

**UPDATE on MAIN ELEMENTS of
EU R&TTE DIRECTIVE
1999/5/EC**

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R&TTED - main elements (1)

- ◆ **Aim: Secure functioning of the EU market by assuring adequate safety, EMC and spectrum use.**
- ◆ **free movement of compliant equipment but possible national restrictions on putting into service on account of certain specific spectrum issues.**
- ◆ **Application of harmonised standards = voluntary but gives "presumption of conformity".**

R&TTED – main elements (2)

- ◆ **Conformity assessment based on a choice for manufacturer depending on equipment type and availability of harmonised standards.**
- ◆ **Involvement of third-parties (NB – Notified Bodies or CAB (via MRA)).**
- ◆ **Post-market control through Member State surveillance authorities; administrative requirements assist post-market control.**

What is the R&TTED scope?

- ◆ **Radio equipment (RE) & Telecom Terminal Equipment (TTE).**
Combination possible (e.g. mobile phone),
incl: "relevant components" (eg antennas & radio modules).
- ◆ **Medical & Automotive devices are covered in *parallel* by both R&TTED and specific directives.**

What are the Exclusions?

- ◆ **Apparatus exclusively used for:**
 - **Public Security,**
 - **Defence, State Security and**
 - **Activities of the State in the area of criminal law**
- ◆ **Radio amateur equipment, if not commercially available.**
- ◆ **Marine equipment & most aeronautical equipment.**
- ◆ **Cabling & wiring & receive only broadcast equipment.**
- ◆ **All non radio equipment used in public networks.**

The Essential Requirements

- ◆ Health and Safety.

Alignment of essential requirements with the Low Voltage Directive This covers e.g. Human exposure to RF.

- ◆ Electromagnetic compatibility.

Alignment of essential requirements with EMC Directive. (Procedure will change when new EMC Directive is operational = 20/07/2007!)

- ◆ Effective use of the spectrum

To avoid harmful interference.

New EMCD and effect on R&TTED

Current situation:

R&TTED provides for an alternative conformity assessment procedure for the essential EMC requirements; *"At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Article 3(1b) may be demonstrated using the procedures specified in the EMCD 89/336/EEC"*

New Situation:

From 20/07/2007, the alternative procedures of Directive 89/336/EEC disappear for R&TTE equipment, and are **NOT** replaced by any procedure of the new Directive 2004/108/EC.

R&TTED – Essential Requirements

- ◆ Additional public interest requirements to be defined such as:
 - end-to-end inter-working;
 - no network harm;
 - privacy protection;
 - avoidance of fraud;
 - access to emergency services and
 - features for the disabled.

[in practice very limited requirements: e.g. “access to emergency services” such as “avalanche beacons”]

R&TTED – Harmonised Standards

- ◆ **Special status but are voluntary. For 3 reasons:**
 - **Come from private sector/democratic process;**
 - **There may be mistakes;**
 - **Always behind technology.**

**BUT USE of HS IS THE PREFERRED METHOD
and probably used in > 95% of cases!**

- ◆ **Prepared by European standardisation body, CEN, CENELEC or ETSI through EC Mandate.**

Some examples of standardisation mandates:

- **M/363 - Specific SRD used for short range radar equipment operating in the 24 GHz range;**
- **M/362 - Safety of batteries in hand-held radio;**
- **M/329 - Ultrawide band (UWB) applications**
- **M/305 - Protection from EM fields (0 Hz to 300 GHz)**

R&TTED – Harmonised Standards (2)

- ◆ **Must be referenced in the Official Journal of the EU (OJEU).**
- ◆ **Give “presumption of conformity” with those of the essential requirements covered by the standards (or parts of the Standard).**
- ◆ **Harmonised standards are (as far as possible) technology neutral.**
- ◆ **R&TTED provides for safeguards against faulty standards**

Important Note:

Harmonised standard ≠ Harmonised spectrum use!!

R&TTED – Harmonised Standards (3)

Currently > 200 R&TTE harmonised standards!

