SGS COMPLIANCE SYMPOSIUM

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WHEN YOU NEED TO BE SURE

SGS

Changes to IEC 61000-4-5 Edition 3

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- > IEC 61000-4-5 changes in Ed.3:2014-05

As of May 2014 the new standard document IEC 61000-4-5 has been published. Compared to the former Edition 2:2005-11 a couple of considerable changes have been introduced.

These changes affect several aspects. They have also an impact on existing products on the market.

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- > IEC 61000-4-5 changes in Ed.3:2014-05

What are the most important changes?

- Specification of test levels now given for tests line-to-line and line-to-ground
- Pulse/waveform verification completely changed for 1.2/50us – 8/20us surge pulse
- New specification added for pulse/waveform verification at the generator output
- Selection of the coupling/decoupling network method
- Extended pulse/waveform verification at the EUT port of the CDN
- Pulse/waveform verification completely changed for 10/700us Telecom surge pulse
- New specification for coupling/decoupling networks for unshielded unsymmetrical and symmetrical interconnection lines
- Introduction of calibration processes and pulse/waveform specifications for CDNs for unshielded unsymmetrical and symmetrical interconnection lines

- > IEC 61000-4-5 changes in Ed.3:2014-05

What are the most important changes? (cont.)

- Introduction of calibration processes and pulse/waveform specifications for CDNs for unshielded unsymmetrical and symmetrical interconnection lines
- New specification for coupling/decoupling networks for unshielded outdoor communication lines
- Introduction of calibration processes and pulse/waveform specifications for CDNs for unshielded outdoor symmetrical communication lines
- Coupling on unshielded symmetrical connection lines (high-spped up to 1GB/sec)
- Slightly changed test set-up defined for testing shielded lines
- Revised definition of port types and test levels depending on port types

- > IEC 61000-4-5 changes in Ed.3:2014-05

What are the most important changes? (cont.)

- Additional informative Annexes
  - E (Mathematical modeling of surge waveform),
  - F (Measurement uncertainty (MU) consideration),
  - G (Method of calibration of impulse measuring systems),
  - H (Coupling/decoupling of surges to lines rated above 200A)
    -> not specifically addressed in this presentation

- Compliance of EM TEST product ranges to IEC 61000-4-5 Ed.2 resp. Ed.3 and possibilities to upgrade

- > IEC 61000-4-5 changes in Ed.3:2014-05

New Specification of test levels – 1.2/50us – 8/20us

Test levels are now specified much more precise than before distinguishing between line-to-line and line-to-ground testing as shown in table 1.

Level	Open circuit test voltage kV	
	Line to Line	Line to ground
1	---	0,5
2	0,5	1
3	1	2
4	2	4
X [a]	Special	Special

[a] "X" can be any level, above, below or in between the others. The level shall be specified in the dedicated equipment specification.

New test level specification in IEC 61000-4-5 Ed.3

Former test level specification in IEC 61000-4-5 Ed.2

Level	Open-circuit test voltage ±10 %
	kV
1	0,5
2	1,0
3	2,0
4	4,0
X	Special

NOTE X can be any level, above, below or in between the other levels. This level can be specified in the product standard.

> IEC 61000-4-5 changes in Ed.3:2014-05

New requirements for pulse/waveform verification – 1.2/50us – 8/20us

As per the new IEC 61000-4-5 Ed.3 the former specifications for pulse/waveform verification are completely changed. None of the former specifications as IEC 60060-1 or IEC 60469-1 are valid any more but a new specification has been introduced as outlined in tables 2 and 3 resp. figures 2 and 3.

Table 2 – Definitions of the waveform parameters 1,2/50 µs – 8/20 µs

Definitions	In accordance with IEC 60060-1		In accordance with IEC 60469-1	
	Front time µs	Time to half value µs	Rise time (10 % – 90 %) µs	Duration time (50 % – 50 %) µs
Open-circuit voltage	1,2 ± 30 %	50 ± 20 %	1 ± 30 %	50 ± 20 %
Short-circuit current	8 ± 20 %	20 ± 20 %	6,4 ± 20 %	16 ± 20 %

NOTE In existing IEC publications, the waveforms 1,2/50 µs and 8/20 µs are generally defined according to IEC 60060-1 as shown in Figures 2 and 3. Other IEC recommendations are based on waveform definitions according to IEC 60469-1 as shown in Table 2.

Both definitions are valid for this part of IEC 61000 and describe just one single generator.

Table 3 – Relationship between peak open-circuit voltage and peak short-circuit current

Open-circuit peak voltage ±10 %	Short-circuit peak current ±10 %
0,5 kV	0,25 kA
1,0 kV	0,5 kA
2,0 kV	1,0 kA
4,0 kV	2,0 kA

This is how the specification was given in IEC 61000-4-5 Ed.2

Table 2 – Definitions of the waveform parameters 1,2/50 µs and 8/20 µs

	Front time T_f µs	Duration T_d µs
Open-circuit voltage	$T_f = 1{,}67 \times T = 1{,}2 \pm 30\ \%$	$T_d = T_w = 50 \pm 20\ \%$
Short-circuit current	$T_f = 1{,}25 \times T_r = 8 \pm 20\ \%$	$T_d = 1{,}18 \times T_w = 20 \pm 20\ \%$

Table 3 – Relationship between peak open-circuit voltage and peak short-circuit current

Open-circuit peak voltage ± 10 % at generator output	Short-circuit peak current ± 10 % at generator output
0,5 kV	0,25 kA
1,0 kV	0,5 kA
2,0 kV	1,0 kA
4,0 kV	2,0 kA

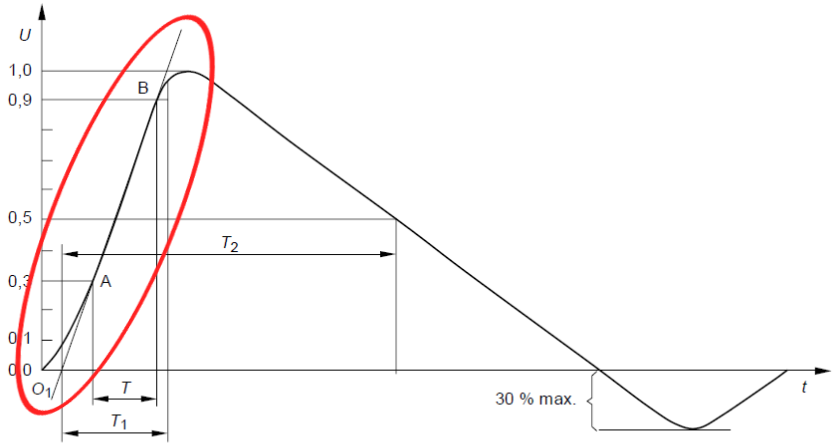
A generator with floating output shall be used.

