EUROPEAN RADIOCOMMUNICATIONS COMMITTEE

ERC Decision of 30 June 1997 on the mutual recognition of conformity assessment procedures including marking of radio equipment and radio terminal equipment (ERC/DEC/(97)10)
EXPLANATORY MEMORANDUM

1. INTRODUCTION

The Decision provides a regime for mutual recognition of conformity assessment procedures which includes type examination (module B) accompanied by conformity to type (module C) and full quality assurance (module H) as defined in Council Decision 93/465/EEC. The regime of this Decision applies to radio equipment including radio terminal equipment for which the Directives 91/263/EEC (Council Directive of 29 April 1991 on the approximation of the laws of the Member States concerning telecommunications terminal equipment, including the mutual recognition of their conformity) and 93/97/EEC (Council Directive of 29 October 1993 supplementing Directive 91/263/EEC in respect of satellite earth station equipment) are not applicable. For receiver parts of transceivers or separate receivers of closed radio systems the Internal Production Control (module A) as detailed in the above mentioned Council Decision and Annex 1 to this Decision will be applied.

The aim of this ERC Decision is that CEPT administrations who have implemented the Decision, accept without additional national procedures, the conformity assessment procedures complying with the provisions of this ERC Decision, carried out under the responsibility of the administration of another CEPT member country.

The arrangements of this Decision are of an interim nature in the EEA countries, pending legislative action of the European Union.

2. BACKGROUND

Traditionally, CEPT administrations have required radio equipment and radio terminal equipment to be type approved to a relevant (national) technical standard or standards. At the same time it is in the interest of the European industry to produce radio equipment for the largest possible market and through economy of scale to achieve minimum of cost and effort and to this end ETSI have prepared a number of standards. Since these ETSI standards are now available, CEPT administrations should promote them as a common basis for conformity assessment procedures and should mutually recognise the rights given in one country based on such procedures for placing on the market of radio equipment and radio terminal equipment and introduce a common marking scheme.

As a first step the CEPT Recommendation T/R 71-03 which detailed the procedures for type testing and type approval for radio equipment intended for Land Mobile non-public networks was adopted in 1991. This Recommendation was revised in 1994 in order to broaden its scope. Subsequently CEPT Recommendation ERC/REC 01-06, replacing T/R 71-03, which covers all kinds of radio equipment and all international standards was adopted within the CEPT/ERC. It can therefore be used as a basis for type approval.

The only exception was equipment covered by EEC Directives 91/263/EEC and 93/97/EEC within those CEPT member countries where the Directives are applicable. In the course of 1994 the ERC adopted new policy goals with related recommendations. Some of these recommendations deal with the mutual recognition of type approval and the implementation of standards. In order to comply with these policy goals and recommendations this ERC Decision on the procedures for mutual recognition of conformity assessment procedures for radio equipment and radio terminal equipment was developed.

3. SCOPE OF THE ERC DECISION

The Decision provides a regime for mutual recognition of conformity assessment procedures of radio equipment and radio terminal equipment within the CEPT administrations. This Decision covers the radio equipment and radio terminal equipment as defined in Annex 3, as far as the procedures of EU Directives are not applicable. Amateur radio equipment is outside the scope of this Decision.

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1 Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives.
The aim of this Decision is that CEPT administrations will not impede, for reasons related to the requirements covered by this Decision and the relevant ERC Decision(s) on the adoption of the particular standard(s), the placing on the market of radio equipment or radio terminal equipment which complies with the provisions of this Decision. A basic element of the mutual recognition of these procedures is the adoption of common European standards within the ERC and the harmonised implementation of these standards within the CEPT administrations. The use of uniform application forms for testing, a uniform test report form as well as a uniform type approval certificate and a uniform Declaration of Conformity document of manufacturers with a full quality assurance system certified by a conformity assessment body will facilitate this process.

Marking of radio equipment is essential for control and enforcement purposes and therefore a marking scheme is developed in Annex 2.

It should also be noted that the assessment to electromagnetic compatibility requirements and low voltage requirements in accordance with the procedures of the EMC Directive (Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility) and Low Voltage Directive 73/23/EEC (Council Directive of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits) are outside the scope of this Decision.

