

***DOING BUSINESS IN
AUSTRALIA AND NEW ZEALAND:
CONFORMITY ASSESSMENT***

**A Guide for EC Designating Authorities, EC Conformity
Assessment Bodies and European Industry**

SECOND EDITION

This report was prepared with financial assistance from the Commission of the European Communities. The views expressed herein are those of the Consultant and do not represent any official view of the Commission.

Consultant:

NATA
71-73 Flemington Road
North Melbourne
Victoria 3051
AUSTRALIA

Project officer	Rob Oke
Telephone	+61 3 9329 1633
Facsimile	+61 3 9 326 5148
Email	Rob.Oke@nata.asn.au
Website	www.nata.asn.au

Foreword

Businesses engaged in international trade find themselves in a world where technical barriers to trade involving product standards and conformity assessment procedures appear to be ever increasing. Such barriers are always costly and sometimes even prohibitive for companies to sell their products on foreign markets.

The European Union's overall trade policy objective is to facilitate trade. In the specific area of product standards and conformity assessment procedures our aims are, on the basis of an open and accessible European market, to reduce technical barriers to trade in overseas markets and prevent the emergence of new ones. Secondly, we encourage Europe's trading partners to adopt standards and regulatory approaches based on, or compatible with, international and European practices.

These trade objectives are being pursued through a five-fold strategy comprising:

- 1) Reliance on actions under the World Trade Organisation, notably the Agreement on Technical Barriers to Trade, in the multilateral framework, and on agreements in the bilateral framework to reduce barriers and open markets;
- 2) International harmonisation of standards, technical regulations and conformity assessment procedures;
- 3) Conclusion of Mutual Recognition Agreements on conformity assessment (MRAs) to reduce the costs of testing and certification in other markets;
- 4) Technical assistance to a large number of countries to ensure that regulatory regimes are transparent and trade friendly; and
- 5) Regulatory cooperation aimed at harmonising standards and regulations with other trading partners.

The MRAs with Australia and New Zealand are the first such agreements to be concluded by the European Community and fall under the third of these five actions. With these agreements, manufacturers are able to have the conformity of their products assessed to Australian and New Zealand regulatory requirements by appropriately designated European laboratories, inspection bodies and certification bodies, hence reducing the cost of such assessments and time to markets. Additionally, companies will find no technical obstacles to placing products within the scope of the agreement on the foreign market. This is achieved without affecting consumer safeguards provided by regulatory controls currently in place. They are important steps to achieve our trade policy aims to facilitate trade and market access for regulated products.

To try and give some quantification of the scale of the benefit, exports of European products falling within the scope of these MRAs are estimated to be in excess of four billion ECUs to Australia and approaching half a billion ECUs to New Zealand. The agreements cover around one-third of all EU merchandise exports to these countries.

The operation of MRAs will also have the secondary benefit of providing a vehicle to facilitate an environment conducive to the greater harmonisation of standards and conformance systems.

The intention of this guide is to, in a practical way, help EU authorities manage correctly their designation of conformity assessment bodies (CABs), help (CABs) to avoid discrepancies in the implementation of the MRAs and raise awareness of European industry of the opportunities created by the MRAs.

The first edition of this guide was well received by European business, Conformity Assessment Bodies and Designating Authorities. We expect this updated second edition will provide continuing assistance to those wishing to reap the benefits of the MRA's within Australia and New Zealand.

Pascal Lamy
Member of the European Commission
Responsible for Trade

Erkki Liikanen
Member of the European Commission
Responsible for Enterprise and the
Information Society

24 March 2000

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About This Guide

This is a guide to the Mutual Recognition Agreements (MRAs) in relation to conformity assessment, certificates and markings between the European Community and Australia and the European Community and New Zealand. Testing, inspection and certification of exported products can now take place in Europe rather than having to be carried out in Australia or New Zealand.

The guide has been prepared for the Directorates General for Trade and for Enterprise of the European Commission with input from the regulatory authorities in Australia and New Zealand.

The intention of this guide is to, in a practical way, help EC authorities manage correctly their designation of Conformity Assessment Bodies (CABs); help European CABs to avoid discrepancies in the implementation of the MRAs and raise awareness of European industry of the opportunities created by the MRAs.

The States which are parties to the Agreement on the European Economic Area (EEA) and the Convention on the European Free Trade Association (EFTA), i.e. Norway, Iceland and Liechtenstein, are in the process of concluding parallel MRAs with Australia and New Zealand. Once these Agreements have entered into force, this Guide will also be relevant to authorities, CABs and industry in Norway, Iceland and Liechtenstein.

While every effort has been made to ensure that the information in this guide is accurate at the time of publication, the European Commission expressly disclaims any liability to any person who relies on information and comment in this guide. Authoritative interpretation of requirements should be obtained from the Australian and New Zealand regulatory authorities.

The MRAs were signed in June 1998 and entered into force on 1 January 1999. The full texts of the MRAs can be accessed on the European Commission's website: http://www.europa.eu.int/comm/trade/download/index_en.htm. They are published in the L Series of the Official Journal of the European Community, issue number L229 of 17 August 1998, page 1 for the MRA with Australia, and page 61 for the MRA with New Zealand. Readers should contact the Directorates General for Trade and for Enterprise in Brussels for further information.

European Commission:

Directorate General for Trade

DG TRADE/M/2

Rue de la Loi 200, B-1049 Brussels

Tel: +32 2 2961666

Fax: +32 2 2991651

Head of Unit: Mr Mauro Petriccione

Contact: Mr Brian McDonald (brian.mc-donald@cec.eu.int)

Directorate General for Enterprise

DG ENTR/G1

Rue de la Loi 200, B-1049 Brussels

Tel: +32 2 2951304

Fax: +32 2 2953877

Head of Unit: Mr Gwenole Cozigou

Contact: Mr Giacomo Mattino (giacomo.mattino@cec.eu.int)

Definitions

The general terms used in the Mutual Recognition Agreements discussed in this guide have the meaning given in the definitions contained in ISO/IEC Guide 2 (1991) “General terms and their definitions concerning standardisation and related activities” and in EN 45020 (1993 edition) unless the context otherwise requires. In addition, the following terms and definitions apply for the purpose of these Mutual Recognition Agreements:

“Conformity Assessment” means systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

“Conformity Assessment Body” means a body whose activities and expertise include performance of all or any stage of the conformity assessment process;

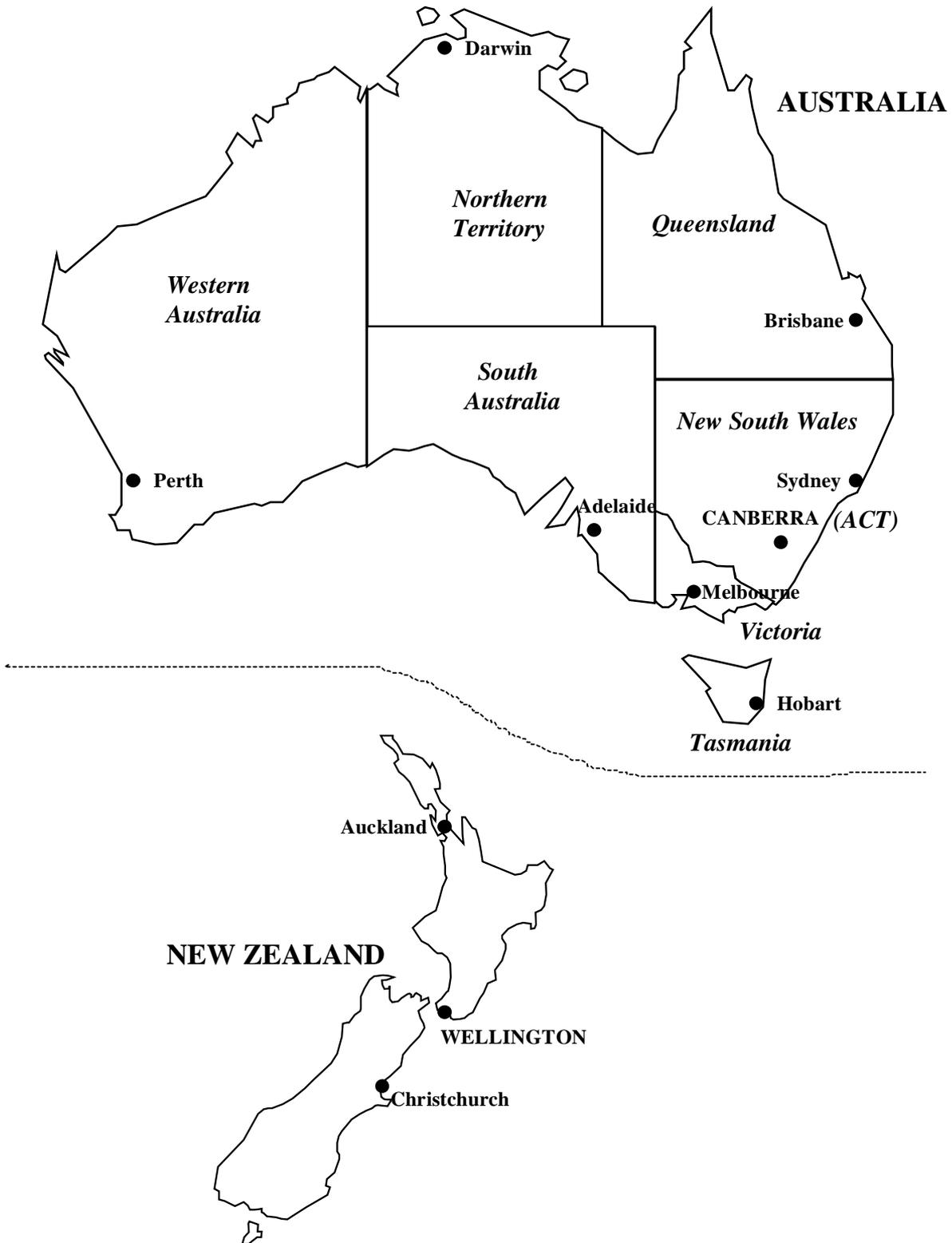
“Designation” means the authorisation by a Designating Authority of a Conformity Assessment Body to perform conformity assessment activities; “designated” has a corresponding meaning;

“Designating Authority” means a body with the legal power to designate, suspend or withdraw designation of Conformity Assessment Bodies under its jurisdiction.

Acronyms

ACA	Australian Communications Authority
ADR	Australian Design Rule
ANZ	Australia and New Zealand
APLAC	Asia-Pacific Laboratory Accreditation Cooperation
ARTG	Australian Register of Therapeutic Goods
AS	Australian standard
AS/NZS	Australian and New Zealand standard
CAB	Conformity assessment body
EA	European Cooperation for Accreditation
EEA	European Economic Area
EC	European Community
EMC	Electromagnetic Compatibility
EMI	Electromagnetic interference
ESS	Energy Safety Service
GMP	Good Manufacturing Practice
IAF	International Accreditation Forum
IANZ	International Accreditation New Zealand
JAS-ANZ	Joint Accreditation System of Australia and New Zealand
MRA	Mutual recognition agreement
NATA	National Association of Testing Authorities, Australia
NML	National Measurement Laboratory (Australia)
NPL	National Physical Laboratory (New Zealand)
NZS	New Zealand standard
OHS	Occupational health and safety
PAC	Pacific Accreditation Cooperation
PECPR	Pressure Equipment, Cranes and Passenger Ropeways
PTC	Permit to Connect
RCM	Regulatory Compliance Mark
RTTE	Radio and Telecommunications Terminal Equipment
SA	Standards Australia
SNZ	Standards New Zealand
TGA	Therapeutic Goods Administration
TGO	Therapeutic Goods Order
TTMRA	Trans Tasman Mutual Recognition Arrangement
TTE	Telecommunications equipment

Maps of Australia and New Zealand Showing State Boundaries and Capital Cities



Checklist for Using the Mutual Recognition Agreements

Questions to ask when exporting to Australia and New Zealand (ANZ)

1. Is the product in one or more sectors covered by the MRA?
2. Is the product within the scope of the MRA sector(s)?
3. Are there ANZ mandatory regulatory requirements for the product?
4. Is the involvement of a designated CAB* mandatory or useful?
5. Is a designated CAB available in Europe?
6. Does a designated CAB report that the product complies with ANZ requirements?
7. Are there approval/registration requirements for the product in ANZ.
8. Must any markings be applied to the product or its packaging?
9. Are separate procedures necessary for both countries?
10. Is there ANZ mutual recognition for the product?
11. Must technical data be sent to ANZ importers?
12. Must the manufacturer or importer make a declaration of conformance/compliance?

If you need further help, contact a relevant Designating Authority, designated CAB or ANZ regulatory authority (listed in Chapter 3 under the relevant section).

* conformity assessment body

CHAPTER 1 : The Conformity Assessment Process

Background to the development of mutual recognition of conformity assessment

In the European Community (EC), the **new approach** (1985) and the subsequent **global approach** (1989) have led to the development of mutual recognition between each of the 15 Member States. Through the close cooperation between the Community, and its Member States and Iceland, Liechtenstein and Norway in the Agreement on the European Economic Area (EEA) this mutual recognition is extended to these 3 countries. There is now a harmonised legal environment for trading of products based on design and production meeting a set of requirements which protect the health and safety of consumers and of the environment.

Testing and inspection takes place under a uniform conformity assessment process with products which meet essential legal requirements being signified by **CE marking**. This unified approach has delivered significant benefits for both producers and consumers throughout the EC and the EEA/EFTA countries.

One of the EC's prime goals in its trade policy is to reduce technical barriers to trade in world markets, and to prevent the emergence of new ones, to facilitate Community trade for products thus enhancing exports and generating employment.

The EC regards mutual recognition as a key instrument for opening markets worldwide as it reduces technical barriers to trade. In keeping with these global goals, **Mutual Recognition Agreements (MRAs)** are now under development with third countries and among the first to be finalised are those with Australia and New Zealand. Agreements have also been concluded with the USA and Canada and negotiations have been completed with Switzerland and are well advanced with Japan. In order to maintain the homogeneity and smooth functioning of the Single Market of the EEA, Liechtenstein, Iceland and Norway are in the process of concluding parallel and identical MRAs with the same partner countries.¹ Australia and New Zealand have concluded parallel MRA's with the three EFTA countries and these will soon come into force.

An MRA can apply to any product for which:

- harmonised, EC wide technical requirements are laid down in EC directives or non harmonised regulations still exist in one or more Member States; and
- mandatory, third party conformity assessment operations are specified.

Objectives of the MRAs between the EC, Australia and New Zealand

In this context a Mutual Recognition Agreement means a binding agreement with a third country under which that country recognises certificates of conformity from designated European CABs issued by them in accordance with that third country's rules and regulations and vice versa.

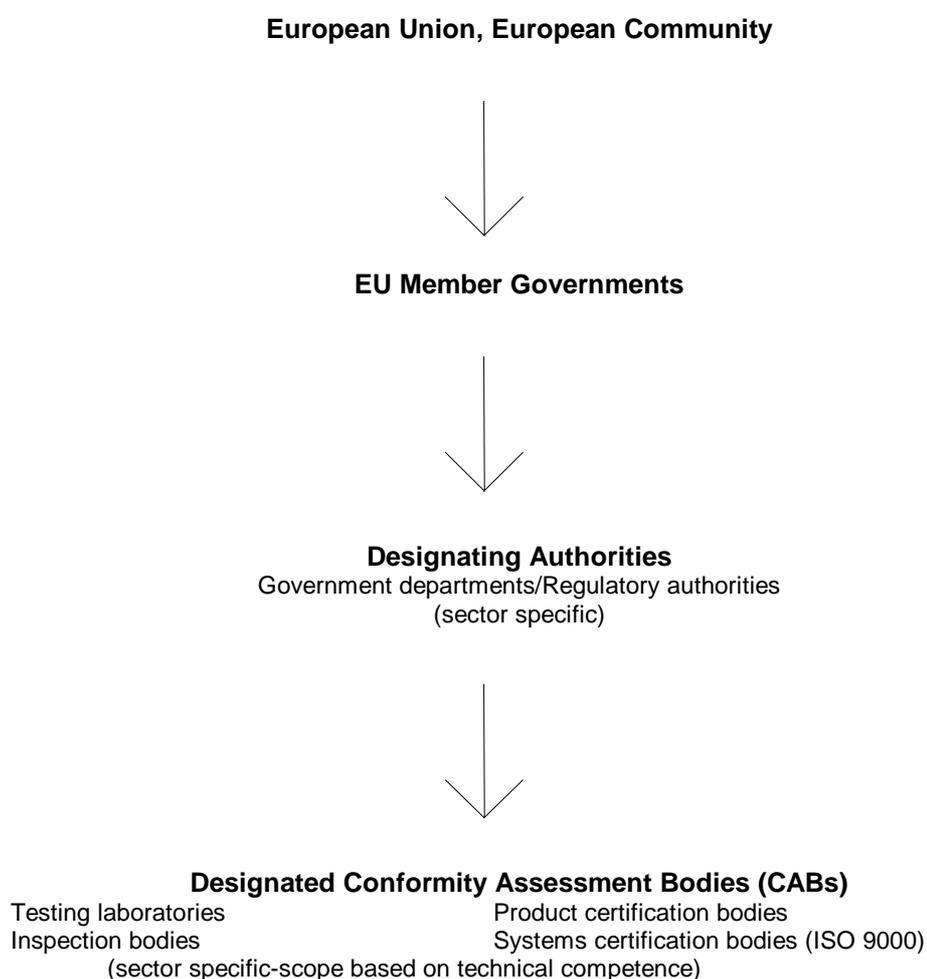
Therefore, under the Mutual Recognition Agreements between the European Community and Australia and New Zealand, EC products exported to Australia and New Zealand with such certificates can access those markets without any further conformity assessment requirement. The MRAs extend similar rights to Australia and New Zealand by allowing conformity assessment of exported products to be undertaken in Australia or New Zealand rather than having to be carried out in Europe.

1. This parallel process is carried out under Protocol 12 of the EEA Agreement. Consequently, reference in this Guide to the EC authorities, EC CABs, etc. should therefore be understood as covering all EEA authorities, CABs, etc..

In recognising that different legislative and regulatory requirements apply between the MRA partners, the agreements do not create a direct equivalence between European and Australian or New Zealand regulations. Rather they allow for mutual recognition of test results and other conformity assessment documentation including certification. **Figure 1** below sets out the structure of European conformity assessment as it applies within the Australian and New Zealand regulatory context.

If European companies and CABs are to take advantage of the MRAs with Australia and New Zealand, they will need to be aware of the exact regulatory and conformity assessment requirements they need to meet – which is the purpose of this guide.

Figure 1: Structure of European Conformity Assessment for Australian and New Zealand Regulatory Requirements²



Product sectors covered by the MRAs

The MRAs with Australia and New Zealand cover all mandatory conformity assessment procedures in the following regulated sectors: simple pressure equipment, machinery, low voltage electrical equipment, telecommunications terminal equipment, electromagnetic compatibility, medical devices, good manufacturing practice for pharmaceuticals, and (in the EC - Australia agreement) automotive products. The MRAs allow other sectors to be added at a later date.

² A separate structure based on **official inspection services** applies to Medicinal Products GMP Inspection and Batch Certification.