This reflects the new specification in IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05

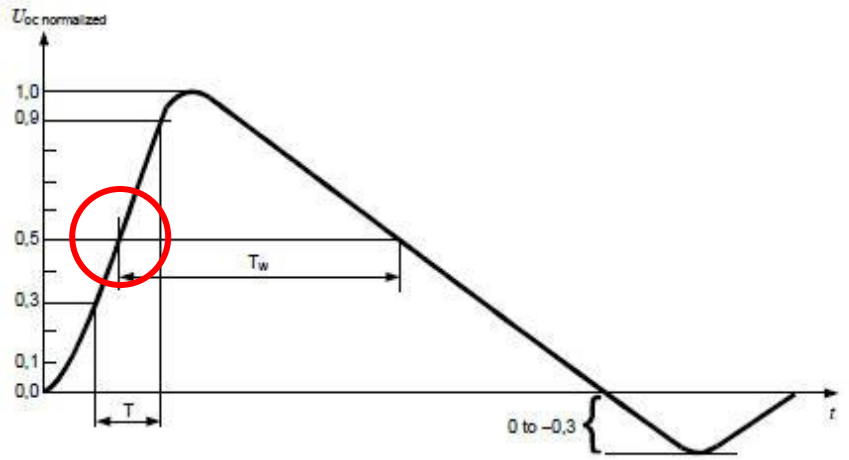
New requirements for pulse/waveform verification for 1.2/50us voltage pulse

As per the new IEC 61000-4-5 Ed.3 the former specifications for pulse/waveform verification are completely changed. None of the former specifications as IEC 60060-1 or IEC 60469-1 are valid any more but a new specification has been introduced as outlined in tables 2 and 3 resp. figures 2 and 3.



Front time: $T_1 = 1{,}67 \times T = 1{,}2\ \mu s \pm 30\ \%$
Time to half-value: $T_2 = 50\ \mu s \pm 20\ \%$.

Former specification for the surge voltage pulse in IEC 61000-4-5 Ed.2 based on IEC 60060-1



Front time: $T_r = 1{,}67 \times T = 1{,}2\ \mu s \pm 30\ \%$
Duration: $T_d = T_w = 50\ \mu s \pm 20\ \%$

NOTE The value 1,67 is the reciprocal of the difference between the 0,9 and 0,3 thresholds.

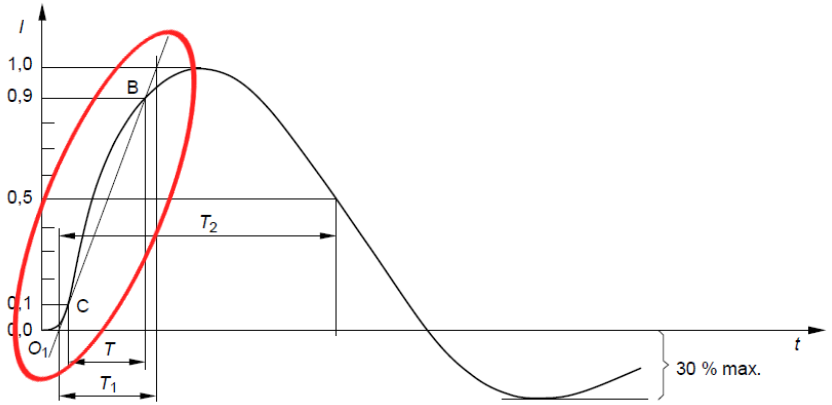
Figure 2 – Waveform of open-circuit voltage (1,2/50 µs) at the output of the generator with no CDN connected

This reflects the new specification for the Surge voltage pulse as in IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05

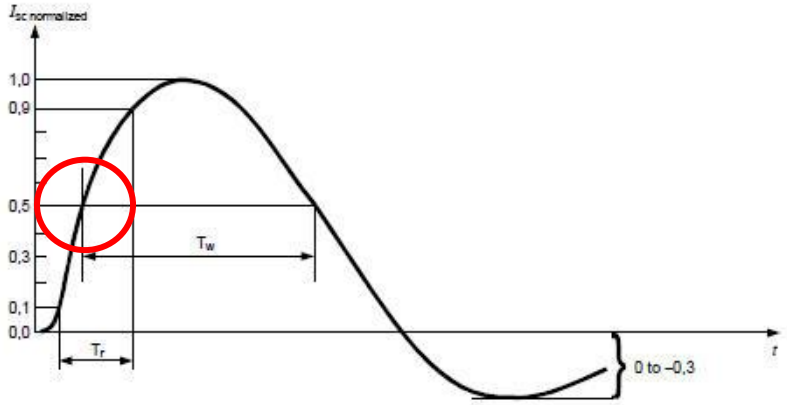
New requirements for pulse/waveform verification – 8/20us current pulse

As per the new IEC 61000-4-5 Ed.3 the former specifications for pulse/waveform verification are completely changed. None of the former specifications as IEC 60060-1 or IEC 60469-1 are valid any more but a new specification has been introduced as outlined in tables 2 and 3 resp. figures 2 and 3.



Front time: $T_1 = 1{,}25 \times T = 8\ \mu s \pm 20\ \%$
Time to half-value: $T_2 = 20\ \mu s \pm 20\ \%$

Former specification for the surge current pulse in IEC 61000-4-5 Ed.2 based on IEC 60060-1



Front time: $T_r = 1{,}25 \times T_f = 8\ \mu s \pm 20\ \%$
Duration: $T_d = 1{,}18 \times T_w = 20\ \mu s \pm 20\ \%$

NOTE 1 The value 1,25 is the reciprocal of the difference between the 0,9 and 0,1 thresholds.

NOTE 2 The value 1,18 is derived from empirical data.

Figure 3 – Waveform of short-circuit current (8/20 µs) at the output of the generator with no CDN connected

This reflects the new specification for the Surge current pulse as in IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05

Calibration of the generator output

Unlike in former standard editions the generator output is now also required to be verified through an external or internal 18uF capacitor both under open-circuit and short circuit conditions.
This is another new requirement specified in IEC 61000-4-5 Ed.3.

UCS 500N5 and UCS 500N7 as well as Surge generators up to 7kV don't have an internal 18uF capacitor. They need the external 18uF capacitor. This is our EM TEST IMN 2 (part number 105563).

Higher voltage Surge generators from 8kV – 12kV may have a built-in 18uF capacitor representing the generator output. In such cases no external IMN 2 is required.

> IEC 61000-4-5 changes in Ed.3:2014-05

Calibration at the EUT output of the coupling network

It is the intention of this standard that the output waveforms meet specifications at the point where they are to be applied to the EUT. The characteristics of the generator shall be measured under:

- **Open circuit voltage**
- **with HV-Probe**

- each:
- DM: L-N
- CM: L-PE
- CM: N-PE

Calibration can be performed with a suitable HV voltage probe.
→Take care that it is properly adjusted in order to avoid false measuring results!!
Important: Use an isolation transformer for powering the oscilloscope!!!

Alternative (actually preferred method by EM TEST):
Use a differential voltage probe such as EM TEST DVP (part number 106668)

> IEC 61000-4-5 changes in Ed.3:2014-05

Calibration at the EUT output of the coupling network

It is the intention of this standard that the output waveforms meet specifications at the point where they are to be applied to the EUT. The characteristics of the generator shall be measured under:

- **Short-circuit current**
- **with current probe**

- each:
- DM: L-N
- CM: L-PE
- CM: N-PE

For measurement of the short-circuit current EM TEST recommends the use of a current probe,
model Pearson 411 (part number 105703).
Additional attenuators could be needed in order to match the measuring signal with the max. input capability of the oscilloscope.

