4.3.5 Staff training records

A Training Record file will be maintained for each Member of the section, including contracted personnel. The file will record professional development activities and events, including relevant authorisations, approval of technical competencies (worker, checker, etc), educational and professional qualifications, training, skills and other experience. Training records must be available during audits and assessments.

4.3.6 Equipment registers

Each section will maintain an equipment register. The information in the register shall include:

- Description
- · Company asset register number
- · Manufacturer/supplier
- Model number
- · Serial number
- · Location
- · Purchase date
- · Calibration history
- · Maintenance history

Other information may be included, as appropriate, such as:

- · Service agent
- Warranty expiry date
- · Usage and personnel restrictions
- · References and manuals
- · Accessories

4.3.7 Correspondence, complaints and feedback

Correspondence may be filed at the discretion of the recipient in MSL. The appropriate location for filing the correspondence is also discretionary. A record of all complaints should be maintained. Complaints must be handled by raising an Improvement Request (see §??).

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Sections should keep records of positive feedback on work and services provided as well as client suggestions for improvement.

4.4 Technical Procedures

Sections use technical procedure documents to describe specific activities.

Technical procedures primarily describe how to carry out technical tasks. They are written for the person who will operate the procedure, which could be the author in several years time, or a colleague familiar only in general terms with the area. A procedure should contain sufficient information to enable a colleague to carry out the procedure in the absence of the author or include references to such information. It should also contain instructions on how to ensure confidence in the integrity of equipment used or contain references to such instructions.

Technical procedures need to be validated. They should contain a concise description of the relevant measurement science, sufficient for the purposes of reviewing the procedure for validation. References to relevant technical documents may be used if they are readily available.

Technical procedures are validated for a definite time period (no more than 5 years). The validation is on the authority of the Quality Manager, based the recommendation of a validation team.

4.4.1 Technical procedure structure

A technical procedure document will contain the following sections:

- Title, Author(s), Date
- Change history
- · Purpose and Description
- Health and Safety. This section will highlight Health and Safety issues related to operation of the procedure, e.g.: chemicals, cryogenic, electrical, radiation hazards, etc. It should reference any other documentation relating to the procedure or the equipment used, such as SOPs or MSDSs.

If the technical procedure is also functioning as an SOP then this section shall identify any hazards associated with operating the procedure, the risks posed by those hazards, and the controls for the risks. If controls (e.g. use of PPE) are associated with specific tasks or steps within the procedure then these should also be indicated at the appropriate places in the procedure description.

Note, SOPs must be reviewed annually. So, this requirement shall be planned for by the section independently of the validation requirements of the technical procedure. It may also be helpful to clearly identify technical procedures that contain SOPs.

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- Environment and equipment (information about the equipment and environmental requirements)
- If the procedure may be used outside MSL labs this needs to be stated, the limitations on the
 off-site environment need to be documented and any additional requirements for off-site work,
 including health & safety precautions, need to be indicated
- CMC support (information about the IANZ classes and the BIPM CMCs that apply to results obtained, and the corresponding best uncertainties)
- References and Records (to papers, reports, manuals, files, computer programmes and files, laboratory books, and any other material that is needed to establish validation)
- Supporting procedures (this may be a standalone section or a subsection of References and Records). When critical traceability (i.e. directly determining the measurand) is derived from another procedure then that relationship must be acknowledged. Any procedure that is used to produce a value (even if that value is part of a traceability chain and will not be reported) must be in validation when used, or else when a report is issued. A dependency diagram may be helpful to explain how critical traceability is derived.

Note, any supporting procedure must be in validation when used to generate a value that is part of a traceability chain, unless a calibration report is issued directly to report the result, in which case the procedure should be valid when the report is issued.

- Action (a description of what must be done, which may be in the form of a convenient guide or check list for the person carrying out the procedure) Note: controls (e.g. use of PPE) associated with specific tasks or steps may be required, see Health and Safety above.
- Validation (any other information required to validate the procedure, such as measurement traceability and uncertainty calculations)

Other section headings may be used if appropriate.

A technical procedure may describe quality-assurance activities that provide evidence of satisfactory performance of the measurement capabilities used. This may be needed to comply with MSL's quality assurance policy (see §??).

4.4.2 Amendments to technical procedures

Amendments to a technical procedure can be made at any time.

In general, an amended procedure must be re-validated. However, minor amendments can be made during the period of validity without triggering a full revalidation, provided that the date of the change is noted, as well as the people who made the change and reviewed it. These annotations must be made on the authoritative version of the procedure and incorporated in the procedure at the next validation.

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A minor amendment is one that does not significantly change the method or its implementation, such as some additional explanation or detail. When the authoritative version of the technical procedure is printed, handwritten amendments may be made. When the authoritative version of the technical procedure is an electronic file, minor amendments may be made to the electronic file, as long as the procedure for making these amendments is documented.

Changes might be made to one part of a procedure that do not impact on the validity of other parts. In such cases, the unaffected parts may continue to be used without re-validation. Nevertheless, the claim that parts remain valid must be reviewed, and the reasons for accepting the claim noted on the authoritative version of the procedure.

4.4.3 Technical procedure validation (and revalidation)

- A validation team, which must include at least one person with 'reviewer' competency for the
 procedure, will review a procedure and report on its validity. The author of the procedure may
 not be a member of this team.
- · The team will check that:
 - the procedure is suitable for its intended purpose
 - evidence is provided that the physical process is sound
 - health and safety issues have been considered
 - evidence of measurement traceability has been provided
 - the process is described in enough detail to be carried out efficiently at a later date
 - the uncertainty analysis is complete and adequately documented (Note, the GUM approach to uncertainty analysis is based on the notion of a measurement model. It is strongly recommended that technical procedures provide such a model)
 - there is sufficient evidence to support the uncertainty claimed, such as
 - * an example of the least measurement uncertainty
 - * results from a measurement comparison
 - references to MSL's IANZ scope of accreditation and entries in the BIPM CMC database should be included as appropriate
 - references and records are readily available
 - the requirements for data processing software have been adequately specified and that the software implementation has been validated
 - there are system and performance checks to provide on-going quality assurance in keeping with MSL's quality assurance policy (see §??)
 - there is a list of things to watch out for (easily made mistakes, misunderstandings, etc),
 with comments as necessary
 - there is a suggested re-validation interval (no more than 5 years)
 - all staff identified in the TCM in respect to the procedure (i.e., author, worker, etc) have maintained the relevant competency

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- If any of the points above are found to be unsatisfactory the author will be asked to make suitable changes.
- When re-validating a procedure, the validation team should ensure that material remains current (e.g., references, diagrams, etc)
- The team will complete a Validation Cover Sheet (available in the Quality Manual folder in AODocs) and submit this, and the procedure, to the Quality Manager.
- The review team will ensure that a record of their analysis and notes about the procedure review are filed with technical procedure documents in the section's file system.
- The Quality Manager will sign the Validation Cover Sheet to accept the validation. Alternatively, the Quality Manager may direct the validation team to reconsider part of their review.
- The Quality Manager will ensure that information about a procedure is updated in the Validated Procedure Register (see §??) and that a copy of the cover sheet and change history is saved in the Technical Procedure Records library in the central files.

When a technical procedure is validated, a new version number is allocated.

Archival copies of all superseded technical procedures shall be retained by the section indefinitely.

4.4.4 Validated Procedure Register

A Validated Procedure Register keeps track of the status of all MSL technical procedures. Entries in this register identify the procedure, the version number and the period of validity.

The Validated Procedure Register is a the spreadsheet 'Validated Procedure List' stored in the Validated Procedure Folder of the AODocs library (see §??).

Procedure to modify the Validated Procedure Register

- Following the review of a procedure by a validation team, a summary of the review will be
 presented to the Quality Manager, in the form of a validation cover sheet and a complete change
 history, as well as a copy of the procedure document.
- The Quality Manager will sign the cover sheet if satisfied with the review.
- One copy of the cover sheet will be filed, by the section, with the technical procedure.
- Scanned copies of the cover sheet and change history will be uploaded to the Technical Procedure Records folder in AODocs.
- The corresponding entry in the register will be updated (by the Section's usual Chief Metrologist delegate checker) and checked by the Quality Manager (who sets the 'approve' attribute of the item – this change is recorded by the AODocs versioning system).

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4.4.5 Documentary standards

Sections will ensure that copies of documentary standards required to carry out technical procedures, or referenced in technical procedures, are up to date. In general, the Callaghan Innovation Library should be consulted on how best to check for currency.

For instance, British Standards may be borrowed on a long-term basis from the Library, which will ensure automatic notification of updates. This includes any ISO or IEC standards that have been adopted in the UK by BSI. However, for other types of documentary standards (e.g. ASTMs, API, AS/NZS, AS) there is no updating/alerting in place.

