

**specific criteria
for accreditation**

Electrical Testing

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1 Introduction

International Accreditation New Zealand (IANZ) Specific Criteria amplify or particularise the IANZ general accreditation criteria, for specific fields of technology or for specific types of business activity.

A list of all Criteria documents published to date is available from IANZ on request or can be viewed on www.ianz.govt.nz/publications. Specific Criteria 3 defines specific technical requirements for accreditation of electrical testing laboratories.

This schedule must be read together with current issues of the IANZ general criteria for accreditation NZS ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*, and *Procedures and Conditions of Accreditation*, the latter document describing the organisation and operation of the IANZ Accreditation Programmes.

This schedule provides information on classes of test (Appendix 1), staff, accommodation, equipment and other aspects of good laboratory management practice which are considered a minimum standard for electrical laboratories.

2 Scope

This criteria schedule sets out the specific requirements an electrical testing laboratory has to meet, in addition to the general requirements of NZS ISO/IEC 17025, if it is to be accredited by IANZ.

3 Definitions

Uncertainty, calibration

Definitions of these terms and other terms relating to measurements are contained in *International Vocabulary of Basic and General Terms in Metrology* (VIM) (see references).

4 Classes of Test

IANZ Accreditation does not constitute a blanket approval of all of a laboratory's activities. The classes of test are an arbitrary subdivision of the potential range of activities involved in electrical testing on the basis of the type of measurements being made, the scientific disciplines involved and the techniques employed. It is therefore possible for a particular test or technique to be included under several classes of test. These classes and subclasses do not, however, constitute any restriction on the work which a laboratory can perform but provide a convenient means of expressing an accredited laboratory's capabilities.

Accreditation is normally granted only for work which is performed regularly and for which the laboratory is properly equipped and has demonstrated its capability. The extent of a laboratory's scope of accreditation will therefore vary with the range of work performed, the scope and complexity of the tests involved, the competence and organisation of laboratory staff and the level of technology available in the laboratory.

The field of Electrical Testing covers tests of an essentially electrical nature performed on instruments, equipment, appliances, components, and materials (classes of test are attached in Appendix 1). The calibration of electrical and electronic instruments and equipment is included in the Metrology and Calibration field.

5 Laboratory Accommodation and Safety

5.1 Accommodation

Accommodation requirements for electrical testing laboratories vary quite widely depending upon the nature of the items to be tested and the uncertainty with which measurements are to be made. A formal

laboratory area will be required for precise electrical measurements but many measurements and tests can be satisfactorily performed in production areas or in the field.

Formal laboratory areas must have good lighting (400-500 lux), adequate bench space, freedom from dust and fumes, freedom from vibration and acoustic noise and have appropriate control of temperature and humidity. The extent to which these environmental factors apply will vary according to the precision (uncertainty) with which measurements are made.

When precise measurements are to be made in laboratories, the following factors may assume greater importance:

- (a) Isolation from sources of mechanical vibration and shock likely to have a detrimental effect on sensitive instruments, e.g. lifts, plant rooms, busy roads, etc
- (b) Smooth, antistatic finishes for walls, ceilings and floors and, where necessary, air filtration to facilitate dust control
- (c) Double glazing of windows and shading from direct sunlight
- (d) Temperature control of the laboratory where relevant but in any case with variation less than 2 °C per hour
- (e) Humidity control as required (typically in the range 35 % to 70 % RH)
- (f) Isolation from electromagnetic interference. This is less likely to be necessary for DC and low frequency AC measurements but assumes importance at RF frequencies. Screening may be necessary for some precise electrical measurements (see particular requirements for Open Area Test Sites-OATS below). Radiation from local transmitters and computer equipment may be a hazard to many measurements and its effects may need to be assessed
- (g) Stabilisation or filtering of incoming mains power supply where purity of waveform and constancy of voltage is important
- (h) Management of the laboratory environment by regular cleaning
- (i) Freedom from fumes which are likely to have an adverse effect on equipment (and staff).

5.1.1 Open Area Test Sites (OATS)

OATS must comply with the requirements of CISPR 16.

For category (d) sites, pre-OATS scanning of the device under test (DUT) must be carried out in a screened room and any emissions that could be masked by ambient emissions must be identified in the report.

Note: Use of a screened room for EMC emission measurement is not currently an option under CISPR procedures.

Site attenuation tests must be carried out regularly as required by CSIPR 16.