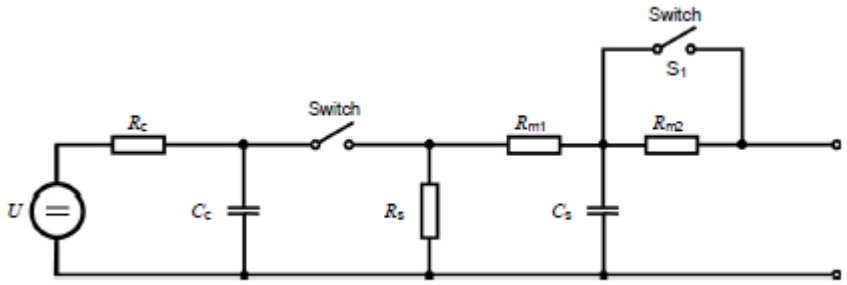
> IEC 61000-4-5 changes in Ed.3:2014-05

New requirements for pulse/waveform verification for 10/700us – 5/320us

The 10/700us Telecom Surge pulse has been relocated to the normative Annex A. This test is now specifically dedicated to be performed on unshielded symmetrical communication lines interconnecting widely dispersed system.

Similar to the pulse/waveform verification for the 1.2/50us – 8/20us pulse the verification of the 10/700us Telecom Surge pulse has also been changed.

The most important change in this content is the line-up of the matching resistor Rm2 with the requirements in ITU-T standards. Unlike before (resistor per line was calculated by number of lines under test multiplied by 25 Ohm) the coupling resistor is always of the same value per line no longer considering the number of lines under test, the value is 25 Ohm per line.



> IEC 61000-4-5 changes in Ed.3:2014-05

New requirements for pulse/waveform verification for 10/700us – 5/320us

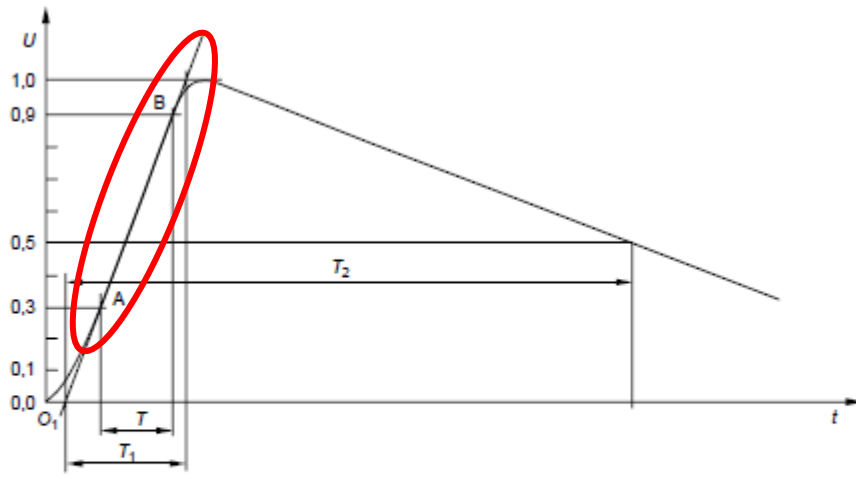


Figure 5 – Waveform of open-circuit voltage (10/700 µs)
(waveform definition according to IEC 60060-1)

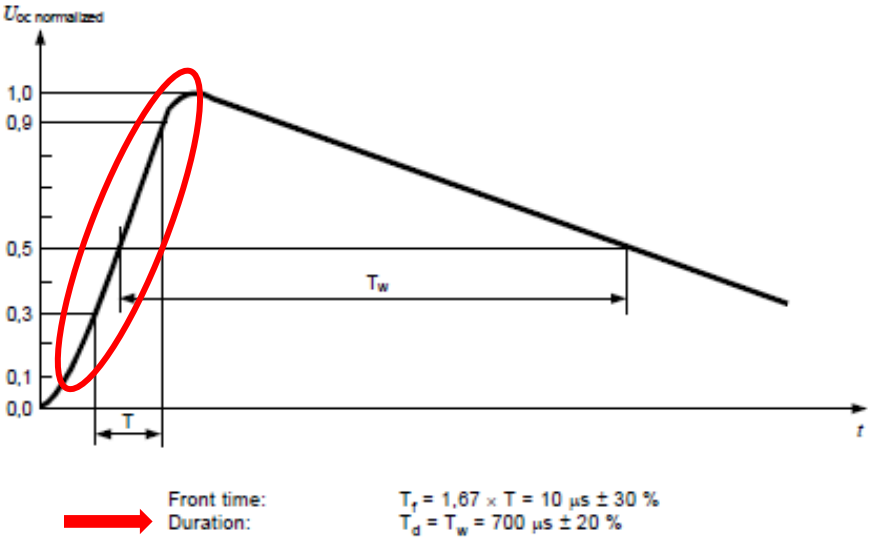


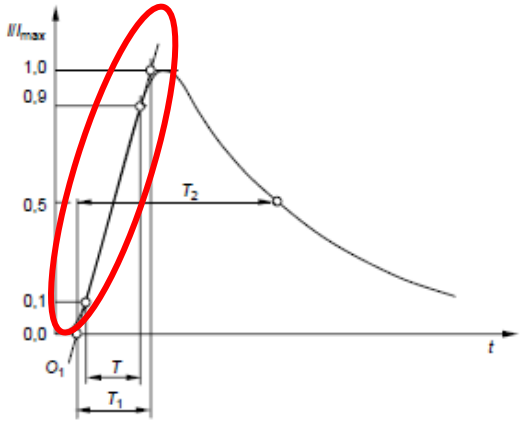
Figure A.2 – Waveform of open-circuit voltage (10/700 µs)

Former specification for the Telecom surge voltage pulse in IEC 61000-4-5 Ed.2 based on IEC 60060-1

This reflects the new specification for the Telecom surge voltage pulse as in IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05

New requirements for pulse/waveform verification for 10/700us – 5/320us

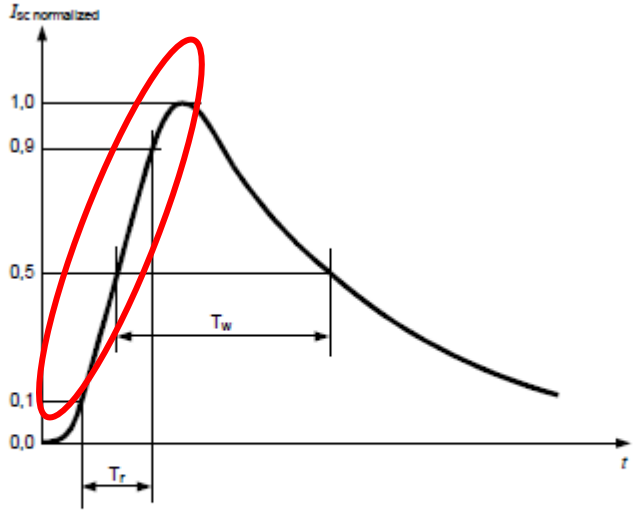


Front time: $T_1 = 1{,}25 \times T = 5\ \mu s \pm 20\ \%$

Time to half-value: $T_2 = 320\ \mu s \pm 20\ \%$.