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5 Competencies, Training and Professional Development

MSL recognises that its most valuable assets are the technical competencies of staff. The performance and reputation of MSL as a respected National Metrology Institute is founded on the calibre and achievements of its members.

MSL also recognises that to acquire, develop and maintain competencies, staff will become involved in a variety of training and professional development activities. Such as (but not limited to):

- · providing or receiving mentoring;
- participating in technical meetings, such as scientific conferences, seminars and specialist metrology workshops;
- secondments to other institutions, to acquire knowledge or skills not available at MSL;
- formal study, such as tertiary programmes and professional development courses;
- · conducting scientific research.

5.1 Training and Professional Development Planning

MSL will ensure that staff have the technical competencies required to carry out all relevant present and anticipated tasks.

Training and development needs will be identified by Team Managers in consultation with each staff member and development plans will be prepared and reviewed at regular intervals. Such planning will consider technical training needs and any requirements to ensure on-going technical competence.

A record of all training and professional development activities will be maintained for each individual (see §??). Among other things, these records support formal recognition of technical competencies. They must therefore contain evidence that required standards of competency have been achieved. This evidence will be validated by a mentor (e.g., indicated by initialling relevant documents in the training record, lab notebooks, etc) who will then prepare a summary of evidence for the Quality Manager, for final approval.

Sometimes, technical competencies are recognised based on the prior experience of an individual. In such cases, a justification for the competency claimed will be filed in the staff member's training record and validated by the Chief Metrologist, before final approval by the Quality Manager.

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5.2 Mentoring

Mentoring is an important aspect of professional development at MSL. It is the primary means for transfer of expertise from senior to junior metrologists. It is also the primary method for evaluating and validating technical competence.

The Team Manager, in consultation with the Quality Manager or Chief Metrologist, will assign suitable mentor(s) to a staff member. The purpose of mentoring, and an expected time frame to achieve the goals set, will be noted and filed as a note or memo in the training records of both the staff member and the mentor. Note, an individual may have several mentors concurrently.

5.2.1 Working under supervision

While someone is acquiring experience in a particular competency, they will generally work under the supervision of a mentor. In such cases, the mentor assumes responsibility for the work outputs of the mentee. In particular, if a staff member is working under supervision on a commercial job, careful records must be kept (e.g., in the lab book or job file) to show that the mentor has supervised the work and accepts responsibility for the mentee's activities.

5.3 Technical Competency Classes

There is a set of five competency classes used to classify competencies. Two classes relate to the development and maintenance of technical procedures, two relate to the execution of test and calibration work and one relates to the authority to issue IANZ-endorsed reports.

Author An author can develop new technical procedures (and other technical material, e.g.: technical guides).

Note, although 'author' suggests the preparation of written material, the core competency is development of technical procedures, which includes appropriate documentation.

Reviewer A reviewer can review material prepared by an 'author'.

Worker A worker is considered competent to execute a particular technical procedure for test or calibration work, and to prepare the test or calibration report.

Checker A checker can review work done by a 'worker'.

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Key Technical Person A person with authority to issue IANZ-endorsed test, calibration or measurement reports.

5.3.1 Competency requirements for different classes

The particular competencies expected of an author, reviewer, worker and checker vary across the different technical areas in MSL. In some sections, checking a report amounts to little more than verifying that numbers have been transposed without error, while in others checking requires a detailed understanding of the measurement principles.

Core requirements

Technical staff in MSL will all have an appropriate set of skills, experience and knowledge in a technical area, or a related field, including:

- · science, engineering, mathematics and statistics;
- instrumentation and measurement techniques;
- software development, testing and validation;
- traceability and ISO 17025 requirements.

Author

An author is expected to have appropriate skills, experience and knowledge in the particular competency area.

Appropriate training may involve the development of technical procedures, including written material, under supervision.

An author in training is usually mentored by someone with 'reviewer' competency in the same, or a closely related area. A person with 'author' competency in the same area could act as mentor.

Reviewer

A reviewer is expected to have an appropriate set of skills, experience and knowledge in a particular technical area to adequately review technical material prepared by an 'author'. In addition, a reviewer is generally expected to have sufficient knowledge of the technical processes involved in the particular competency to be able to mentor all other roles.

A reviewer in training is usually someone with several years of experience in the same, or a closely related area; a mentor for a reviewer will usually be someone with 'reviewer' competency in the same, or a closely related, area.

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Appropriate training may involve the critical review of technical material under supervision.

Worker

A worker in a particular technical area is expected to

- understand the technical basis of the relevant technical procedures, specifically an understanding of the key influence quantities and be able to recognise when something has gone wrong with a measurement;
- have successfully operated the relevant technical procedures an appropriate number of times under minimal supervision.

A worker in training is usually mentored by someone with 'reviewer' competency in the same area. A 'worker' in the same competency could act as mentor.

Appropriate training will generally involve working under supervision but may also include the development of skills in operating instrumentation and software systems, an understanding of relevant measurement uncertainty concepts and knowledge about ISO 17025.

A checker in a particular technical area is expected to have an appropriate set of skills, experience and knowledge to be able to adequately review the output of a 'worker'.

A checker in training is usually mentored by someone with 'reviewer' competency in the same area. A person with 'checker' competency in the same area could act as mentor.

Appropriate training may involve reviewing test or calibration work and reports under supervision. An appropriate understanding of relevant instrumentation and software systems, measurement uncertainty concepts and knowledge about ISO 17025 is also required.

Key technical person

Someone with Key Technical Person (KTP) status is authorised to issue measurement, calibration and test reports endorsed with the IANZ accreditation logo. In doing so, they take full responsibility for the validity of the work.

KTP are experienced staff. They shall hold at least three of the competency classes: Worker, Checker, Author and Reviewer, for the technical procedure in which KTP competency is recognised. They shall also be familiar with MSL's quality management system, with the IANZ rules pertaining to the use of IANZ endorsement and with the requirements of the ISO/IEC 17025 standard.

KTP competency will be approved by the Quality Manager.

Applications for KTP competency must be in writing and shall include a brief CV for IANZ (see figure ??). Evidence supporting the competency shall be available (usually individual training records)

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when the application is made.

An example showing the format for an IANZ CV follows:

Name	Blair Hall
Position	Principal research scientist
MSL technical section	RF and microwave
IANZ Classes	5.93(b), 5.95
Qualification (highest relevant)	Doctorate
Relevant experience	Worked in RF and microwave at MSL since 1998;
-	Designed and developed all current MSL RF and microwave
	standards and services;
	Attended ISO/IEC 17025 training by NZQC
	(for both 2005 and 2017 standards);
	Written more than 100 reports and research papers in the field of radio and microwave frequency metrology;
	Provided training courses in RF and microwave metrology
	in NZ and abroad;
	Acted as technical expert for IANZ audits of NZ calibration
	laboratories since 2009;
	Participated in an international measurement comparison
	for calibration factor of RF power meters (APMP.EM.RF-K8.CL).

Figure 2: An example of the type of CV required by IANZ for a new Key Technical Person.

5.4 The Technical Competency Matrix

A register of technical competencies, called the Technical Competency Matrix (TCM – see ??), is maintained.

The Quality Manager may add or delete TCM entries.

Competency, once established, is reviewed during revalidation of technical procedures (see §??). The review team shall ensure that each qualified individual (worker, author, etc) has maintained competency and is aware of any changes to the procedure. This will be noted on the validation report.

5.4.1 Procedure for adding a technical competency

A competency may be added:

• The mentor will provide the Quality Manager with a summary of the individual's training and experience in support of the competency claim (in some cases the Chief Metrologist, rather than a mentor, will validate evidence in support of a competency and present it to the Quality Manager, see §??). Note, there is a Training Record Template in the AODocs Quality Management System Library, but any document will do.

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When requesting KTP competency, a mentor is not required. The applicant shall apply to the Quality Manager directly and provide the necessary evidence of competency.

- The Quality Manager can authorise the new competency by signing, if a paper document has been provided, or clearly indicating acceptance by some other means for electronic documents
- One copy is returned to the individual concerned, to be filed in their training record
- Another copy is provided to the Section's usual Chief Metrologist delegate checker, who will
 make a new entry in the TCM (with status 'pending')
- The Quality Manager will verify the TCM change and set the status to 'approved' in the TCM (a record of this is retained by the AODocs versioning system)
- A copy of the documents presented to the Quality Manager in support of the new competency will be saved in the relevant Competency Records folder in AODocs.

5.4.2 Procedure for deleting a technical competency

To remove a competency from the TCM, an application may be made to the Quality Manager by the Team Manager or Chief Metrologist at any time.