The Decision relates only to conformity assessment and placing on the market of equipment and does not cover the licensing or free circulation and use which might be subject to separate ERC Decisions.

4. EXPLANATORY REMARKS

4.1 The adoption of standards within the ERC

In 1993 a Memorandum of Understanding between the ERC and ETSI was concluded and a co-operation procedure established. One of the principles of co-operation agreed in this MoU is that for radio standards developed by ETSI, not within the scope of the Directives 91/263/EEC and 93/97/EEC, separate ERC Decisions will be developed. These should make reference to the essential requirements for efficient use of the radio frequency spectrum (ETS Part A), to its application domain, to any additional regulatory requirements, and to a date for its introduction into national conformity assessment regimes.

4.2 Conformity assessment procedures

The procedure described in Annex 1, applicable to radio equipment for which there is a standard adopted by an ERC Decision for national type approval regulations, will be:

- The conformity assessment bodies within the CEPT member countries will accept as a basis for type approval the ERC/WGRR approved application form together with the test report using the ERC/WGRR approved test report form of tests carried out to a technical standard by an accredited testing laboratory.

- For receivers it is in the interest of the user and the licensing authority to be informed what spectrum related requirements the receiver meets. In justified cases conformity assessment to receiver requirements may be required.

- For receive only equipment used in safety services i.e. receive only equipment which is subject to international regulations issued by IMO, ICAO etc, conformity assessment to receiver requirements is justified.

- When equipment is to be placed on the market in more than one country, it is the manufacturers responsibility that the equipment is tested according to the essential spectrum management requirements of all the countries where it will be marketed.

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2 In the case where the application form and/or the test report form are not available they shall be derived from the model application form and the test report form as approved by CEPT/WGRR.
- The applicants shall take ETS 300 793 into account when presenting the equipment for testing.

- A conformity assessment body of a CEPT member country shall require the applicant to give a written declaration that the same application has not been lodged with any other conformity assessment bodies in countries which have implemented this ERC Decision.

- When this CEPT conformity assessment body grants the type approval as well as when the Declaration of Conformity document is issued by a manufacturer with a certified full quality assurance system, this will be mutually accepted by those CEPT administrations having committed themselves to implement the ERC Decision on the adoption of the specific standard and this ERC Decision.

- The type approved equipment or the equipment with a Declaration of Conformity of a manufacturer can then be placed on the market in the countries where the CEPT administrations have committed themselves to implement the ERC Decision on the adoption of the specific standard and this ERC Decision.

It should be noted however that mutual recognition of conformity assessments between EEA and non-EEA countries is subject to the conclusion of separate agreements.

All administrations, as a part of their market surveillance may perform checks on products placed on the market. A procedure for withdrawal of non-complying equipment from the market is described in decides 11 of this Decision. Such a procedure should be initiated e.g.

- if equipment which is put on the market fails to comply with the technical requirements used as the basis for the type approval or of the certification of the full quality assurance system of a manufacturer or;

- if equipment is placed on the market with a single type designation but as two variants from which one complies with the type approval requirements and the other does not.

4.3 Mutual recognition of type approval and of the Declaration of Conformity document of a manufacturer (full quality assurance system)

A signatory of this Decision is obliged to mutually recognise conformity assessment when the ERC has adopted a Decision, implemented by that signatory, on the use of a common European standard on the basis of the procedures of the MoU with ETSI.

4.4 Type testing

A condition for the application of this procedure is that the type testing will be carried out by a testing laboratory accredited in accordance with the ISO guide 25:1990 or EN 45001 or a National Standard conforming to ISO guide 25 or EN 45001, thus improving the consistency, authority, and standard of calibration and testing within Europe.

The accreditation should be acceptable to the conformity assessment body granting certification.

For information purposes, a register will be kept by the ERO on testing laboratories and their competence with respect to different standards. The ERO will also maintain information on certified full quality assurance systems of manufacturers. Information contained in the register will be based on material provided by the CEPT administrations who will supply this information on a regular basis.

Further, the EAL (European Accreditation of Laboratories) agreement has been developed in order to facilitate mutual recognition agreements with other national schemes thus obtaining international acceptance of accredited laboratories.

