SLOVENSKI STANDARD
SIST EN 302 195-2 V1.1.1:2004

01-oktober-2004

Elektromagnetna združljivost (EMC) in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenļnem območju od 9 kHz do 315 kHz za aktivne medicinske vsadke ultra majhnih moļi (ULP-AMI) in pribor - 2. del: Harmonizirani evropski standard (EN), ki zajema bistvene zahteve ļlena 3.2 direktive o radijski in telekomunikacijski terminalski opremi (R&TTE)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

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Candidate Harmonized European Standard (Telecommunications series)

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Foreword

This Candidate Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document is part 2 of a multi-part deliverable covering Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories, as identified below:

Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [5] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which will be published in the Official Journal of the European Communities referencing the Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ("the R&TTE Directive").

National transposition dates	
Date of adoption of this EN:	12 March 2004
Date of latest announcement of this EN (doa):	30 June 2004
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 December 2004
Date of withdrawal of any conflicting National Standard (dow):	31 December 2005

Introduction

The present document is part of a set of standards designed to fit in a modular structure to cover all radio and telecommunications terminal equipment under the R&TTE Directive [1]. Each standard is a module in the structure. The modular structure is shown in figure 1.

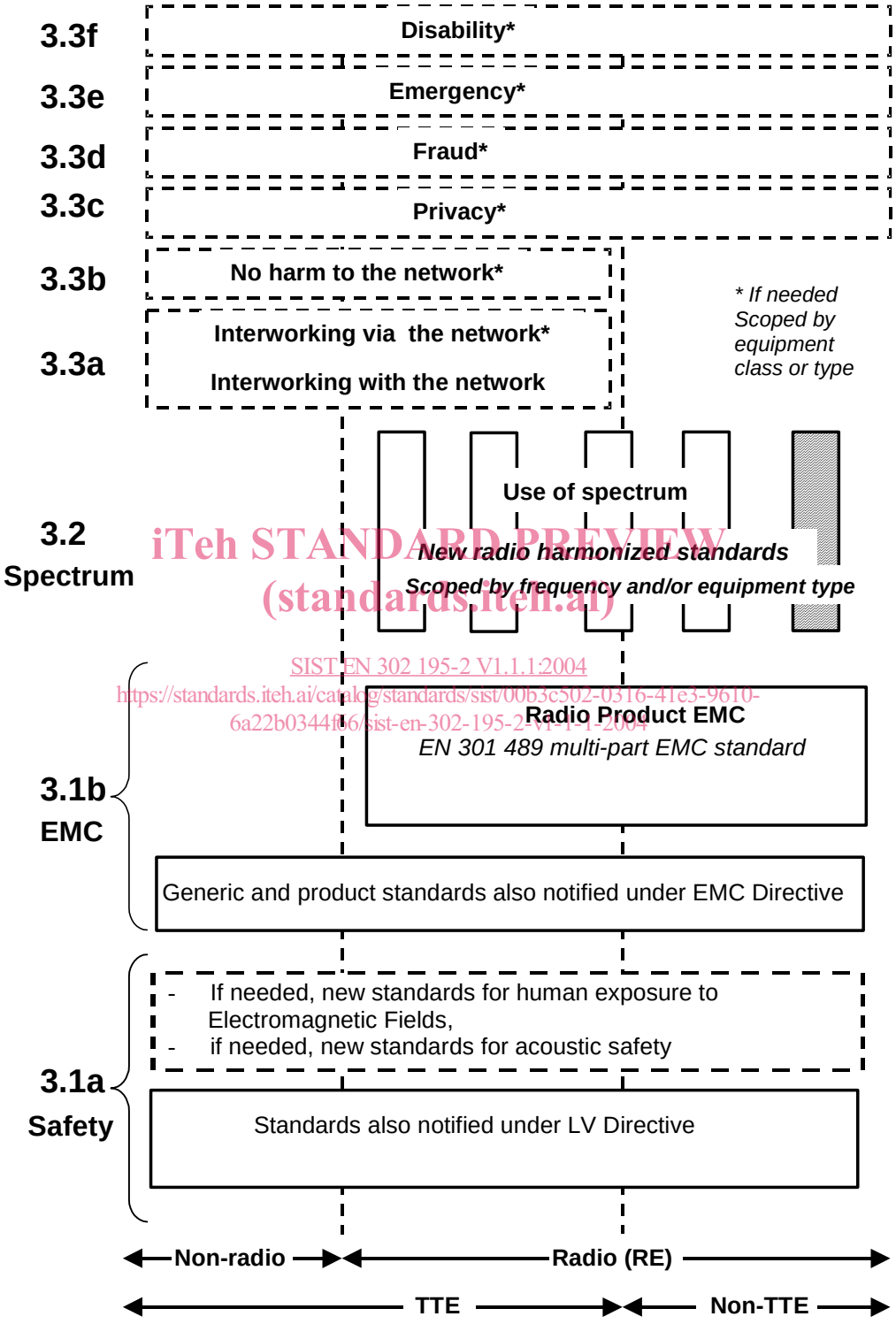

Figure 1: Modular structure for the various standards used under the R&TTE Directive [1]