- the Quality Manager will consider the application and authorise the requested change (by signing, if the application is on paper, or clearly indicating acceptance by some other means for electronic documents).
- · one copy will be returned to the individual concerned, to be filed in their training record
- another copy will be provided to the EDI site administrator, who will delete the TCM entry and set the status to 'pending'
- the Quality Manager will verify the change and set the TCM item status to 'approved' (recorded by the EDI version control system)
- a copy of the documents presented to the Quality Manager in support of the change will be filed for future reference in the Competency Records library on EDI.

The Quality Manager may delete complete rows in the TCM when a person no longer works with MSL. The Quality Manager shall consult with the Team Manager concerned, or with senior members of the team, before removing the rows (sometimes staff agree to remain available, in special circumstances, for a period of time after leaving MSL).

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6 Reporting and Publishing

MSL staff report on activities in a number of ways. Of particular importance are the metrological reports (calibration and test reports) issued by MSL. These are covered in the next section (§??).

A variety of other works may be produced for 'publication' outside MSL, including:

- · Scientific journal and conference papers (peer-reviewed or not)
- Conference posters + presentation slides
- · Callaghan Innovation technical reports
- · Trade journal articles
- · International measurement comparison reports
- Reports/submissions to technical committees (TCs, CCs, ...)
- · MSL consultancy reports
- · MSL Technical Guides
- · MSL training course slides and notes
- MSL software manuals (for external use)
- · Items for MSL web pages
- Web-based videos (YouTube channel)
- MSL newsletter
- · Publicity material

Section ?? describes MSL policy for this broader category of publication.

Measurement results shall be traceable to primary measurement standards held by MSL, or other NMIs. A statement to this effect is included on all calibration and test report covers (see [?, §4.2]). Any exceptions to this policy must be approved by the Chief Metrologist (see §??).

6.1 Metrological Reports

Metrological reports are of high importance to MSL, so an elaborate system has been developed to ensure that they are of consistently high quality.

6.1.1 Report types

A metrological report will be one of the following types:

Calibration Report - entitled "Report on the Calibration of . . . " or "Report on the Measurement
of "

A Calibration Report is used for IANZ classes beginning "5", except when the instrument or device under test is deemed to be unfit for calibration (in which case the measurement results may be issued in a "Report on the Failure of ...").

Test Report - entitled "Report on the Test of ..."

A Test Report may be used for IANZ classes beginning "5" or "6"

6.1.2 Authority to write and review reports

A person designated as a 'worker' will carry out calibration or test work and write the report; a person designated as a 'checker' will check the measurements and the report. The worker(s) and checker share responsibility for the report.

The last page in the body of the report shall be signed, and all other pages initialled, by the worker, the checker, and the Chief Metrologist (or delegate).

For IANZ-endorsed reports, either the worker or checker signing the report must be a IANZ Key Technical Person for the measurement class(es) covering the measurements.

The report shall be reviewed by the checker with respect to the following:

- there is sufficient documentary evidence of the measurements made;
- the process used is described in a technical procedure, or procedures, and that each procedure used has a current validation and has been correctly interpreted (where 'current validation' is understood to mean that the technical procedure is valid on the report date);
 - Note, see §?? for validity requirements when a supporting procedure provides part of a traceability chain.
- records clearly show who did the checking and what was checked (for routine work a checklist is recommended).

The report must be reviewed by the Chief Metrologist, or delegate, to ensure that:

- the report has been written and checked as required above;
- the report is free of typographical errors or inconsistencies;

- the correct front cover has been used, indicating whether the measurements are within the IANZ scope of accredited services and whether the measurements are within MSL's CMCs (see also §?? regarding measurement conditions);
- for IANZ-endorsed reports, at least one signatory has been approved;
- the report date should normally be less than one month before the date that the report is signed.

6.1.3 Reporting measurement conditions

Sometimes, conditions of measurement are reported that involve quantities from a different technical discipline. For example, when calibrating a thermometry resistance bridge, staff with specialist knowledge in temperature measurement report a value of sensing current (an electrical quantity). Staff qualified to carry out the technical procedure (i.e., who appear in the Technical Competency Matrix for that procedure) are considered to have the expertise to assess associated measurement conditions. This is confirmed by external peer-review of signatories by IANZ. Therefore, reporting of measurement conditions is assumed to be compatible with the MSL scope of accreditation and the signatory status of the staff involved.

6.1.4 Reporting format

Details about the reporting format requirements are given in the Metrological Reports section of the MSL Guidelines on Reporting and Publishing [?, §4].

Statement about applicability of results For most calibration work, the MSL report format clearly identifies the item(s) being calibrated or tested. However, there are some situations where MSL is effectively sent an item or items that may be considered, from the point of view of the client, as a sample from a larger population (e.g., a piece of shade-cloth sent to MSL for characterisation). In all such cases, the MSL report shall clearly state that the results provided relate only to the item(s) actually measured. This is a requirement of the 17025:2018 standard [?, clause 7.8.2.1 (I)].

6.1.5 Issuing Paper Reports and Summary Data

Only one printed report shall be signed and sent to the client.

A scanned copy of this signed report shall be filed in the central file system (see §??).

An electronic copy of the document used to create the report shall be retained in the section file system (see §??).

The client may be supplied with a copy of the scanned PDF version of the signed report, if requested.

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A laminated card of the table of corrections may be supplied to the client, if required. This card will show: the name of the instrument, the serial number of the instrument, the MSL report number and the correction table data. The card will go through the same checking process as described above.

Clients may request calibration information in electronic format, such as an Excel spreadsheet. Such information may be provided, but only after the report has been issued. The electronic data must be checked with the same care given to written reports. Moreover, it should be made clear to the client that the written report remains the authoritative document.

Every effort should be made to ensure that the items calibrated or tested will be returned to the client at the same time as the report. If the report is delayed, the client should be informed. If it is known in advance that the report will be issued after return of the client's items, the client should be advised before the work begins.

6.1.6 Issuing Electronic Reports and Summary Data

- Ensure that a report in electronic format is acceptable to the client.
- The electronic report file shall be signed (see procedure in §??) and a record of this signing process shall be saved in the central file system (see §??).
- Sufficient information about the data and documents used to create the report shall be retained in the section file system to allow the report to be recreated (see §??).
- The client will be supplied with a copy of the electronic report and the MD5 checksum for the file (see "Checking the integrity of a report file", in [?, §4.13]).
- The following message should be provided to the client with the report (make appropriate replacements for <report ID> and <checksum>):

MSL's electronic calibration, test and measurement reports are produced in the same format as paper reports, but are provided as electronic files (PDF format). Distributing electronic reports carries with it a small risk that the file may become corrupted, or inadvertently changed somehow, after it has left MSL. To address this, we provide what is called an MD5 checksum, which allows the integrity of a file to be checked. You can use the MD5 checksum to make sure that the file you receive is valid. MSL Technical Guide 43 explains how to do this (online: https://www.measurement.govt.nz/download/55).

The MD5 checksum for report <report ID> is: <checksum>

 Clients may request other calibration information in electronic format, such as an Excel spreadsheet. Such information may be provided, but only after the report has been issued. The electronic data provided must be checked with the same care given to written reports. Moreover, it should be made clear to the client that the report remains the authoritative document.

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Every effort should be made to ensure that the items calibrated or tested will be returned to the client at the same time as the report. If the report is delayed, the client should be informed. If it is known in advance that the report will be issued after return of the client's items, the client should be advised before the work begins.

6.1.7 Signing electronic reports

Technical information on how to produce a calibration report, with a suitable report cover and electronic signature images, is given in the "Electronic reports" section of [?, §4.12].

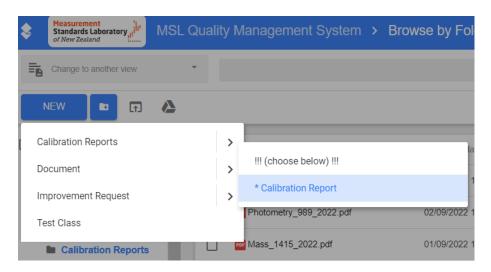
The process required to create a record of signing for the quality system is as follows:

1. Create a PDF version of the report file. Note, the file name should be in the following format:

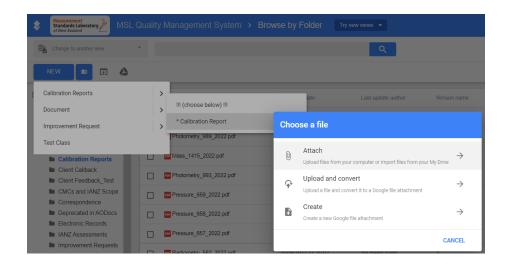
```
"section name"_"section file number"_year
```

2. Upload the PDF file to the "Calibration Reports" class within the AODocs Quality Management System library.

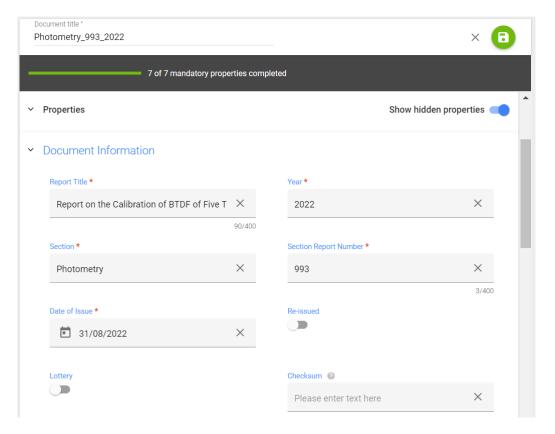
Create new Calibration Report:



Select 'Attach' and navigate to the PDF. Do NOT select 'Upload and convert' or 'Create'.