Sectors covered are shown in **Table 1** below with the associated EC technical requirements. The Australian and New Zealand technical requirements for each sector are described in sections 3.1 to 3.8 in Chapter 3 of this guide.

An objective of the parties is that the MRAs include all the technical requirements involving conformity assessment applying to items covered by a particular sector. For example medical devices may also need to comply with electrical safety and electromagnetic compatibility regulations. Exporters need to be aware, however, that some products will be subject to other conformance requirements under Australian or New Zealand law. Examples might be energy efficiency of a refrigerator or acoustic performance of machinery.

Table 1: Sectors Covered by EC MRAs with Australia and New Zealand

Product Sector	EU Technical Requirements ³
Medicinal Products GMP Inspection and Batch Certification.	EU pharmaceutical legislation.
Medical Devices.	90/385/EEC, 93/42/EEC.
Telecommunications Terminal Equipment.	91/263/EEC, 93/97/EEC.
Low Voltage Equipment.	72/23/EEC as amended.
Electromagnetic Compatibility (EMC).	89/336/EEC as amended.
Machinery.	89/392/EEC plus tower cranes and mobile cranes.
Pressure Equipment.	87/404/EEC as amended.
Automotive Products (Australia only).	Selected Directives for which there is a UN/ECE regulation.

Origin of products

The MRAs with Australia and New Zealand include an origin provision. This clause means that only goods undergoing the final significant manufacturing step in the EEA can be assessed in Europe under the terms of the MRAs and have the statement of their conformance with Australian and New Zealand requirements accepted by its authorities. These clauses may be reviewed in the future as the EC and Australia/New Zealand negotiate more bilateral arrangements with other trading partners.

³ Australian and New Zealand technical requirements are described in Chapter 3.

Scope and coverage of the Australian and New Zealand MRAs

Each MRA is divided into an overall framework agreement and **sectoral annexes** specific to each product sector and their relevant regulations. The annexes give the scope and product coverage for each sector and list regulations that each party applies.

The general sections of the Australian and New Zealand MRAs are essentially identical, but the annexes vary because of the regulatory differences between Australia and New Zealand. For example, the Australian scope of the Medical Devices Annex is much broader than the New Zealand Annex. The reverse is true for Pressure Equipment. Automotive products is a sector of the MRA with Australia, but not the MRA with New Zealand.

The MRAs do not cover all sectors with mandatory third party conformity assessment operations, or necessarily all products within an included sector. Other sectors are expected to be added in due course. For example, negotiations are continuing for the addition of the Aircraft Airworthiness sector and it is planned to extend the scope of the Pressure Equipment sector. If you are exporting to Australia or New Zealand you could check developments with the European Commission's Directorates General for Trade or for Enterprise.

Authorities responsible for overseeing the conformity assessment process

The European Commission has guaranteed to the Australian and New Zealand governments that their standards and assessment systems (see Chapter 2) will be maintained when assessing whether products comply with their regulations. To this end each EC Member State has appointed national **designating authorities** in each sector to recommend and monitor **CABs** capable of carrying out in Europe the assessment of the products destined for Australia and New Zealand.

These designating authorities are listed in the sections on each product sector in Chapter 3 of this guide.

Determining the eligibility of a CAB prior to designation

Designated CABs in the EC are equivalent to **notified bodies** and **competent bodies** associated with CE marking. Often they will be the same organisations, but they will have been assessed for their competence to apply the Australian and New Zealand requirements.

Any conformity assessment body may seek designation from the relevant designating authority appointed by their member state. These authorities are not, however, obliged to consider all applicants seeking designation for assessment of products for conformance to Australian or New Zealand requirements. It is also stated in the MRA's that it is not a pre-requisite for designation for CABs to have approval for assessment of conformity of products to EC requirements.

In order to be designated, CABs must demonstrate their technical competence based on:

- technological knowledge of the relevant products, processes or services;
- understanding of the technical standards and the general risk protection requirements for which designation is sought;
- the experience relevant to the applicable legislative, regulatory and administrative provisions;
- the physical capability to perform the relevant conformity assessment activity;
- an adequate management of the conformity assessment activities concerned; and

- any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

Australia and New Zealand regulations do not require that conformity assessment bodies be third parties, but rather rely on the accreditation procedures to ensure the independence of conformity assessments. Therefore European manufacturers may be designated to assess the conformity of their products with ANZ regulations.

Process for determining a CAB's technical competence

Each MRA Sectoral Annex lists the procedures the Australia and New Zealand governments require the European Community to follow when determining the technical competence of CABs.

Usually the **accreditation** procedures set out below must be applied, but in some cases **other means** procedures (also set out below) are allowed. The possible ways of demonstrating competence can be quite specific. For example, where CABs sub-contract testing it may be mandatory that the testing only be sub-contracted to testing laboratories accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing or be able to demonstrate competence under an equivalent accreditation scheme.

- **Accreditation**

A presumption of technical competence sufficient to constitute accreditation arises when:

- the accreditation process is conducted in conformance with the relevant international documentation (EN 45000 series or ISO/IEC guides); and either
- the accreditation body participates in mutual recognition arrangements where they are subject to peer evaluation by individuals with recognised expertise in the field of the work being evaluated; or
- the accreditation body, operating under the aegis of the designating authority, takes part in comparison programmes and exchanges of technical experience in order to ensure continued confidence in its technical competence. Such programmes may include joint assessments, special cooperation programmes or peer evaluation.

When a conformity assessment body seeks designation to evaluate a particular product, process or service for compliance with essential requirements, the accreditation process is to incorporate elements which permit assessment of the CAB's capability. Capability is defined as having the technological knowledge and understanding of the generally stated risk protection requirements of the product, process or service or their use.

- **Other means**

If appropriate accreditation is not available or special circumstances apply, the designating authorities can require the conformity assessment bodies to demonstrate their competence through other means such as participation in regional/international mutual recognition arrangements or certification systems; regular peer evaluations; proficiency testing; and comparisons between conformity assessment bodies.

Joint Committees and their role in relation to CABs

Each MRA has a **Joint Committee** composed of European and either Australian or New Zealand representatives. The Joint Committees are responsible for the effective functioning of the MRAs and the implementation of the MRAs at a detailed level.

One of the Joint Committees' responsibilities is amending the Sectoral Annexes to give effect to the decision by a designating authority to approve or withdraw designation. If agreed to be warranted, a joint team of experts is appointed to verify the technical competence of a particular CAB and its compliance with other relevant requirements.

Adding or withdrawing a CAB to a specific sector

A proposal to amend a Sectoral Annex to give effect to a decision by a designating authority to add or withdraw designation of a conformity assessment body has to be forwarded to the other party in writing, along with supporting documentation. A copy of the proposal and documentation is sent to the Chair of the Joint Committee.

If the other party contests the technical competence or compliance of a CAB within a 60 day objection period, the Joint Committee may decide to carry out a verification of the CAB concerned.

When a conformity assessment body is withdrawn from a Sectoral Annex, all its decisions up to the date its withdrawal took effect remain valid – unless otherwise determined by the Joint Committee. In the case of the inclusion of a new CAB, its decisions are considered valid from the date the parties agree to its inclusion in the Sectoral Annex.

Verification of designation procedures

Under the guidance of the Joint Committees the European Community, Australia and New Zealand will exchange information, undertake comparisons of their designation procedures, etc to ensure that their designated CABs comply with the regulatory requirements outlined in the MRA Sectoral Annexes and the competence requirements specified in the Annex of the MRA.

Uniformity of conformity assessment

In the interest of promoting a uniform application of conformity assessment procedures the European Community, Australia and New Zealand will organise coordination and comparison exercises involving their designated CABs. Where possible the relevant designated CABs of the other parties will participate in these activities. Alternatively the documents, including reports, associated with these activities will be provided to the designated CABs of the other parties.

CHAPTER 2 : Australian and New Zealand Standards and Conformance Infrastructure

Legislative and regulatory framework

The Commonwealth of Australia comprises six States: New South Wales, Victoria, Queensland, South Australia, Western Australia and Tasmania. In addition, there are two Territories: the Northern Territory and the Australian Capital Territory.

Legislative powers are shared between the Federal Government and the governments of the States and Territories. Federal powers are spelt out in the Australian constitution which reserves for the Federal Government powers over defence, foreign affairs, trade and commerce, taxation, customs and excise duties, pensions, immigration and postal services. Other powers are left to the States, but federal law prevails where there is a conflict over concurrent powers.

The split of powers has led to a lack of uniformity and non-harmonisation of approach in the regulatory sphere between the States and Territories. Mutual recognition of regulations was introduced in 1993 with the aim of removing regulatory barriers to the free flow of goods and labour between Australian States and Territories. It involves each jurisdiction recognising particular regulations created and administered by other jurisdictions, even where such regulations vary from their own rules and regulations. It enables most goods which are sold within the regulations of one jurisdiction to be sold freely throughout Australia.

New Zealand does not have a federal system and therefore does not have internal mutual recognition issues.

Mutual recognition between Australia and New Zealand

There is a close trade relationship between Australia and New Zealand which has been developed by the Australia and New Zealand Closer Economic Relations Trade Agreement and the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The latter scheme entered into force on 1 May 1998 and is based on the principle that goods that can be legally sold in Australia can be sold in New Zealand and vice versa, regardless of differences in sale-related standards and regulatory requirements.

There are, however, a number of exceptions to this principle based on the grounds of protection of public health and safety and the environment. Of relevance to the European MRA's are **special exemptions** in the areas of motor vehicles, therapeutic goods, telecommunications equipment and electromagnetic compatibility. The situation in each MRA product sector is described in the relevant section of Chapter 3.

Technical infrastructure in Australia and New Zealand

The European Community was able to conclude the mutual recognition agreements with Australia and New Zealand because of the high level of confidence provided by their well developed and transparent standards and conformance infrastructures.

In a similar way to the modular approach to conformity assessment in EU **new approach** Directives, Australian and New Zealand regulators make use of the technical infrastructure by calling up, as appropriate, accredited testing laboratories, accredited inspection bodies or organisations with product or quality management system certification. In addition regulators are able to use Australia and New Zealand's comprehensive systems for the development of product standards and test and inspection methods.

- **Technical standards writing**

Standards Australia (SA) and Standards New Zealand (SNZ) are the peak non government standards writing organisations. There are certain sectors where standards writing is the province of other bodies, usually government agencies, but it is usual for these bodies to have an active working arrangement with SA and SNZ. Such sectors which are relevant to the MRAs include telecommunications, pharmaceuticals and motor vehicles.

SA and SNZ, where possible, produce joint standards (prefixed AS/NZS). It is the policy of both organisations to align standards with those enjoying wide international acceptance and thus reduce technical barriers to trade.

- **Standards of measurement**

In Australia the National Measurement Laboratory (NML) maintains the physical standards base for all measurement, testing and quality systems. The New Zealand equivalent is the National Physical Laboratory (NPL). NML and NPL ensure that the national standards of measurement are compatible with international standards and provide the top-level calibration services that ensure that measurements in industry, commerce and the community are traceable to national standards.

The NML and NPL collaborate closely with the International Bureau of Weights and Measures and with other national measurement laboratories.

- **Accreditation of testing laboratories and inspection bodies**

The National Association of Testing Authorities, Australia (NATA) and International Accreditation New Zealand (IANZ) provide the national systems for the assessment and accreditation of testing laboratories and they provide accreditation of inspection bodies. NATA was the first national comprehensive laboratory accreditation scheme in the world (1947) and IANZ (formerly Telarc) was the second (1972). NATA and IANZ ensure measurement traceability to national standards through their networks of accredited calibration laboratories. JAS-ANZ (see below) also provides accreditation for inspection bodies.

NATA and IANZ are members of the International Laboratory Accreditation Cooperation (ILAC). They are subject to peer review through their membership of the European cooperation for Accreditation (EA) and the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) multilateral mutual recognition agreements.

- **Certification bodies (product and quality management)**

The Joint Accreditation System for Australia and New Zealand (JAS-ANZ) has the responsibility for accrediting product certification bodies and quality management system certification bodies in both countries. It was established by a Treaty between the Australian and New Zealand Governments in 1991 and shows the growing level of integration of the Australian and New Zealand conformity assessment infrastructures. JAS-ANZ is a member of the International Accreditation Form (IAF) and is subject to peer review through its membership of the AIF and the Pacific Accreditation Cooperation (PAC) multilateral mutual recognition agreements.

CHAPTER 3 : Product Sector Details For MRAs

Introduction

The Australian and New Zealand regulatory approaches differ between each product sector and between each country. The two countries do not have an overall approach equivalent to the European Community's **new approach**.

The following sections therefore detail for each product sector and for each country:

- The scope and coverage of the MRA;
- Regulatory compliance requirements;
- Any product marking requirements;
- Technical standards and their relationship to European standards;
- Any ANZ mutual recognition;
- The role of European designated CABs in Europe;
- Procedures for designating CABs;
- Contact information for the regulatory authorities;
- EU designating authorities;

The product sectors initially covered by the MRAs are set out in Table 1 (refer Chapter 1).

Up to date listings of European designated CABs for each sector are available from the European Commission Directorate General for Enterprise (DGENTR/G/1) in Brussels as well as each EC member government's designating authority for the relevant sector. The Commission's website to visit is:<http://europa.eu.int/comm/dg03/directs/dg3b/b1/indexbl.htm>

3.1 (a) Medicinal Products GMP Inspection and Batch Certification Australia and New Zealand

Scope and Coverage

The MRAs with both Australia and New Zealand have equivalent Medicinal Products Sectoral Annexes because the fully harmonised GMP inspection and batch certification requirements of Australia and New Zealand are very similar. The provisions of the Sectoral Annexes cover all medicinal products which are industrially manufactured in Australia or New Zealand and the European Community, and to which Good Manufacturing Practice (GMP) requirements apply.

For these medicinal products, each party recognises the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other party and the relevant manufacturing authorisations granted by the Competent Authorities of the other party.

In addition, the manufacturer's certification of the conformity of each batch to its specifications is recognised by the other party without re-control at import.

"Medicinal products" means all products regulated by the pharmaceutical legislation in the European Community and Australia or New Zealand. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feeding stuffs, and, where appropriate, vitamins, minerals, herbal remedies and homoeopathic medicinal products.⁴

"GMP" is that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the Marketing Authorisation granted by the importing party. It includes the system whereby the manufacturer receives the specification of the product and/or process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (Equivalent to Qualified Person certification in the European Community).

There are some differences between Australian and New Zealand definitions of medicinal products. For example some herbal, vitamin and mineral products for which no therapeutic claim is made are not medicinal products in New Zealand, but are in Australia and vice versa. Another example is sunscreen products: they are not medicinal products in New Zealand but those with an SPF of 4 and above are in Australia. Specific details should be obtained from the Australian and New Zealand regulatory authorities.

With respect to medicinal products covered by the legislation of one party but not the other, the manufacturing company can request, for the purpose of the MRA, an inspection be made by the locally competent inspection service. This provision shall apply *inter alia* to the manufacture of active pharmaceutical ingredients and intermediate products and products intended for use in clinical trials, as well as agreed pre-marketing inspections. Operational arrangements are detailed below.

⁴ In New Zealand homeopathic products have not been regulated under the Animal Remedies Act 1967 and are likely to be exempt from registration under the new Agricultural Compounds and Veterinary Medicines Act 1997 which is planned to be implemented in October 2000.

Certification Arrangements

• Certification of manufacturers

At the request of an exporter, importer or the competent authority of the other party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products certify that the manufacturer:

- is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;
- is regularly inspected by the authorities; and
- complies with the national GMP requirements recognised as equivalent by the two parties. In case different GMP requirements are used as a reference (in line with Reference GMP part (b) provisions below), this is mentioned in the certificate.

The certificates also identify the sites of manufacture (and contract testing laboratories, if any). The certificates must be in the format shown in Appendix 2 to the Medicinal Products Sectoral Annexes.

Certificates are to be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 days.

• Batch certification

Each batch exported is to be accompanied by a batch certificate prepared by the manufacturer (self certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate attests that the batch meets its specifications and must be kept by the importer of the batch. It must be made available upon request of the competent authority.

When issuing a certificate, the manufacturer must take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate must detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It must contain a statement that the batch processing and packaging records were reviewed and found in conformity with GMP. The batch certificate is to be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Community the "qualified person" referred to in article 21 of Directive 75/319/EEC relating to proprietary medicinal products.

Product Marking

Product marking for the Australian or New Zealand market is arranged through the Australian or New Zealand sponsor. All products are required to have either a registration number or a listing number, depending on the type of product. There are other specific labelling requirements - details should be obtained from the Australian or New Zealand sponsor.

Medicinal Products GMP Standards

Australian/New Zealand and EU medicinal products standards for GMP are regarded as being equivalent. Certification is done to the standards of the party where the product is manufactured. However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, shall be those of the relevant product Marketing Authorisation granted by the importing party.

Operational Provisions

- **Transmission of inspection reports**

Upon reasoned request, the relevant inspection services must forward a copy of the last inspection report of the manufacturing or control site. The request may concern a "full inspection report" or a "detailed report" (see below). Each party must deal with these inspection reports with the degree of confidentiality requested by the party of origin.

If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years or a particular need to inspect has been identified, a specific and detailed inspection may be requested. Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 days should a new inspection be carried out.

- **Inspection reports**

A "full inspection report" comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A "detailed report" responds to specific queries about a firm by the other party.

- **Reference GMP**

- (a) Manufacturers shall be inspected against the applicable GMP of the exporting party;
- (b) With respect to medicinal products covered by the pharmaceutical legislation of the importing party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations inspects against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing party. This will also be the case when the locally applicable GMP are not considered equivalent, in terms of quality assurance of the finished product, to the GMP of the importing party.

Equivalence of GMP requirements for specific products or classes of products (e.g. investigational medicinal products, starting materials) will be determined according to a procedure established by the Joint Committees of the MRAs.

- **Nature of inspections**

- (a) Inspections will routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).
- (b) "Product- or process-oriented" inspections (which may be "pre-marketing" inspections as relevant) focus on the manufacture of one or one series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) is to be provided in confidence to the inspectorate.

- **Inspection/establishment fees**

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees will not be charged to manufacturers located on the territory of the other party for products covered by this MRA.

- **Safeguard clause for inspections**

Each party reserves the right to conduct its own inspection for reasons identified to the other party. Such inspections are to be notified in advance to the other party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception. Should such an inspection take place, inspection costs may be recovered.

- **Official batch release**

The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (vaccines) and blood derivatives, carried out by the competent authorities before the distribution of each batch of product. These MRAs do not encompass this mutual recognition of official batch releases. However, when an official batch release procedure applies the manufacturer must provide, at the request of the importing party, the official batch release certificate if the batch in question has been tested by the control authorities of the exporting party.

For the European Community, the official batch release procedure for medicinal products for human use is specified, in document "Administrative EC Batch Release Procedure III/3859/92" and different specific batch release procedures.

- **Alert system**

Contact points listed below are to be used by competent authorities and manufacturers to inform the authorities of the other party of quality defects, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. For details contact an official inspection service (see Section 3.1 (b)).