5.2 Safety

Electrical testing laboratories are expected to comply with the New Zealand Electricity Regulations. Laboratories performing electrical approval tests must have at least two staff members present during approval tests.

Joint Australian/New Zealand Standard AS/NZS 2243 is recommended as a guide to safe practices in laboratories. Part 1 of this Standard provides general guidelines.

5.3 Access to Test Areas

Laboratories carrying out type tests on electrical equipment will be expected to control access to test areas to provide security for new client designs and innovative technical solutions, particularly where the laboratory is contained within a production facility and performs tests on other company's products.

It is the responsibility of all laboratory staff and their management to ensure that they comply with the Health and Safety in Employment Act.

6 Laboratory Equipment Management and Calibration

Management and calibration requirements for equipment are given in clauses 5.5 and 5.6 of NZS ISO/IEC 17025:2005.

Guidelines on calibration intervals for laboratory equipment are given in Appendix 2.

6.1 Traceability

Traceability of measurement is ensured when there is an unbroken chain of comparisons of equipment of known uncertainty which link one measurement result to the next and eventually to a national standard of measurement (and therefore to the SI system). Each link in the chain compares equipment with reference equipment of the same or (usually) smaller uncertainty and may involve reference artefacts or materials.

The concept of traceability also includes the competence of all the people involved, the fitness of each measurement environment, the suitability of the methods used and all other aspects of the quality and technical systems involved at each step in the chain of measurements.

Traceability must be established for all critical* measurement and calibration equipment either:

- (a) Directly to the national metrology institute (IRL - Measurement Standards Laboratory) or another such national body (e.g. NPL - UK, NMI - Australia) that is a part of the international mutual recognition arrangement for NMIs
- (b) From an IANZ accredited calibration laboratory which is accredited for the particular measurement **or** which is accredited by a national accreditation body (such as NATA, UKAS, etc) with which IANZ has a mutual recognition arrangement
- (c) The calibration certificates issued by accredited laboratories must be endorsed in accordance with the requirements of the accreditation bodies concerned. This constitutes proof of traceability to national standards.

**Critical measurements/calibrations are those which will significantly affect the accuracy or proper performance of tests.*

IRL Industrial Research Limited
NPL National Physical Laboratory
NMI National Measurement Institute, Australia

6.2 Calibration

Calibration involves controlled comparison of the device under test (DUT) against a "known" instrument over the range of values of use of the DUT. The differences between the "known" instrument and the DUT are tabulated for a range of pre-selected calibration points. The uncertainty and these differences must be reported for the comparison process. Electrical laboratories must obtain such calibration certificates for all critical measuring equipment. Alternatively, they may perform comparisons in-house themselves where they have appropriate reference equipment and can demonstrate performance to a documented method. Uncertainty of measurement must be determined for internal calibration of critical items.

Where electrical instruments submitted to a calibration laboratory are likely to be adjusted, appropriate "as received" measurements must be requested by the submitting electrical laboratory. The full calibration is then carried out after the adjustment. If this procedure is not followed, then historical stability data is lost along with the electrical laboratory's ability to take appropriate corrective action on out-of-calibration equipment. Historical stability data can be used to justify extending calibration intervals.

When the laboratory's reference equipment contains software adjustments for calibration purposes, these adjustments must be made only by the laboratory carrying out the reference equipment calibration.

6.3 Performance Verification

The manufacturer's performance verification against the equipment specification is not considered to be a calibration unless an appropriate range of the instrument's hardware and software is covered. The reporting requirements of 6.2 must be followed by the calibration laboratory.

6.4 Electronic Instruments

Electronic and software controlled instruments are acceptable as reference devices providing their long term stability and total uncertainty are considered appropriate (see Appendix 2 - Calibration Intervals).

7 Laboratory Staff

NZS ISO/IEC 17025 gives the general requirements for laboratory staff and management. The requirements for laboratory approved signatories are set out in Appendix 3.

Staff assessing products for conformance with electrical safety requirements will be expected to have a tertiary electrical engineering or related qualification and to have extensive knowledge of the risks against which protection is required e.g. electric shock, fire, burning of skin and of other important aspects of the relevant test specifications.

Staff assessing products for conformance with EMC requirements will be expected to have a tertiary electrical engineering or related qualification and to have extensive knowledge of the risks against which protection is required e.g. the effect of unwanted emissions on other users of the spectrum, the effect of emissions on critical electrical and electronic equipment such as medical equipment for critical care, air traffic control equipment, etc. In addition, staff seeking signatory approval would need to be familiar with immunity requirements for equipment under test as specified in the relevant test specifications.