3. Fill in the metadata for the report. For example,



- 4. The first person can now 'sign' the report by inserting an image of their signature using PDF reader software (see [?, §4.12]). In AODocs, this can be done by the signatory either downloading the PDF, signing and then uploading to the same file name, OR by using the AODocs Universal File Opener (UFO) browser extension. The UFO is the more efficient solution with guidance available through the AODocs MSL Quality Management System home page.
 Note,
 - the file name must not be changed (AODocs maintains a version history based on file name)

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- it is not necessary to initial each page (as is done with paper reports)
- for technical reasons, the document must be opened with a PDF reader running on a local machine (it is not possible to sign and re-store the document directly from a browser)
- 5. The second person can now 'sign', following the process above.
- 6. Chief Metrologist, or delegate, can 'sign'.

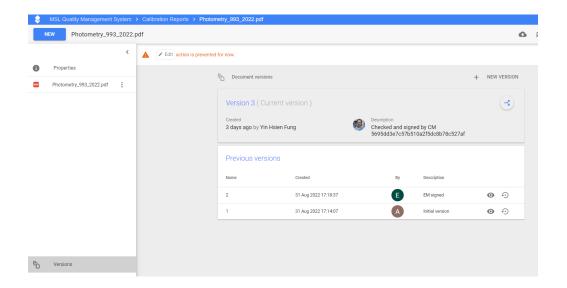
Before uploading the final version, signed by everyone, an MD5 checksum must be calculated (see [?, §4.13]).

The MD5 checksum must be saved in the 'Checksum' property and as a note in the version history.

7. If corrections to the report are necessary during the signing process, the faulty version can be annotated with comments, highlighted sections, etc (using a PDF reader), and uploaded to AODocs. Doing so maintains a full record of the signing/issuing process.

Once corrected, the new report file must be signed again by everyone.

This process generates a version history similar to the one below. All intermediate versions can be reviewed by clicking on the links at the left. Note the checksum in the comment associated with the final version.



6.1.8 Withdrawal due to a reporting or measurement error

If any significant error is found in the most recent report on an instrument or artefact, within five years of first issue, the report must be withdrawn. "Significant" would include a significant error of measurement or data processing, incorrect values, dates, serial numbers, etc, but not simple spelling or typing errors unless these could be misinterpreted.

In order to reissue the report, the instrument or artefact may need to be recalled so the test or calibration can be repeated. A new test date will be used if the test or calibration was repeated.

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Any change of information in the reissued report shall be clearly identified and, where appropriate, the reason for change shall be given.

To withdraw paper reports

- 1. Contact the client and ask for the return of the original report and also that any copies be destroyed.
- 2. On receipt of the original report, stamp all pages "CANCELLED" and initial.
- 3. Where paper photocopies are held by MSL, all pages should be stamped "CANCELLED" and initialled.
- 4. Electronic copies in the central file, and in the section file, should be cancelled:
 - For a PDF file, add the text "CANCELLED" to each page (in red text, with bold, large, font size there are PDF reader programmes that can do this).
 - For the central file copy, the name of the file should not be changed. Rather, the cancelled file should be saved with the same name and a note added about the cancellation in the AODocs version history of the document.
- Produce a corrected report using the original report number. Retain the original issue dates throughout, but add, after each issue date, the words 'reissued on [new issue date]', e.g. 'Report No. Pressure/1997/155, 11 August 1997, reissued on 10 February 2000'.
- 6. Any change of information in the report must be clearly identified and, where appropriate, the reason for the change should be included in the report (some advice on formatting is given in [?, §4.8]).
- 7. Make copies of the signed corrected original and file in the central file and the section file.
 - The name of the central file copy should not be changed (i.e., the new copy of the report replaces the cancelled original).
 - A note should be added in the AODocs version history to indicate a reissued report.
 - If the reissued report is of electronic format instead of paper, upload the final signed reissued report to AODocs. The Chief Metrologist, or delegate, shall add the MD5 to both the version notes and the Checksum property.
 - Set the AODocs 'Re-issued' property to TRUE.
- 8. Reissue the corrected report and the cancelled original report to the client.

To withdraw electronic reports

- 1. Contact the client and ask that any copies be destroyed.
- 2. Electronic copies in the central file, and in the section file, should be cancelled:

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- For a PDF file, add the text "CANCELLED" to each page (in red text, with bold, large, font size there are PDF reader programmes that can do this).
- For the central file copy, the name of the file should not be changed. Rather, the cancelled file should be saved with the same name and a note added about the cancellation in the AODocs version history of the document.
- 3. Produce a corrected report using the original report number. Retain the original issue dates throughout, but add, after each issue date, the words 'reissued on [new issue date]', e.g. 'Report No. Pressure/1997/155, 11 August 1997, reissued on 10 February 2000'.
- 4. Any change of information in the report must be clearly identified and, where appropriate, the reason for the change should be included in the report (some advice on formatting is given in [?, §4.8]).
- 5. Reissue the corrected report to the client with the new MD5 checksum. Send a copy of the cancelled original report to the client.
- 6. File copies of the signed corrected original in the central file and the section file.
 - The name of the central file copy should not be changed (i.e., the new copy of the report replaces the cancelled original).
 - Add a note to the AODocs version history to indicate a reissued report.
 - Upon upload of the final signed reissued report to AODocs, the Chief Metrologist, or delegate, shall add the latest MD5 to both the version notes and the Checksum property.
 Usually the Checksum property will already populated with the MD5 for the prior issued report. This shall be overwritten.
 - · Set the AODocs 'Re-issued' property to TRUE.

Note In general, changes to the central file should only be carried out by an MSL administrator or the Quality Manager. The procedure for signing electronic reports is an exception to this rule.

Finally If appropriate, amend the technical procedure associated with the report to reduce the likelihood of a similar mistake occurring in the future.

Also, if the likelihood of a similar error occurring in the future can be reduced by amending the Quality Manual, follow the Improvement Procedure.

6.1.9 Replacing a report at the client's request

When a report has been lost, a replacement may be issued.

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Electronic reports no special procedure is required to replace an electronic report. Simply dispatch a copy of the report to the client.

There is no need to record the replacement of the report in the central file system.

Paper reports The new report must be identified as a replacement and have a new report issue date (i.e. to ensure that any original is unique). The replacement must be signed and copies stored in the central file and section job file.

- The first replacement of a lost report should be labelled "Replacement of Report ...".
 - Retain the original issue dates throughout but add the words 'reissued on (new issue date)', e.g.: "Replacement of Report No. Pressure/1997/155, 11 August 1997, reissued on 10 February 2000".
 - Any subsequent replacements should be labelled "Second Replacement of Report ...",
 etc.
- Where an original signatory is not available, a person appointed to carry out the test and calibration work, or checking, in the designated field may sign the report per persona (p.p.). The name of the original signatory must remain on the report.
- · Reissue the report to the client.
- File copies of the report in the central file and the section file.
 - The name of the central file copy should not be changed (i.e., the new copy of the report replaces the original).
 - Add a note to indicate a replaced report in the AODocs version history.
 - If the reissued report to the client is of electronic format instead of paper, the Chief Metrologist, or delegate, shall add the MD5 to both the version notes and the Checksum property.
 - Set the AODocs 'Re-issued' property to TRUE.

Note, the client, on request, may be supplied with a copy of an original paper report, in which case the copy is not considered "reissued". However, the client should be advised that the copy is not authoritative and, for example, may not be acceptable in court.

6.1.10 Replacing a report issued with an incorrect report number

A replacement may be issued if a report has been issued with an incorrect report number.

Follow the first steps of the procedure in §?? for re-issuing a report, namely:

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- 1. If a paper report was issued, contact the client and ask for the return of the original report and also that any copies be destroyed.
 - · If an electronic report was issued, ask the client to destroy all copies.
- 2. On receipt of an original paper report, stamp all pages "CANCELLED" and initial.
- 3. Where paper photocopies of paper reports are held by MSL, all pages should be stamped "CANCELLED" and initialled.
- 4. Electronic copies in the central file, and in the section file, should be cancelled:
 - For a PDF file, add "CANCELLED" to each page (in red text, with bold, large, font size there are PDF reader programmes that can do this).
 - Do not change the file name in the central file. Rather, the cancelled file should be saved with the same name and a note added to the AODocs version history of the document about the cancellation.