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3 For that radio equipment which is subject to licensing, the right to possess and/or to use the equipment is dependent on the licensing regimes.
4.5 Full quality assurance system

A condition for the application of the procedure described in the Decision is that the full quality assurance system of the manufacturer is in conformance with the applicable requirements of module H of the global approach (93/465/EEC). Guidance to the assessment of the quality systems can be found in the Telecommunications Terminal Directive (91/263/EEC) and the ADLN Handbook.

4.6 Use of uniform application forms and test report forms

In order to facilitate the regime for mutual recognition of conformity assessment procedures defined in this Decision, standard application forms and test report forms can be used for each standard. These forms are to be drafted in co-operation between ETSI and the ERC/WGRR, approved by ERC/WGRR, and based on the model forms that are approved by ERC/WGRR. The reason for the development of standard forms is that the use of uniform type test application forms and test report forms will ensure that the same information will be available to all conformity assessment bodies or the bodies issuing certificates of full quality assurance systems. Use of the uniform forms make the conformity assessment procedures more consistent.

4.7 Use of uniform type approval certificates and uniform Declaration of Conformity documents of manufacturers

Annex 1 points 4 and 5 detail the minimum information which should be included on type approval certificates and on Declaration of Conformity documents of manufacturers. The uniform use of such information will assist mutual recognition of conformity assessment procedures.

Point 5 lists specific additional information for those characteristics which are not harmonised in the standards.

4.8 Marking of equipment within the CEPT

The equipment will be marked as defined in Annex 2 with the letter R followed by a four digit number identifying the conformity assessment body and an equipment identification, which will be defined in separate ERC Decisions or Recommendations.

Apart from this marking radio equipment (transmitter, receiver, transceiver) shall bear a unique type designation and the name of manufacturer and/or supplier responsible for placing it on the market.

Additional marking is also required by EC Directives such as the EMC Directive (89/336/EEC) within the EEA countries.

4.9 Central register of type approvals and of the Declaration of Conformity documents of manufacturers

For market surveillance purposes, the central register of type approvals and Declaration of Conformity documents of manufacturers granted under this Decision shall be available for consultation by all CEPT administrations and the general public. This register is kept by the ERO. Each conformity assessment body of a CEPT member country will be responsible for providing the ERO with the necessary information about the type approvals and certificates of full quality assurance systems it has granted under this Decision including the Declaration of Conformity documents of manufacturers.
5. REQUIREMENT FOR AN ERC DECISION

The prescriptions on type approval and of full quality assurance systems in CEPT member countries are laid down by law, regulations or administrative actions. The ERC recognises that a harmonised implementation of standards, harmonisation of type approval procedures and the mutual recognition of type approval and the Declaration of Conformity documents of manufacturers with a certified full quality assurance system will be of the greatest benefit to the manufacturers of radio equipment and therefore to the users of this equipment. A commitment by CEPT member countries to implement an ERC Decision as described above will provide a clear indication that the mutual recognition of conformity assessment procedures for radio equipment in general will be introduced throughout Europe and that barriers to trade will be removed.
The European Conference of Postal and Telecommunications Administrations,

considering:

a) that, in the absence of provisions under existing EU Directives, there is an urgent need for a procedure for mutual recognition of type approvals and conformity declarations for radio equipment;

b) that this implies the definition of common procedures for conformity assessment including type approval, recognition of full quality assurance systems and marking of radio equipment;

c) that it is required to have harmonised conditions for accreditation of testing laboratories;

d) that it is advantageous to have a common marking system based on common procedures, introduced in the CEPT countries in order to facilitate free placing on the market of radio equipment and radio terminal equipment complying with essential requirements relating to the use of the spectrum laid down in CEPT/ERC Decisions implementing (parts of) European Standards;

e) that the use of uniform type test application forms and test report forms will ensure that the same information will be available to all bodies responsible for issuing conformity certificates, hereafter referred to as conformity assessment bodies, and to the manufacturers having a certified full quality assurance system, which will make the assessment of conformity by the conformity assessment bodies or the preparation of Declaration of Conformity documents by manufacturers having a certified full quality assurance system more consistent;