Staff assessing products for conformance with Telecom New Zealand, Australian Communications and Media Authority (ACMA) or similar telecommunications requirements will be expected to have a tertiary electrical engineering or related qualification and to have extensive knowledge of the electrical safety risks against which protection is required e.g. the risks associated with any low voltage items which form a part of the telecommunications terminal equipment (TTE), the additional risks to the public switched telephone network (PSTN) posed by the low voltage equipment, the additional risks to the network introduced by the PSTN side of the TTE. Testing staff would be expected to be familiar with relevant test specifications.

Laboratory staff performing electrical safety type tests, tests on TTE and EMC tests within a production facility must be independent of the production management and any influence or direction from that management that could affect the proper outcome of the tests. They would also be expected to have a good knowledge, **whether they use it to advise clients or not**, of the design types and general component arrangements that provide physical protection to the product, network or user against such risks.

8 Laboratory Test Methods

Where test methods and in-house calibration methods are based on standard test methods or manufacturer's methods, these must be tailored for the laboratory's own test equipment. Calibration procedures must exercise all relevant parts of the hardware and software of the instrument, particularly for in-house calibration purposes.

9 Uncertainty of Measurement

Electrical testing laboratories certifying conformance with specification limits for electrical safety and electromagnetic compatibility tests must define and document a policy on calculation of measurement uncertainties (see the first three references for guidance). *Note: The second is preferred.*

The policy must include consideration of all contributions to uncertainty (type A and type B) and must define the method the laboratory will use to combine these effects and the confidence interval within which the test result can be expressed. Where relevant, measurement uncertainties must be reported in test reports.

When test results lie within the uncertainty band about a specification limit, the laboratory must define its policy on reporting conformance and must report the uncertainty.

10 Identification of Test Items

Test/inspection items must be uniquely and unambiguously identified. This may include circuit diagrams, block diagrams, operating manuals, board layouts, photographs, drawings as well as the version and configuration of any software used in the item. For type testing, in particular, accurate characterisation of the design type that was certified as complying is critical.

The test/inspection item submitted for final approval must be representative of production. Any modifications made to the hardware or software of the item to enable it to comply must also be explicitly identified in the records of the test unless the test is to be completely repeated.

11 Reports and Records

Reports covering electrical safety testing or EMC type tests must cover all clauses of the applicable test method. Where any clause is not applied, the report must clearly show that it is not relevant or the report must refer to another report where those clauses were assessed.

When test methods relating to particular appliances or equipment call up clauses from generic methods such as AS/NZS 3100, AS/NZS 60335.1, or AS/NZS 3350, then the report must clearly and unambiguously show that these have been covered in the tests. One way to ensure that is to use the testing report format of the IECCE CB Scheme.

Reports covering retests of equipment that has previously failed to comply must clearly show what modifications have been made to the equipment/appliance and where these are partial tests, must make clear reference to the earlier report covering the other compliant clauses. Where complete retests are carried out, detail of modifications is not as important as specifying the new design with drawings, photos, layouts, PCB designs, etc.

Where cords, switches, plugs, etc. are complied on the basis of test reports supplied by the customer, these must be:

- (a) From a laboratory accredited by IANZ or by a national laboratory accreditation authority with which IANZ has a mutual recognition arrangement or from a CB accredited laboratory, and
- (b) The applicable report must be referenced as required by IANZ subcontracting criteria (see NZS ISO/IEC 17025:2005 Clause 4.5 and the appendix in *Procedures and Conditions of Accreditation*).

12 Computer-Controlled Test Equipment

Appropriate quality assurance is needed of all in-house developed software (see NZS ISO/IEC 17025:2005, 5.4.7.2). Automatic test equipment must be calibrated in a similar manner to other equipment being calibrated.

The following comments apply to the use of computers for direct data capture and control of the calibration operation. Where control is by proprietary software such as that supplied with some calibrators, validation will only be required of the individual calibration routines for instruments and not for the programme supplied by the manufacturer.

For in-house developed software, standard packages of raw data can be developed for feeding through the system to check routines on development or modification of the system. Care should be taken to ensure that such packages cover the expected range of values and include combinations of peculiar circumstances to highlight faults in basic logic of the programme or its subroutines. Alternative systems using spreadsheets or other software may also be used.

Reference artefacts may be held to check the operation of the whole system at appropriate intervals.