The rest of the procedure is then as follows:

5. The replacement report should use the correct (new) report number, followed by a line beginning "Replacement of Report ...", which describes the previously issued report. For example,

Report No. Humidity/2020/428, 3 March 2020 Replacement of Report No. Humidity/2020/248, 16 February 2020

- 6. The replacement report must be signed.
 - Where an original signatory is not available, a person appointed to carry out the test and calibration work, or checking, in the designated field may sign the report per persona (p.p.). The name of the original signatory must remain on the report.
- 7. Copies of the report must be stored in the central file and the section file.
 - The name of the central file copy should be the new file name. (The old file name may
 be changed on AODocs without breaking the version history. Seek help from the Quality
 Manager or site administrator to do this before uploading the new version of the file.)
 - The central file metadata tag 'reissued' should be set.
 - Add a note to the AODocs version history to indicate a replaced report.
- 8. Reissue the report.

6.2 MSL Publications policy

This section describes MSL policy for publications in general (other than the measurement reports described in §??). The policy is intended to enhance the science culture within MSL and mitigate risk to MSL's reputation by ensuring consistently high publication standards.

It is intended that

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- One of the MSL authors will take responsibility for coordinating the publication clearance process.
- Every document will be reviewed before publication, and some record of review will be kept.
 The potential for a publication to harm MSL's reputation shall be considered when deciding how to review a document.
- Documents for publication will be made available to all MSL, usually by placing a copy in a common repository (see §??). A record of approvals will be kept with material in the repository
- All measurement results reported shall be traceable to primary measurement standards held by MSL, or other NMIs (see notes below for exceptions)
- No results will be published without the approval of the Chief Metrologist (or delegate)

Notes:

- Sometimes a publication may not seem sufficiently important to warrant a review. However, our experience has been that the review process is always beneficial.
- The ease with which corrective action can be taken, if a problem is recognised after publication, may be taken into account when deciding how to review a document (e.g., it is easy to change material on the MSL website, but much harder to correct mistakes in an external publication).
- The review record (in the repository) may briefly record that the work has been considered by someone to be of acceptable quality (a template for publication clearance is provided). Where appropriate, more detailed records of review can be kept.
- Vigilance is needed to avoid unintentional publication of untraceable measurements. A notable example was the time-of-day widget displayed on the MSL website as 'Official Time'.¹
- Very rarely, untraceable measurements may be approved for publication by the Chief Metrologist.
 In such cases, a clear statement about the lack of traceability must accompany the results (see
 the section 'Informal reporting of measurements' in the Guidelines on Reporting and Publishing
 [?, §4.11]).

It may at the same time be possible to offer useful advice. For instance,

This time-of-day display is affected by unpredictable transmission delays between MSL and the display device. It should not be used as a time standard. Advice on how to obtain accurate time services from MSL is available here link to guides>.

- Some material may be produced too close to the time of publication to allow for review—slides
 for a technical presentation, for example. The material should nevertheless be placed in the
 repository as soon as possible.
- There may be situations where it is sensible for records related to a publication to be stored elsewhere from the repository.

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¹Note, all traceable measurements will include an uncertainty statement and documentation that can be independently checked as evidence of traceability and accuracy.

6.2.1 Responsibilities

- One MSL author will take the 'lead' and be responsible for coordinating the publications clearance process.
- It is the Quality Manager's responsibility to review the material, but this authority is usually delegated to a reviewer proposed by the lead author.
- It is the responsibility of the lead author's Team Manager to consider potential issues related to confidentiality, impartiality or intellectual property.
- It is the lead author's responsibility to ensure that a final copy of the material is placed in the
 repository, with a record of the review, and to advise the Quality Manager when the publications
 clearance process has been completed.

6.2.2 MSL publications repository

The MSL Publications library is the common repository for publications. It is a folder within the 'MSL Quality Management System' library in AODocs. Various categories of document can be stored there, including:

- · Peer-reviewed journal article
- Conference proceedings article
- · Book chapter
- Book
- · MSL Technical Guide
- · Callaghan Innovation technical report
- · MSL Training Course
- · Conference presentation
- · Conference poster
- · MSL consultancy report
- Software

6.2.3 Publications clearance form

A Publication Clearance Form can be used to record the review of a publication in the repository. The form is available within AODocs by navigating to the Publications folder then selecting New > Document > Publication Clearance.

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The version control system in AODocs keeps track of the different individuals who contribute to the clearance process (e.g., a Team Manager can save comments about IP issues before, or after, a technical review by someone in the team). Extra rows can be added to the form for authors or reviewers (a table structure is used in the form).

A Publication Clearance Form template is provided for convenience, but other types of document could also be used to keep a record of review. The form has been designed for technical reports and scientific papers (i.e., traditional types of scientific publication).

6.2.4 Publication led by another organisation

When MSL staff are co-authors in a publication that is led by an external organisation, the publication process will probably follow that organisations policies, not MSL's.

Nevertheless, there should be an agreement, between MSL and other parties, about the nature of the collaboration, intellectual property, confidentiality, etc. This agreement should allow MSL staff to approve any final draft before it is submitted to a journal or a conference. If any measurements are reported, MSL authors should ensure that our metrological traceability policy is followed (see §??).

The Publications folder should be used to store the final manuscript draft, and a record of MSL staff approval for submission. Other information, such as the agreement between authors, may also be saved in the library.

6.3 Guidelines for authors and reviewers

All material must be presented clearly for the intended audience.

Technical material will be of appropriate scientific rigour and technical correctness.

Material will be of appropriate visual appearance and graphic standards (see [?, §3]). Sometimes existing documents can serve as a guide, and templates for some types of publication are available.

When the document will be published by an external body, such as a trade journal, authors should try to check proofs prior to publication. This is very important when the publisher is unfamiliar with typesetting mathematical symbols, units and equations.

6.3.1 Check lists

The following lists may be helpful

Scientific papers (journals and conference papers)

- · Review for technical correctness.
- Review for clarity of expression and the consistent use of mathematical language and symbols. If available, follow a publisher's guidelines, otherwise ([?, §3] contains advice).
- Review tables and figures for consistency of appearance and clarity. Follow the publisher's style guide, if available, otherwise see [?, §3].
- Check bibliographic references. Follow the publisher's style guide, if available.
- Is any part of the work covered by third party agreements? If so, is the publication consistent with those agreements?
- · Are any IP protection steps needed before publication?
- Have all contributors been acknowledged?
- · Are all authors satisfied with the final draft?
- · Has funding been acknowledged?

Sometimes, a last-minute rush before a conference deadline limits the time available for review. Nevertheless, many of the points above can already be checked using early drafts of the work, before the final version is ready. In particular, the issues of concern to a Team Manager can usually be anticipated.

Trade journals

- Follow the points listed above for scientific papers.
- Is the writing suitable for the intended audience?
- Remember to insist on a review of proofs before publication.

Callaghan Innovation technical reports

- Follow the points listed above for scientific papers.
- Consider publishing under a Creative Commons licence (see [?, §6]).
- Has a report number been allocated by the Library?

Note the Library keeps its own archival copy of a report in an EDI bucket, which is created at the same time as a report number is issued. So a PDF copy of the final version of the report should be stored there and the status attribute of the bucket modified accordingly.

Consult Library staff if you need assistance with this process.

Technical Guides

- Templates for Technical Guides are kept with the current guide documents on the G-drive (look for: G:\Shared drives\MSL Private\Technical Guides).
- MSL Technical Guides should be readily identifiable as a product of MSL. They should display the MSL logo on the front page and include generic contact information for MSL (email, www).
- The current MSL email contact is: info@measurement.govt.nz.
- The current MSL website URL is: www.measurement.govt.nz.
- Make sure the guide has been allocated an MSL technical guide number.
- A version number and date of publication should appear on the front page.
- The person responsible for the Technical Guide should be identified, but individual contact details should not be given.
- · Review for technical correctness.
- Review for clarity of expression and consistent use of mathematical language and symbols (see [?, §3] for useful advice).
- Review tables and figures for consistency of appearance and clarity (see [?, §3]).
- · Check bibliographic references.
- Use a Creative Commons licence (see [?, §6]).

Training course slides and notes In most cases, PowerPoint slides will be combined with slide notes to produce handouts for attendees (although some courses provide a separate booklet).