- ◆ **General policy information on HS:**
http://ec.europa.eu/enterprise/standards_policy/index_en.htm
- ◆ **List of all HS is regularly updated and on:**
<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/whatsnew.htm>
- ◆ **List of R&TTED HS is regularly updated on:**
<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/radiotte.html>
- ◆ **How to get a HS?**
 1. **Contact the Member Bodies of CEN, CENELEC or**
 2. **Standardisation body of your country if you are located outside the EEA.**
 3. **ETSI Harmonised Standards can be freely downloaded from <http://www.etsi.org>**

Administrative Requirements

- ◆ For all equipment
 - information on the intended use;
 - Declaration of Conformity (with the product)
 - CE marking on apparatus, packaging and in manual
 - identification of manufacturer & batch/serial number
 - NB(CAB) number if applicable.
- ◆ + For radio equipment
 - information on packaging & in manual on geographic limitations of use + “Alert Mark”
 - advance (at least 4 weeks) notification of equipment that is using non-harmonised spectrum
- ◆ + For terminal equipment
 - indication of networks to which terminals can be connected

The “Alert Sign”



- ◆ Equipment placed on the market & put into service without restrictions = 'Class 1'. There is no special mark.
- ◆ Radio Equipment for which Member States apply restrictions on the putting into service or on the placing on the market = 'Class 2'. Equipment must bear the "Equipment Class Identifier" ("Alert Sign")
- ◆ Restriction may take the form of:
individual licensing requirements;
Prohibition on use in certain geographical regions;
etc and
is frequently (but not exclusively)
associated with non-harmonised spectrum
- ◆ the Alert Sign is part of the CE Marking

Member State Responsibilities

- ◆ **Notification & publication of regulated radio interface specifications.**
- ◆ **Ensure publication of network technical characteristics by public operators.**
- ◆ **Control of placing on the market & putting into service (market surveillance & enforcement).**
- ◆ **Appoint and control Notified Bodies (in USA, Japan etc for the the CAB's).**

Conformity Assessment Procedures (CAP)