The results of this testing should be recorded and incorporated in the maintenance history. Software maintenance should include a back-up regime and a system recovery plan.

Electronic data must be treated in an equivalent way to hard copy to ensure it is not lost or changed without an audit trail.

13 Proficiency Testing

Proficiency testing is defined as the “Determination of laboratory testing performance by means of interlaboratory comparisons” (ISO/IEC Guide 2:2004) and is thus a very important tool in a laboratory’s quality control programme to demonstrate the validity and comparability of results.

In accordance with the policy of the Asia Pacific Laboratory Accreditation Co-operation (APLAC), to which IANZ is a full member of their Mutual Recognition Arrangement (MRA), (see Reference 10), it is IANZ policy that applicant/accredited electrical testing laboratories shall:

- (a) Demonstrate their technical competence by satisfactory participation in proficiency testing activity where such activity is available, and that
- (b) The minimum amount of appropriate proficiency testing required per laboratory is one activity prior to gaining accreditation, followed by participation in as many inter-laboratory comparison programmes (where available) required to cover the scope of accreditation.

Aside from the issues of coverage and frequency, laboratories are expected to select proficiency testing activities according to the following criteria (in a generally decreasing order of preference):

- (a) Mandated programmes (where relevant)
- (b) International inter-laboratory comparison programmes
- (c) National inter-laboratory comparison programmes
- (d) Proficiency testing programmes operated in accordance with ISO/IEC Guide 43: Part 1
- (e) Formal inter-laboratory comparison programmes involving several independent laboratories
- (f) Less formal inter-laboratory comparison programmes between two or more laboratories
- (g) Where none of the above is available or applicable, intra-laboratory comparisons between technicians within the same laboratory could be considered a valid proficiency testing activity.

Participation in a programme is of little value without the combined results being analysed to determine the nature of any discrepancies and the effect of this on any routine test results. Discrepancies may be in the order of expected uncertainty or they may indicate a serious shortcoming in a laboratory’s procedure. It is important for laboratories to have undertaken this analysis and to have adequately determined and implemented appropriate corrective action.

Records of the above analysis and any action taken of all proficiency testing results are required, including those for which no further action is considered appropriate i.e. satisfactory results.

The results from proficiency testing activities and their analysis will be viewed by IANZ at each assessment.

13.1 APLAC Proficiency Testing Programmes

From time to time APLAC arranges for proficiency testing programmes to be run and expects accredited laboratories in all economies which are members of the MRA to participate. (The European Accreditation (EA) co-operation also operates similar programmes and the following comments apply equally given that IANZ is also a member of the EA MRA.)

On receipt of an invitation to participate, IANZ nominates (usually to a maximum of four) accredited laboratories to participate, provided the programme is relevant to their scope of accreditation. Nominated laboratories are expected to participate (usually no fee is charged) unless there are valid reasons for not doing so.

The results from these APLAC Proficiency Testing Programmes are required to be treated by IANZ in a formal manner. Both the participating laboratories and IANZ receive a copy of the report. Where a particular laboratory has outlier or non-conforming results, they will be required to submit to IANZ detail on the investigations conducted and any corrective action taken. (It should be noted that all accredited laboratories in any inter-laboratory comparison programme are expected to do this, but would not normally report it to IANZ. Such records would be reviewed at the next on-site visit.)

IANZ staff will review the response and comment where appropriate. The records will also be reviewed at subsequent on-site assessments – particularly by a technical assessor where appropriate.

It should be noted that APLAC Proficiency Testing Programmes are as much a measure of the IANZ performance in accrediting laboratories as they are a measure of the participating laboratories' performance. The co-operation of the nominated laboratories is appreciated by IANZ.

14 References

1. *The expression of Uncertainty and Confidence in Measurement for Calibration*, NAMAS M3003, Edition 2, Jan 2007.
2. *Guide to the Expression of Uncertainty in Measurement (GUM)*, 1995, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, and OIML.
3. *Radio Equipment and Systems; Uncertainties in the measurement of mobile radio equipment characteristics*, ETSI Report ETR 028, Edition 2, 1994
4. *International Vocabulary of Basic and General Terms in Metrology (VIM)*, 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.
5. *Procedures and Conditions of Accreditation*, IANZ AS 1.
6. CISPR 16-1: *Specification for Radio Disturbance and Immunity Measuring Apparatus and Methods*, Part 1: Radio Disturbance and Immunity Measuring Apparatus
7. *The Electricity Regulations*, 1997.
8. NZS ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*
9. Health and Safety in Employment Act, 1992
10. APLAC MR-001: *Procedures for Establishing and Maintaining Mutual Recognition Arrangements amongst Accreditation Bodies*.