NOTE In IEC 60060-1 the specification of the waveform is defined as 5/320 µs, while in IEC 60469-1 it is defined as 4/300 µs. Moreover this waveform is measured with the switch S1 in Figure 4 opened.

Figure 6 – Waveform of the 5 µs × 320 µs short-circuit current waveform (definition according to IEC 60060-1)



Front time: $T_r = 1{,}25 \times T_r = 5\ \mu s \pm 20\ \%$

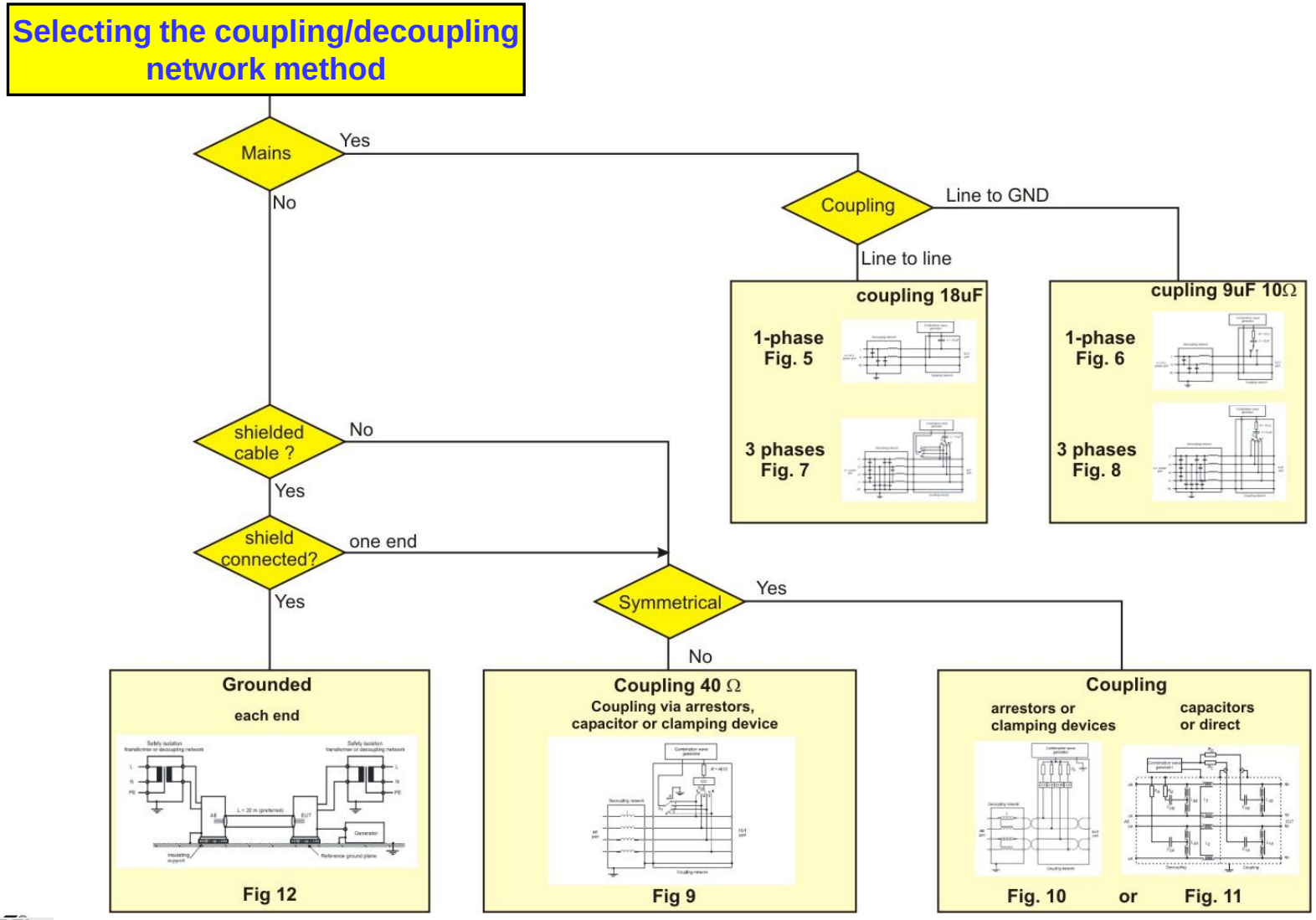
Duration: $T_d = T_w = 320\ \mu s \pm 20\ \%$

Figure A.3 – Waveform of the 5/320 µs short-circuit current waveform

Former specification for the Telecom surge current pulse in IEC 61000-4-5 Ed.2 based on IEC 60060-1

This reflects the new specification for the Telecom surge voltage pulse as in IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05



> IEC 61000-4-5 changes in Ed.3:2014-05

Extended pulse/waveform verification requirement at the EUT port of the CDN

Depending on the rated current of a CDN the open-circuit peak voltage and the front/duration time have to meet the related values within a given tolerance band.
For the duration time tolerances are different for line-to-line or line-to-ground coupling conditions.

Surge voltage parameters under open-circuit conditions [a]	Coupling impedance	
	18 µF	9 µF + 10 Ω
Peak voltage		
Current rating ≤ 16 A	Set voltage +10 %/-10 %	Set voltage +10 %/-10 %
16 A < Current rating ≤ 32 A	Set voltage +10 %/-10 %	Set voltage +10 %/-10 %
32 A < Current rating ≤ 63 A	Set voltage +10 %/-10 %	Set voltage +10 %/-15 %
63 A < Current rating ≤ 125 A	Set voltage +10 %/-10 %	Set voltage +10 %/- 20 %
125 A < Current rating ≤ 200 A	Set voltage +10 %/-10 %	Set voltage +10 %/- 25 %
Front time	1,2 µs ± 30 %	1,2 µs ± 30 %
Duration		
Current rating ≤ 16 A	50 µs +10 µs/-10 µs	50 µs +10 µs/-25 µs
16 A < Current rating ≤ 32 A	50 µs +10 µs/-15 µs	50 µs +10 µs/-30 µs
32 A < Current rating ≤ 63 A	50 µs +10 µs/-20 µs	50 µs +10 µs/-35 µs
63 A < Current rating ≤ 125 A	50 µs +10 µs/-25 µs	50 µs +10 µs/-40 µs
125 A < Current rating ≤ 200 A	50 µs +10 µs/-30 µs	50 µs +10 µs/-45 µs

[a] The measurement of the surge voltage parameters shall be done with the a.c./d.c. mains supply port of the CDN open-circuit.

- Waveshape defined for common mode coupling to PE
- Tolerances are increased at higher current in the coupling network.

Decoupling inductivity:

- Maximum 1.5 mH @16A; needs to be decreased to keep the voltage drop low
- Voltage Drop across CDN < 10% of Un

> IEC 61000-4-5 changes in Ed.3:2014-05

Extended pulse/waveform verification requirement at the EUT port of the CDN

A critical point to observe is the use of a CDN with higher current rating for testing in a lower current range. Such CDN can only be used for the lower current range if it meets the tolerance requirements for the lower range of current.

Why can't high-current CDNs be used for testing small current DUTs?