f) that the type approval certificate or the Declaration of Conformity with the user information (in the case where the manufacturer has a certified full quality assurance system) will ensure that the necessary information will be available in the same form to all CEPT administrations, and will ensure that all the relevant information of the equipment which has been legally placed on the market will be available;

g) that it is useful for licensing and market surveillance but also for the users that all relevant information on the equipment will be publicly available from a single source.
recognising

a) the Directives 91/263/EEC and 93/97/EEC, which lay down provisions on the conformity assessment and marking of certain classes of radio equipment to allow their placing on the market within the EU;

b) that there is a MoU between ERC and ETSI dealing with the preparation and adoption of standards for radio equipment;

c) that the ERC, according to the MoU with ETSI, will adopt standards using the mechanism of ERC Decisions and will adopt regulatory aspects for the standards concerned, notably the selection of which aspects of the standards relate to essential spectrum usage requirements;

d) that the conformity assessment bodies of the CEPT member countries recognise the method of assessment as described in ETSI Technical Report 028, (annex B, 2nd Edition, March 1994), when examining the results of the measurements in order to decide whether or not to grant type approval or recognise the Declaration for Conformity of the manufacturer with a certified full quality assurance system who has made the assessment applying the same methods;

e) that common procedures will make consultation between conformity assessment bodies in case of misinterpretations of test results much easier;

f) that the assessment of conformity to electromagnetic compatibility and electrical safety requirements is outside the scope of this Decision and within the EU governed by the Directives 89/336/EEC and 73/23/EEC;

g) that the notification of the measures implementing this Decision is governed by the provisions of Directive 83/189/EEC;

h) that this Decision relates only to the conformity assessment and placing on the market of radio equipment and bears no relation to licensing or free circulation and use, which shall be subject to separate ERC Decisions;

i) that in general receive-only equipment shall be subject only to conformity assessment relating to electromagnetic compatibility and electrical safety;

j) that it is in the interest of the user and the licensing authority to be informed what spectrum related requirements the receiver meets;

k) that in justified cases conformity assessment to receiver requirements may be required;

l) that for radio communication based on international regulations issued by IMO, ICAO etc, conformity assessment to receiver requirements is justified;

m) that the arrangements of this Decision are interim in the EEA countries, pending legislative action of the European Union and therefore this Decision needs to be reconsidered when the new legislation is adopted.

n) that when equipment is to be placed on the market in more than one country, it is the manufacturers responsibility that the equipment is tested according to the essential spectrum management requirements of all the countries where it will be marketed.

o) the negotiations between the EU and certain CEPT countries to arrive at mutual recognition agreements on conformity assessment:
DECIDES

1. that this Decision shall cover equipment as defined in Annex 3;

2. that administrations which have implemented this Decision shall, without additional requirements, recognise the conformity assessment to the relevant requirements of the applicable European standards adopted by ERC Decisions and the marking that has been carried out in accordance with this Decision under the responsibility of another administration that has implemented this Decision;

3. that mutual recognition of type approvals may be subject to agreements between CEPT administrations on the mutual recognition of conformity assessment;

4. that CEPT administrations shall not impede, for reasons related to requirements covered by this Decision and the relevant ERC Decision(s) on the adoption of the particular standard(s), the placing on the market of equipment the conformity of which has been assessed according to Decides 2) on the condition that all provisions of this Decision are met;

5. that conformity assessment bodies in CEPT member countries shall adopt the conformity assessment procedures as laid down in Annex 1;

6. that type approval shall be granted or the Declaration of Conformity documents issued on the condition that all the provisions of this Decision and all the relevant requirements of the applicable European standards adopted by ERC Decisions are met;

7. that type testing shall be carried out by a testing laboratory recognised by the Administration and accredited in accordance with ISO guides 25:1990 or EN 45001, or a National Standard conforming to ISO guides 25 or EN 45001;

8. that the full quality assurance system of the manufacturer shall be certified by a conformity assessment body to be in conformance with module H of the Global Approach as described in Annex 1;

9. that type approval certificates or Declarations of Conformity documents shall include as a minimum the information as laid down in 4) and 5) of Annex 1;