Transitional Arrangements for Veterinary Medicinal Products

- **New Zealand**

In respect of veterinary medicinal products, New Zealand will, subject to satisfactory verification of the European Community's GMP inspection programme, recognise the conclusions of the European Community's inspections and of the European Community's manufacturers' certifications of batch conformity three years after the entry into the force of the MRA. The European community will, subject to satisfactory verification of New Zealand's GMP inspection programme, recognise the conclusions of New Zealand GMP inspections and of New Zealand Manufacturers' certifications of batch conformity, three years after the entry into force of the MRA. During this three year period, joint inspections, carried out in accordance with Section III, item 10 of the Medicinal Products Sectoral Annex, may be authorised as a means to build further confidence between the parties regarding the application and interpretation of their respective requirements.

The terms of any existing recognition arrangements concerning imports into New Zealand will remain valid during this three year period.

- **Australia**

There are no transitional arrangements for veterinary medicinal products exported to Australia. However a two year transitional period will apply to Australian veterinary products exported to the EU.

Australian - New Zealand Mutual Recognition

Medicinal Products is a sector with a special exemption under the Trans Tasman Mutual Recognition Arrangement. As a result medicinal products legally sold in Australia must separately meet New Zealand's regulatory requirements and vice versa. However there is mutual recognition between

Australia and New Zealand for GMP inspections. Therefore European manufacturers acceptable to Australia are also acceptable to New Zealand and vice versa.

Contact Details for the Australian/New Zealand Regulatory Authorities for Medicinal Products

- **Medicinal products for human use**

Australia

Chief GMP Auditor
Therapeutic Goods Administration
Department of Health and Aged Care Services
MDP 122
PO Box 100
Woden ACT 2606
Australia

Telephone +61 2 6232 8632
Fax +61 2 6232 8426
Email tga.information-officer@health.gov.au
Website <http://www.health.gov.au/hfs/tga>

New Zealand

Medsafe
New Zealand Medicines and Medicinal Devices
Safety Authority
Ministry of Health
PO Box 5013
Wellington
New Zealand

Telephone +64 4 496 2000
Fax +64 4 496 2229
Website <http://www.medsafe.govt.nz>

- **Products for use in animals**

Australia

Quality Assurance Group
National Registration Authority
PO Box E240
Parkes ACT 2600
Australia

Telephone +61 2 6272 5158
Fax +61 2 6272 4753
Email gsavage@nra.gov.au
Website <http://www.affa.gov.au/mra/welcome.html>

New Zealand

National Manager (ACVM Conformance)
Agricultural Compounds and Veterinary Medicines
Ministry of Agriculture & Forestry
PO Box 2526
Wellington
New Zealand

Telephone +64 4 460 8762
Fax +64 4 460 8771
Email acvm@maf.govt.nz
Website <http://www.maf.govt.nz/ACVM>

**3.1 (b) EU Official Inspection Services under the Medicinal Products
GMP Inspection and Batch Certification Sectoral Annexes**

BELGIUM	Inspection générale de la Pharmacie Cité administrative de l'Etat Quartier Vésale Algemene Farmaceutische Inspectie Rijksadministratief Centrum Vesalius Gebouw B-1010 BRUXELLES BRUSSEL	Tel. : +32-2-210 4924 Fax : +32-2-210 4880
DENMARK	Sundhedsstyrelsen -Medicines Division Frederikssundsvej 378 DK-2700 BRØNSHØJ	Tel. : +45-44-889 320 Fax : +45-42-847 077
GERMANY	Bundesministerium für Gesundheit Am Propsthof 78a D-53108 BONN	Tel. : +49-228-941 2340 Fax : +49-228-941 4923
	for immunologicals : Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines Postfach D-63207 LANGEN	Tel. : +49-6103-77 1010 Fax : +49-6103-77 1234
GREECE	Εθνικός Οργανισμός Φαρμάκου National Drug Organization (E.O.F.) Mesogion 284 GR-ATHENS 15562	Tel. : +30-1-654 5530 Fax : +30-1-654 9591
SPAIN	Ministerio de Sanidad y Consumo Subdirección General de Control Farmaceutico Paseo del Prado 18-20 E-28014 MADRID	Tel. : +34-1-596 4068 Fax : +34-1-596 4069
FRANCE	for medicinal products for human use : Agence du Médicament 143-145 boulevard Anatole France F-93200 SAINT-DENIS	Tél. : +33-1-4813 2000 Fax : +33-1-4813 2478
	for veterinary medicinal products : Agence Nationale du Médicament Vétérinaire la Haute Marche - Javené F - 35133 FOUGERES.	Tel.: +33-9994 7878 Fax : +33-9994 7899

IRELAND	National Drugs Advisory Board 63-64 Adelaide Road IRL-DUBLIN 2	Tel. : +353-1-676.4971 - 7 Fax : +353-1-676.7836
ITALY	Ministero della Sanità Direzione Generale del Servizio Farmaceutico Viale della Civiltà Romana 7 I-00144 ROMA	Tel. : +39-6-5994 3676 Fax : +39-6-5994 3365
LUXEMBOURG	Division de la Pharmacie et des Médicaments 10 rue C.M. Spoo L-2546 LUXEMBOURG	Tel. : +352-478 5590 / 93 Fax : +352-22 44 58
NETHERLANDS	Ministerie van Volksgezondheid, Welzijn, en Sport Inspectie voor de Gezondheidszorg Postbus 5850 NL-2280 HW RIJSWIJK	Tel. : +31-70-340 6839 Fax : +31-70-340 7159
AUSTRIA	Bundesministerium für Gesundheit und Konsumentenschutz Radetzkystraße 2 A-1031 WIEN	Tel. : +43-1-711 724 642 Fax : +43-1-714 92 22
PORTUGAL	Instituto Nacional da Farmácia e do Medicamento - INFARMED Av. do Brasil, 53 P - 1700 LISBOA	Tel. : +351-1-795 7836 Fax : +351-1-795 9116
FINLAND	National Agency for Medicines P.O. Box 278 FIN-00531 HELSINKI	Tel. : +358-0-396 72 112 Fax : +358-0-714 469
SWEDEN	Läkemedelsverket - Medical Products Agency Husargatan 8, P.O. Box 26 S - 751 03 UPPSALA	Tel. : +46-18-174 600 Fax : +46-18-548 566
UNITED KINGDOM	for human and veterinary (non immunologicals) : Medicines Control Agency 1 Nine Elms Lane GB-LONDON SW8 5NQ	Tel. : +44-171-273 0500 Fax : +44-171-273 0676
	for veterinary immunologicals : Veterinary Medicines Directorate Woodham Lane New Haw, Addlestone GB - SURREY KT15 3NB	Tel. : +44-1932-336911 Fax : +44-1932-336618

3.2 (a) Medical Devices Australia

Scope and Coverage

For products exported to Australia the Medical Devices Sectoral Annex covers all medical devices subject, under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulations,⁵ to third party conformity assessment procedures. It covers both product related and quality system related procedures, but excludes the following products:

- radioactive materials to the extent these may be considered medical devices;
- medical devices incorporating tissues of animal origin. However, medical devices:
 - (a) incorporating refined derivatives of animal derived waxes, heparin and gelatine which conform to pharmacopoeial standards and sintered hydroxyapatite, or
 - (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only,

are included within the scope of this Sectoral Annex.

A transitional period, for the purpose of strengthening confidence in the designating systems of each of the parties will apply for the certain high risk devices specified in Schedule 3 of the Therapeutic Goods Regulations and medical devices Directives (90/385/EEC and 93/42/EEC) and listed below:⁶

- active implantable devices;
- intra-uterine contraceptive devices;
- heart valves;
- intra-ocular lenses;
- intra-ocular visco elastic fluids;
- powered drug infusion pumps;
- implantable breast prostheses (other than those containing only saline or water);
- barrier contraceptive devices (excluding condoms);
- instrument grade disinfectants.

The confidence building period will be completed within 18 months from the date of entry into force of the MRA. During this period the Therapeutic Goods Administration (TGA) will request sponsors to provide evaluation and audit reports from designated CABs.

⁵ The Australian regulator is the Therapeutic Goods Administration (TGA) which is a Division of the Commonwealth Government's Department of Health and Aged Care

⁶ For more specific details, including some exemptions, see Schedule 3 of the Therapeutic Goods Regulations and DR4 documents.

Compliance Arrangements

- **General**

Detailed information on medical devices regulations and requirements is available from the TGA and much of this information is on the TGA website. In particular, exporters should refer to the **Therapeutic Goods Act 1989** and the **Therapeutic Goods Regulations** and TGA documents **DR4: Australian Medical Devices Requirements** and **DR4: Appendices**.

Unless specifically excluded or exempt medical devices may not be supplied to the Australian market or exported unless included in the Australian Register of Therapeutic Goods (ARTG).

Medical devices are categorised as **excluded, exempt, registrable** or **listable**. It is the responsibility of the **Australian sponsor** /authorised representative to make application to the TGA to list or register devices in the ARTG. Application procedures are detailed in TGA document DR4.

- **Registrable devices**

Medical devices which are required to be registered are specified in Schedule 3 of the Therapeutic Goods Regulations. Sponsors are required to submit data to establish the quality, safety and efficacy for review by the TGA prior to the entry in the ARTG. Within the registrable category is a group of products incurring lower application and evaluation fees which reflect their different requirements for premarket assessment. Application and evaluation fees as well as annual charges apply to all registrable devices.

- **Listable devices**

Medical devices which are not required to be registered, or are not excluded or exempted, are required to be “listed” in the ARTG. Test certificates to applicable standards and/or acceptable evidence of quality systems certification are also required for some products. Application fees and annual charges apply to listable devices.

- **Medical devices incorporating medical substances**

In order to meet Australian requirements, the following procedures apply to medical devices incorporating medicinal substances referred to Article 1, paragraph 4 of Directive 93/42/EEC:

- (a) if a medical device incorporates a substance with ancillary medicinal action and which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex 2 or 3 of Directive 92/42/EEC will be carried out with the European Community competent authority;
- (b) if a medical device incorporates a substance with ancillary medicinal action other than one specified in the European Pharmacopoeia, consultation shall take place with the TGA before taking a decision.

- **Electromedical devices**

- **Electrical safety**

Electrically powered medical devices are required to meet a minimum level of electrical safety prior to entry in the ARTG. Compliance requirements are described in publication DR4. In addition Australian State and Territory electrical regulatory authorities have approval schemes for electrical articles - see Section 3.4 (a) of this guide.

- **Electromagnetic compatibility (EMC)**

Electrically powered therapeutic devices are exempted from the Australian Communications Authority (ACA) EMC regulations, but must meet the TGA's compliance requirements. These are described in the TGA document DR4.

- **Compliance file**

Sponsors are required to maintain a file for all electromedical devices, containing all relevant documentation to support the declaration made in the application for entry in the ARTG that the device is electrically safe and it is in compliance with appropriate standards.

The compliance file must include the following:

- a description of the device, including photographic documentation (this may be in the form of promotional or application literature);
- technical description and specifications;
- a reference to standards used to demonstrate compliance, with both electrical safety and EMC requirements of the TGA;
- copies of test reports used to support declarations of compliance;

The compliance file is subject to audit by the TGA for both electrical safety compliance and for EMC compliance.

Product Marking

All medical devices must comply with the Therapeutic Goods Order (TGO) for labelling (**TGO 37**), any other applicable TGO's and Sections 4 and 7 of the **Therapeutic Goods Advertising Code**. All registrable devices must carry the Australian registration number assigned by the TGA following inclusion in the ARTG.

Australia - New Zealand Mutual Recognition

Medical devices is a sector with a special exemption from the Trans Tasman Mutual Recognition Arrangement. As a result medical devices legally sold in New Zealand must, if sold in Australia, also meet Australian medical device requirements.

Australian Medical Devices Standards

The standards applied to medical devices under the Therapeutic Goods Act are referred to as Therapeutic Goods Orders. The TGA is committed to the adoption of internationally accepted standards unless it can be demonstrated there is a clear need to modify these standards in the interest of public health. The monographs of the British or European Pharmacopoeia are generally applicable. Where appropriate, specific Australian standards, e.g. those standards developed by Standards Australia or the TGA, have been adopted. Document DR4 should be consulted for details on applicable Therapeutic Goods Orders. Copies are available from the TGA Information Officer.

The Role of European Designated CABs

Under the MRA the TGA recognises the competence of European designated CABs to undertake conformity assessment of medical devices manufactured in the EU. The role of the designated CAB is to issue a certificate of conformity to the Australian requirements.

Within the framework of the MRA the TGA will within five working days register or list on the ARTG a product from the EU upon receipt of an application accompanied by the conformity assessment certificate and the designated fee without further assessment of the product.^{7,8}

In summary, where a designated CAB is involved, all medical devices supplied in Australia from the EU must have:

- a sponsor located within Australia;
- the Australian sponsor must complete and submit a Therapeutic Devices Application form and provide the certification of conformity issued by the European designated CAB;
- for registrable devices, the actual evaluation and audit reports of the European designated CAB must accompany the application for entry in the ARTG. All reports must be written in English;
- the Australian sponsor must also complete and submit an Enterprise Details form if it is the first application for entry of a therapeutic device in the ARTG or if details of the enterprise have changed (see document DR4);
- payment of the current application fees (evaluation fees will apply for the first 18 months that the MRA is in force).

Procedures for Designating CABs in Europe

The procedures for designating European CABs must be consistent with the procedures and principles set out in Annex 1 of the MRA.

For the purposes of designation under the Medical Devices Sectoral Annex, CABs which are notified **bodies** under Directives 93/42/EEC or 90/385/EEC are presumed competent to carry out conformity assessment to Australian requirements, for those devices and procedures for which they have been correspondingly notified by their competent authorities in Europe. **Notified bodies** must be **designated CABs** under the MRA to participate in the MRA.

⁷ The TGA reserves the right to refuse an application if it is considered that the device may compromise the health or safety of patients or users.

⁸ The five day time frame does not apply to registrable devices during the first 18 months of operation of the MRA.

Contact Details for the Therapeutic Goods Administration

The Director
Conformity Assessment Branch
Therapeutic Goods Administration
Department of Health and Family Services
MDP 122
PO Box 100
WODEN ACT 2606

Telephone +61 2 6232 8700
Fax +61 2 6232 8687
Email tga-information-officer@health.gov.au
Website <http://www.health.au/tga>

3.2 (b)

Medical Devices New Zealand

Scope and Coverage

For products for export to New Zealand the Medical Devices Sectoral Annex covers all medical devices subject, under the New Zealand Radiocommunications Act 1989, Radiocommunications (Radio) Regulations 1993, Electricity Act 1992 and Electricity Regulations 1997, to third party conformity assessment procedures, both product related and quality system related, but excluding the following products:

- radioactive materials to the extent these may be considered medical devices;
- medical devices incorporating tissues of animal origin. However, medical devices:
 - (a) incorporating refined derivatives of such tissues, or
 - (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only,

are included within the scope of this Sectoral Annex.

For the purposes of the MRA the New Zealand regulator is the Manager, Energy Safety Service, Ministry of Consumer Affairs.

Compliance Arrangements

- **General**

The MRA applies only to medical devices that fall within the scope of the New Zealand Electricity and Radiocommunications legislation.

Third party conformity assessment may be required under the Electricity and Radiocommunication legislation where a medical device falls within the scope of this legislation. Guidance on the provisions of the MRA with respect to the Radiocommunications Act and Regulations and the Electricity Act and Regulations is given in Sections 3.4 (b) and 3.5 (b) of this guide. It is important to read these sections in conjunction with the information given in this section.

Exporters should consult the Energy Safety Service, Ministry of Consumer Affairs for advice on compliance with the Electricity Act and Regulations and the Radiocommunications Act and Regulations.

Compliance with the Medicines Act 1981 and Medicines Regulations 1984 is required for medical devices distributed within New Zealand. At the present time third party conformity assessment is not a pre-market requirement of this legislation.

Some advice is given below on the requirements for medical devices distributed in New Zealand; this does not form part of the requirements of the MRA but is provided as a guide to exporters. Exporters should consult the Medsafe (New Zealand Medicines and Medical Devices Safety Authority) of the Ministry of Health for advice on compliance with the Medicines Act (1981) and Medicines Regulations (1984) and other relevant legislation.

Certain medical devices may be defined as medicines under New Zealand legislation. Under the Medicines Act 1981, some products which are classified as medical devices in Europe are classified as medicines in New Zealand. Exporters should consult Medsafe if advice is required on this matter.

- **Regulatory development**

The Ministry of Health is developing new legislation that is expected to bring the regulation of medical devices within New Zealand into line with the risk protection principles of major trading partners. Exporters should be aware that the proposed legislation is expected to impose similar controls to those of the European Community.

Product Marking

Medical devices must comply with the requirements of the Medicines Act (1981) and Medicines Regulations (1984) for labelling and advertising.

Australia - New Zealand Mutual Recognition

Medical devices is a sector with a special exemption from the Trans Tasman Mutual Recognition Arrangement. Negotiations on harmonisation of New Zealand and Australian medical device requirements are progressing.

Medical Devices Standards

The standards applied to medical devices must be appropriate to ensure their safety and efficacy. The Ministry of Health is committed to the adoption of internationally accepted standards unless it can be demonstrated there is a clear need to modify these standards in the interest of public health. Further advice may be obtained from Medsafe.

The Role of European Designated CABs

Electromedical devices exported to New Zealand must comply with low voltage equipment and electromagnetic compatibility regulatory requirements - see Sections 3.4 (b) and 3.5 (b) for details for the relevant Sectoral Annex. For products coming within the coverage of these Sectoral Annexes, the roles for CABs are described in those Sections of this guide. The standards to be applied by the CABs would be expected to be those applicable to electromedical devices.

Procedures for Designating CABs in Europe

The procedures for designating European CABs must be consistent with the procedures and principles set out in Annex 1 of the MRA. The designating procedures for low voltage equipment and electromagnetic compatibility are described in Sections 3.4 (b) and 3.5 (b).

Contact Details for the New Zealand Regulatory Authority for Medical Devices

For advice and information regarding the third party conformity assessment required for those medical devices falling within the scope of the MRA:

The Manager
Energy Safety Service
Ministry of Consumer Affairs
P O Box 1473
Wellington
New Zealand

Telephone +64 4 472 0030
Fax +64 4 460 1365
Website <http://www.ess.moc.govt.nz>

For advice and information on the general requirements for medical devices that are intended for distribution in New Zealand:

The Manager
Medsafe
New Zealand Medicines and Medical Devices Safety Authority
Ministry of Health
P O Box 5013
Wellington
New Zealand

Telephone +64 4 496 2000
Fax +64 4 496 2229
Website <http://www.medsafe.govt.nz>

3.2 (c) **EU Authorities Responsible for Designating European CABs under the Medical Devices Sectoral Annexes**

<ul style="list-style-type: none"> • Belgium Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • Denmark Sundhedsministeriet • Germany Bundesministerium für Gesundheit • Greece Υπουργείο Υγείας και Πρόνοιας Ministry of Health • Spain Ministerio Sanidad y Consumo • France Ministère du Travail et des Affaires Sociales • Ireland Department of Health • Italy Ministero Sanita • Luxembourg Ministère de la Santé 	<ul style="list-style-type: none"> • Netherlands Ministerie van Volksgezondheid, Welzijn en Sport • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Ministerio da Saude • Finland Sosiaali- ja terveystieteistö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • United Kingdom Department of Health <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs
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More information on designation of CABs for the medical devices sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.3 (a) Telecommunications Terminal Equipment Australia

Scope and Coverage

For Australia the scope of the Telecommunications Terminal Equipment Sectoral Annex covers all products defined as customer equipment or cabling under the Telecommunications Act 1997. This basically is all equipment and cabling connected to the customer side of the public telephone network.