APPENDIX 1 Classes of Test

Laboratories are accredited for classes of test. Individual laboratories may be accredited for the performance of a single class of test, for any combination of the classes of test listed or even for one specific test within a class of test.

Divisions in the list of classes of test are based essentially on the nature of instruments, equipment, components or materials under test. While some exceptions to the general principle have been inevitable, this method of division of the field has been adopted to reduce repetition. As the scope of accreditation of any individual laboratory normally details the range of frequency, current, voltage, etc, in which measurements are made, it is possible for each class of test to cover the work of laboratories with widely differing interests.

The list of classes of test is used with flexibility to ensure that the scope of accreditation of each laboratory is fully informative, to the advantage of both the laboratory and its clients.

3.01 Conductors and Resistance Alloys

3.02 Resistors, Resistance Boxes and Potential Dividers

3.03 Insulators and Insulating Materials

- (a) Electric strength tests
- (b) Insulation resistance tests
- (c) Surface and volume resistivity tests
- (d) Loss tangent tests
- (e) Relative permittivity tests
- (f) Direct voltage tests
- (g) Alternating voltage tests
- (h) Tracking
- (i) Dielectric dispersion coefficient
- (j) Moisture absorption
- (k) Insulating oils and oil insulated systems
- (l) Ageing
- (m) Partial discharge tests
- (n) Impulse voltage tests
- (o) Thermal stability tests
- (p) Other tests

3.05 Magnetic Materials and Magnetic Instruments

- (a) Magnetic materials
- (b) Magnets, solenoids and Helmholtz coils
- (c) Magnetic permeameters
- (d) Magnetic frames and squares
- (e) Fluxmeters
- (f) Magnetometers and search coils
- (g) Hibbert magnetic standards and other flux linkage generators
- (h) Flux density meters

3.20 Cells and Batteries

- (a) Primary cells
- (b) Accumulators
- (c) Power conditioners

3.21 Power Supplies and Stabilisers

- (a) Power supplies
- (b) Stabilisers
- (c) Power conditioners

3.23 Power Rectifiers and Switches

- (a) Rotary, vibratory, and other mechanical types
- (b) Silicon controlled rectifiers and allied control devices
- (c) Vacuum tube rectifiers
- (d) Semiconductor rectifiers

3.24 Electronic Components

- (a) Fixed resistors
- (b) Capacitors
- (c) Semi-conductor devices
- (d) Printed circuits
- (e) Connectors
- (f) Relays
- (g) Integrated circuits
- (h) Other components and sub-assemblies

3.25 Communications Equipment

- (a) Line transmission measuring equipment
- (b) Radio transmission measuring equipment
- (c) Field intensity measuring equipment
- (d) Electrical noise and interference measuring equipment
- (e) Impedance and reflection measuring equipment
- (f) Spectrum analysis measuring equipment
- (g) Data transmission equipment
- (h) Power measuring equipment
- (i) Attenuators and amplifiers
- (j) Waveguide and coaxial components
- (k) Communication systems
- (l) Data acquisition systems
- (m) Processor controlled systems
- (n) Other equipment

3.30 Electrical Machines and Auxiliary Apparatus

- (a) Motors, generators and other rotating machines
- (b) Starters, controllers, regulators
- (c) Other equipment

3.31 Circuit Switching and Rupturing Devices

- (a) Circuit breakers and controllers
- (b) Protection and control relays
- (c) Switches and isolators
- (d) Time switches
- (e) Fuses and fuse links
- (f) Surge diverters

3.35 Cables and Feeders

- (a) Conductor resistance tests
- (b) Insulation resistance tests
- (c) Capacitance tests
- (d) Direct voltage tests
- (e) Alternating voltage tests
- (f) Spark tests
- (g) Partial discharge tests
- (h) Dielectric tests
- (i) Electric field intensity tests
- (j) Magnetic field flux density tests
- (k) Sequence impedance tests
- (l) Electrical tests on fittings