10. that the registration of all CEPT type approvals granted according to this Decision and all Declaration of Conformity documents shall be maintained by the ERO and the information in this register shall be made publicly available;

11. that where it is determined that radio equipment placed on the market does not comply with the essential requirements relevant to that type of equipment, the conformity assessment body shall take all appropriate measures to withdraw such products from the market and prohibit their being placed on the market. Any such measures shall be notified to ERO which shall in turn notify all CEPT administrations;

12. that CEPT administrations shall notify to the ERO the conformity assessment bodies they have designated, whereupon their codes are issued by the ERO, and that the ERO shall maintain a list containing these codes and make the list publicly available;

13. that CEPT conformity assessment bodies shall inform ERO of type approvals and quality system certificates they have granted, modified or withdrawn as well as the declaration of conformity documents. This information shall be submitted to ERO within two weeks;
14. that the equipment shall carry the appropriate marking as laid down in Annex 2;

15. that only radio equipment in conformity with the description of the type approval certificate or the user's information annexed to the Declaration of Conformity shall carry this marking;

16. that this Decision shall enter into force on 1 October 1997;

17. that CEPT administrations shall communicate the national measures implementing this Decision to the ERC Chairman and the ERO when the Decision is nationally implemented.

Note:
Please check the ERO web site (www.ero.dk) under “Documentation / Implementation” for the up to date position on the implementation of this and other ERC Decisions.
ANNEX 1

PROCEDURES FOR CONFORMITY ASSESSMENT

Transmitter equipment covered by this ERC Decision (see Annex 3) shall be subject to conformity assessment procedures based on either:

- **Type Examination (module B)** accompanied by **Conformity to Type (module C)**

or

- **Full Quality Assurance (module H)** alone, as defined in Council Decision 93/465/EEC (Global Approach).

Module C shall be applied without supplementary requirements for production control.

When requirements for receiver parts of transceivers or separate receivers of closed radio systems are justified, the internal production control (module A) as detailed in the above mentioned Council Decision shall be applied. For radiocommunication based on international regulations issued by IMO, ICAO etc, receivers may be required to fulfil other modules than A.

For better understanding on the application of the conformity assessment modules for the purposes of this ERC Decision the following replacements have to be made in the text of the Council Decision:

- Any reference to a specific directive is understood to mean this ERC Decision.
- Any reference to CE marking is understood to mean Annex 2 to this ERC Decision.
- Any reference to Community means CEPT member countries which have implemented this ERC Decision.
- Any reference to EC type-examination means type approval in the sense of this ERC Decision.
- Any reference to conformity assessment body means a body which is designated by a CEPT administration for carrying out the certification, product checks and associated surveillance tasks pertaining to the procedures referred to in this Annex. The conformity assessment body can also be the administration itself.
- Any reference to notified body means the conformity assessment body in the sense of this Decision.
- Any reference to essential requirements means ERC Decisions implementing European standards.

In addition to the general guidelines given above, the following specific items shall be applied:

1) Manufacturers with a certified full quality assurance system, applicants and/or accredited testing laboratories shall provide information as detailed in application forms and test report forms approved by the ERC/WGRR for each particular standard or, when these are not available, the documents shall be based upon the 'model' application form and 'model' test report form approved by the ERC/WGRR. Manufacturers not located in a CEPT member country shall submit their applications using an authorised representative in a CEPT member country.

2) A conformity assessment body in a CEPT member country shall require the applicant to give a written declaration that the same application has not been lodged with any other conformity assessment body of a CEPT country.
3) CEPT administrations shall supply the ERO with a list of accredited test laboratories and of manufacturers with a certified full quality assurance system and their competence with respect to different radio product standards and ERO shall maintain this information.

4) Type approval certificates or the Declarations of Conformity according to this Decision with the user information of a manufacturer who has a certified full quality assurance system shall include as a minimum the following information:

- date of certificate;
- name of the national conformity assessment body granting the type approval or which has certified the full quality assurance system;
- name of the manufacturer;
- name and contact information of the applicant or the person responsible for the manufacturer’s Declaration of Conformity;
- the type designation of the equipment and each variant if any;
- description of the equipment (e.g. base station, mobile station, portable or other);
- description of equipment use;
- reference to the ERC Decision adopting the relevant European standard;
- type approval certificate number or reference number of the Declaration of Conformity;
- Effective Radiated Power (ERP or EIRP, fixed or variable) range in the case of integral antenna equipment;
- carrier power (fixed or variable) in the case of antenna socket equipment;
- designation of emission:
  - the version of software affecting the radio frequency parameters where applicable;
- marking requirements.