The Australian regulator is the Australian Communications Authority (ACA)⁹. The ACA operates a customer equipment and cabling compliance scheme which is based on a declaration process. The manufacturer or importer must affix a label (including the A-tick symbol) to their product and hold documents supporting claims of compliance with technical standards determined by the ACA.

Compliance Arrangements

- **General**

Detailed information on telecommunications equipment compliance arrangements is available on the ACA website. Of particular relevance is the Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice and the Explanatory Statement regarding this labelling notice.

The fundamental policy approach is to rely on industry self-regulation with the ACA empowered to intervene where compliance is negligent or in other limited circumstances. The ACA makes technical standards on matters considered inappropriate for self-regulation. If a standard or an item of customer equipment is not specified in the labelling notice, there is no requirement to comply with that standard.

- **Compliance levels**

A graded approach with three levels is used to define what is required to determine compliance with relevant standards. Level 1 is the lowest level and Level 3 the highest. The applicable compliance level is specified in Schedule 1 of the labelling notice in relation to specified equipment and specified standards.

- **Level 1** requires the Australian manufacturer or the Australian importer to make a declaration of conformity and provide a description of the equipment. The declaration must be on the form set out in Schedule 6 of the labelling notice.
- **Level 2** in addition requires a test report (which may be an in-house report) or a compliance statement from an ACA appointed Certification Body, indicating compliance with all relevant standards.
- **Level 3** has the same requirements as level 2 except that the test report must be from a NATA determined Recognised Testing Authority¹⁰.

⁹ The ACA is also responsible for the regulation of EMC in Australia.

¹⁰ The list of Recognised Testing Authorities is maintained on the NATA website.

- **Overseas approvals**

In relation to levels 2 and 3 the requirement to obtain test reports or compliance statements is taken to have been complied with if there is a type approval of a kind listed in Schedule 7 of the labelling notice which includes:

- GSM equipment type approved under Directive 91/263/EEC;
- type approval:
 - (a) for DECT, CT2 or ETSI ISDN telecommunications technical equipment under Directive 91/263/EEC; and
 - (b) if the item is labelled with the “permission to connect” marking mentioned in annex VI of the Directive.
- Advanced Mobile Phone System (AMPS) and Code Division Multiple Access (CDMA) equipment approved by the FCC (USA) or the manager of the network facility in Australia to which the equipment is to be connected.

If this route is used, then a test report or a Statement of Compliance made by a Certification Body against any requirements in an applicable standard that differs from the requirements in a standard under which the approval was given must be kept in the relevant compliance folder.

- **Electrical authority certificates**

The procedures for obtaining certificates from electrical authorities are described in Section 3.4 (a).

Level 2 and Level 3 requirements for test reports or compliance statements are also met if:

- where technical standard TS001 applies to equipment, and there is an electrical safety certificate of approval or certificate of suitability by an electrical safety authority of a State or Territory of Australia; and
- any differences between the above and the relevant standard have been subjected to one of the compliance options.

- **Modifications**

For modifications to equipment shown to meet a particular compliance level there must be a statement in the compliance folder that:

- identifies the modification;
- describes the differences;
- provides a technical explanation of how the ‘new’ product complies with all the relevant standards.

- **Compliance records**

Compliance records must contain all the documents required in relation to the relevant compliance level. They may be held anywhere (except for the declaration of conformity) but made available to the ACA auditor when requested. All documents that must be retained must be in English.

Product Marking

Equipment and cabling controlled under the labelling notice must be labelled with the A-tick symbol - see Clause 10 of the labelling notice for particulars. This symbol must be accompanied by information which allows the identification of the manufacturer or importer.

Equipment not complying with all relevant standards may be supplied to market. However it is an offence to connect this equipment to the public network.

Before applying a label for the first time, a manufacturer or importer must notify the ACA of the intention to apply labels. This has to be done once only - it does not have to be done in relation to each new type or model of the product. The purpose of this requirement is to ensure that the ACA is aware of all the manufacturers and importers who are applying labels. The notification form to be used is included in the labelling notice as Schedule 4.

Telecommunications equipment which is within the Australian EMC framework (see Section 3.5 (a)) must also comply with the requirements of that framework for the A-tick symbol to be applied. The equipment does not however need the C-tick marking.

Australia-New Zealand Mutual Recognition

Telecommunications is a sector that has a special exemption from the Trans Tasman Mutual Recognition Arrangement. As a result products legally sold in New Zealand must separately, if sold in Australia, meet ACA Technical Standards and regulatory requirements.

Australian Telecommunications Terminal Equipment Standards

Equipment categories and relevant ACA Technical Standards are listed in Schedule 1 of the labelling notice. The standards are particularly directed towards protecting the integrity of the telecommunications network, covering safety issues and ensuring interoperability (of a standard telephone service). The explanatory statement to the labelling notice discusses each category and notes where ETSI standards are called up. In some cases the ACA standards are similar to equivalent European standards and the amount of additional testing involved is not too onerous. In other cases there are significant differences - for example the 7 kV impulse test under the safety testing requirements.

The Role of European Designated CABs

As noted above, for level 2 and level 3 equipment there must be documentation showing compliance with the requirements of each applicable standard. In this respect the importer is taken to comply if there are documents showing conformity issued by European CABs that have been designated under the MRA for the relevant ACA standards.

Where designated CABs sub-contract some or all of the testing for level 3 equipment, this sub-contracting must only be to testing laboratories accredited in accordance with clause.(a) below.

Procedures for Designating CABs in Europe

The procedures for designating European CABs must be consistent with the principles and procedures set out in Annex 1 of the MRA.

- (a) Testing Laboratories:

The following procedures are deemed to be consistent with those set out in Annex of the MRA:

- accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing; or
- able to demonstrate competence under an equivalent accreditation scheme.

(b) Certification Bodies:¹¹

The following procedures are deemed to be consistent with those set out in Annex 1 of the MRA:

- accreditation by an Accreditation Body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification;
- accreditation by an Accreditation Body with which JAS-ANZ has a Mutual Recognition Agreement; or
- able to demonstrate competence under an equivalent accreditation scheme.

Contact Details for the Australian Communications Authority

Executive Manager
Standards and Compliance Group
Australian Communications Authority
PO Box 13122 Law Courts
MELBOURNE VIC 8010
AUSTRALIA

Telephone +61 3 9963 6800
Fax +61 3 9963 6970
Email tech.notices@aca.gov.au
Website <http://www.aca.gov.au>

¹¹ These bodies are not the same as the ACA appointed Certification Bodies referred to in clause 2.2.

3.3 (b) Telecommunications Terminal Equipment New Zealand

Scope and Coverage

For New Zealand the scope of the Telecommunications Terminal Equipment (TTE) Sectoral Annex covers equipment offered for sale for attachment to the public and leased networks of Telecom New Zealand Ltd (Telecom) or any of its subsidiary companies. In general, this includes:

- single-line and multi-line TTE intended for connection to the public switched telecommunications network or leased lines, whether for voice or data transmission, including PABX and similar switching systems;
- ISDN basic rate access;
- ISDN primary rate access;
- AMPS and D-AMPS cellular telephone;
- cordless telephones, CT-1, CT-2 and CT-3, DECT and PHS;
- bandwidth management systems;
- trunked mobile radio terminals;
- power supplies, where these are supplied as separate items for use with any appropriate TTE items;
- telex TTE;
- modems and other analogue line interfaces;
- PC cards or peripherals which determine signal levels, voice quality, etc as perceived by other users of the network (but not generally PCs and other computer hardware connected on the customer's side of a Telepermitted network interface);
- jackpoints and associated cable and hardware used in residential premises.

Under s.6 of the Telecommunications Act 1987 each network operator has the right to specify conditions under which any additional line, apparatus or telecommunications terminal equipment may be connected to its network. The TTE Sectoral Annex of the EU MRA as it currently stands applies only to the public and leased networks operated by Telecom New Zealand Ltd (Telecom) and its subsidiary companies. Telecom operates an equipment approval system known as the Telepermit system. In practice, however, other facilities-based networks in New Zealand conform to similar requirements. The coverage of the Annex may at the request of the New Zealand government be extended to products intended for connection to other company's networks.

Regulatory Environment/Network Requirements

- **Industry regulation**

There is no industry specific telecommunications regulator in New Zealand, where the emphasis is reliance on general competition law. The Government does not own any telecommunications service providers in New Zealand.

The Ministry of Commerce has a policy advice role in relation to the telecommunications regulatory regime (Resources and Networks Branch), as well as a regulatory function in relation to electrical safety and EMC (Operations and Risk Management Branch). Further detail on the structure and functions of the Ministry can be found at its website.

- **Compliance arrangements**

TTE products may need to comply with New Zealand's low voltage equipment and EMC regulatory requirements. These are described in Sections 3.4 (b) and 3.5 (b).

- **Network attachment requirements**

Any TTE intended for connection to the Telecom network must have a "green tick" Telepermit label affixed securely to it. This indicates to a Telecom customer that the product may be connected to the Telecom network. The label may be attached by the manufacturer in the country of origin provided the process followed by the manufacturer conforms to Telecom's requirements. Further detail on this scheme can be obtained from Telecom Access Standards via their website (<http://www.telepermit.co.nz>). Any issue not covered on the website can be handled via direct communication with Access Standards' staff (see contact details below).

The Telepermit label is required to:

- incorporate a Registered Telecom trade mark, prepared to the format specified by Telecom;
- show the brand and model of the product and the number allocated to that product under the Telepermit scheme.

In brief, the process for obtaining a Telepermit is as follows:

- the manufacturer or New Zealand importer of the product completes the relevant Telepermit Application Form (available off the website), assembles the necessary documentation, and applies to Telecom Access Standards for a Telepermit. The grant of a Telepermit gives the applicant the right to label products which conform;
- the manufacturer or importer contracts with Telecom to continue to supply only those products which comply with Telecom's requirements.

- **Testing**

The initial requirement for most products is for samples to be tested by a Recognised Testing Authority, a list of which can be obtained from Telecom Access Standards. The number of samples required for testing depends on the type of product. This and other details are contained in the Permit To Connect (PTC) specifications. Information on these (including prices), together with similar information about Telepermit application charges and relevant publications are published on the website. This is revised regularly, and also contains a copy of the Telepermit application form.

When the tests are completed to the relevant PTC specifications, the full test results and all necessary supporting documentation (in English) are to be forwarded to Access Standards, Telecom New Zealand Ltd, with a completed Telepermit application form.

The following information must be included as part of all Telepermit applications:

- sample of the equipment and/or colour photographs;
- an electrical safety test report (see section 3.4 (b));

- test reports indicating compliance with relevant Telecom PTC specifications, and prepared by a Recognised Testing Authority;
- a description of the primary function/s of the product;
- a list of any additional facilities or properties which the product has;
- copies of user instructions and marketing brochures.

- **Granting of a Telepermit**

A Telepermit will only be granted to an individual or company based in New Zealand. Provisional applications from overseas companies are accepted but are not confirmed until a New Zealand representative is appointed. When a product of EU origin is placed on the New Zealand market, the supplier's New Zealand agent is required to lodge with Telecom Access Standards a copy of the certificate of compliance, the supporting test reports and other documentation as outlined above. Telecom retains this information as its basic technical file, and may verify compliance with PTC requirements through post-marketing surveillance.

In making an application, the local agent enters into a contractual relationship with Telecom under which that agent undertakes to comply with the conditions of grant. Where the test results show that the product has fully complied with the specified standards and all other necessary requirements, Telecom will grant a Telepermit to the New Zealand agent. This will include the provision of label artwork, which shows the product name to be used for marketing purposes in New Zealand and the Telepermit number. The Telepermit grant may also be subject to specific provisions, depending on the nature of the product and its proposed use, especially where it is necessary for the supplier to provide information to the end-user.

- **Intellectual property**

All test results are considered to be the property of the company to whom they have been addressed by the testing authority. Evidence of the link between the owner and the party applying for Telepermit is required by Telecom, usually in the form of either a letter of authority or a completed Authorisation form. The owner is free to authorise other agents to make use of the same test results, should this be considered necessary.

- **Design and product marketing changes and transfers**

Any design changes which may affect compliance with Telecom's technical requirements will mean the product has to be retested. A new Telepermit may have to be granted if the description of the product is changed. If a transfer of Telepermit ownership is proposed after a Telepermit has been granted, a new application is required from the proposed Telepermit holder, together with written agreement to the transfer from the original Telepermit holder. Provided the relevant PTC specifications are not affected, a minimal charge will be made for registering the changes and it is not usually necessary to have the product re-tested.

Product Marking

In addition to the Telepermit label, the marking requirements for low voltage equipment and EMC must be met if relevant.

Australia - New Zealand Mutual Recognition

Telecommunications is a sector that has a special exemption from the Trans Tasman Mutual Recognition Arrangement. As a result products legally sold in Australia must, if sold in New Zealand, also meet Telecom Permit to Connect specifications and Telepermit labelling requirements.

Telecom New Zealand Ltd Permit to Connect Specifications

Equipment categories and relevant Telecom Permits to Connect specifications are listed in the Telepermit System Overview. The specifications are not only directed towards protecting the integrity of the telecommunications network and safety, but also cover interoperability issues and other aspects designed to ensure that the quality of service delivered by the network is not adversely affected by the customer's equipment. Mandatory requirements are supplemented by numerous recommendations and explanatory notes, such that an overseas supplier is able to understand the reasoning behind many of the network specific requirements. Telecom specifications are based primarily on ITU Recommendations and, in many respects, align fairly closely with the equivalent European standards.

General information on Telecom New Zealand Ltd Permit to Connect Requirements

Telecom Access Standards publish a Newsletter providing up-dates on Specifications and general information for the industry on matters related to Telepermit procedures, new developments and operational issues. These Newsletters are published and archived on the website.

The Role of European Designated CABs

As noted above Telecom New Zealand accepts test reports to the relevant PTC specification from a Recognised Testing Authority. Reports from EU countries are also accepted if they are from a European CAB designated with respect to its ability to carry out testing to the relevant PTC Specification.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with Annex 1 of the MRA and are to be followed in designating CABs to assess TTE products against New Zealand requirements:

- (a) Testing laboratories accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or are able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.
- (b) Certification bodies are to be accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, or by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or are able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

Contact Details for Telecom New Zealand Ltd and Ministry of Commerce.

- **Telecom New Zealand Ltd**

General enquires

Website <http://www.telepermit.co.nz>

Access Standards
Telecom New Zealand Ltd
PO Box 570
Wellington
New Zealand

NOTE The following contact details are subject to change and will be up-dated as and when necessary on the above website

Telephone +64 4 382 5358
Fax +64 4 384 5368
Email janine.jackson@telecom.co.nz

Technical or procedural information on telephones and all voice type equipment:

Telephone +64 4 382 5345
Fax +64 4 473 384 5368
Email doug.burrus@telecom.co.nz

Technical or procedural information on ISDN, fax and other non-voice type equipment:

Telephone +64 4 382 5344
Fax +64 4 384 5368
Email richard.brent@telecom.co.nz

- **Ministry of Commerce**

Communications Network
Resources and Networks Branch
Ministry of Commerce
P O Box 1473
Wellington
New Zealand

Telephone +64 4 472 0030
Fax +64 4 384 7010
Website <http://www.moc.govt.nz>

3.3 (c) **EU Authorities Responsible for Designating European CABs under the Telecommunications Terminal Equipment Sectoral Annexes**

<ul style="list-style-type: none"> • Belgium Institut Belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie • Denmark Telestyrelsen • Germany Ministerium für Post und Telekommunikation • Greece Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications • Spain Ministerio de Fomento • France Ministère de l'Industrie, de la Poste et des Télécommunications • Ireland Department of Transport, Energy and Communications • Italy Ispettorato Generale TLC • Luxembourg Administration des Postes et Télécommunications 	<ul style="list-style-type: none"> • Netherlands Ministerie van Verkeer en Waterstaat • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Instituto das Comunicações de Portugal • Finland Liikenneministeriö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs
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More information on designation of CABs for the telecommunications terminal equipment sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.4 (a) Low Voltage Equipment Australia

Scope and Coverage

For Australia the Low Voltage Equipment Sectoral Annex covers electrical products which are within the scope of the various Australian State and Territory legislation for safety of electrical equipment. Electrical safety is a State responsibility and each regulatory authority administers a uniform, reciprocal approvals scheme. Under this scheme electrical articles are classified as either **declared** or **non-declared**.

- **Declared electrical articles**

There are currently 60 declared electrical articles (see **Table 2** below) that, in order to be supplied in Australia, must comply with the relevant safety standard, be approved by an Australian regulatory authority or certified by a JAS-ANZ accredited certification body, and clearly marked as required. The types of declared electrical articles and the relevant standards are listed in AS/NZS 4417.2¹²

- **Non-declared articles**

Electrical appliances and equipment, which are not declared, may be supplied without first being approved. However, it is the responsibility of the supplier to ensure that they are safe. AS/NZS 3820¹³ provides essential safety parameters that are based on the Low Voltage Equipment Directive.

Approval/Registration Arrangements

Detailed information, advice, application forms and fees relating to electrical approvals can be obtained from any one of the regulatory authorities listed below. For declared articles a Certificate of Approval is issued by the regulator following the supplier's provision of essential information including an acceptable test report that establishes that the equipment complies with the relevant Australian standard. The Certificate remains valid for up to 5 years following which it may be renewed. Alternatively a product may be issued with certification by a product certification body accredited by JAS-ANZ and accepted by all electrical regulators.

For non-declared articles there is a voluntary certification system that is similar in procedure to the Certificate of Approval arrangement.

Product Marking

Declared articles must display their assigned marking. This marking usually comprises a letter identifying the State or Territory from which the approval is given followed by the certificate number.

For non-declared articles there is a recommended, but voluntary marking arrangement and comprises the certificate number preceded by "CS" indicating Certificate of Suitability, and followed by the single first letter of the State of issue.

For all products, declared and non-declared, an alternative RCM¹⁴ marking is available. This marking is a multi-regulatory scheme incorporating EMC and other regulatory requirements. Rules applicable to the use of the RCM marking are contained in AS/NZS 4417.

¹² AS/NZS 4417: Marking of electrical products to indicate compliance with regulations

¹³ AS/NZS 3820: Essential safety requirements for low voltage electrical equipment

¹⁴ Regulatory Compliance Mark

Australia-New Zealand Mutual Recognition

Under the Trans Tasman Mutual Recognition Arrangement as from 1 May 1999 electrical equipment which can legally be sold in New Zealand can be exported from New Zealand to Australia.

Australian Electrical Safety Standards

Regulators have adopted Australian and New Zealand standards for specifying the necessary test requirements. It can be seen from Table 2 that many AS/NZS standards are now based on IEC standards. For example the IEC 60335 series (with some Australian and New Zealand additions where necessary). For lighting products the AS/NZS clones of the IEC 60598 series apply. As these IEC based standards are introduced the older standards remain in place for a number of years. Manufacturers have the option of using either standard during the overlap.