- (m) Mechanical tests on fittings
 - (n) Other tests
- 3.36 Power Supply Equipment and Systems
- (a) Electrical parameters
 - (b) Waveform characteristics
 - (c) Power system disturbances
 - (d) Temperature rise and thermal rating tests
 - (e) Other tests
- 3.40 High Voltage Testing
- (a) Direct voltage tests
 - (b) Alternating voltage tests
 - (c) Impulse voltage tests
 - (d) Impulse current tests
 - (e) Partial discharge tests
 - (f) Dielectric tests
 - (g) Switching impulse voltage tests
- 3.41 Radio communication Equipment
- (a) Receiving equipment
 - (b) Transmitting equipment
- 3.42 Electromagnetic Compatibility Testing
- (a) Radiated emissions
 - (b) Radiated susceptibility
 - (c) Conducted emissions
 - (d) Conducted susceptibility
 - (e) Transient testing
- 3.45 High Power and High Current Testing
- (a) Short time withstand and peak withstand current tests
 - (b) Short circuit making and breaking capacities
 - (c) Making and breaking capacities
 - (d) Overload performance
 - (e) Electrical endurance
 - (f) Arcing fault tests due to internal fault
 - (g) Determination of cut-off current characteristic
 - (h) Determination of joule integral characteristic
 - (i) Temperature rise tests
 - (j) Other tests
- 3.50 Optical Fibre Systems
- (a) Optical power
 - (b) Optical attenuation
 - (c) Optical wavelength
 - (d) Optical time-domain reflectometry
 - (e) Optical bandwidth
 - (f) Optical fibre system components
 - (g) Fibre and core geometry
 - (h) Other tests
- 3.60 Environmental Tests
- (a) Cold tests
 - (b) Dry heat tests
 - (c) Damp heat tests
 - (d) Impact tests
 - (e) Vibration tests

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- (f) Acceleration tests
 - (g) Storage tests
 - (h) Mould growth tests
 - (i) Corrosion tests
 - (j) Low air pressure tests
 - (k) Change of temperature tests
 - (l) Sealing tests
 - (m) Solar radiation tests
 - (n) Soldering tests
 - (o) Robustness of terminations tests
 - (p) Combined tests
 - (q) Other specified tests
- 3.65 Miscellaneous Electrical Tests
- (a) Insulating gloves and tools
 - (b) High voltage operating equipment
 - (c) Insulated platform vehicles
 - (d) Fire extinguishers
 - (e) Other tests
- 3.70 Antistatic Materials
- (a) Flooring
 - (b) Other tests
- 3.75 Performance Tests on Telecommunications Equipment
- 3.80 Approval Tests on Electrical Appliances
- (a) General requirements to AS/NZS 3100 *
 - (b) Particular requirements to AS/NZS 31XXX
 - (c) General requirements to AS/NZS 3350.1 or AS/NZS 60335.1
 - (d) Particular requirements to AS/NZS 3350.2.XX or AS/NZS 60335.2.XX
 - (e) IP ratings to AS/NZS 60529 *
 - (f) Fire hazard testing of electrotechnical products to AS/NZS 60695 series*
 - (g) Insulation tests
 - (h) Temperature measurements
 - (i) DC component from AC equipment
 - (j) (Switch endurance tests
 - (k) Motor rating tests
 - (l) Socket outlet's current-breaking tests
 - (m) Other tests
- *and other IEC equivalents
- 3.85 Performance Tests on Electrical Appliances and Accessories
- 3.90 Electrical Equipment for Explosive Atmospheres
- 3.95 Electromedical Equipment
- (a) Approval tests
 - (b) Performance tests
- 3.96 Medical Treatment Areas
- (a) Antistatic flooring
 - (b) Patient equipotential areas

APPENDIX 2 Calibration Intervals

The following table sets out the normal periods between successive calibrations for a number of reference standards and measuring instruments. It must be stressed that each period is generally considered to be the maximum appropriate in each case providing that the other criteria as specified below are met:

- (a) The equipment is of good quality and of proven adequate stability, and
- (b) The laboratory has both the equipment capability and staff expertise to perform adequate internal checks, and
- (c) If any suspicion or indication of overloading or mishandling arises, the equipment will be checked immediately and thereafter at frequent intervals until it can be shown that stability has not been impaired.

Where the above criteria cannot be met, appropriately shorter intervals may be necessary. IANZ is, however, prepared to consider submissions for extension of calibration intervals based on factors such as history of stability, frequency of use, accuracy required, ability of staff to perform regular checks and successful participation in proficiency testing programmes. It is the responsibility of the testing laboratory to provide evidence that its calibration system will ensure that confidence in the equipment is maintained. Application of the requirements of ISO 10012, Parts 1 and 2 need to be considered when seeking an extension of intervals.