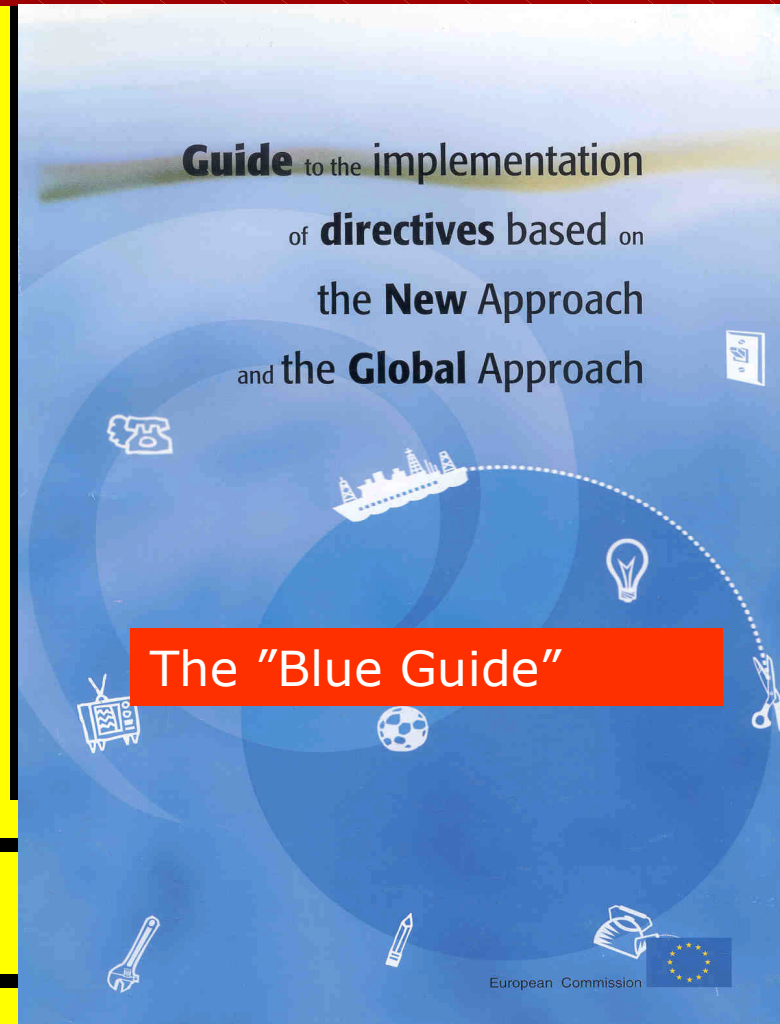
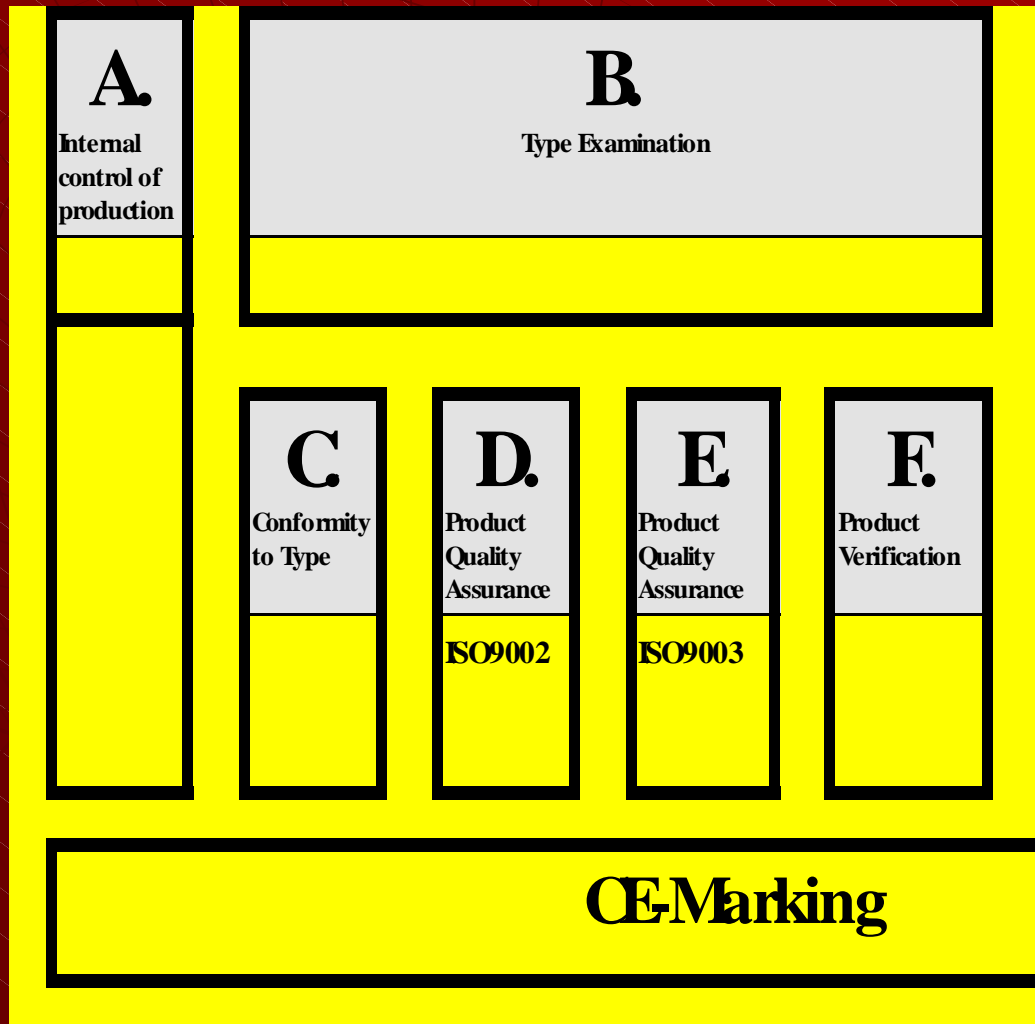


CONFORMITY ASSESSMENT Modules

- ◆ All CE marking Directives (>27) choose CA from the Modules given by the “New Approach” and will:
 - describe range & contents of possible CAP, considered to give the necessary level of protection.
 - set out the criteria and the conditions for the manufacturer to make a choice, if more than one option is available.
- ◆ Detail information on the New Approach can be found in: “The Blue Guide”

Note: The New Approach system is under review. More information will be given in later presentation

The 8 Basic Modules



R&TTE Routes to compliance - Overview

- ◆ **Annex II – Module A (internal production control) = Self-declaration by manufacturer, no NB involved**
- ◆ **Annex III = Annex II + specific apparatus tests (may involve NB)**
- ◆ **Annex IV – Technical Construction File (involves NB)**
- ◆ **Annex V – Module H Full Quality Assurance (involves NB)**