- · Make sure that the cover page is easily identifiable as a product of MSL (name, logo, etc)
- Make sure there is a description of the course structure and learning objectives
- Make sure that there is support for navigating the notes (e.g., contents, page numbering, section breaks, etc)
- · Review material for technical correctness.
- Review material for suitability and for continuity of ideas (is the message clear; are things being introduced in the right order; are there unnecessary bits that could distract attention?)
- · Review for clarity of expression and consistent use of mathematical language and symbols.
- · Check any bibliographic references.
- Consider publishing under a Creative Commons licence (see [?, §6]).

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Posters and presentations

- Follow the points listed above for scientific papers.
- Make sure that the work is easily identifiable as a product of MSL (use of name and logo, contact details, web URL, etc). Templates are available, or recycle an existing document.

Often, posters and presentations are not reviewed, because there is not enough time. Nevertheless, the final work should still be made available in the repository.

Articles for the MSL website It is important that quality principles be applied to material intended for the MSL website. MSL has tended to underestimate the importance of checking this kind of publication.

Substantial pieces should be reviewed and a record of the review kept (a good example is the clearance record of a Callaghan Innovation report 'Maori measurement student project', which also led to a website publication). Smaller pieces can be approved with an email.

- Make sure that the science is correct and that the writing is suitable for a general reader (these
 objectives may be difficult to reconcile)
- · Make sure that copyright (especially for images) has been respected
- Make sure that all contributors have been suitably acknowledged and that all individuals concerned are satisfied with the final text
- If parties external to MSL are involved, ensure that they too are satisfied with the publication
- Check references to other documents, in particular hyper-links. Consider the robustness of hyper-links (e.g., it may be possible to use a search in a URL, rather than a direct file reference)

6.3.2 MSL consultancy reports

MSL consultancy reports are written in the form of a letter, unless specific format is requested by, or deemed appropriate for, the client. A consultancy report must NOT be used to present the results of measurements. Any such results shall be contained in a separate test report to which reference may be made in the consultancy report.

A report must be checked by the Quality Manager or nominee primarily for soundness of approach to the problem and clarity of exposition. The Quality Manager shall also check whether:

- · The author is qualified to write the report
- · The opinions expressed are fundamentally sound

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• The ramifications of the report (legal, financial etc) require that it be approved at a higher level (e.g. Group Manager)

A copy, signed by both the author and the checker, shall be deposited in the publications repository (see §??).

6.3.3 Reporting on international measurement comparisons

Reports on MSL participation in international comparisons should be made in the form of a calibration report, unless another format is dictated by the requirements of the comparison. In any case, the report will be checked as if it were a calibration report.

6.3.4 Acknowledgement of national standards funding

Suitable wording to acknowledge the funding of national standards is either:

This work was funded by the New Zealand Government

or

This work was funded in part by the New Zealand Government

Such wording should normally be included in an Acknowledgements section at the end of works appearing in external publications, such as scientific journals and conference proceedings.

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7 Inwards and outwards goods control

It is important that all inwards goods be tracked and delivered promptly to the appropriate staff member without loss or damage. This includes all items received for testing, calibration, examination, use on client work or otherwise borrowed or leased by MSL.

It is also important that outwards goods are properly packaged and dispatched to ensure prompt service and to avoid loss or liability due to damage.

7.1 Inwards goods procedure

Any member of MSL who accepts inwards goods must follow this procedure.

7.1.1 Documentation

Goods Log Book A "Goods Log Book" may be used to record the date of receipt, item, client name, recipient for each client item handled. Alternatively, this information may be recorded electronically as part of the section file system.

Goods Control Form Alternatively, a "Goods Control Form" may be used to record the details above. The form may be used to record further detail, such as enumerating the contents of a package. The form will be filed in the job records in the section file system.

A Goods Control Form must be used if goods are received damaged.

A template Goods Control Form is provided in the Quality Manual folder within the MSL Quality Management System AODocs site.

Goods control label A small, removable, self-adhesive label marked with MSL, section name and identifying the job, may be used in addition to a Goods Control Form or Goods Log Book. Where appropriate, the label may be attached to a plastic luggage tag tied to the goods or its packaging.

7.1.2 Client goods

Including all items received for testing, calibration, examination, use on client work or otherwise borrowed or leased by MSL.

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- The person who accepts the goods shall arrange transfer to an appropriate member of MSL staff.
- The MSL staff member shall record the arrival of the goods in the Goods Log Book (or alternative as outlined above) and to inspect for damage.
- If the goods are damaged, or need a detailed description, a Goods Control Form shall be used.
 If the goods may be confused with others in the workplace, or are at risk of being mislaid, they should be labelled with goods control labels.
- Every person having custody of goods is required to ensure safe storage and handling.
- If goods are accepted prior to receipt of a contract or Work Order Agreement signed by the client, then a signed contract shall be sought immediately.

7.2 Outwards goods procedure

Any member of MSL with goods for dispatch must follow this procedure.

7.2.1 Documentation

Goods Log Book A "Goods Log Book" may be used to record the date of despatch, the despatcher's details and the carrier for each client item handled. Alternatively, this information may be recorded electronically as part of the section file system.

Goods Control Form Another alternative is to record details on a "Goods Control Form", which will be filed within job records in the section file system.

A "Goods Control Form" can be used to record additional details, such as enumerating the contents of a package.

7.2.2 Packaging

- When returning goods, check that everything that arrived is present, using the Goods Control Form or Goods log book.
- · Use suitable packaging.
- Attach a clear label to the package with the client's address.
- When the goods are classed as dangerous goods, refer to corporate dangerous goods procedures

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7.2.3 Dispatch

The organisation's Logistics department handles the dispatch of goods from the site.

- Callaghan Innovation's Courier Request Form should be completed and accompany the package.
- Logistics must be advised that a package is ready for dispatch.
- The client may be advised that the package is being dispatched
- Details of the dispatch should be entered in the Goods control form or Goods log book and a copy of the courier request form stored with job records in the section file system

7.2.4 Goods on loan from MSL

When goods are lent to other MSL staff or to staff in the parent organisation, a record shall be kept in a section Loan Book, or a Goods Log Book, or be recorded electronically as part of the section file system. The record will show the time and date of despatch, the borrower's name, phone number or email and location.

When MSL goods are leased, or sent outside the organisation on loan, or for repair, modification, compatibility testing, etc, a record shall be made in the Goods Log Book or be recorded electronically as part of the section file system.

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8 Audits and reviews

8.1 Internal Audits

A comprehensive internal audit of MSL technical sections and of the quality management system must be carried out annually.

It is the responsibility of the Quality Manager to plan and organize internal audits, to appoint audit teams, and to ensure that actions in response to the findings of the audits are carried out. The audits will be held at a time convenient to both the audit team and the section members.

Some sections are sub-divided into smaller technical areas (e.g., Photometry and Radiometry, Mass and Pressure, Temperature and Humidity). Audits of these areas alternate, so each is audited biennially.

The QMS audit complements the technical section audits by reviewing overarching aspects of the quality management system. The review should look at those parts of the QMS that have not been delegated to technical sections, such as the central filing system, improvements, meetings, etc. A subset of clauses from the standard will be reviewed each year (MSL QS form). When selecting clauses, consideration should be given to those already covered in recent audits.

For all audits, a summary of corrective actions and recommendations from previous audits, as well as any IRFs associated with the section, should be reviewed by audit teams before conducting an audit: a response should be recorded against each recommendation arising from earlier audits. A record of previous internal audit findings is kept in the Internal Audit Register in the MQC Documents library of the central file system. A summary of corrective actions and recommendations from previous IANZ audits is kept in the IANZ Audit Register, also in the MQC Documents library of the central file system.

The audit team shall identify any quality system non-compliance by requesting a corrective action (CAR). The audit team may also recommend improvements (R) and make suggestions (S).

Within one week of the audit, the audit team shall produce a report on the scope, findings and decided actions in response to the audit, and provide a copy of that report to the Team Manager and section members involved in the audit. Corrective actions, recommendations and suggestions shall be clearly listed in the audit report (e.g. C1, R1, S1 etc). An Internal Audit Check-list may be used to assist documentation of the audit process for technical sections (there is an audit form template available in the docset (bucket) of the Internal Audits library).

The Team Manager shall sign the report to indicate acceptance of the audit findings (if areas of disagreement cannot be resolved, they may be noted on the signed document). Corrective actions arising from the audit shall be raised immediately as improvement requests (IRFs) by the Team Manager.

The report will be provided to the Quality Manager no later than two weeks after the audit. The Quality

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Manager will sign the report when satisfied (and after ensuring that any IRFs have been raised).

A copy of the report will be filed in the Internal Audits library of the central file system. The Internal Audit Register file in the MQC Documents library will be updated by the Quality Manager.

8.2 Management review

A management review of MSL will be carried out annually by the laboratory's top management.