Test reports to the equivalent IEC standards may be accepted by electrical regulators as establishing compliance, at least in part, with the listed Australian/New Zealand standards. Additional testing or inspection processes will need to be considered to address any additional requirements or deviations of the listed standards. For example there are substantial differences in combustion propagation assessments. It should also be noted that the Australian mains supply is 240V, 50 Hz and this impacts on markings, rating and heating rise and abnormal tests. Advice should be obtained from an electrical regulator on these requirements. The IECEE CB Bulletin also provides a useful reference to the Australian and New Zealand deviations.

The Role of European Designated CABs

As noted above, in accordance with Australian legislation certain types of electrical equipment (declared articles) are required to be approved (registered) before they can be placed on the market.

Under the framework of the MRA, an Australian State or Territory regulatory authority will, within five working days, register a product from the European Community upon receipt of an application accompanied by a report from a designated CAB and the relevant fee, without further assessment of the product. (The designated fee is related to the costs of the electrical equipment registration, enforcement and post-market surveillance activities of the Australian regulatory authorities).

Similarly certificates of suitability will be promptly issued on receipt of an application accompanied by a report from a designated CAB.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the procedures set out in the Annex of the MRA regarding procedures to be followed by the European Community in designating CABs to assess electrical products against Australia's requirements:

(a) Testing Laboratories

- accredited by accreditation bodies which are signatories to the European cooperation for Accreditation of (EA) Multilateral Agreement on Calibration and Testing;
- recognised within the IECEE CB Scheme;
- able to demonstrate competence under an equivalent accreditation scheme.

(b) Certification Bodies

- accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification;
- membership of the IECEE CB Scheme;
- accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement; or
- able to demonstrate competence under an equivalent accreditation scheme.

Contact Details for Australian Electrical Safety Regulatory Authorities

• Victoria	Office of Chief Electrical Inspector PO Box 262 Collins Street West Melbourne 8007	Telephone +61 3 9203 9771 Fax +61 3 9686 2197 Website www.ocei.vic.gov.au
• New South Wales	Safety and Standards Branch Department of Fair Trading PO Box 972 Parramatta 2124	Telephone +61 2 9895 0715 Fax +61 2 9895 0423 Website www.fairtrading.nsw.gov.au
• Queensland	Office of the Energy Regulator Department of Mines and Energy GPO Box 995 Spring Hill 4041	Telephone +61 7 3237 0278 Fax +61 7 3237 0229 Website www.dme.qld.gov.au/safety/electric.htm
• Western Australia	Technical & Safety Division Office of Energy 20 Southport Street Leederville 6007	Telephone +61 8 9422 5209 Fax +61 8 9422 5244 Website www.energy.wa.gov.au
• South Australia	Office of The Technical Regulator PO Box 77 Adelaide 5001	Telephone +61 8 8226 5516 Fax +61 8 8226 5531 Website www.energysafety.sa.gov.au
• Tasmania	Office of Electricity Standards & Safety Department of Infrastructure Energy & Resources PO Box 56 Rosny Park 7018	Telephone +61 3 6233 7585 Fax +61 3 6233 8338 Website www.wsa.tas.gov.au/ess/electric.htm
• Australian Capital Territory	Department of Urban Services - BEPCON GPO Box 1908 Canberra 2601	Telephone +61 2 6207 7161 Fax +61 2 6207 7750 Website www.palm.act.gov.au/bepcon
• Northern Territory	Department of Industry & Business GPO Box 4169 Darwin 0801	Telephone +61 8 8999 5024 Fax +61 8 8999 6650 Website www.nt.gov.au

Contact Details for Electrical Regulatory Authorities Council (ERAC)

Website: www.erac.gov.au

Information is provided on ERAC's role and explains why in Australia electrical regulatory functions have been relocated to independent organisations which are no longer directly linked to utilities

Table 2: Australian Electrical Safety Declared Articles
(Table provided by an Australian Regulator - information current at 17 February 2000)

TYPE OF DECLARED ARTICLE	AUSTRALIAN/ NEW ZEALAND STANDARD	RELEVANT IEC STANDARD
APPLIANCE CONNECTOR	AS/NZS 3109.1	320.1*
ARC WELDING MACHINE	AS/NZS3195	
BATTERY CHARGER - AUTOMOTIVE TYPE	AS/NZS3350.2 29	60335-2-29*
BATTERY CHARGER - GENERAL TYPE		
- Transformer	AS/NZS3350.2.29 or AS/NZS3108	60335-2-29* 742*
- Electronic	AS/NZS3250 or AS/NZS3260	60065* 60950*
BAYONET LAMPHOLDER	AS3117	
BAYONET LAMPHOLDER ADAPTOR	AS3119	
BLANKET	AS/NZS3164	967*
BREAD TOASTER	AS/NZS3350.2.	60335-2-9*
CLOTHES DRYER		
- Rotary	AS/NZS3350.2.11	60335-2-11*
- Cabinet	AS/NZS3350.2.43	60335-2-43*
CONTROL OR CONDITIONING DEVICE	AS/NZS3197	
COOKING APPLIANCE - PORTABLE TYPE		
- Grillers, roasters, breadmakers	AS/NZS3350.2.9 or AS/NZS3350.2.78	60335-2-9* 60335-2-78*
- Warming plates	AS/NZS3350.2.12	60335-2-12*
- Frying pans, deep fryers, woks	AS/NZS3350.2.13	60335-2-13*
CORD EXTENSION SOCKET	AS/NZS3120	
CORD-LINE SWITCH	AS3127	1058-2-1**
DECORATIVE LIGHTING OUTFIT	AS/NZS60598.2.20 or AS/NZS3152	60598-2-20*
tree lights and chains		
DISHWASHING MACHINE	AS/NZS3350.2.5	60335-2-5*
EDISON SCREW LAMPHOLDER	AS3140	
EXTRA-LOW VOLTAGE POWER SUPPLY UNIT		
- Transformer (general use)	AS/NZS3108	742*
- Transformer (specific use)	AS/NZS3108 or AS/NZS3250 or AS/NZS3260	60065* 60950*
- Electronic	AS/NZS3250 or AS/NZS3260	60065* 60950*
FAN	AS/NZS3350.2.80 or AS/NZS3302	60335-2-80* 342-1*
FENCE ENERGISER ^(a)	AS/NZS3350.2.76 or AS/NZS3129	60335-2-76* 1011*
FLEXIBLE HEATING PAD	AS/NZS3164	
FLOOR POLISHER/SCRUBBER ^(a)	AS/NZS3350.2.10	60335-2-10*
FLUORESCENT LAMP BALLAST		
- Reactive	AS3168	
- Electronic	AS3134	
FLUORESCENT LAMP STARTER	AS3138	60155* & 926**
HAIR CARE APPLIANCE	AS/NZS3350.2.23	60335-2-23*
HEDGE CLIPPER ^(a)	AS/NZS3160	745**
IMMERSION HEATER	AS/NZS3350.2.73 or AS/NZS3350.2.74 or AS/NZS3350.2.55	60335-2-73* or 60335-2-74* or 60335-2-55*
INSECT ELECTROCUTOR	AS/NZS3350.2.59 or AS/NZS3150	60335-2-59*
INSPECTION HANDLAMP	AS/NZS 60598.2.8 or AS/NZS3118	60598-2-8*
IRON	AS/NZS3350.2.3	60335-2-3*
JUG	AS3106	
KITCHEN MACHINE	AS/NZS3350.2.14	60335-2-14*

Table 2 continued

LAWN CARE APPLIANCE	AS3156 or AS/NZS3160	
LIQUID HEATING APPLIANCE	AS/NZS3350.2.15	60335-2-15*
LUMINAIRE - PORTABLE TYPE	AS/NZS60598.2.4 or AS/NZS60598.2.10 or AS/NZS3128	60598-2-4* 60598-2-10
MASSAGE APPLIANCE	AS/NZS3350.2.32	60335-2-32*
MICROWAVE OVEN	AS/NZS3350.2.25	60335-2-25*
MINIATURE OVERCURRENT CIRCUIT-BREAKER	AS/NZS4898 or AS3111	898*
OUTLET DEVICE – PORTABLE TYPE	AS/NZS3105	
PLUG	AS/NZS3112	
PROJECTOR ^(a)	AS/NZS3350.2.56 or AS3181	60335-2-56*
RANGE includes hotplates, hobs and ovens	AS/NZS3350.2.6 or AS/NZS3172	60335-2-6*
RANGE HOOD	AS/NZS3350.2.31	60335-2-31*
RAZOR/HAIR CLIPPER	AS/NZS3350.2.8	60335-2-8*
REFRIGERATING APPLIANCE	AS3303/NZS6324 AS/NZS3350.2.24	60335-2-24*
RESIDUAL CURRENT DEVICE	AS/NZS3175.1 or AS/NZS61009.1 or AS/NZS3190	1008-1* 1009-1*
ROOM HEATER - Thermal storage - Radiant or other	AS/NZS3350.2.61 AS/NZS3350.2.30	60335-2-61* 60335-2-30*
SEWING MACHINE ^(a)	AS/NZS3350.2.28	60335-2-28*
SOCKET-OUTLET	AS/NZS3112	
SOCKET-OUTLET ADAPTOR	AS/NZS3122	
SOLDERING IRON	AS/NZS3350.2.45	60335-2-45*
SUPPLY FLEXIBLE CORD	AS/NZS3191	
SWIMMING POOL/ SPA EQUIPMENT	AS/NZS3136 or AS/NZS3350-2-60	60335-2-60**
TELEVISION RECEIVER	AS/NZS3250	60065*
THERAPEUTIC LAMP ^(a)	AS/NZS3350.2.27	60335-2-27*
TOOL - PORTABLE TYPE	AS/NZS3160 AS/NZS7450.1	745.1*
VACUUM CLEANER	AS/NZS3350.2.2	60335-2-2*
WALL SWITCH	AS3133	
WASHING MACHINE	AS/NZS3350.2.7	60335-2-7*
WATER BED HEATER	AS/NZS3350.2.66 or AS3148	60335-2-66*
WATER HEATER - PRESSURE STORAGE TYPE	AS3142 AS/NZS3350.2.21	60335-2-21*

^(a) These articles are intended to be deleted from the schedule of declared articles on 1 November 2000.

CONSIDERATION OF IEC STANDARDS

* These IEC standards have equivalent AS/NZS standards with differences (local deviations) being listed therein.

** These standards are expected to be more closely aligned by revisions of the IEC and/or AS/NZS standards.

CHANGES TO DECLARED ARTICLES

An up to date listing of classes of equipment and applicable Australian standards is maintained by Standards Australia and published in standard AS/NZS 4417.2

3.4 (b)

Low Voltage Equipment New Zealand

Scope and Coverage

For New Zealand the Low Voltage Equipment Sectoral Annex covers electrical products which are **Declared Articles** within the meaning of the Regulation 101 of the New Zealand Electricity Regulations 1997.

The regulations set performance based criteria for electrical safety via a code of practice - NZECP3.¹⁵ This defines safety in a similar way to the Low Voltage Directive and cites official standards and acceptable testing laboratories for industry based verification. A small range of products (**declared articles**) require certification by the regulator or other recognised agencies. The full range of legislation, regulations, codes and guidance information is contained on the Energy Safety Service website.

- **Declared electrical articles**

There is currently a transition period in which New Zealand is moving from 15 declared electrical articles (see Section E3 of AS/NZS 4417.2)¹⁶ to just two or three. These must comply with the relevant safety standards and be certified (approved) by the New Zealand Energy Safety Service or a recognised agency and marked as required. At the same time a supplier declaration system similar in concept to the Low Voltage Directive is being introduced. The new regime is expected to be in place by early 2001. Details of the current situation can be found on the Energy Safety Service website.

- **Non-declared articles**

For electrical appliances and equipment which are not declared, it is the responsibility of the supplier to ensure that they meet essential safety requirements. Recognised official standards and acceptable testing laboratories are listed in NZECP3.

Approval/Registration Arrangements

Detailed information, advice, application forms and fees relating to electrical approvals can be obtained from the Energy Safety Service (ESS). A Certificate of Approval is issued by the ESS following the supplier's provision of essential information including an acceptable test report that establishes that the equipment complies with the relevant standard. The certificate remains valid for 5 years following which it may be renewed. Alternatively a product may be issued with certification by a recognised agency, including product certification bodies accredited by JAS-ANZ and accepted by the ESS.

For non-declared articles an industry based testing regime is available which is defined in AS/NZS 4417.

Product Marking

Declared articles must display their assigned marking. The form of marking is flexible but generally is the prefix NZ followed by the certificate number. For all products, declared and non-declared, an alternative marking (RCM) is available. This marking is a multiregulatory scheme incorporating EMC and other regulatory requirements. Rules applicable to the use of the RCM marking are contained in AS/NZS 4417.

¹⁵ NZECP3 New Zealand Electrical Code of Practice for Electrical Safety of Fittings and Electrical Appliances

¹⁶ AS/NZS 4417:Marking of electrical products to indicate compliance with regulations.

New Zealand-Australia Mutual Recognition

Under the Trans Tasman Mutual Recognition Arrangement as from 1 May 1999 electrical products legally sold in Australia may be exported to and sold in New Zealand, and vice versa.

New Zealand Electrical Safety Standards

The ESS has adopted New Zealand and Australian standards for specifying the necessary test requirements - see NZECP3. It can be seen from Table 2 in Section 3.4(a) that many AS/NZS standards are now based on the IEC 60335 series (with some Australian and New Zealand additions where necessary). For lighting products the AS/NZS clones of the IEC 60598 series apply. As these IEC based standards are introduced the older standards remain in place for a number of years. Manufacturers have the option of using either standard during the overlap.

Test reports to the equivalent IEC standards (see Table 2 in Section 3.4 (a)) may be accepted by the ESS as establishing compliance, at least in part, with the listed New Zealand and Australian standards. Additional testing or inspection processes will need to be considered to address any additional requirements or deviations of the listed standards. Advice should be obtained from the ESS on these requirements.

The Role of European Designated CABs

As noted above, in accordance with New Zealand legislation, certain types of electrical equipment (see NZECP3) are required to be registered before they can be placed on the market.

Currently within the framework of the MRA, the ESS will, within five working days, register a product from the European Community upon receipt of an application accompanied by a report from a designated CAB and the relevant fee without further assessment of the product. (The designated fee is related to the costs of the electrical equipment registration, enforcement and post-market surveillance activities of the ESS.)

The New Zealand legislation is currently being reviewed and it is planned to amend Regulation 101 to permit certification (approval) to be issued by agencies in Europe recognised by the ESS. Under this approach the European certification body would only be required to make available on the ESS website the necessary information regarding those products certified for the New Zealand market.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the procedures set out in Annex 1 of the MRA regarding procedures to be followed by the European Community in designating CABs (testing laboratories) to assess electrical products against New Zealand's requirements:

- accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing;
- recognised within the IECEE CB Scheme; or
- able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

Contact Details For New Zealand Electrical Safety Regulatory Authority

Principal Technical Advisor

Energy Safety Service
Ministry of Consumer Affairs
PO Box 1473
Wellington
NEW ZEALAND

Telephone +64 4 472 0030
Fax +64 4 460 1365
Website <http://www.ess.moc.govt.nz>

3.4 (c) **EU Authorities Responsible for Designating European CABs under the Low Voltage Equipment Sectoral Annexes**

<ul style="list-style-type: none"> • Belgium Ministère des Affaires Economiques Ministerie van Economische Zaken • Denmark Bygge- og Boligstyrelsen • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria y Energia • France Ministère de l'Industrie, de la Poste et des Télécommunications • Ireland Department of Enterprise and Employment • Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports 	<ul style="list-style-type: none"> • Netherlands Ministerie van Economische Zaken • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Kauppa- ja teollisuusministeriö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk controll (SWEDAC) • UK Department of Trade and Industry <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs
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More information on designation of CABs for the low voltage equipment sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.5 (a) Electromagnetic Compatibility (EMC) Australia

Scope and Coverage

For Australia the EMC Sectoral Annex covers electromagnetic compatibility of equipment regulated under the Australian Radiocommunications Act 1992. Under this Act the Australian Communications Authority (ACA)¹⁷ has developed the Australian EMC scheme. The ACA is also responsible for the regulation of telecommunications terminal equipment.

It is important to note that radiocommunications transmitters are outside the scope of the EMC Sectoral Annex. In Australia these products are excluded from the EMC scheme as they are covered by a different set of standards and compliance arrangements administered by the ACA.

Within the EMC scheme there are electromagnetic interference (EMI) controls on products within the scope of ACA mandated standards (see ACA website). These cover a wide range of finished electrical and electronic products such as white goods, brown goods, office equipment, and consumer electronics. All must comply with the standards mandated in the scheme.

The scope of the Australian EMC scheme is more limited than that of the European EMC Directive. For example some systems and devices used in heavy industry and transport are subject to EMC compliance in Europe, but are excluded in Australia. Suppliers in Europe must also meet requirements for several EMC phenomena such as immunity, harmonics, voltage fluctuation and flicker. Currently in Australia only emissions are regulated by the EMC scheme. (There are immunity requirements for high risk medical devices – see Chapter 3.2 (a)).

Compliance Arrangements

- **General**

Detailed information on the EMC scheme and compliance arrangements are available on the ACA website.

Compliance with the mandated standards of the EMC scheme may be demonstrated by one of two compliance routes, depending upon the nature of the device and the extent to which standards are applied. These are through either the application of a test report or through the Technical Construction File (TCF).

¹⁷ Other agencies with a role in EMC management in Australian and the products covered by their regulatory arrangements are:

- Therapeutic Goods Administration: listed and registered electromedical and implantable electromedical devices - for immunity only;
- Department of Transport and Regional Services - Vehicle Safety Standards: road vehicles;
- Civil Aviation Safety Authority: avionics and aviation ground facilities;
- Airservice's Australia: VHF airband;
- Commonwealth Department of Defence: Defence equipment.

Under the EMC scheme it is the responsibility of suppliers – manufacturers, their agents or product importers - to ensure that products placed on the Australian market satisfy the technical requirements of the EMC scheme.

Australian suppliers must satisfy four basic requirements under the EMC scheme. They must:

- establish sound technical grounds for product compliance;
- make and hold a Declaration of Conformity to ACA mandated standards;
- prepare and keep a Compliance Folder; and
- label the product as directed.

Once these basic requirements have been satisfied a product can be offered for sale.

- **Declaration of conformity**

The supplier's Declaration of Conformity is the formal attestation that the product placed on the market meets the requirements of the EMC scheme. The test report or the TCF provides the technical grounds for making the Declaration of Conformity. This document must be completed and held in Australia by the supplier - for imported products the supplier is the Australian importer.

- **Compliance folder**

The term 'Compliance Folder' refers to the body of documentation which suppliers must assemble and hold in order to adequately support the Declaration of Conformity for any device placed on the market.

The Compliance Folder may comprise up to five main elements:

- test reports or TCF;
- a signed supplier's Declaration of Conformity to ACA mandated standards;
- a description of the apparatus which positively identifies it, possibly including a photograph and/or block diagram;
- reference to specifications for conformity;
- a technical description of the apparatus.

With the exception of the Declaration of Conformity, which must be held in Australia, the other elements of the Compliance Folder may be held outside Australia. The documents may be held in electronic form but must be available in non-electronic form, in English, if requested at an audit.

- **Compliance through testing**

The EMC scheme requires products to meet the applicable EMC standard. For most products testing will be the most direct route to market. (Where the basic model has been shown by testing to meet the EMC scheme, then certain variants will not need further testing.)