Applicability of the routes to R&TTE compliance

**◆ TTE & radio receivers
Apply Annex II, IV or V**

**◆ Radio transmitters
Apply Annex III , IV or V**

The Conformity Assessment Procedures in detail

CA Procedures – Annex II (1)

Annex II = only for TTE without radio function

- ◆ **Manufacturer** , or his authorised representative within the Community **declares compliance.**
- ◆ **Technical File** with details how essential requirements are met.
- ◆ **Declaration of Conformity + CE marking.**
- ◆ **Take measures for production to comply.**

CA Procedures – Annex II (2)

- ◆ **The manufacturer must:**
 - **Ensure and declare that the products concerned satisfy the requirements of the R&TTED that apply to them.**
 - **Affix the CE Marking to each product**
 - **Draw up a written EC Declaration of Conformity.**
 - **Establish the technical documentation and keep it for at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.**

CA Procedures – Annex II (3)

- ◆ **The technical documentation must enable the conformity of the product with the essential requirements to be assessed.**
- ◆ **The manufacturer must:**
 - **Keep a copy of the declaration of conformity with the technical documentation.**
 - **Must take all measures to ensure that the manufacturing process ensures compliance of the manufactured products with the technical documentation.**

CA Procedures – Annex III (1) (Internal production control plus specific apparatus tests)

Annex III For Radio Only!

- ◆ To apply Annex III one needs to apply also Annex II!
- ◆ Manufacturer declares compliance. = Annex II
- ◆ **Notified Body defines test suites only if no harmonised standards are used.**
- ◆ Declaration of Conformity + CE. = Annex II
Take measures for production to comply

CA Procedures – Annex III (2)

- ◆ **Manufacturer or person on his behalf must carry out all essential radio test suites.**
- ◆ **The identification of the essential test suites is the responsibility of a **Notified Body** except where the test suites are defined in the harmonised standards (99% of cases).**
- ◆ **Manufacturer must declare that:**
 - **these tests have been carried out.**
 - **the apparatus complies with the essential requirements and he must affix the NB identification number during the manufacturing process.**

CA Procedures - Annex IV

Annex IV for all products!

- ◆ **To apply Annex IV one needs to apply also Annex III and II!**
- ◆ **Manufacturer (his representative) makes Technical Construction File –TCF**
- ◆ **Must include how Radio tests are considered to be in compliance**
- ◆ **Notified Body reviews TCF**
- ◆ **Declaration of Conformity + CE marking**
Take measures for production to comply

CA Procedures – Annex IV (2)

- ◆ **The Technical Construction File (TCF) consists of:**
 - **Technical documentation described in Annex II &**
 - **For radio products, the declaration regarding specific radio test suites (described in Annex III).**
- ◆ **The manufacturer must present the TCF to a NB.**
 - **The NB must review the TCF and if the requirements of the R&TTED have been met, the NB may issue an opinion to the manufacturer**
 - **Such an opinion must be given by the NB within 4 weeks**
 - **On receipt of this opinion, or after the end of the 4 weeks, the apparatus may be placed on the market.**
- ◆ **The manufacturer must keep the file for a period of 10 years after the last apparatus has been manufactured.**

CA Procedures – Annex V

Annex V for all products!

- ◆ **Manufacturer has:**
 - “Full quality assurance system”**
 - Covers Design and production**
 - Comparable to ISO 9001 (*not mandatory*)**
- ◆ **Notified Body reviews QA System.**
- ◆ **Declaration of Conformity + CE marking rules identical to Annex II.**

Manufacturer CAP Obligations

The conformity assessment is and stays always only the sole responsibility of the manufacturer, even if help is asked from a Notified Body or any other third party!

The manufacturer is fully responsible for the **appropriate** choice of the assessment to be carried out.

The manufacturing process must ensure compliance of the products with the Technical Documentation that was made after the assessment!