The purpose of the review is to assess the suitability and effectiveness of the laboratory's management system, calibration and testing activities, and to introduce any necessary changes or improvements.

Guidelines have been prepared for panellists involved in the review [?].

8.2.1 Management review procedure

- The Quality Manager will organise a management review once every twelve months.
- The review team shall consist of, at least, the MSL Group Manager, an MSL Leadership Team member, and a member of the MQC.
- The review is intended to assess the suitability and effectiveness of the MQS and shall consider, at least:
 - The previous management review report;
 - Reports from the Quality Manager, the Chief Metrologist and the Team Managers;
 - Submissions from staff
- The Quality Manager shall report on the effectiveness of the quality system since the previous management review. In particular:
 - Status of quality objectives;
 - Status of external and internal audits;
 - Status of improvement requests, risks and opportunities;
 - Activities of the Measurement Quality Council;
 - Assessments of customer satisfaction;
 - Suitability of policies and procedures;
 - Other factors, such as monitoring activities and staff training.
- The Chief Metrologist shall report on the effectiveness of MSL as New Zealand's NMI. In particular:
 - The suitability and effectiveness of technical competencies and technical section measurement capabilities;

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- MSL's participation in international measurement comparisons;
- MSL's scientific activities and outputs.
- Team Managers shall report on the effectiveness of the technical sections in their teams. In particular:
 - Changes in the volume and type of work or in the range of activities;
 - Resources, staffing and technical competencies;
 - Improvement requests, risks and opportunities;
 - Outcomes of external and internal audits;
 - Traceability, standards maintenance, development and quality assurance;
 - Scientific activity and output.

(Note, where bullet points under Team Manager reporting coincide with items under the Quality Manager or Chief Metrologist reporting, it is intended that Team Managers report on specific details for their technical sections.)

- The review team shall produce a report on any decisions and actions in relation to, at least:
 - The effectiveness of the management system and its processes;
 - Improvements to laboratory;
 - Provision of required resources;
 - Any needs for change.
- The report will be filed in the MSL Main AO Docs library. Management shall ensure that actions are carried out within an appropriate and agreed time frame.

Note that quality system issues are discussed at monthly MSL Leadership Team meetings attended by the Quality Manager, the Chief Metrologist, the Team Managers and the Director. This is considered another part of the management review process.

8.2.2 Management review reporting

The Quality Manager will ensure that MSL staff are made aware of the new Quality Objectives for the year.

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9 Review of requests and contracts

9.1 Policy

This policy covers calibration, testing and consultancy work for clients inside and outside the organisation.

Any new request shall be reviewed to determine whether the work requested is adequately defined, whether MSL has an appropriate capability and sufficient resources to undertake the work, and whether the service can be supplied in an acceptable timeframe.

A record of the review will be kept with other job records in the section file system.

As a provider of testing services, it is important to understand the nature of the service that a client is requesting. If there are any differences between the request and the work that will be carried out at MSL, including the timeframe, these differences must be resolved before a contract is agreed.

9.1.1 Confidentiality

MSL must keep confidential all information obtained from clients, and we must inform the client of this responsibility. The organisation's Work Order Agreement clearly states this, and, in most cases, a Work Order Agreement will be signed by the client.

However, when a Work Order Agreement is not used, the client must be made aware of MSL's responsibility to keep information confidential. In such cases (expected to be jobs of very low monetary value), the following text may be adapted to the particular work and given to the client (e.g., by email):

Further to our agreement that Callaghan Innovation will conduct work for you, being to [insert] (Work), please note that we will maintain as confidential at all times all information that you share with us in any form, except as reasonably required for the purpose of the Work or where we are required by law or governmental authority, or where authorised by you.

9.1.2 Additional work for IANZ

IANZ engages MSL for ad hoc services from time to time. The nature of these jobs is varied. Examples include: a request for a technical guidance document about a specific type of measurement; review of existing documents; the technical evaluation of documents supporting a scope extension by one of IANZ's clients; review of software tools.

The review of a new request from IANZ is also covered by this policy.

There is a streamlined process for registering and managing IANZ work, which available as an alternative to the usual job registration process. If this streamlined process is used, the record of review should be filed in the generic job for that section's IANZ work.

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10 Improvements

MSL will continually improve the effectiveness of its quality management system. The laboratory shall take a proactive approach: rather than merely checking for conformity, we will actively seek to identify potential risks and opportunities for improvement.

There are two mechanisms for formally identifying issues with the quality management system, or opportunities to improve it. One is the MSL 'Improvement Request' (IRF) process, the other is the Risks and Opportunities register. Any member of MSL may raise an improvement request or add an item to the Risks and Opportunities register.

The Risks and Opportunities register was introduced by 17025:2017. We generally use it as a way to flag things that would previously have been classified as "preventative actions" under 17025:2005. The register records potential issues or opportunities at an early stage, allowing them to be managed. Entries may grow (as an opportunity or potential issue is realised) or disappear. Entries that grow will usually be promoted to an IRF.

The IRF process is used when non-conformities are identified (corrective actions) and when substantial opportunities for improvement arise, or potential future instances of non-conformity arise (formerly called "preventative actions"). The IRF process allows detailed documentation to be collected about an issue, it's context, discussions and actions taken. Note that risks to business continuity, health and safety, conflicts of interest are managed by other corporate policies.

10.1 Risks and Opportunities

The laboratory needs to review risks and opportunities to the quality management system regularly, just as risks and opportunities related to Health and Safety, etc, are reviewed.

The MSL implementation of Risk and Opportunities uses the Callaghan Innovation Risk Management Framework and is implemented as the JIRA Smart Risk project (https://callaghaninnovation.atlassian.net/jira/software/c/projects/CISR/boards/122). Instructions for creating a new risk are available at https://sites.google.com/callaghaninnovation.govt.nz/msl-qms/home/risk-and-opportunities-register

Each Risk or Opportunity entered records the nature of a risk or opportunity, assigns a Reporter, Assignee, Risk Owner, possible contingencies (planning) should the issue arise, and the most recent review taken (with the date).

Note: The Reporter is set by default as the person logged in while raising the risk in JIRA. Assignee and Risk Owner are initially set to the Reporter's manager. The appropriate people to be Assignee and Risk Owner are reassigned as appropriate when the risk is initially reviewed by the management team.

This register shall be reviewed regularly by the MQC and by the MSL Leadership group. It is the responsibility of MSL management to ensure that staff are consulted regularly.

The Risks and Opportunities in JIRA act as a light-weight register; as soon as an item in the register becomes substantial, an IRF will usually be raised.

10.2 Improvement requests (IRF)

Improvement requests may arise in relation to instances of non-conformity, as well as when an opportunity for improvement or a potential future source of non-conformity is identified.

Improvement requests may be generated by different types of activity, including internal and external audits, analysis of data, management reviews, and customer feedback.

A corrective action must be undertaken when a quality problem is identified. This process is documented and managed within the quality system using an IRF. A complaint (or someone simply drawing attention to a quality problem) originating from outside MSL should also trigger an IRF (see §??).

It is important to recognise that a corrective action is intended to address and preferably eliminate the underlying cause of a problem, not merely correct a detected non-conformity. There will be occasions when the appropriate response to a non-conformity is just a simple correction, but more generally a corrective action should determine the root cause of a non-conformity and eliminate that cause. The effectiveness of a corrective action will be monitored by the MQC to ensure that it has been successful. An improvement request will be considered closed when the MQC is satisfied that the action has been effective.

Whenever a potential non-conformity or needed improvement is identified, this finding can also be raised as an IRF. The IRF should then be investigated to determine a suitable preventative action to avoid or mitigate an occurrence of a non-conformity or to improve the system. While an opportunity to strengthen the quality system may be identified, the risk of not carrying out a preventative action should be weighed against the potential benefits. If a decision is made not to proceed with a preventative action, the justification for this decision needs to be recorded in the IRF.

The effectiveness of a preventative action will be monitored by the MQC. The MQC will decide on the most appropriate monitoring process and the IRF will remain open until MQC is satisfied that the action has been effective.

10.2.1 IRF procedure

Improvement requests are currently managed using the Improvement Request folder within the central file system (see ??).

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Instructions on how to raise a new IRF are provided on the MSL Quality Management System help site, or for convenience

https://sites.google.com/callaghaninnovation.govt.nz/msl-qms/home/improvement-requests.

The person raising the IRF should fill in the first part of the Improvement Request form, including a description of any immediate action that has been taken.