This is plain physics!
Lowering the value of the decoupling inductor means we reduce the impedance vs. the mains supply voltage side. By reducing the impedance more of the pulse energy is actually dissipated in the decoupling and as a result of this the pulse becomes shorter.

This physical fact is considered and taken into account by the larger lower tolerance being applied for the voltage waveform, the higher the rated current of the CDN is.

Conclusion of the above:
Strictly according to the standard stipulation it is not possible to use a high-current CDN to test the whole range of DUTs from 0A – 100A. In order to perform really full-compliant tests over the full range of current, considering the pulse form requirements it might become necessary to use several different CDNs for the various current ranges specified.

> IEC 61000-4-5 changes in Ed.3:2014-05

Extended pulse/waveform verification requirement at the EUT port of the CDN

As an example, How does the situation look like while using EM TEST CNI 503x?

What we can guarantee:

The way the CNI 503 series are designed measurements so far have shown that:

- CNI 503A2 up to 32A also fulfills the requirements of a CNI 503A up to 16A
- CNI 503A3 up to 63A also fulfills the requirements of a CNI 503A2 from 16A to 32A
- CNI 503A4 up to 100A also fulfills the requirements of a CNI 503A3 from 32A to 63

- CNI 503B7 up to 32A also fulfills the requirements of a CNI 503B5 up to 16A
- CNI 503B8 up to 63A also fulfills the requirements of a CNI 503B7 from 16A to 32A
- CNI 503B9 up to 100A also fulfills the requirements of a CNI 503B8 from 32A to 63

> IEC 61000-4-5 changes in Ed.3:2014-05

Extended pulse/waveform verification requirement at the EUT port of the CDN

Current waveform and short-circuit peak current are given as a function of the coupling impedance

Table 5 – Current waveform specification at the EUT port of the CDN

Surge current parameters under short-circuit conditions [a]	Coupling impedance	
	18 µF (line-to-line)	9 µF + 10 Ω (line-to-ground) [b]
Front time	$T_f = 1{,}25 \times T_r = 8$ µs ± 20 %	$T_f = 1{,}25 \times T_r = 2{,}5$ µs ± 30 %
Duration	$T_d = 1{,}18 \times T_w = 20$ µs ± 20 %	$T_d = 1{,}04 \times T_w = 25$ µs ± 30 %

[a] The measurement of the surge current parameters shall be performed with the a.c./d.c. power port of the CDN open-circuit.

[b] The value 1,04 is derived from empirical data.

Table 6 – Relationship between peak open-circuit voltage and peak short-circuit current at the EUT port of the CDN

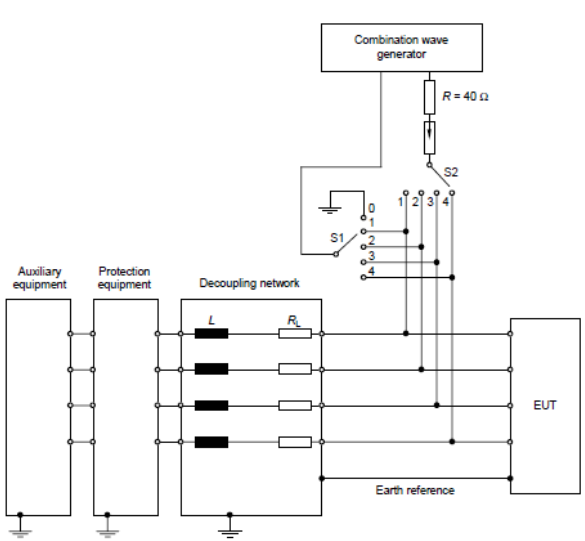
Open-circuit peak voltage ± 10 % at EUT port of the CDN	Short-circuit peak current ± 10 % at EUT port of the CDN (18 µF)	Short-circuit peak current ± 10 % at EUT port of the CDN (9 µF + 10 Ω)
0,5 kV	0,25 kA	41,7 A
1,0 kV	0,5 kA	83,3 A
2,0 kV	1,0 kA	166,7 A
4,0 kV	2,0 kA	333,3 A

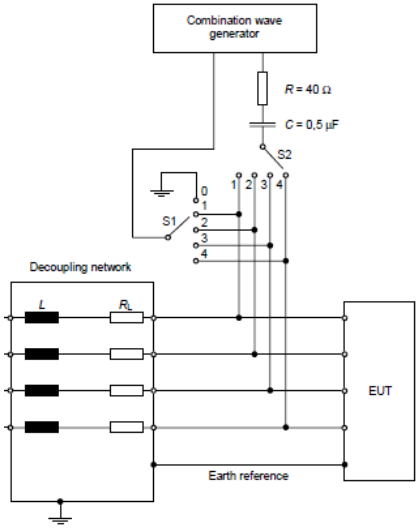
The above mentioned characteristics are applicable for single-phase systems (line, neutral, protective earth) and three-phase systems (three-phase wires, neutral and protective earth).

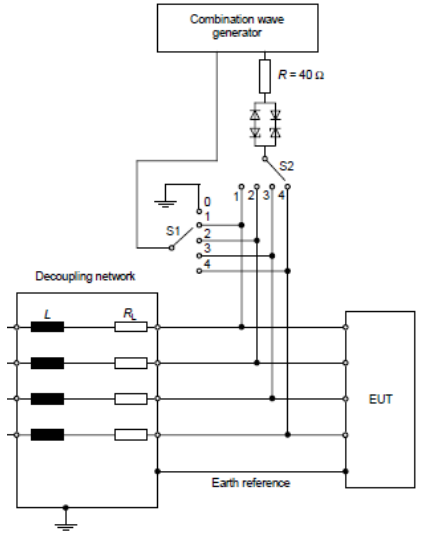
> IEC 61000-4-5 changes in Ed.3:2014-05

New specification for coupling/decoupling networks for unshielded unsymmetrical interconnection lines and calibration process

The specifications of the CDNs for unshielded unsymmetrical interconnection lines have been changed within IEC 61000-4-5 Ed.3.







Specification for CDNs for unshielded unsymmetrical lines as per IEC 61000-4-5 Ed.2

1) Switch S1
   - line to ground: position 0
   - line to line: positions 1 to 4
2) Switch S2
   - during the test positions 1 to 4, but not in the same position with switch S1
3) L = 20 mH, R_L represents the resistive part of L

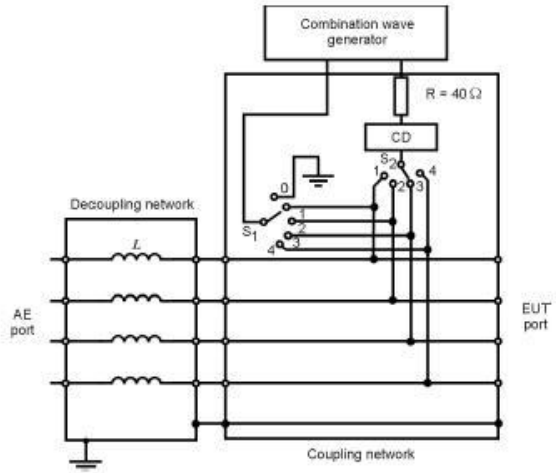
> IEC 61000-4-5 changes in Ed.3:2014-05

New specification for coupling/decoupling networks for unshielded unsymmetrical interconnection lines and calibration process

Instead of three different figures illustrating the different coupling methods there is only one figure showing a general coupling device (CD). This might be a 0.5uF capacitor or a GDT (Gas Discharge Tube

There is no longer indication about a Protection Equipment although it might be needed for appropriate decoupling and protection of the auxiliary equipment.