5) In addition to the information under 4), the type approval certificate or the Declaration Conformity of a group 3 radio equipment shall contain also the following information against which the equipment has been tested:

- frequency (transmitter and receiver) range;
- channel spacing(s);
- temperature range(s);
- further information relevant to each particular standard (e.g. communal site usage, simplex, duplex, bit rate etc.);

and breakdown of the above mentioned information if contained in coded form in the type designation;

6) The certificates defined under items 4) and 5) shall be written at least in English.

7) At the applicant’s request, equipment may be tested to a number of options included within a technical standard for a given parameter in order to assess conformity with all the national regulatory requirements for all the variants the manufacturer chooses to make.

8) The type approval certificate is valid only for products which are identical with the tested sample. Any changes, that could affect the performance characteristics covered by the conformity assessment requirements, should be discussed with the conformity assessment body which has granted the type approval. The conformity assessment body has to determine (with the support of the testing laboratory originator of the report if necessary) whether the manufacturer is presenting an upgrade to the initial product or a new product. Depending on the modifications, the conformity assessment body may require additional tests to be carried out in consultation with applicant and therefore the technical variants and upgrades related to the original approved type designation must be included to certificates in items 4 and 5.
In the cases where a manufacturer has a certified full quality assurance system, the manufacturer has to decide whether the changes of the product are an upgrade or not. In the case of an upgrade the manufacturer has to produce a new Declaration of Conformity and send a copy to the conformity assessment body. In every case the manufacturer is responsible for the quality of his product series.

9) CEPT administrations should inform the conformity assessment body which has granted the type approval or which has certified the full quality assurance system, of any problems encountered in the market surveillance.

10) Upon request a conformity assessment body of a CEPT member country shall give the administrations of other CEPT member countries information concerning the certification of the type of equipment concerned.
ANNEX 2

MARKING OF RADIO EQUIPMENT
COVERED BY THIS DECISION

1. The radio equipment shall be marked by the letter R and a four-digit number identifying the conformity assessment body, which issued the type approval certificate or certified the manufacturers quality system. This number shall be followed by an equipment identification defined by the ERC for the relevant categories of radio equipment. This CEPT mark shall be placed beside the CE mark, if there is any.

   Example: R1234 PMR

2. The marking shall be affixed visibly, legibly and indelibly.

3. The mark described above shall only be used on equipment, the conformity of which has been assessed in accordance with this Decision.

4. Apart from the mark described above, each equipment shall bear a unique type designation and the name of the manufacturer and/or supplier responsible for placing the equipment on the market.

The information concerning the codes of the conformity assessment bodies and the equipment identifications is available in the ERO.
ANNEX 3

Equipment covered by this ERC Decision

For the purpose of this Decision, the following definitions apply:

− *Terminal equipment* means equipment that is defined in Article 1 of the Telecommunications Terminal Directive (91/263/EEC), as amended by Directives 93/68/EEC and 93/97/EEC.
− *European standard* means a standard which has been approved pursuant to the statutes of the standards bodies with which the European Community has concluded agreements.

The following equipment is covered by this Decision:

1. terminal equipment
   − intended to be connected to a public telecommunications network,
   − employing the radio frequency spectrum,
   − for which the legal placing on the market is not covered by the Telecommunications Terminal Directive and
   − for which there exists an ERC Decision referring to an European Standard;

2. radio equipment
   − which operates on harmonised radio parameters (including frequency bands) according to an ERC Decision and
   − for which there exists an ERC Decision referring to an European Standard;

3. radio equipment outside the scope of 2
   − which may operate on frequency bands not necessarily harmonised,
   − the frequency parameters of which may be regulated by individual licences and
   − for which there exists an ERC Decision referring to an European Standard.

Amateur radio equipment is outside the scope of this Decision.