The ACA recommends that test reports be from a NATA accredited laboratory, or an overseas NATA Mutual Recognition Agreement partner accredited laboratory. In the event of product conformity being called into question, the ACA will accept such test data as final in any determination of whether or not the product complies.

Telecommunications terminal equipment and equipment covered under ISM group 2 (RF generators) can only be declared on the basis of a NATA or NATA MRA partner accredited test report. Telecommunications terminal equipment means equipment that is, or is to be, the subject of the Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice 1997.

- **Compliance through the technical construction file**

The Technical Construction File (TCF) provides a second route for suppliers to demonstrate product compliance with ACA mandated standards under circumstances where it is impractical or not feasible to test. To use the TCF route suppliers must apply to a NATA determined Competent Body¹⁸ for a NATA endorsed technical report.

The TCF is prepared in two parts. The first or draft part is prepared by the supplier and comprises claims by the supplier for product conformity and supporting evidence. The second part is made by a Competent Body in the form of a technical assessment verifying the claims in the draft TCF.

When completed the TCF should contain:

- an adequate description of the device to be marketed under the TCF;
- a technical rationale for the use of the TCF route;
- a statement of the steps taken to manage the emissions of the device, including reference to the applicable standards;
- all technical reports relevant to the product; and
- any reports issued by the Competent Body.

Product Marking

Articles controlled under the EMC scheme must be labelled and must contain either the C-Tick Mark or the Regulatory Compliance Mark (RCM). Details are provided in the EMC scheme document on the ACA website.

Before a device is labelled with the C-Tick Mark, the Australian supplier must submit a written notice to the ACA on a form downloadable from the ACA website. A supplier is only required to submit one application to the ACA advising of their intention to use the C-Tick Mark on compliant products.

The RCM is described in AS/NZS 4417 and is intended for use by a number of regulators. Suppliers intending to use the RCM for EMC compliance must complete the application forms in AS/NZS 4417 and submit them as directed in the standard.

¹⁸ See ACA or NATA websites for the current list of NATA determined Competent Bodies.

Australia-New Zealand Mutual Recognition

Electromagnetic compatibility is a sector that has a special exemption from the Trans Tasman Mutual Recognition Arrangement. As a result products legally sold in New Zealand must, if sold in Australia, also meet Australian EMC standards and regulatory requirements. Negotiations on harmonisation of Australian and New Zealand EMC requirements are underway and it is hoped that mutual recognition will apply sometime in 2001.

Australian EMC Standards

The EMC scheme is based on a suite of Australian/New Zealand standards, made into law by the ACA. Most have been adopted from CISPR standards with as little variation as possible. One of these (AS/NZS 2064.1/2) which covers industrial, scientific and medical equipment does have some specific variations from the CISPR 11 parent to cater for Australian frequency band plans. Other differences between the standards tend to relate to the time delay in adoption of the CISPR as an AS/NZS standards or the adoption of amendments. Often the delay is between one to two years. Testing for Australia must be conducted at 240V, 50 Hz

The EMC scheme document on the ACA website details mandatory standards and their international equivalent. Testing to the equivalents is acceptable, but the Declaration of Conformity must be to the Australian standard.

The Role of European Designated CABs

Under the Australian EMC, scheme suppliers must demonstrate compliance of products with the relevant standards, prior to marketing. Australian suppliers are asked to declare that their products meet the requirements and hold evidence that supports their claim for future audits.

The evidence may be provided through test reports from a laboratory or a Technical Construction File (TCF) prepared by a Competent Body.

The role of a laboratory is to test the product to the applicable Australian/New Zealand standard or the equivalent international or European standard. The laboratory must issue a test report addressing the tests it has used, the results of the tests and whether the test shows that the product meets the requirements of the applicable standard.

Reports by European testing laboratories accredited by a body that has a mutual recognition agreement with NATA or designated as a CAB under the EMC Sectoral Annex of the MRA will be accepted in Australia.

The role of a Competent Body or MRA designated CAB is to issue a technical assessment against the applicable Australian/New Zealand standard, or its equivalent, based on material provided by the manufacturer. Where additional testing is required as part of the assessment the Competent Body may require the report to be from an accredited laboratory. Note: The mandatory compliance with a standard is quite different from the EMC Directive's essential requirements approach.

It should be noted that:

- suppliers require accredited test reports for TTE or group 2 ISM equipment and designated CABs (Competent Bodies) should secure accredited testing where this is required to complete a technical assessment;

- the ACA reserves the right to require further testing from an accredited test house where there are doubts about compliance.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the procedures set out in Annex 1 of the MRA regarding procedures to be followed by the European Community in designating CABs to assess products for electromagnetic compatibility against Australia's requirements:

(a) Testing Laboratories

Operating according to the requirements of ISO 17025 or EN 45001, and either:

- accredited by accreditation bodies which are signatories to the European cooperation for Accreditation Multilateral Agreement on Testing and Calibration;
or
- able to demonstrate competence under an equivalent accreditation scheme.

(b) Inspection Bodies

Operating according to the requirements of ISO 17020 or EN 45004 and either:

- accredited by accreditation bodies which are signatories to a European Multilateral Agreement; or
- able to demonstrate competence under an equivalent accreditation scheme.

Contact Details for the Australian Communications Authority

Manager
Radiocommunications Standards Team (EMC)
PO Box 78
Belconnen ACT
Australia 2616

Telephone +61 2 6256 5555
Fax +61 2 6253 2424
Email emc@aca.gov.au
Website <http://www.aca.gov.au>

3.5 (b)

Electromagnetic Compatibility (EMC) New Zealand

Scope and Coverage

For New Zealand the EMC Sectoral Annex covers electromagnetic compatibility of equipment regulated under the New Zealand Radiocommunications Act 1989. Under this Act New Zealand's Ministry of Commerce (Ministry) has developed and administers the New Zealand EMC framework. Telecommunications terminal equipment (TTE) is covered by this framework. However the telecommunications industry is de-regulated in New Zealand, and telecommunications network providers regulate other aspects of compliance (eg network compatibility) for equipment directly connected to their networks.

Within the EMC framework electromagnetic interference (EMI) is divided into four distinct environments. Currently there are only EMI controls in the **Commercial, Residential and Light Industry Environment** covering the supply of a wide range of finished electrical and electronic products such as white goods, brown goods, office equipment, and consumer electronics. The Commercial, Residential and Light Industry Environment is defined in Generic Emission Standards AS/NZS 4251 and EN50081-1.

The scope of the New Zealand EMC framework is more limited than that of the European EMC Directive. For example many systems and devices used in heavy industry and transport are subject to EMC compliance in Europe, but are excluded in New Zealand. Suppliers in Europe must also meet requirements for several EMI phenomena such as immunity, harmonics, voltage fluctuation and flicker in addition to emissions. In New Zealand emissions only are regulated.

Compliance Arrangements

- **General**

Detailed information on the EMC framework and compliance arrangements is available from the Ministry of Commerce. Refer to the section *Contact Details for the Ministry of Commerce*.

Compliance with the requirements of the EMC framework must be demonstrated with a test report and/or possibly a technical report.

Under the EMC framework it is the responsibility of suppliers - manufacturers or product importers - to ensure that products placed on the New Zealand market satisfy the technical requirements of the EMC framework.

Suppliers must satisfy two basic requirements under the EMC framework. They must:

- establish sound technical grounds for product compliance;
- submit a Declaration of Conformity;

Once these basic requirements have been satisfied a product can be offered for sale.

Suppliers may additionally apply for authorisation to label products although this does not absolve them from the requirement to submit a Declaration of Conformity.

- **Declaration of Conformity**

The supplier's Declaration of Conformity is the formal attestation that the product placed on the market meets the requirements of the EMC framework. The test report is the technical grounds for making the

Declaration of Conformity. The declaration must be completed and submitted to the Ministry of Commerce by the supplier.

- **Compliance through testing**

The EMC framework requires products to meet the applicable EMC standard. For most products testing will be the most direct route to market. (Where the product has been shown by testing to meet the EMC framework, then certain variants will not need further testing).

The Ministry of Commerce requires that test reports be from an approved laboratory. A list of Ministry approved laboratories may be viewed on the Ministry website. The Ministry of Commerce may, in the event of particular product or variant conformity being called into question, require additional testing.

- **Compliance through a technical report**

In New Zealand the Technical Construction File (TCF) is not formally offered as a second route for suppliers to demonstrate product compliance under circumstances where it is impractical or not feasible to test. Instead the equivalent of a TCF may be incorporated as a technical report with any applicable test reports.

A technical report is prepared by the supplier and comprises claims by the supplier for product conformity and supporting evidence including where possible a test report from a Ministry approved laboratory.

When completed the technical report should contain:

- an adequate description of the device to be marketed;
- a technical rationale for the use of a technical report;
- a statement of the steps taken to manage the emissions and/or susceptibility;
- characteristics of the device, including reference to the applicable standards;
- all additional technical reports relevant to the product; and
- any reports issued by a testing body.

Product Marking

Articles controlled under the EMC framework may be labelled with either the C-Tick Mark or the Regulatory Compliance Mark (RCM).

Before a device is labelled with the C-Tick Mark, the supplier must submit a Declaration of Conformity to the Ministry. A supplier must register with the Ministry to use the C-Tick Mark.

The RCM is described in AS/NZS 4417. It covers mains connected devices and a wider ranged regulatory regime. Suppliers intending to use the RCM for EMC compliance must complete the application form in AS/NZS 4417 part 3.

New Zealand EMC Standards

The EMC framework is based on a suite of Australian/New Zealand standards, mandated under regulations pursuant to the Radiocommunications Act 1989. They have been developed from CISPR standards with as little variation as possible. One of these, AS/NZS 2064.1/2, which covers industrial,

scientific and medical equipment does have some specific variations from CISPR 11 to cater for New Zealand frequency band plans. Other differences between AS/NZS and international standards tend to relate to the time delay in mandating respective standards or standard amendments. Often the delay is between one to two years.

Australia-New Zealand Mutual Recognition

Electromagnetic compatibility is a sector that has a special exemption from the Trans Tasman Mutual Recognition Arrangement. As a result products legally sold in Australia must meet Australian requirements and products sold in New Zealand must meet New Zealand EMC standards and regulatory requirements. Negotiations on harmonisation of Australian and New Zealand EMC requirements are well advanced. Full harmonisation is expected in due course.

Under harmonised trans-Tasman EMC compliance regimes, products labelled and sold in Australia will automatically fulfil the regulatory requirements for New Zealand and vice versa. At the time of harmonisation the New Zealand framework requirements will be similar to the existing Australian requirements.

The Role of European Designated Conformity Assessment Bodies (CABs)

Under the New Zealand EMC framework, suppliers must demonstrate compliance of products with the relevant standards, prior to marketing. New Zealand suppliers are asked to declare that their products meet the requirements and hold evidence that supports their claim for future audits. The evidence may be provided through test reports from a laboratory and possibly additional supporting technical reports.

The role of a laboratory is to test the product to the applicable Australian/New Zealand standards or equivalent international or European standards that have been approved for use in New Zealand. The laboratory must issue a test report addressing the tests it has used, the results of the tests and whether the tests show that the product meets the requirements of the applicable standard.

Reports by European testing laboratories accredited by a body that has a mutual recognition agreement with IANZ or is designated as a CAB under the EMC Sectoral Annex of the MRA will be accepted in New Zealand.

It should be noted that the Ministry of Commerce reserves the right in accordance with Article 8 of the MRA to require further testing from an accredited test house where there are doubts that the test report or technical assessment indicates compliance based on the applicable standard.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the procedures set out in Annex 1 of the MRA regarding procedures to be followed by the European Community in designating CABs to assess products for electromagnetic compatibility against New Zealand's requirements:

- Testing laboratories operating according to the requirements of ISO 17025 or EN 45001, and either:
 - (a) accredited by accreditation bodies which are signatory to the European co-operation for Accreditation (EA) Multilateral Agreement on Calibration and Testing; or
 - (b) able to demonstrate competence through other means; such as:
 - participation in regional/international MRAs or certification systems;

- regular peer evaluations;
- proficiency testing; and
- comparisons between CABs.

Contact Details for the Ministry of Commerce

Technical Officer (Regulatory)
Radio Spectrum Management
Ministry of Commerce
PO Box 8562
Riccarton
Christchurch
New Zealand

Telephone +64 3 343 1240
Fax +64 3 343 1219
Email brian.emmett@moc.govt.nz
Website <http://www.moc.govt.nz/rsm>

3.5 (c) **EU Authorities Responsible for Designating European CABs under the Electromagnetic Compatibility Sectoral Annexes**

<ul style="list-style-type: none"> • Belgium Ministère des Affaires Economiques Ministerie van Economische Zaken • Denmark Telestyrelsen • Germany Bundesministerium für Post und Telekommunikation • Greece Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications • Spain for telecommunications equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energia • France Ministère de l'Industrie, de la Poste et des Télécommunications • Ireland Department of Transport, Energy and Communications • Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports 	<ul style="list-style-type: none"> • Netherlands Ministerie van Verkeer en Waterstaat • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português de Comunicações de Portugal • Finland Kauppa- ja teollisuusministeriö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs
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More information on designation of CABs for the electromagnetic compatibility sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.6 (a) Machinery Australia

Scope and Coverage

The scope of the Machinery Sectoral Annex of the MRA with Australia covers products listed in Annex IV of Directive 89/392/EEC, plus tower cranes and mobile cranes.

Regulatory Environment/Requirements

- **General**

In Australia occupational health and safety (OHS) is a State/Territory responsibility. Each has its own occupational health and safety legislation and each has similar requirements.

- **Occupational Health and Safety Acts**

Each State/Territory OHS Act is the principal piece of legislation which imposes duties of care on designers, manufacturers, importers, suppliers, employers, self-employed and employees to ensure that plant, equipment and substances used in the workplace are controlled in a manner that is not harmful to the health or safety of any person.

Each OHS Act has the power to make regulations, such as OHS (Plant) Regulations relating to machinery (plant) safety.

- **Plant/Machinery Safety Regulations**

All States/Territories have similar (but not identical) plant safety regulations. These regulations are mandatory requirements. However, the approach is performance based rather than prescriptive. Within this approach, workplace safety management systems are required to carry out:

- identification of all hazards;
- assessment of risks; and
- apply the appropriate risk control measures

for the plant/machinery, substances, etc., in the workplace.

These regulations also require all relevant health and safety information to be passed on from designer/manufacturer, etc, to all employers.

Each regulation contains a schedule of certain “high risk” plant that require registration or notification of design. **Table 3** is an example of a schedule of plant designs requiring design registration. In addition some items of “high risk” plant must be registered with the regulatory authority. It will be noted that in the schedule items of plant that are within the scope of the Machinery Sectoral Annex of the MRA are vehicle hoists, tower cranes and mobile cranes.

The registration process normally requires verification from a person who has not participated in the design of the plant. The design verifier must state that the design was produced in accordance with the record of published technical standards or engineering principles (as the case may be). Mutual recognition of registered plant designs exists between the States/Territories. Therefore plant that requires design registration and is registered in one in general will not need to be registered in another.

- **Australian Standards Referenced in Regulations**

Some principal standards are referenced in the Plant Regulations. However, not all States/Territories mandate these standards.

- **State and Territory Specific Information**

In general if machinery meets the requirement of the Machinery Directive (89/392/EEC) it will be acceptable to Australian regulators. However exporters must be aware of the information which must be provided by designers, manufacturers and suppliers.

Applicable legislation, regulations, codes of practice, application/registration forms and details of fees payable are available from each regulatory authority (see contact details below).

Australia-New Zealand Mutual Recognition

Under the Trans Tasman Mutual Recognition Arrangement machinery which can legally be sold in New Zealand can be exported to Australia, ie design verification accepted in New Zealand is automatically accepted in Australia. Requirements by Australian State/Territory for registration of design and of plant items still apply.

Product Marking

There are no specific Australian marking requirements for cranes or machinery.

Australian Machinery Standards

- **Cranes**

The AS 1418, **Cranes (including hoists and winches)**, series of standards specify requirements for cranes in general and specific requirements for particular types of cranes, including tower cranes and mobile cranes. As these standards are revised they are harmonised, as much as is relevant and applicable, with ISO and EN Standards.

- **Machinery**

AS 4024, **Safeguarding machinery**, is a new series of standards. AS 4024.1 specifies the general underlying principles for safeguarding industrial machinery and is focussed on risk control. This standard has been aligned with several EN standards including EN 292, EN 294, EN 954.1 and EN 1050 and has many similarities to Directive 89/392/EEC. As a result machinery conforming to the European machinery Directive is likely to conform with the principles of AS 4024.1.

Subsequent standards in the AS 4024 series cover electro-sensitive systems (based on prEN 61496) and pressure-sensitive devices. There are also a number of Australian standards covering safeguarding of specific machines, including power presses and woodworking machinery.

The Role of European Designated CABs

State and Territory regulations have requirements for the design and registration of high risk plant, including cranes and vehicle hoists and require various activities to be undertaken by “competent” persons. There are, however, few requirements for the mandatory involvement of conformity assessment bodies. In all States/Territories registration of design of plant is required (see Table 3). In circumstances where the designer and design verifier are employed by the same person there is a role for designated CABs (see below). As the occupational health and safety regulatory environment

currently is subject to considerable change exporters should check the latest situation with the relevant regulatory authority (see contact details below).

With regulators no longer taking responsibility for design verification, fabrication inspection and in-service inspection of machinery, including cranes, these activities are being undertaken in Australia by private organisations. Accreditation of these conformity assessment bodies is offered by NATA through its Inspection accreditation program.

For cranes and other items of machinery exported to Australia for which there are no mandatory involvement of third party CABs, voluntary involvement of CABs designated in accordance with the requirements detailed below would be of value in giving Australian industry confidence that it has met its OHS duty of care obligations.

Procedures for Designating CABs in Europe

Where State/Territory legislation covering cranes makes compliance with Australian standards mandatory and where the designer and design verifier are employed by the same person then the whole of the design process must, if the legislation requires, operate:

- a) within a quality system meeting requirements of ISO 9001 and be certified by a Quality Systems Certification Body operating according to the requirements of ISO Guide 62 or EN 45012, and either:
 - accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification; or
 - accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement; and
- b) in conformity with EN 45004 or ISO 17020 and accredited by an accreditation body meeting the requirements or ISO Guide 58 or EN 45002/3.