**Conformity Assessment Body
(CAB)
= Notified Body (NB)
ISSUES**

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**MRA CAB = totally
equal to EU NB, only
the country location
is different.**

**I will use the wording CAB but meaning
also EU NB**

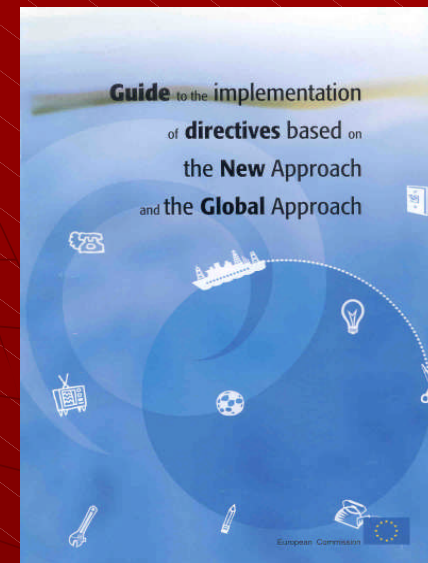
The Role of CABs

- ◆ **The R&TTE Directive is based on the manufacturers DoC!**
- ◆ **Role EU CAB different from CAB role for US or Japanese market/regulation:**
 - **An EU CAB gets involved when harmonised standards don't exist**
 - **Outside EU that role is typically reserved for the authority.**
 - **Where HS exist: voluntary role**

General Background on CAB

- ◆ The service required of the CAB is in fact to assist the manufacturer in the conformity assessment process for his product.
- ◆ The R&TTED has only a limited involvement of CAB.

General information on the operation of CAB's can be found in **Chapter 6 of the Blue Guide.**



General Background on CAB

- ◆ **Member States:**
 - Are responsible for the competence of the CAB,
 - Will designate NB, based on minimum criteria given in Annex VI of the R&TTD in conjunction with essential requirements and the task of the CAB in question.
 - Will regularly survey the competence of the CAB
- ◆ **To be eligible a CAB must be either:**
 - a legal entity established on the territory of the EU,
or
 - a legal entity established on the territory of the "MRA State.

Accreditation

Accreditation and Designation (Notification) are 2 different processes and in principle legally not always connected.

The Directive only formally requires Designating (“notification”) the CAB without the need for the CAB to be Accredited. However in many cases the CAB has undergone an Accreditation prior to the Designation as CAB

Basis for Assessment of CAB

- ◆ **Assessment options for a potential CAB to demonstrate competence to be Designated as CAB.**

Annex Type	Standard
Internal production control plus specific apparatus test	EN45004 or EN45011
Technical construction file	EN45004 or EN45011
Full quality assurance	EN45012 (+ product knowledge)

(Use of these standards is not mandatory!)

Role of a R&TTED CAB

R&TTED CAB have 3 roles:

- ◆ To identify the essential radio test suites – (Annex III of the R&TTED);
- ◆ To review and give opinions of technical construction files – (Annex IV);
- ◆ To assess and perform periodic surveillance of manufacturers full quality assurance systems – (Annex V).

**Note that Annex II (Module A)
has no external body mandatory involved**

OUTPUT of CAB

- **DRAWS UP AND AGREES on a TEST SUITE WHERE NO HARMONISED STANDARDS EXIST; III**
- **REVIEWS TECHNICAL CONSTRUCTION FILE AND ISSUES AN OPINION; IV**
- **ACCESS MANUFACTURERS QUALITY CONTROL SYSTEM. V**

Overview of CAB

- ◆ **CAB can have a designation, restricted to specific Annex and/or equipment**
- ◆ **Currently there are approx.:**
 - **70 NB for R&TTED**
(from which 20 CAB outside EU based on MRA's)
 - **Annex III: 66**
 - **Annex IV: 67**
 - **Annex V: 26**

Involvement of CAB

A major EU NB that was in business from start of R&TTED 1999 and appointed for all Annexes, performed until now:

- ANNEX III 2 cases**
- ANNEX IV 389 cases**
- ANNEX V 0 cases**

CAB experience

Some EU NB experience =

- **75 % of NB clients from non-EU countries**
- **in > 95% of the cases, ANNEX IV clients were using adequate harmonised standards so the process could be done by solely applying ANNEX II only (or III without using a CAB!)**

Market value of CAB

Why do manufacturers still want to involve a CAB?