The left hand edge of the figure 1 shows the different clauses of article 3 of the R&TTE Directive [1].

For article 3.3 various horizontal boxes are shown. Dotted lines indicate that at the time of publication of the present document essential requirements in these areas have to be adopted by the Commission. If such essential requirements are adopted, and as far and as long as they are applicable, they will justify individual standards whose scope is likely to be specified by function or interface type.

The vertical boxes show the standards under article 3.2 for the use of the radio spectrum by radio equipment. The scopes of these standards are specified either by frequency (normally in the case where frequency bands are harmonized) or by radio equipment type.

For article 3.1b the diagram shows EN 301 489, the multi-part product EMC standard for radio used under the EMC Directive [6].

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive [7] and new standards covering human exposure to electromagnetic fields. New standards covering acoustic safety may also be required.

The bottom of the figure shows the relationship of the standards to radio equipment and telecommunications terminal equipment. A particular equipment may be radio equipment, telecommunications terminal equipment or both. A radio spectrum standard will apply if it is radio equipment. An article 3.3 standard will apply as well only if the relevant essential requirement under the R&TTE Directive is adopted by the Commission and if the equipment in question is covered by the scope of the corresponding standard. Thus, depending on the nature of the equipment, the essential requirements under the R&TTE Directive [1] may be covered in a set of standards.

The modularity principle has been taken because:

- it minimizes the number of standards needed. Because equipment may, in fact, have multiple interfaces and functions it is not practicable to produce a single standard for each possible combination of functions that may occur in an equipment;
- it provides scope for standards to be added:
  - under article 3.2 when new frequency bands are agreed; or
  - under article 3.3 should the Commission take the necessary decisions

  without requiring alteration of standards that are already published;
- it clarifies, simplifies and promotes the usage of Harmonized Standards as the relevant means of conformity assessment.

1 Scope

The present document applies to Ultra Low Power Active Medical Implants (ULP-AMI) transmitters and receivers:

- transmitters operating in range from 9 kHz to 315 kHz with power levels ranging up to 30 dBuA/m;
- receivers operating in the range from 9 kHz to 315 kHz.

The present document applies to ULP-AMI devices:

- either with a Radio Frequency (RF) output connection and dedicated antenna, or with an integral antenna;
- for telecommand, telemetry etc. applications;
- for all types of digital modulation;
- with or without speech.

The present document covers fixed stations (physician programmer/controllers), mobile stations (patient programmers, handheld or otherwise) and portable stations (implanted devices providing medical benefit to the implanted patient).

All types of digital modulation for implanted radio devices and associated accessories are covered by the present document.

The power class designation is based on CEPT/ERC Recommendation 70-03 [3].

Table 1: Maximum radiated H-field or power (e.i.r.p.)

Power Class	Radiated H-field or power level
1	7 dBµA/m at 10 m
2	42 dBµA/m at 10 m
3	72 dBµA/m at 10 m (at 9 kHz to 30 kHz, descending 3 dB/octave from 30 kHz 135 kHz
4	37,7 dBµA/m at 10 m (at 135 kHz, descending 3 dB/octave from 135 kHz to 1 MHz)
	29 dBµA/m at 10 m (at 1,0 MHz descending 9 dB/octave from 1 MHz to 4,642 MHz)
5	9 dBµA/m at 10 m (4,642 MHz to 30 MHz)
Refer to annex 12, band (b)	30 dBµA/m at 10 m

The present document is intended to cover the provisions of article 3.2 of Directive 1999/5/EC (R&TTE Directive) [1] article 3.2, which states that "... radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communications and orbital resources so as to avoid harmful interference".

In addition to the present document, other ENs that specify technical requirements in respect of essential requirements under other parts of article 3 of the R&TTE Directive [1] may apply to equipment within the scope of the present document.

NOTE: A list of such ENs is included on the web site http://www.newapproach.org.