Contact Details For Australian OHS Regulatory Authorities

<ul style="list-style-type: none"> • New South Wales State Coordinator Plant OHS Division WorkCover Authority of NSW GPO Box 5364 Sydney 2001 • Victoria Director Field Services WorkCover Safety P O Box 414 Melbourne 3005 • Queensland Senior Principal Advisor (Technology) Department of Employment, Training and Industrial Relations GPO Box 69 Brisbane 4001 • South Australia Manager - Workplace Services Department for Administrative & Information Services GPO Box 465 Adelaide 5001 • Western Australia Director of Inspection Services Worksafe Western Australia PO Box 294 West Perth 6872 • Tasmania Sector Leader - Standards Workplace Standards Tasmania GPO Box 56 Rosny Park 7018 • Australian Capital Territory Director ACT WorkCover PO Box 224 Civic Square 2608 • Northern Territory Manager Occupational Health and Safety Division Department of Industries and Business GPO Box 4160 Darwin 0801 	<table style="width: 100%; border: none;"> <tbody> <tr> <td style="width: 30%;">Telephone</td> <td style="width: 70%;">+61 2 9370 5163</td> </tr> <tr> <td>Fax</td> <td>+61 2 9370 6106</td> </tr> <tr> <td>Website</td> <td>www.workcover.nsw.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 3 9628 8111</td> </tr> <tr> <td>Fax</td> <td>+61 3 9628 8199</td> </tr> <tr> <td>Website</td> <td>www.workcover.vic.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 7 3872 0584</td> </tr> <tr> <td>Fax</td> <td>+61 7 3247 0211</td> </tr> <tr> <td>Website</td> <td>www.detir.qld.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 8 8303 0288</td> </tr> <tr> <td>Fax</td> <td>+61 8 8303 0444</td> </tr> <tr> <td>Website</td> <td>www.eric.sa.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 8 9327 8777</td> </tr> <tr> <td>Fax</td> <td>+61 8 9481 6497</td> </tr> <tr> <td>Website</td> <td>www.wt.com.au/safetyline</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 3 6233 7662</td> </tr> <tr> <td>Fax</td> <td>+61 3 6233 8338</td> </tr> <tr> <td>Website</td> <td>www.wsa.tas.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 2 6205 0200</td> </tr> <tr> <td>Fax</td> <td>+61 2 6205 0797</td> </tr> <tr> <td>Website</td> <td>www.workcover.act.gov.au</td> </tr> <tr> <td colspan="2"> </td> </tr> <tr> <td>Telephone</td> <td>+61 8 8999 5025</td> </tr> <tr> <td>Fax</td> <td>+61 8 8999 5141</td> </tr> <tr> <td>Website</td> <td>www.nt.gov.au</td> </tr> </tbody> </table>	Telephone	+61 2 9370 5163	Fax	+61 2 9370 6106	Website	www.workcover.nsw.gov.au			Telephone	+61 3 9628 8111	Fax	+61 3 9628 8199	Website	www.workcover.vic.gov.au			Telephone	+61 7 3872 0584	Fax	+61 7 3247 0211	Website	www.detir.qld.gov.au			Telephone	+61 8 8303 0288	Fax	+61 8 8303 0444	Website	www.eric.sa.gov.au			Telephone	+61 8 9327 8777	Fax	+61 8 9481 6497	Website	www.wt.com.au/safetyline			Telephone	+61 3 6233 7662	Fax	+61 3 6233 8338	Website	www.wsa.tas.gov.au			Telephone	+61 2 6205 0200	Fax	+61 2 6205 0797	Website	www.workcover.act.gov.au			Telephone	+61 8 8999 5025	Fax	+61 8 8999 5141	Website	www.nt.gov.au
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Table 3: Example of Plant Designs and Items of Plant Requiring Registration in Australia¹⁹

1. Plant Requiring Registration of Design

- *pressure equipment*, other than *pressure piping*, and categorised as hazard level A, B, C or D according to the criteria identified in AS 3920 Part 1, *Pressure Equipment Manufacture - Assurance of Product Quality*;
- *gas cylinders* covered by AS 2030;
- *tower cranes*;²⁰
- *lifts*;²¹
- *building maintenance units*;
- *hoists*, with a platform movement in excess of 2.4 metres, designed to lift people;²
- *work boxes* suspended from cranes;
- *amusement structures* covered by AS 3533, with the exception of class 1 structures
- *prefabricated scaffolding*;
- *boom-type elevating work platforms*;
- *gantry cranes* with a safe working load greater than 5 tonnes or *bridge cranes* with a safe working load of 10 tonnes, and any *gantry crane* or *bridge crane* which is designed to handle molten metal or dangerous goods;²
- *Note: dangerous goods means dangerous goods as defined in the ADG Code; vehicle hoists*;²
- *mast climbing work platforms*;²
- *mobile cranes* with a safe working load greater than 10 tonnes.²

2. Items of Plant Requiring Registration

- *boilers* categorised as hazard level A, B or C according to the criteria identified in AS 3920 Part 1, *Pressure Equipment Manufacture - Assurance of Product Quality*;
- *pressure vessels* categorised as hazard level A, B or C according to the criteria identified in AS 3920 Part 1, with the exception of *gas cylinders* covered by AS 2030, LP gas fuel vessels for automotive use covered by AS 3509 and serial produced vessels covered by AS 2971;
- *tower cranes*;²²
- *lifts*;²³
- *building maintenance units*;
- *amusement structures* covered by AS 3533, with the exception of class 1 structures;
- *truck-mounted concrete placing units with booms*;⁴
- *mobile cranes* with a safe working load greater than 10 tonnes.⁴

¹⁹ National Standard For Plant [NOHSC:1010 (1994)]: Schedule 1. Note: Hazard levels are now defined in AS 4343-1999

²⁰ For the purposes of registration, *cranes*, and *hoists* in Schedule 1 exclude those that are manually powered, *elevating work platforms* and tow trucks

²¹ Registration of *lifts* includes escalators and moving walkways

²² For the purposes of registration, *cranes* and *hoists* in Schedule 1 exclude those that are manually powered

²³ Registration of *lifts* includes escalators and moving walkways

3.6 (b) Machinery New Zealand

Scope and Coverage

The Machinery Sectoral Annex of the MRA with New Zealand covers any machinery²⁴ that falls within the scope of the Health and Safety in Employment Act 1992.

For the avoidance of doubt it is stated in the MRA that coverage of this Sectoral Annex includes tower cranes, port type container cranes and mobile cranes including truck mounted cranes with a lifting capacity exceeding five tonnes used for loading and unloading that vehicle.

Regulatory Environment/Requirements

- **Regulatory authority**

The New Zealand regulatory authority for machinery is the Occupational Safety and Health Service of the Department of Labour.

- **Acts and regulations**

Relevant regulations under the HSE Act are:

- Health and Safety in Employment (HSE) Regulations 1995; and
- Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) (PECPR) Regulations 1999.

The HSE Regulations 1995 cover noise, cleaning maintenance and repair of machinery, woodworking and abrasive grinding machinery, roll-over protective structures on self propelled mobile mechanical plant.

The PECPR Regulations 1998 cover cranes and passenger ropeways.

In addition the Machinery Act 1950 covers amusement devices.

- **Duties under the Acts and Regulations**

The HSE Act places a general duty on employers to ensure the safety of employees. Employers are required to identify hazards, and to take all practicable steps to eliminate, isolate or minimise these hazards.

²⁴ **Machinery** is defined as an engine, motor, or other appliance that provides mechanical energy derived from compressed air, the combustion of fuel, electricity, gas, gaseous products, steam, water, wind or any other source; and includes

- (a) Any plant by or to which the motion of any machinery is transmitted; and
- (b) A lifting machine, a lifting vehicle, a machine whose motive power is wholly or partly generated by the human body, and a tractor.

The PECPR regulations place duties on controllers, designers, manufacturers and suppliers of cranes and passenger ropeways.

The duties on the designer, manufacturer and supplier include:

- to design the equipment in accordance with standards of generally accepted design practice, gazetted in New Zealand;
- design equipment in such a way that every activity for which the equipment was designed can be carried out safely;
- determine and specify the hazard level of the equipment;
- determine and specify the design verification requirements;
- ensure that if design verification is required the design is verified by a design verifier qualified to verify it;
- take into account in the design and verification the nature of the New Zealand seismic environment;
- to manufacture the equipment in compliance with any manufacturing requirements specified in the design;
- to ensure any changes to the structural strength or safety of the equipment during manufacture are verified by the design verifier;
- to ensure that any fabrication inspection requirements specified are carried out by a fabrication inspector qualified to inspect it;
- to ensure, when importing for supply equipment manufactured in an overseas country that it has been designed to standards that are equivalent to or better than those specified and gazetted in New Zealand.

The duties on the controller include:

- to hold information to enable the equipment to be operated safely;
- to notify OSH of accidents involving the equipment;
- to ensure the equipment is safe, is operated safely and is maintained in a safe condition;
- to ensure the equipment is not operated unless it has a current certificate of inspection;
- to ensure that repairs and alterations to the equipment are properly carried out and re-certified.

• **Verification and inspection arrangements**

The PECPR regulations require cranes and passenger ropeways to be design verified and inspected during manufacture by inspection bodies accredited to EN 45004 and recognised by the regulatory body.

The Machinery Act requires amusement devices, defined in the Act, to be registered by the Occupational Safety and Health Service. Part of the registration requirement is for an engineer registered under the Engineers Registration Act to issue a Certificate of Examination of the amusement device.

Australia - New Zealand Mutual Recognition

The Trans Tasman Mutual Recognition Arrangement took effect on 1 May 1998. Under this legislation goods that may be lawfully sold in one participating jurisdiction, may be lawfully sold in any other participating jurisdiction without the need to conform with any of the requirements relating to sale that are imposed by or under the law of that other jurisdiction.

While sale requirements for goods will be overridden by the TTMRA, nothing in it affects the operation of any laws in New Zealand regarding the inspection of goods within New Zealand as long as the laws are directed at matters affecting health, safety or the environment.

Safety considerations under the PECPR Regulations require cranes and passenger ropeways to have a certificate of inspection from an inspection body that is accredited to EN 45004 before it can be put into operation. To get this certificate importers and controllers will need to provide documented proof that the equipment has been design verified and inspected during fabrication to the same standard as similar equipment manufactured in New Zealand.

Product Marking

Cranes and passenger ropeways should be marked with appropriate operating and inspection information as required by the design standard. There are no specific New Zealand requirements for marking comparable to the CE mark.

New Zealand Machinery Standards

Cranes are required to be designed and manufactured to the appropriate British Standard - see **Table 4**.

Passenger ropeways must comply with the New Zealand Code of Practice for Passenger Ropeways. This code is largely based on the Canadian Standard CAN/CSA-Z98-96.

The OSH code of practice for amusement devices is in draft form at the moment.

Forklift trucks must comply with the ASME/ANSI B56.1 safety standard for low and high lift trucks.

The Role of European Designated CABs

The PECPR Regulations require design verification and fabrication inspection of cranes by inspection bodies (equivalent to conformity assessment bodies) that are accredited to EN 45004 and have been recognised by the Occupational Safety and Health Service. European CABs that have been designated under the MRA for relevant standards (see Table 4) will be recognised. For machinery other than cranes see the section below.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the principles and procedures set out in Annex 1 of the MRA for the designation of CABs to assess machinery against New Zealand's requirements:

- **For cranes**

- (a) Design Verification:

- operate in conformity with EN 45004 or ISO 17020; and
- operate a quality system conforming with ISO 9001; and
- employ design verifiers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance.

- (b) Inspection Bodies:

- operate in conformity with EN 45004 Type A or ISO 17020; and
- employ engineers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance.

- (c) Certification Bodies

- accredited by an accreditation body which is a signatory to European cooperation for Accreditation (EA) Multilateral Agreement on Certification; or
- accreditation by an accreditation body with which JAS-ANZ has a mutual recognition agreement; or
- able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

- (d) Testing Laboratories

- accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing; or
- able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

- **For machinery other than cranes**

- Either notified as a conformity assessment body in the European Community in accordance with the requirements established in Annex VII of Directive 89/392/EEC and Directive 93/465/EEC; or
- procedures that will ensure that the machinery meets the performance based risk protection requirements of the New Zealand legislation.

Contact Details for Occupational Safety and Health Service

Engineering Safety
Occupational Safety and Health Service
Department of Labour
PO Box 3705
Wellington

Telephone +64 4 915 4444
Fax +64 4 915 4370
Website <http://www.osh.dol.govt.nz>

Table 4: Crane Standards Applicable in New Zealand

Number	Title	Year
NZS/BS 302	Stranded steel wire ropes Part 1: 1987 - general requirements Part 2: 1987 - ropes for general purposes Part 8: 1989 - higher breaking load ropes	1987 & 1989
BS 466	Specification for power driven overhead travelling cranes, semi-goliath and goliath cranes for general use	1984
BS 1757	Specification for power driven mobile cranes	1986
BS 2452	Specification for electrically driven jib cranes mounted on a high pedestal or portal carriage	1954
NZS/BS 2573	Rules for the design of cranes, parts 1 & 2	
	Part 1 - classification, stress calculations and design criteria for structures	1983
	Part 2 - classification, stress calculations and design of mechanisms	1980
BS 2853	Design and testing of steel overhead runway beams	1957
BS 5744	Code of practice for the safe use of cranes	1979
BS 7121	Code of practice for the safe use of cranes	1989
	Part 1:1989 - General	1991
	Part 2: 1991 - Inspection, testing and examination	1997
	Part 4: 1997 - Lorry loaders	1997
	Part 5: 1997 - Tower cranes	
BS 7262	Specification for automatic safe load indicators	1990

3.6 (c) *EU Authorities Responsible for Designating European CABs under the Machinery Sectoral Annexes*

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
<ul style="list-style-type: none"> • Belgium Ministère de l'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • Denmark Direktoratet for Arbejdstilsynet • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria, Comercio y Turismo • France Ministère du Travail et des Affaires Sociales et Ministère de l'Industrie, de la Poste et des Télécommunications • Ireland Department of Enterprise and Employment • Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports 	<ul style="list-style-type: none"> • Netherlands Ministerie van Sociale Zaken en Werkgelegenheid • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Työministeriö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs

More information on designation of CABs for the machinery sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.7 (a) Pressure Equipment Australia

Scope and Coverage

The Pressure Equipment Sectoral Annex of the MRA with Australia is currently limited to products within the scope of the European simple pressure vessels directive (87/404/EEC). It has been agreed that this scope will be extended and negotiations to that effect have started now that the European pressure equipment directive 97/23/EC has entered into force.

Regulatory Environment/Requirements

- **General**

In Australia occupational health and safety (OHS) is a State/Territory responsibility. Under the OHS Acts of each State/Territory there are regulations covering pressure equipment. The Australian OHS legislative environment was traditionally prescriptive but has been changing to one of self-regulation with a performance-based approach. Each OHS Act imposes duties of care on designers, manufacturers, importers, suppliers, installers, employers, self-employed and employees to ensure that plant (which embraces pressure equipment), is controlled in a manner that does not cause injury or illness to a person or damage the environment. This approach requires those with duties under the Act and having management control of equipment to:

- identify hazards;
- assess the risks of those hazards; and
- control those risks.

While Australian regulatory authorities have been withdrawing from their traditional approval and inspection functions, many items of pressure equipment still must be individually registered and are required to be built to a registered design which has been subject to independent design verification. Fabrication inspection may also be required.

- **Approval/Registration Arrangements**

State/Territory pressure equipment regulations base the need for design verification and its registration, followed by equipment registration, on the hazard level of the equipment as defined in AS 4343.²⁵ (This must not be confused with the class of construction of the equipment.) AS 4343 categorises pressure equipment into five hazard levels: A, B, C, D and E, with A being the highest hazard level. Equipment built to EN 286 could be E, D or C depending on its volume and pressure.

In most States/Territories registration (or notification) of design is required for pressure equipment of hazard levels A, B, C and D and the equipment must be registered if of level A, B or C (see Table 1 of AS 4343). Designs registered with one regulatory authority do not normally require registration with another. Specific requirements, application/registration forms and details of fees payable are available from each regulatory authority.

Australia-New Zealand Mutual Recognition

Under the Trans Tasman Mutual Recognition Arrangement pressure equipment which can legally be

²⁵ AS 4343-1999: Pressure equipment – Hazard levels

sold in New Zealand can be exported to Australia and design verification accepted in New Zealand is automatically accepted in Australia. Requirements by Australian States/Territories for registration of design and of pressure equipment still apply.

Product Marking

Product standards of the AS/NZS 1200 series specify marking requirements for pressure equipment.

Australian Pressure Equipment Standards

Under the framework of AS/NZS 1200: Pressure Equipment a number of Australian standards have been developed as guidance to the requirements of pressure equipment design verification, manufacture, fabrication, inspection, installation, operation, maintenance and in-service inspection. Other equivalent international pressure equipment standards (including EN 286) or internally developed procedures could be used if permitted by State regulations.

The Role of European Designated CABs

While State/Territory regulations have requirements for the design and registration of pressure equipment, and require various activities to be undertaken by “competent” persons, there are few requirements for the mandatory involvement of conformity assessment bodies. In some States/Territories design verification is required in accordance with AS 3920.1²⁶ and in South Australia and Western Australia fabrication inspection is required in accordance with AS 3920.1. There is a role for designated CABs, including quality systems certification bodies, in these later situations. Table 2.1 of AS 3920.1 relates the need for external design verification and fabrication inspection to the hazard level and whether the manufacturer’s quality system is certified. As the pressure equipment regulatory environment currently is subject to considerable change exporters should check the latest situation with the relevant regulatory authority.

With many regulatory authorities no longer undertaking their traditional services of design verification, fabrication inspection and plant in-service inspection, these activities are increasingly being undertaken in Australia by private organisations. Accreditation of these conformity assessment bodies is offered by NATA through its Inspection accreditation program. In addition, voluntary certification schemes have been introduced for design verifiers, fabrication inspectors and in-service inspectors. The Australian Institute for the Certification of Inspection Personnel provides certification for welding fabrication inspectors and in-service inspectors. Certification of design verifiers is being conducted by the Institution of Engineers Australia. While formal accreditation or certification is not usually required by regulatory authorities, records of inspections and resultant certification as defined by a product code must be available for audit by the regulatory authority.

For pressure equipment exported to Australia for which there is no mandatory involvement of third party CABs, a designer or manufacturer may choose to follow the designation criteria in the section below. Alternatively, the designer or manufacturer may choose other conformity assessment procedures which will ensure that the pressure equipment complies with the performance duties of the relevant laws and regulations of the particular State/Territory.

It should be noted that pressure equipment that complies with and has been subject to the conformity assessment process contained in the Simple Pressure Vessels Directive (87/404/EEC) may satisfy the obligations on designers and manufacturers as provided for in State legislation. Even if the simple pressure vessel is of hazard level D or C then design registration is sometimes required.

²⁶ AS 3920.1-1993: Assurance of product quality – Part 1 Pressure equipment manufacture

For Victoria there are no mandatory conformity assessment requirements for pressure equipment other than that the design must be verified by someone who did not participate in the design of the equipment subject to design verification.

Procedures for Designating CABs in Europe

Where the laws and regulations in Australian States/Territories make compliance with AS 3920.1 and Australian standards for pressure equipment mandatory²⁷, European CABs are to be designated in accordance with the following criteria:

- Design Verification Bodies complying with AS 3920.1 and
 - (a) operating within a quality system meeting the requirements of ISO 9001 and certified by a Quality Systems Certification Body operating according to the requirements of ISO Guide 62 or EN 45012 and either:
 - accredited by an accreditation body which is a signatory to the European cooperation for Accreditation Multilateral Agreement on Certification;
 - accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement; or
 - able to demonstrate competence under an equivalent accreditation scheme; and
 - (b) operating in conformity with EN 45004 or ISO 17020 and accredited by an accreditation body meeting the requirements of ISO Guide 58 or EN 45002/3
- Inspection Bodies complying with AS 3920.1 and operating according to the requirements of ISO 17020 or EN45004 and either:
 - accredited by an accreditation body which is a signatory to a European Multilateral Agreement; or
 - able to demonstrate competence under an equivalent accreditation scheme.
- Testing Laboratories operating according to the requirements of ISO 17025 or EN45001 and either:
 - accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing; or
 - able to demonstrate competence under an equivalent accreditation scheme.
- Quality Systems Certification Bodies complying with AS 3920.1 and operating according to the requirements of ISO Guide 62 or EN 45012, and either:
 - accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification;
 - accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement; or
 - able to demonstrate competence under an equivalent accreditation scheme.