- ◆ **Second opinion:**
 - **By independent appointed and government controlled party (guarantee!)**
- ◆ **No experience with CA process;**
- ◆ **Think it is necessary;**
- ◆ **Sharing of responsibility;**
- ◆ **Convince their clients of their good intentions.**

CAB Business case

- ◆ **A CAB can only survive if:**
 - **combined activities with other functions and/or**
 - **providing extra service (consultancy)**

- ◆ **when competitive in:**
 - **price**
 - **leadtime**
 - **accuracy of information**

CAB's strong points

- ◆ **Combination of activities**
- ◆ **Operating on a world market**
- ◆ **Up to date know how**
- ◆ **Contacts**
- ◆ **Rapid to adapt**

CAB's strong points (2)

But:

- ◆ **The service provided by a CAB is a commercial activity which means that pricing and timing of the service provided may differ between CAB's as they operate in a competitive market.**
- ◆ **Manufacturers can gain by carefully selecting a CAB taking into account the location of the CAB, the economic aspects and the manner the service is provided.**

Essential items for CAB!

It is absolute essential for CABs to:

- be aware of (national)spectrum plans in Europe: these are NOT always harmonised!**
- know the legal finesses of the Directive and EU law to be able to advice customers.**
- be able to interpret essential requirements on the basis of available harmonised standards.**



HARMONISED STANDARDS

The Use of Standards

In principle all (draft) standards can be used!

IEC/ITU

ETSI/CENELEC

MILStd

Manufacturers Standards

Country Standards (FCC)

Organisation Standards

Etc.

BUT:

**Only the EU HS
referenced in
the OJEU give
Presumption of
Conformity!**

Use of NON Harmonised Standards

If you use non HS, then make sure that:

Applying them leads to the conclusion that:

“”The apparatus complies with the essential requirements””

Selecting the correct Standards

The selection of the correct standards is:

The responsibility of the manufacturer!

MUTUAL Recognition Agreement

Mutual Recognition Agreements - MRA are established between the Community and the Government of third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment.

MRA-Mutual Recognition Agreement

- ◆ **Objective:** promoting trade in goods between the EU and third countries by facilitating market access.
- ◆ **Aim:** Providing easier access to conformity assessment procedures.
- ◆ **Set Conditions** for acceptance of test reports, certificates & conformity marks issued by the conformity assessment bodies (CABs) of the other party.

MRA-Mutual Recognition Agreement

- ◆ **It does not mean that test methods and regulation will be equal between Parties!**

BUT:

There are NB's (called CAB – Conformity assessment Body) appointed in the third countries that perform the work on Annexes III, IV and V of the R&TTED

MRA-Mutual Recognition Agreement

And: as it is mutual

**EU CAB's can already perform all the
Conformity Assessment work for
clients on location in EU before
exporting to third party countries.
This facilitates trade (time and
costs!)**

MRA Countries for Telecom area

Japan

USA

Canada

Australia

New Zealand

Switzerland

More EU MRA's for Telecom expected?

Problem with MRA's:

- ◆ Need for formal contracts between parties at high political level = Timely and costly.
- ◆ Combination with other sectors create specific problems.

EU Future: probably no more MRA with other countries, but it was a good learning process opening up markets on both sides.

It has increased confidence between parties!

What did R&TTED cause for conformity assessment?

- ◆ National type approvals procedures are gone.
- ◆ Most governmental NB's stopped (unfair price competition stopped?).
- ◆ Governmental type approval Labs stopped.
- ◆ Mandatory role of private Test Labs is gone.
- ◆ Manufacturers Labs are fully in business/acceptable.
- ◆ Maximum flexibility for manufacturers.
- ◆ Regular income for Testlabs based on the issue of mandatory (european) approvals has disappeared.

No product certification anymore in EU for R&TTED!

What did R&TTE cause for conformity assessment (2)?

- ◆ **Shift from preliminary type approval to market control.**
 - Major change at authority level.
 - More coordination between Member State authorities.
 - Only Manufacturer & NB (CAB) play role in CAP.
- ◆ **Fear for more complaints when it was foreseen that type approval would be abandoned but actual result was:**
 - No significant increase of complaints
 - While there is constant growth in Telecom products
- ◆ **Rapid availability of modern Telecom standards.**

End of Presentation

Thank you for your attention



Any QUESTIONS ??