Items marked * in the table are those which can be calibrated by the staff of a laboratory if it is suitably equipped and the staff are competent to perform such re-calibrations. Intercomparisons may also be carried out by laboratory staff.

Where calibrations have been performed by the staff of a laboratory, adequate records of these measurements must be maintained which includes the uncertainty.

Types of Equipment	Maximum Period Between Successive Calibrations
Attenuators	Three years (attenuation and frequency response). Resistance and return loss check annually where appropriate.
Bridges	Three years (full calibration). Range check annually.
Capacitors	Three years. Intercompare annually.
Digital meters *	One year
Digital calibrators with self checking	Two years
Inductors	Three years. Intercompare annually.
Instruments, indicating and recording * (analogue only)	Five years. Intercompare every six months or more frequently as required.
Instrument and ratio transformers	Five years. Regular checks using an artefact or inter-comparison to detect major problems.

Types of Equipment	Maximum Period Between Successive Calibrations
Instrument transformer test sets	Three years (full calibration). Regular checks using an artefact or intercomparison to detect major problems. Five years subsequent calibrations.
Potentiometers	Five years.
Resistors	Three years after initial drift rate has been established. Intercompare annually.
RF noise sources	Two years
RF power measuring equipment	One year for power references. Three years for thermistor and diode sensors. Annual check of VSWR.
Signal generators	One year (frequency accuracy, output level and attenuator ratio)
Standard cells and electronic references	One year. Intercompare at least three monthly to establish drift rate of a group. One cell in a group needs to be calibrated annually.
Time, time interval, and frequency standards*	One year but calibration interval dependent on equipment frequency type and accuracy required. This may be as frequently as daily if the highest possible performance is required (via TV line 6). Audit the data collection system every two years.
Transfer standards, AC-DC	Five years maximum with annual self-check for a stand-alone instrument. Two years for best performance.
Volt ratio boxes	Three years. Annual resistance checks.
Watt-hour meters (Electro-mechanical)	One year. Intercompare every three months.
Wattmeters and Watt-hour meters (Electronic)	Two years with regular intercomparisons - intervals to be based on history of performance.
Ancillary Equipment	
Accelerometers	One year.
Anemometers	One year.
Environmental chambers *	Three years initially. Five years subsequent calibration. Time and spatial variation (temperature variations, recovery time, rate of ventilation).
Force testing machines	Two to five years depending on type (where required by a standard method this period may be less).

Types of Equipment	Maximum Period Between Successive Calibrations
Hygrometers (i) Assman and sling type psychrometers * (ii) Recorders accurate to $\pm 1\%$ * (iii) Other recorders including hair types *	Six months (compare thermometers at room temperature with wick dry). Five years (complete calibration). One year initially. Two years subsequently. Three months (with Assman psychrometer).
Masses	One to five years depending on use and accuracy required.
Micrometers, dial gauges, callipers etc *	See IANZ Technical Guide AS TG 1
Pressure and vacuum gauges - reference - working	One year. Three months initially. Six months subsequently.
Thermocouples (i) Rare metal (ii) Base metal	100 hours use or three years whichever is the sooner. Calibration intervals to suit the particular application.
Thermometers (i) reference liquid-in-glass (ii) working liquid-in-glass* (iii) or alternatively	Five years (full calibration). Check ice point immediately after initial calibration then at least every six months. Five years (full calibration). Check ice point immediately after initial calibration then at least every six months. Intercompare with reference thermometer(s) at points in the working range every six months (see IANZ Technical Guide AS TG 3)
(iv) electronic (sensors that are thermocouples, thermistors or other integrated circuit devices)*	One year (full calibration)
(v) Resistance Reference resistance Working resistance	Five years (full calibration) or when the ice point drift is more than five times the uncertainty of calibration. Check at ice point before use or at least every six months. Working hand-held resistance thermometers can be checked using the alternative procedure for glass thermometers above.
Weighing appliances	One year initially. Up to three years at subsequent calibrations.
EMC and Electrical Safety Testing Equipment.	
Absorbing Clamps	Annual check

Types of Equipment	Maximum Period Between Successive Calibrations
Antennae	Three years
Artificial networks (EMC and Telecoms) (LISN etc)*	Annual checks of voltage division factor, rf impedance, and mains voltage drop at rated current and no load.
Attenuators, cables, couplers and preamplifiers*	Annual checks.
Harmonic and voltage fluctuation measuring equipment.	Annual calibration. Intermediate checks as appropriate.
Immunity field strength meters	Three years
Impact hammers	Five years
Impulse testers	Annual checks
ESD testers	Annual full calibration for two years then three years with intermediate checks on voltage network in house.
Receivers	Annual calibration.
Surge generators and other immunity testing equipment	Intermediate checks as appropriate.