Once the initial IRF form has been submitted to the Quality Manager, the Quality Manager shall

- · assign a number to the IRF using the IRF register
- create a new subfolder, identified by the new IRF number and description, within the Improvement Requests folder in the AODocs Quality Management System site
- · move the original submitted IRF form to the new folder
- notify the submitter of the IRF of the IRF number and folder location documents
- · consider whether any immediate action needs taken and initiate any suitable action

The Quality manager and MQC will review each improvement request. They will consider whether an underlying cause has been identified and if not, they will take necessary measures to do so. After identifying the root cause, an appropriate corrective or preventative action will be determined, and an appropriate monitoring process will be put in place to evaluate the effectiveness of the action. The MQC will be responsible for determining when to stop monitoring.

The status of IRFs in the central file system progresses through four states:

Status	Comment
New	The IRF has been raised, but not yet reviewed by the MQC.
Reviewed	The MQC has considered the IRF. A suitable action will be chosen and carried out during this phase.
Completed	The effectiveness of the action will be monitored during this phase.
Closed	The improvement request is closed; the action is considered effective by the MQC.

10.3 Complaints

Complaints provide valuable feedback on the operation of a quality system. The issues raised should be investigated in the same manner as any other quality problem.

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A complaint may simply consist of notification, by someone external to MSL, of a quality issue. For example, something wrong with the MSL Talking Clock.

The issue should be verified, and the complaint acknowledged.

- If the issue is minor and can be dealt with immediately, then do so;
- If the complaint is substantial but straight forward, try to negotiate a solution with the complainant;
- · If the complaint is too complicated, inform the Team or Group Manager

In all cases of complaint, an improvement request (IRF) must be raised. The responsibility for this lies with the person receiving the complaint but may be passed to another appropriate member of MSL.

The MQC will review the IRF (see ??), to ensure that the root cause is identified and that an appropriate corrective action is carried out. The MQC will also ensure that a complaint has been acknowledged and that, where appropriate, the complainant is updated on progress until the issue is resolved (e.g., a negotiated solution has been actioned).

Communication with the complainant shall be made, or reviewed and approved, by staff not directly involved in the activity in question.

When the issue has been resolved, the MQC will recommend a suitable closing action. In most cases, the Team or Group Manager will contact the complainant to ensure that the outcome is satisfactory.

A record of all complaints should be maintained by MSL sections. Records of positive feedback and client suggestions for improvements should also be kept. (note, this 'Complaints Section' of the Quality Manual can be made available to any interested party.)

10.4 Assessing Client Satisfaction

10.4.1 Call backs

MSL contacts a fraction of clients shortly after work is complete to assess satisfaction.

The intention of the call-back process is to contact roughly 25% of clients and to record their feedback. The call should be made within roughly a month of the work being done.

A selection of clients can be achieved by a running lottery of jobs completed, or by simply choosing clients. Our policy is to avoid calling a client twice within a 24-month period.

The person making the call-back will keep a record of the conversation, which is filed centrally in the Client Callbacks library.

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Callback records are reviewed by the MQC and a register of call-backs is maintained in the MSL Quality Management System AODocs library.

10.4.2 Client survey

A formal client survey will be carried out occasionally. The timing of surveys will be determined by MSL management.

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11 Project management

11.1 Science research project management

Scientific research projects cannot be project-managed in the way that many other technical activities can. Research is, by its nature, unpredictable. In research, one does not know exactly what will be found, where it will be found, or how long it will take to find. So, MSL manages research in a flexible way that provides transparency and allows projects to evolve and adapt.

MSL maintains a portfolio of science projects that are reviewed annually to ensure research goals and strategies remain sensible and robust. The review process is intended to raise the visibility of these activities within MSL and to encourage discussion and engagement across the laboratory. The reviews also provide an opportunity to consider future resourcing requirements.

Every year, projects give a brief presentation (Tea-Time-Talk), summarising activities in the recent past (12-18 months) and outlining proposed activities (12-18 months). The audience is MSL. A written summary is prepared. The presentation documents (slides and summary) are retained from year to year, to capture project outcomes and evolution.

New R&D proposals present an explanation of the project and how it sits within MSL's strategies. Again, a written summary, together with presentation slides, is retained. Sizeable projects may need to provide a "road map" of anticipated milestones and resourcing requirements over a longer time span, so that an initial assessment of programme feasibility can be made.

In evaluating projects, it is as impossible to pick "winners" as is it is to identify "losers". Nevertheless, there are some basic attributes of a good project:

- Natural Inclination: A project that harnesses the natural inclinations, interests and expertise of the individuals involved will yield considerably better results than a directed approach.
- Benefit to MSL: Research activities and goals will align with MSL's strategy and contribute to the development of informal-knowledge and expertise.
- Feasibility: Projects will be financially and logistically feasible. The resources required must be reasonable, including capital equipment, laboratory space, FTE, etc.
- Quality and Diversity: It is unwise for MSL to concentrate research activities and resources
 narrowly; but it is also unwise to support research activities of poor quality. Projects should
 (or, in the early stages, have the potential to) deliver high-quality research outcomes (see
 figure ??).

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Figure 3: A schematic representation of science research project policy.

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A Abbreviations

Abbreviation	Stands For
APMP	Asia Pacific Metrology Programme
BIPM	Bureau International des Poids et Mesures
CC	Consultative Committee of the BIPM
CGPM	Conférence Générale des Poids et Mesures
CIPM	Comité International des Poids et Mesures
CMC	Calibration and Measurement Capability
DI	Designated Institute
EDRMS	Electronic Document and Records Management System
EU	European Union
IANZ	International Accreditation New Zealand
ILAC	International Laboratory Accreditation Cooperation
JCRB	Joint Committee of Regional Metrology Bodies
KCDB	Key comparison database (of the BIPM)
MOU	Memorandum of Understanding
MQC	MSL Quality Council
MRA	Mutual Recognition Arrangement
MSL	Measurement Standards Laboratory of New Zealand
NMIA	National Measurement Institute, Australia
QMS	Quality Management System
RMO	Regional Metrology Organisation
SI	Système International d'Unités (International System of Units)
ТСМ	Technical Competency Matrix

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B Calendar of responsibilities

When prefixed by an asterisk, the "Frequency" in this table is a requirement (e.g., *Monthly), otherwise it is a recommendation.

Role	Responsibility	Frequency
Quality Manager	Organise an internal audit of all sections	Annually
Quality Manager	Ensure that a Management Review is held	Annually

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C ISO/IEC 17025 Cross-reference

Some cross-references between sections in the ISO 17025:2005 and 17025:2017 standards and sections in this Quality Manual. Click on the section number in the 'This document' column.

This document	17025:2017	17025:2005
Organisational structure §??	5.5	4.1
Impartiality §??	4.1	-
Documents and Document Control §??	7.5, 8.2, 8.3, 8.4	4.3
Technical competency records §??	6.2	4.1.5 f)
Quality Assurance Policy §??	7.7	5.9
Quality Policy Statement (page ??)	6.2.6	5.2.5
Equipment register §??	6.4.13	5.5.5
MSL Technical Procedures §??	7.2	5.4
Competencies, Training and Professional Development §??	6.2	5.2
Mentoring §??	5.5 b)	4.1.5 g)
Metrological Reports §??	7.8	5.10
Reissue of reports §??	7.8.8	5.10.9
Inwards and Outwards goods §??	7.4	5.8
Internal Audit §??	8.8	4.15
Management Review §??	8.9	4.15
Review of Requests and Contracts §??	7.1	4.4
Confidentiality §??	4.2	-
Improvements §??	8.5, 8.6, 8.7	4.8, 4.10, 4.11, 4.12
Complaints §??	7.9	4.8
Client satisfaction §??	8.6.2	-

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D References

- [1] Comité International des Poids et Mesures, Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, Paris, 14 October 1999 (http://www.bipm.org/en/cipm-mra/).
- [2] Metre Convention (Convention du Mètre), also known as the Treaty of the Metre, is an international treaty that was signed in Paris on 20 May 1875. The treaty set up an institute for the purpose of coordinating international metrology and for coordinating the development of the metric system. In 1960, the system of units it had established was overhauled and relaunched as the "International System of Units" (SI).
- [3] New Zealand Standard, ISO-IEC 17025:2018, General requirements for the competence of testing and calibration laboratories, Standards New Zealand, Wellington, 2018.
- [4] Measurement Standards Act 1992, http://www.legislation.govt.nz/act/public/1992/0052/latest/whole.html
- [5] National Standards Regulations, http://www.legislation.govt.nz/regulation/public/2019/0091/latest/whole.html
- [6] Guidelines on Reporting and Publishing: A supplement to the MSL Quality Manual (in the AODocs MSL Quality Management System library)
- [7] Management Review Panel Guidelines (in the AODocs MSL Quality Management System library)
- [8] CIPM/2009-24: Traceability in the CIPM MRA, https://www.bipm.org/en/cipm-mra/ cipm-mra-documents/
- [9] ILAC-P10:07/2020: ILAC Policy on Metrological Traceability of Measurement Results, https://ilac.org/publications-and-resources/ilac-policy-series/

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