Capacitors or gas arrestor as well as other components like avalanche diodes may be used as CDs, selected as a function of the type of lines, the circuit or the operational conditions.



Specification for CDNs for unshielded unsymmetrical lines as per IEC 61000-4-5 Ed.3

> IEC 61000-4-5 changes in Ed.3:2014-05

Introduction of calibration processes and pulse/waveform specifications for CDNs

for shielded unsymmetrical and symmetrical interconnection lines

They are no longer specified based on the components but the pulses/waveforms need to be verified based on coupling mode (line-to-line or line-to-ground) and coupling elements used (0.5uF capacitor or GDT).

Table 7 – Summary of calibration process for CDNs for unsymmetrical interconnection lines

	Coupling	Measuring	AE side	EUT side
Surge voltage at EUT side	Single line to PE	Single line Peak voltage, front time, duration	All lines shorted to PE	Open–circuit
Surge current at EUT side	Single line to PE	Single line Peak current, front time, duration	All lines shorted to PE	Short-circuit
Surge voltage at EUT side	Single line-to-line	Single line Peak voltage, front time, duration	All lines shorted to PE	Open-circuit
Surge current at EUT side	Single line-to-line	Single line Peak current, front time, duration	All lines shorted to PE	Short-circuit
Residual voltage on AE side (with protection	Single line to PE	Line to PE at a time	Open-circuit	Open-circuit

> IEC 61000-4-5 changes in Ed.3:2014-05

Introduction of calibration processes and pulse/waveform specifications for CDNs
for shielded unsymmetrical and symmetrical interconnection lines

Table 8 – Surge waveform specifications at the EUT port of the CDN for unsymmetrical interconnection lines

Coupling method	CWG output voltage [a,b,c]	V_{oc} at CDN EUT output ± 10 %	Voltage front time T_f $T_f = 1,67 \times T_r$ ± 30 %	Voltage duration T_d $T_d = T_w$ ± 30 %	I_{sc} at CDN EUT output ± 20 %	Current front time T_f $T_f = 1,25 \times T_r$ ± 30 %	Current duration T_d $T_d = 1,18 \times T_w$ ± 30 %
Line to PE R = 40 Ω CD = 0,5 µF	4 kV	4 kV	1,2 µs	38 µs	87 A	1,3 µs	13 µs
Line to PE R = 40 Ω CD = GDT	4 kV	4 kV	1,2 µs	42 µs	95 A	1,5 µs	48 µs
Line-to-line R = 40 Ω CD = 0,5 µF	4 kV	4 kV	1,2 µs	42 µs	87 A	1,3 µs	13 µs
Line-to-line R = 40 Ω CD = GDT	4 kV	4 kV	1,2 µs	47 µs	95 A	1,5 µs	48 µs

[a] It is recommended to calibrate the CDN at the highest rated impulse voltage, as this will minimise the effects of the switching noise generated by CLDs and GDTs. The value shown in the table is for a generator setting of 4 kV. In case the CDN is rated for another maximum impulse voltage, the calibration shall be done at this maximum rated impulse voltage. The short-circuit peak current specification shall be adapted accordingly. For example, if the maximum voltage is 1 kV the short-circuit current value shown in this table shall be multiplied by 1/4.

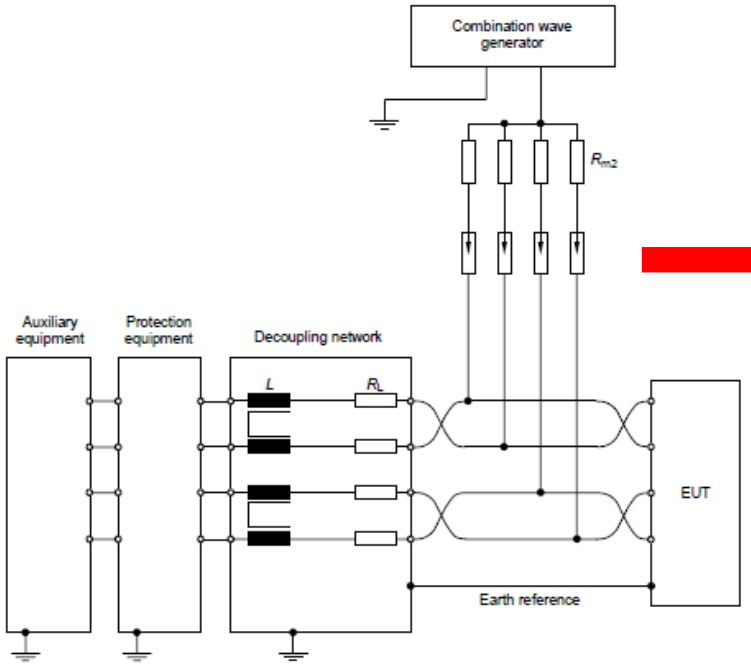
[b] Coupling via gas arrestors, clamping or avalanche devices will show some switching noise on the impulse waveform. Working with the highest possible impulse voltage will minimise their impact on measurements; it is recommended to neglect the switching noise for the front times and duration values measurements.

[c] The values shown in this table are for a CWG with ideal values. In case the CWG generates parameter values close to the tolerances, the additional tolerances of the CDN may generate values out of tolerances for the CWG-CDN combination.

> IEC 61000-4-5 changes in Ed.3:2014-05

New specification for coupling/decoupling networks for unshielded symmetrical interconnection lines and calibration process

The specifications of the CDNs for unshielded symmetrical interconnection lines have also been changed within IEC 61000-4-5 Ed.3.



Calculation of R_{m2} when using CWG (1,2/50 µs generator)

Example for n = 4:

R_{m2} = 4 × 40 Ω = 160, max. 250 Ω

Calculation of R_{m2} when using CWG (10/700 µs generator)

The internal matching resistor R_{m2} (25 Ω) is replaced by external R_{m2} = n × 25 Ω per conductor (for n conductors with n equal or greater than 2).

Example for n = 4:

R_{m2} = 4 x 25 Ω = 100 Ω, R_{m2} shall not exceed 250 Ω.

L = 20 mH, current compensation may include all 4 coils or only pairs as shown in the figure to be effective.

R_L: value depending on negligible attenuation of the transmission signal

NOTE The gas arrestors shown can be replaced by a clamping circuit such as that shown in Figure 13.