²⁷Note: AS 3920.1 is currently being revised and some of the requirements may be relaxed.

Contact Details For Australian Pressure Equipment Regulatory Authorities

<ul style="list-style-type: none"> New South Wales State Coordinator Plant OHS Division WorkCover Authority of NSW GPO Box 5364 Sydney 2001 	Telephone +61 2 9370 5163 Fax +61 2 9370 6106 Website www.workcover.nsw.gov.au
<ul style="list-style-type: none"> Victoria Director Field Services WorkCover Safety P O Box 414 Melbourne 3005 	Telephone +61 3 9628 8111 Fax +61 3 9628 8199 Website www.workcover.vic.gov.au
<ul style="list-style-type: none"> Queensland Senior Principal Advisor (Technology) Department of Employment, Training and Industrial Relations GPO Box 69 Brisbane 4001 	Telephone +61 7 3872 0584 Fax +61 7 3247 0211 Website www.detir.qld.gov.au
<ul style="list-style-type: none"> South Australia Manager - Workplace Services Department for Administrative & Information Services GPO Box 465 Adelaide 5001 	Telephone +61 8 8303 0288 Fax +61 8 8303 0444 Website www.eric.sa.gov.au
<ul style="list-style-type: none"> Western Australia Director of Inspection Services Worksafe Western Australia PO Box 294 West Perth 6872 	Telephone +61 8 9327 8777 Fax +61 8 9481 6497 Website www.wt.com.au/safetyline
<ul style="list-style-type: none"> Tasmania Sector Leader - Standards Workplace Standards Tasmania GPO Box 56 Rosny Park 7018 	Telephone +61 3 6233 7662 Fax +61 3 6233 8338 Website www.wsa.tas.gov.au
<ul style="list-style-type: none"> Australian Capital Territory Director ACT WorkCover PO Box 224 Civic Square 2608 	Telephone +61 2 6205 0200 Fax +61 2 6205 0797 Website www.workcover.act.gov.au
<ul style="list-style-type: none"> Northern Territory Manager Occupational Health and Safety Division Department of Industries and Business GPO Box 4160 Darwin 0801 	Telephone +61 8 8999 5025 Fax +61 8 8999 5141 Website www.nt.gov.au

3.7 (b)

Pressure Equipment New Zealand

Scope and coverage

The Pressure Equipment sectoral annex of the MRA with New Zealand covers pressure equipment subject to third party conformity assessment procedures under the following Act and Regulations:

- Health and Safety in Employment Act 1992; and
- Health and Safety in Employment (Pressure Equipment, Cranes and Passenger Ropeways) Regulations 1999.

• General

In New Zealand occupational health and safety is under the jurisdiction of the Occupational Safety and Health Service of the Department of Labour. The Pressure Equipment, Cranes and Passenger Ropeways Regulations are effective under the Health and Safety in Employment Act.

The HSE Act places a general duty on employers to ensure the safety of employees. Employers are required to identify hazards, and to take all practicable steps to eliminate, isolate or minimise these hazards. The Pressure Equipment, Cranes and Passenger Ropeways (PECPR) Regulations place duties on controllers, designers, manufacturers and suppliers of pressure equipment.

The duties on the designer, manufacturer and supplier include:

- to design the equipment in accordance with standards of generally accepted design practice, gazetted in New Zealand;
- design equipment in such a way that every activity for which the equipment was designed can be carried out safely;
- determine and specify the hazard level of the equipment;
- determine and specify the design verification requirements;
- ensure that if design verification is required the design is verified by a design verifier qualified to verify it;
- take into account in the design and verification the nature of the New Zealand seismic environment;
- to manufacture the equipment in compliance with any manufacturing requirements specified in the design;
- to ensure any changes to the structural strength or safety of the equipment during manufacture are verified by the design verifier;
- to ensure that any fabrication inspection requirements specified are carried out by a fabrication inspector qualified to inspect it;
- to ensure, when importing for supply equipment manufactured in an overseas country that it has been designed to standards that are equivalent to or better than those specified and gazetted in New Zealand.

The duties on the controller include:

- to hold information to enable the equipment to be operated safely;
- to notify OSH of accidents involving the equipment;
- to ensure the equipment is safe, is operated safely and is maintained in a safe condition;
- to ensure the equipment is not operated unless it has a current certificate of inspection;
- to ensure that repairs and alterations to the equipment are properly carried out and re-certified.

- **Verification and inspection arrangements**

The PECPR Regulations base the need for design verification and fabrication inspection on the hazard level of the equipment as defined in AS 4343-1999.²⁸ The standard is not cited in the regulations, but will be gazetted as an applicable standard.

In New Zealand registration of pressure equipment is not required, however a certificate of inspection is required for equipment in accordance with AS 3920.1-1993²⁹ and AS/NZS 3788-1996³⁰. The requirement for design verification and/or fabrication inspection for individual items of pressure equipment is defined in Table 2.1 of AS 3920.1-1993 and is based on the hazard level and whether the manufacturer has a certified quality system.

Design verification and fabrication inspection are required to be undertaken by inspection bodies that are accredited to EN 45004, or equivalent and are recognised by the Occupational Safety and Health Service.

The Authority no longer has any direct involvement in design verification or inspection, but maintains a monitoring role over the inspection bodies that are accredited in New Zealand by International Accreditation New Zealand (IANZ) to carry out this work.

Australia/New Zealand Mutual Recognition

The Trans Tasman Mutual Recognition Arrangement took effect on 1 May 1998. Under this legislation goods that may be lawfully sold in one participating jurisdiction, may be lawfully sold in any other participating jurisdiction without the need to conform with any of the requirements relating to sale that are imposed by or under the law of that other jurisdiction.

While sale requirements for goods will be overridden by the TTMRA, nothing in it affects the operation of any laws in New Zealand regarding the inspection of goods within New Zealand as long as the laws are directed at matters affecting health, safety or the environment.

Safety considerations under the PECPR Regulations require pressure equipment to have a certificate of inspection from an inspection body that is accredited to EN 45004 before it can be put into operation. To get this certificate importers and controllers will need to provide documented proof that the equipment has been design verified and inspected during fabrication to the same standard as similar equipment manufactured in New Zealand.

²⁸ AS 4343:1999 Pressure Equipment – Hazard levels

²⁹ AS 3920.1 - 1993: Assurance of product quality - Part 1 Pressure equipment manufacture

³⁰ AS/NZS 3788-1996 Pressure equipment – In-service inspection

Product Marking

Pressure equipment should be marked with appropriate operating and inspection information as required by the design standard. There are no specific New Zealand requirements comparable to CE marking.

New Zealand Pressure Equipment Standards

As described in AS/NZS 1200 - 1994, British, ASME and Australian Standards are acceptable in New Zealand for pressure equipment design and manufacture. The primary standard chosen must be used in its entirety and not mixed with another.

The Role of European Designated CABs

Where the PECPR Regulations require external design verification and fabrication inspection it must be by inspection bodies (equivalent to conformity assessment bodies) that are accredited to EN 45004 and have been recognised by the Occupational Safety and Health service. Certification of the manufacturers' quality system may be an acceptable alternative (see AS 3920.1 - Table 2.1). European CABs that have been designated under the MRA for relevant product standards will be recognised.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the principles and procedures set out in Annex 1 of the MRA for the designation of CABs to assess pressure equipment against New Zealand's requirements:

- (a) Design Verification:
 - operate in conformity with EN 45004 or ISO 17020; and
 - operate a quality system conforming with ISO 9001; and
 - employ design verifiers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance.
- (b) Inspection Bodies:
 - operate in conformity with EN 45004 Type A or ISO 17020; and
 - employ engineers who through qualifications, training and experience can demonstrate that they have the necessary skills and ability to fully understand and apply the detailed requirements of the legislation and standards in which they will operate and with which they are certifying compliance.
- (c) Certification Bodies
 - accredited by an accreditation body which is a signatory to European cooperation for Accreditation (EA) Multilateral Agreement on Certification;
 - accreditation by an accreditation body with which JAS-ANZ has a mutual recognition agreement; or

- able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

(d) Testing Laboratories

- accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing; or
- able to demonstrate competence by other means in accordance with Sections A and B of Annex 1 of the MRA.

Contact Details for Occupational Safety and Health Service

Engineering Safety
Occupational Safety and Health Service
Department of Labour
PO Box 3705
Wellington

Telephone +64 4 915 4444
Fax +64 4 915 4370
Website <http://www.osh.dol.govt.nz>

3.7 (c) EU Authorities Responsible for Designating European CABs under the Pressure Equipment Sectoral Annexes

<ul style="list-style-type: none"> • Belgium Ministère de l'Emploi et du Travail Ministerie van Tewerkstelling en Arbeid • Denmark Direktoratet for Arbejdstilsynet • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria, Comercio y Turismo • France Ministère de l'Industrie, de la Poste et des Télécommunications • Ireland Department of Enterprise and Employment • Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports 	<ul style="list-style-type: none"> • Netherlands Ministerie van Sociale Zaken en Werkgelegenheid • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Kauppa- ja teollisuusministeriö • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs
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More information on designation of CABs for the pressure equipment sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

3.8 (a) Automotive Products Australia

Scope and Coverage

For Australia, the Automotive Products Sectoral Annex covers mutual recognition and acceptance of results of conformity testing and conformity of production procedures of those Australian regulations that are substantially equivalent to UN/ECE Regulations and EC Directives for which no UN/ECE Regulation exists. (See Section 1 of the Sectoral Annex: Regulatory Requirements.)

Australia's regulatory system has operated as a whole vehicles type approval system since 1970. This allows vehicles to be registered with minimal inspection.

This type approval system currently operates under the Commonwealth ***Motor Vehicle Standards Act 1989*** which requires approval before supply to the market for first use in transport.

Approval/Certification Arrangements

Detailed information, advice and application documentation can be obtained from the regulatory authority, the Department of Transport and Regional Services (DOTRS). Some relevant information is available on the DOTRS website.

The vehicle regulatory requirements are administered under a "type approval" system by DOTRS. Under this system, each model of a particular design is required to demonstrate compliance with the relevant vehicle regulatory requirements. The Act applies to vehicles when first supplied to the market for use in transport in Australia.

The arrangements to provide assurance that vehicles sold in Australia comply with the relevant vehicle regulatory requirements are broken up into the following areas:

- certification of the vehicles to the standards;
- examination of the first vehicle of the type (Single Uniform Type Inspection);
- audit of vehicle manufacturing and testing facilities.

Manufacturers seeking Compliance Plate Approval need to assure the Administrator of Vehicle Standards (a Senior Executive Service Officer in DOTRS) that the model for which certification is sought complies with all applicable vehicle regulatory requirements.

The Administrator of Vehicle Standards issues an approval to the manufacturer which allows the fitment of a Compliance Plate to the vehicle. A sample vehicle is inspected to ensure that the vehicle is of the type described in the supporting documentation. This action is known as a Single Uniform Type Inspection and is a prerequisite for "bulk registration" of these vehicles.

The presence of a Compliance Plate on a vehicle is taken as proof by State and Territory registration authorities that a vehicle complies with all applicable requirements.

Product Marking

Currently there are no requirements for components to be marked to signify compliance with vehicle regulatory requirements. In some cases, such as seat belts, marking in accordance with technical specifications is required however ECE markings are generally not acceptable.

For the complete vehicle, the Compliance Plate is the only marking that is required and the process for obtaining Compliance Plate Approval is described above.

Australia-New Zealand Mutual Recognition

Currently the automotive products sector is a special exemption from the Trans Tasman Mutual Recognition Arrangement. Each country's conformity requirements and procedures therefore still apply. A cooperation program aimed at harmonising standards and certification procedures is underway and when completed mutual recognition will apply.

Australian Vehicle Safety Standards

Vehicle regulatory requirements are set down in the Australian Design Rules for Motor Vehicles and Trailers (ADRs) which are largely based on UN/ECE Regulations and are enshrined in legislation under the Motor Vehicles Standards Act 1989.

It is the Government's policy to harmonise, wherever possible, with international standards unless there are significant safety grounds to do otherwise.

Australia and New Zealand are currently carrying out a major review of the ADRs which when completed will provide a common set of vehicle regulatory requirements for the two countries. The aim is to achieve even closer harmonisation with the UN/ECE. Information on draft proposals is posted on the DOTRS website.

The Role of European Designated CABs

As mentioned above, auditing of vehicle manufacturing facilities is carried out to confirm production vehicles conform to the same requirements as the type approved. These "Conformity of Production" assessments involve auditing of the production process to confirm that the company has controls which ensure that regulatory requirements are being met on production vehicles.

Although quality systems accreditation is not a prerequisite for obtaining vehicle approvals, manufacturers are expected to have quality management systems in place incorporating relevant elements of the ISO 9000 series of standards for quality management. Assessors use ISO 9001 as a guide when carrying out conformity of production assessments. Assessments are conducted on manufacturing plants every 18-24 months.

Laboratories engaged in testing to the ADRs are subject to audit every 18-24 months.

Currently DOTRS arranges for agents to carry out conformity assessments and inspections of testing and manufacturing facilities in some of the EU member states.

Designated CABs may, under the MRA, assess compliance of components and vehicles against the requirements of the ADRs listed in the Automotive Products Sectoral Annex - see Section 1: Regulatory Requirements.

Designated CABs may also conduct assessments of testing and manufacturing facilities to the standards and procedures mentioned below.

Procedures for Designating CABs in Europe

The following procedures are deemed to be consistent with the requirements of Annex 1 of the MRA regarding procedures to be followed by the European Community in designating CABs to assess automotive products against Australia's requirements:

- a) Testing Laboratories
 - Technical services appointed under the provisions of Directive 70/156/EEC as amended by Directive 92/53/EEC; or
 - Laboratories accredited under the EA Multilateral Agreement on Calibration and Testing; or
 - Bodies able to demonstrate competence and designated by the authorities listed in Section 3.8 (b).

- b) Conformity Assessment
 - Certification bodies complying with harmonised standard EN 45012 and either qualified by the approval authority of a Member State itself or accredited by a national accreditation organisation of a Member State and recognised by that Member State's approval authority to conduct assessments to the ISO 9001 quality management standard as defined in Administrator's Circular 0-13-2.

Contact Details for the Department of Transport and Regional Services

The Administrator of Vehicle Standards
Vehicle Safety Standards
Department of Transport and Regional Services
GPO Box 594
CANBERRA ACT 2601
AUSTRALIA

Telephone +61 2 6274 7450
Fax +61 2 6274 6013
Email standards@dotrs.gov.au
(information on standards and their availability)
Website <http://www.dotrs.gov.au/land/vehicle/safety/safehome>

3.8 (b) EU Authorities Responsible for Designating European CABs under the Automotive Products Sectoral Annex

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
<ul style="list-style-type: none"> • Belgium Ministère des Communications et de l'Infrastructure Ministerie van Verkeer en Infrastructuur • Denmark Road Safety and Transport Agency • Germany Kraftfahrt-Bundesamt • Greece Υπουργείο Μεταφορών Ministry of Transport • Spain Ministerio de Industria, Comercio y Turismo • France Ministère des Transports • Ireland Department of Enterprise and Employment • Italy Ministero dei Trasporti • Luxembourg Ministère des Transports 	<ul style="list-style-type: none"> • Netherlands Rijksdienst voor het Wegverkeer • Austria Bundesministerium für öffentliche Wirtschaft und Verkehr • Portugal Direcção-General de Viação • Finland Liikenneministeriö • Sweden Vägverket • UK Vehicle Certification Agency <p>EEA EFTA Authorities</p> <ul style="list-style-type: none"> • Iceland Ministry of Health and Insurance • Liechtenstein Government of Liechtenstein* • Norway Ministry of Health and Social Affairs

More information on designation of CABs for the automotive products sector, including details of European CABs designated for this sector, can be obtained from the above authorities.

* The Government of the Principality of Liechtenstein is entitled to appoint appropriate specific national administration bodies as designators of conformity assessment bodies at a future date.

CHAPTER 4 : Useful Contacts

4.1 For general information on the MRAs

- **Europe**

DG ENTR/G1
Directorate General for Enterprise
European Commission
Rue de la Loi 200
B-1049, Brussels
BELGIUM

Telephone +32 2 295 1304
Fax +32 2 295 3877
Email giacomo.mattino@cec.eu.int
Website <http://www.europa.eu.int>

Mutual Recognition Agreements, Technical Barriers to Trade
Goods Unit
EFTA Secretariat
74 Rue de Trèves
B-1040 Brussels
BELGIUM

Telephone +32 2 286 1757
Fax +32 2 286 1750
Email beltrametti@secrbu.efta.be

- **Australia**

General Manager
Business Environment Branch
Department of Industry Science and Resources
GPO Box 9839
Canberra ACT 2601
AUSTRALIA

Telephone +61 2 6213 6510
Fax +61 2 6213 6617
Website <http://www.isr.gov.au>

New Zealand

Manager
International Issues Group
Ministry of Economic Development
PO Box 1473
WELLINGTON

Telephone +64 4 472 0030
Fax +64 4 499 1791
Email rowin.buist@med.gov.nz
Website <http://www.med.gov.nz>

4.2 For sector specific information

For sector specific information appropriate contacts in Europe, Australia and New Zealand are given in the relevant sections of Chapter 3. Lists of European designated CABs for each sector can be obtained from the European Commission - see Section 4.1 above.

4.3 Australian and New Zealand accreditation bodies

(a) For laboratories and inspection bodies

- **Australia**

Chief Executive
National Association of Testing Authorities, Australia
7 Leeds Street
Rhodes NSW 2138
AUSTRALIA

Telephone +61 3 9736 8222
Fax +61 3 9743 5311
Email NATA@nata.asn.au
Website <http://www.nata.asn.au>

- **New Zealand**

Chief Executive
International Accreditation New Zealand
(previously Telarc New Zealand)
Private Bag 28908
Remuera 1136
Auckland
NEW ZEALAND

Telephone +64 9 525 6655
Fax +64 9 525 2266
Email info@ianz.govt.nz
Website <http://www.ianz.govt.nz>

(b) For product certification and quality management system certification bodies.

• **Australia and New Zealand**

Chief Executive
Joint Accreditation System for Australia and New Zealand
PO Box 79
Deakin West ACT 2600
AUSTRALIA

Telephone +61 2 6 282 5840
Fax +61 2 6282 6818
Email admin@jas-anz.com.au
Website <http://www.jas-anz-com.au>

4.4 Australian and New Zealand standards bodies

Information on, and copies of, Australian and New Zealand standards can be obtained from the addresses below. These standards can also generally be purchased from European standards bodies.

• **Australia**

Standards Australia
PO Box 1055
Strathfield NSW 2135
AUSTRALIA

Telephone +61 2 9746 4748
Fax +61 2 9746 4765
Email sic@standards.com.au
Website <http://www.standards.com.au>

• **New Zealand**

Standards New Zealand
Private Bag 2439
Wellington
NEW ZEALAND

Telephone +64 4 498 5992
Fax +64 4 498 5994
Email standards@standards.cynet.net.nz
Website <http://www.standards.co.nz>