APPENDIX 3

Approved Signatories and Other Staff

Supervisory staff in accredited organisations must be competent and experienced in the areas covered by their accreditation. They must be able to oversee the operations and cope with any problems that might arise in their work or that of their colleagues or subordinates. Such staff members, nominated by their organisations, may be granted signatory approval by IANZ. Approved Signatories authorise technical procedures and the release of IANZ endorsed work.

The qualifications and experience required of Approved Signatories and other staff members cannot be rigidly specified but must be appropriate to the work in which they are engaged. Approved Signatories would normally hold tertiary qualifications or equivalent professional recognition in the relevant discipline. Organisations engaged in a restricted range of repetitive work may have that work controlled by a Signatory with appropriate practical experience and specific training in that work but without formal qualifications.

Approved Signatories

Approved Signatories are the knowledgeable staff members who, where relevant:

- (a) Develop and implement new procedures
- (b) Design quality control procedures, set action criteria and take corrective actions
- (c) Identify and resolve problems
- (d) Authorise the release of reports
- (e) Take responsibility for the validity of test results.

Every accredited organisation must have at least one Approved Signatory covering each item of its scope of accreditation. Accreditation is automatically suspended for any scope item(s) where there is no Signatory for the item(s) due to Signatory/ies leaving the organisation.

All IANZ endorsed work must be authorised for release by an Approved Signatory holding approval in that discipline who will take full responsibility for the validity of the work.

Signatory approval is recognition of personal competence. However, it relates to the accreditation of the employing organisation and is therefore not automatically transferable to another organisation. It lapses when a Signatory leaves the accredited organisation or changes their role significantly within the accredited organisation.

The following are considered when IANZ assesses the suitability of staff members as Approved Signatories:

- (a) Relevant qualifications and/or experience. If the signatories do not have relevant tertiary qualifications they must have sufficient relevant experience enabling them to comply with the requirements listed below
- (b) Position in the staff structure. Approved Signatories must be personnel closely involved in the day to day operations of the accredited organisation
- (c) Familiarity with procedures and awareness of any limitations of these procedures. Approved Signatories must have appropriate personal experience in the work procedures for which they hold approval. They must be aware of any limitations of these procedures and must understand the scientific basis of the procedures
- (d) Ability to evaluate test results critically and a position in the staff structure which makes them responsible for their adequacy
- (e) Knowledge of the quality assurance procedures in operation and ability to take appropriate and effective corrective action, when required
- (f) Knowledge of and a commitment to the IANZ requirements for Approved Signatories and for accreditation. This will include being conversant with the principles of effective quality management embodied in NZS ISO/IEC 17025 and relevant Specific Criteria

- (g) Sufficient experience with the accredited organisation to address the above points. It is difficult to specify an exact time a proposed Signatory should have spent in the organisation, as it is dependent on their previous knowledge and experience and their current role in the accredited organisation. It is unlikely that the time would be less than six months, but exceptional circumstances may apply.

Signatory approval is normally granted only to a staff member in charge, a section leader, a departmental manager or a senior staff member who authorises the release of reports and who can also satisfy the above requirements.

Staff members may be granted signatory approval for all of the work included in their organisation's scope of accreditation or for only specific work or classes of work relating to their area of personal expertise.

Signatory approval is available to a person engaged by an accredited organisation as a consultant, with respect to work done within the scope of accreditation of that organisation, provided that there is a written agreement between the parties setting out the extent of the authority and responsibility of the consultant in relation to the services provided. The consultant's position in the organisation must be such that they can perform their role as a decision maker as effectively as if they were an employee.

Staff members of the accredited organisation who are not engaged full-time are also eligible for signatory approval, provided that the circumstances in which they are called upon to exercise their signatory function and their access to, and knowledge of, the operations are such that they are able to take full responsibility for the reports they authorise.

The position and function of an Approved Signatory are quite distinct from that of an Authorised Representative. An organisation will normally have only one Authorised Representative who is appointed by the organisation and is only the contact point for IANZ and need not have any particular professional or technical expertise. The organisation may, however, have several Signatories approved by IANZ and with their own individual areas of expertise.

An Authorised Representative who is not also an Approved Signatory may not authorise the release of IANZ endorsed reports.