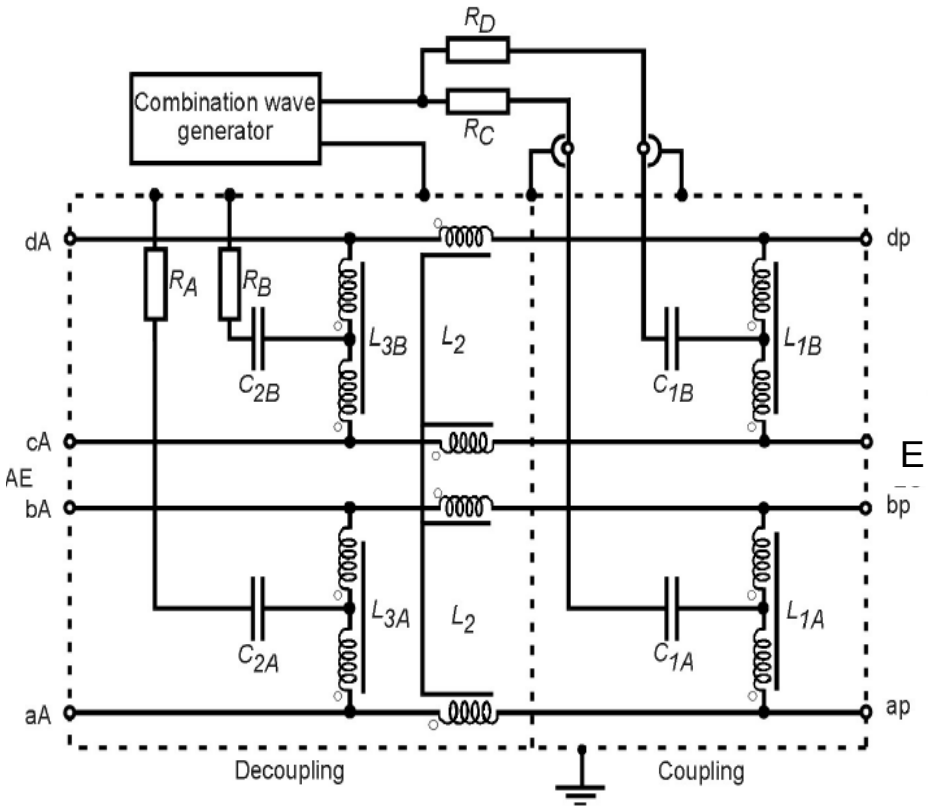
Former specification for the CDNs as per IEC 61000-4-5 Ed.2

> IEC 61000-4-5 changes in Ed.3:2014-05

Coupling/decoupling network for unshielded symmetrical interconnection lines up to 1GBit/sec

- Specification as per figure 11 of IEC 61000-4-5 Ed. 3.0

AE Port
max. 40V

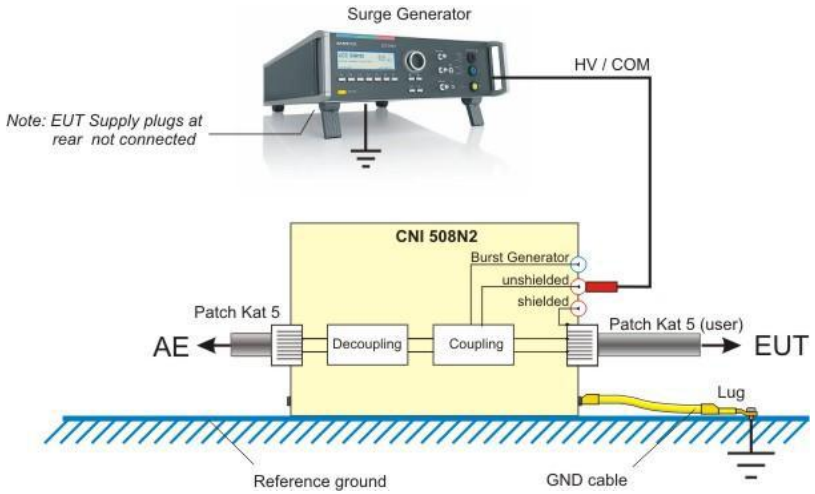


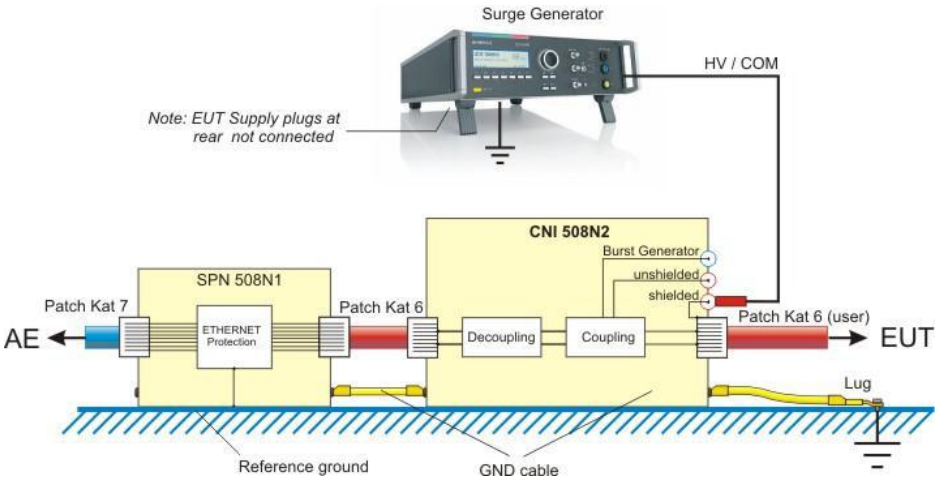
EM TEST CNI 508N2

> IEC 61000-4-5 changes in Ed.3:2014-05

Coupling/decoupling network for unshielded symmetrical interconnection lines up to 1GBit/sec

- Example for test set-up as per figure 11 of IEC 61000-4-5 Ed. 3.0





- Coupling to unshielded lines

Coupling to shield with additional AE protection with SPN 508N1

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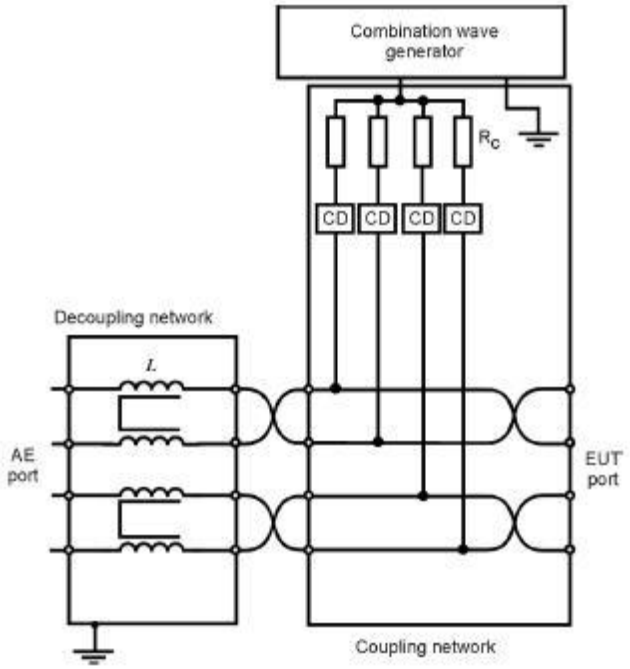
> IEC 61000-4-5 changes in Ed.3:2014-05

New specification for coupling/decoupling networks for unshielded symmetrical interconnection lines and calibration process

The specifications of the CDNs for unshielded symmetrical interconnection lines have also been changed within IEC 61000-4-5 Ed.3.



Calculation of coupling resistor values R_C:

Example for $n = 4$:

$R_C = 4 \times 40\ \Omega = 160\ \Omega$

The coupling resistors values are selected so that their resistance in parallel is equivalent to 40 Ω. A test on a four-line port for example, requires four resistors each of 160 Ω.

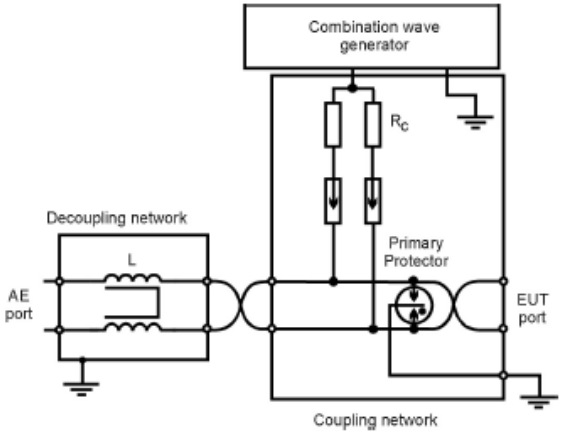
L with current compensation may include all 4 coils or only pairs (as shown in Figure 10) to be effective.

Specification for unshielded symmetrical interconnection lines for CWG 1.2/50us – 8/20us – no changes

> IEC 61000-4-5 changes in Ed.3:2014-05

New specification for coupling/decoupling networks for unshielded outdoor symmetrical lines and calibration process

The specifications of the CDNs for unshielded symmetrical communication lines have been changed within IEC 61000-4-5 Ed.3. First of all these CDNs are dedicated to test outdoor symmetrical lines rather than unshielded symmetrical (communication) lines as called before in a more general way.



The internal matching resistor R_{m2} (25 Ω) is replaced by external R_c = 25 Ω.

NOTE 1 The gas arrestors shown can be replaced by a clamping circuit such as that shown in Figure 9.

NOTE 2 Where the port is always intended to be used with specified primary protection, testing is performed with the primary protection in place to ensure coordination with the protection elements.

Figure A.4 – Example of test setup for unshielded outdoor symmetrical communication lines: lines-to-ground coupling, coupling via gas arrestors (primary protection fitted)

Key difference compared to former Ed.2 is that the value for Rm2 (now R is fixed to be 25 ohm per line irrespective the number of lines to be tested.

The internal matching resistor R_{m2} (25 Ω) is replaced by external R_{m2} = n × 25 Ω per conductor (for *n* conductors with *n* equal or greater than 2).

Example for *n* = 4:

R_{m2} = 4 x 25 Ω = 100 Ω, R_{m2} shall not exceed 250 Ω.

Resistor Rm2 was a function of the number of lines in former IEC 61000-4-5 Ed.2

> IEC 61000-4-5 changes in Ed.3:2014-05

Introduction of calibration processes and pulse/waveform specifications for CDNs for unshielded outdoor symmetrical and symmetrical communication lines

The specifications of the CDNs for unshielded symmetrical communication lines have been changed within IEC 61000-4-5 Ed.3 and require new processes.

Table A.3 – Summary of calibration process for CDNs for unshielded outdoor symmetrical communication lines

	Coupling	Measuring	AE side	EUT side
Surge voltage at EUT side	Common mode – one pair to PE	Both lines from one pair shorted together: peak voltage, front time, duration	All used lines shorted to PE	Open-circuit, both lines from one pair connected together
Surge current at EUT side	Common mode – one pair to PE	Both lines from one pair shorted together: peak current, front time, duration	All used lines shorted to PE	Both lines from one pair shorted to PE
Residual voltage on AE side (with protection elements)	Common mode – one pair to PE	Both lines from one pair shorted together: peak voltage	Open-circuit	Open-circuit

The intention of this calibration process is to check the proper function of the components, the saturation of decoupling chokes, the decoupling effect of the DN part, the current capability and the coupling effect of the CN part. The coupling method described in the above paragraphs has an influence on the voltage and current wave forms. The parameters for the calibration are defined in Table A.4.

> IEC 61000-4-5 changes in Ed.3:2014-05

Introduction of calibration processes and pulse/waveform specifications for CDNs for unshielded outdoor symmetrical and symmetrical communication lines

The specifications of the CDNs for unshielded symmetrical communication lines have been changed within IEC 61000-4-5 Ed.3.

Table A.4 – Surge waveform specifications at the EUT port of the CDN for unshielded outdoor symmetrical communication lines

Coupling method	CWG output voltage [a,b,c]	V_{oc} at CDN EUT output ± 10 %	Voltage front time T_f ± 30 %	Voltage duration T_d ± 30 %	I_{sc} at CDN EUT output ± 20 %	Current front time T_f ± 30 %	Current duration T_d ± 30 %
Common mode CD 1 pair 27,5 Ω	4 kV	4 kV	8 µs	250 µs	145 A	3,2 µs	250 µs

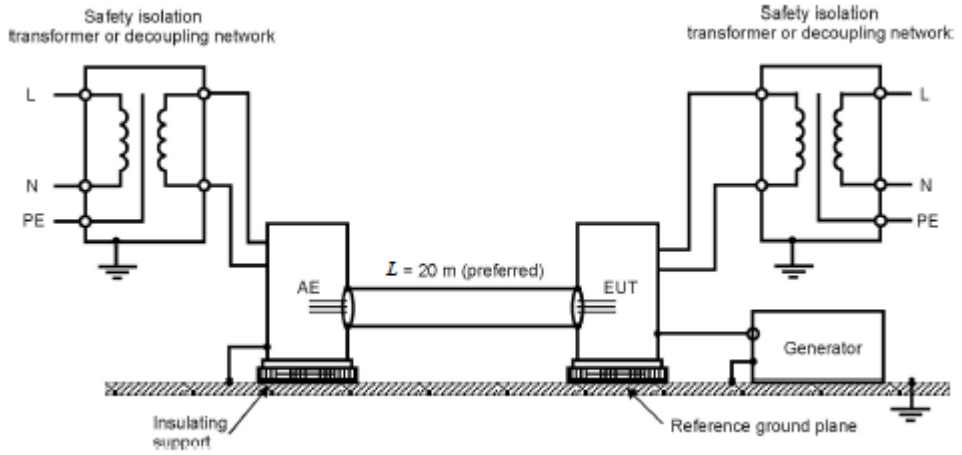
[a] For CDN with more than one pair, each pair has to be calibrated separately, as described in Table A.3.

[b] Coupling via gas arrestors, clamping or avalanche devices will show some switching noise on the impulse waveform. Working with the highest possible impulse voltage will minimize their impact on measurements; it is recommended to neglect the switching noise for the front times and duration values measurements.

[c] The values shown in this table are for a CWG with ideal values. In case the CWG generates parameter values close to the tolerances, the additional tolerances of the CDN may generate values out of tolerances for the CWG-CDN combination.

> IEC 61000-4-5 changes in Ed.3:2014-05

Test set-up for shielded lines grounded at both ends



Rules for application of the surge to shielded lines:

a) Shields grounded at both ends:

– the test shall be carried out according to Figure 12.

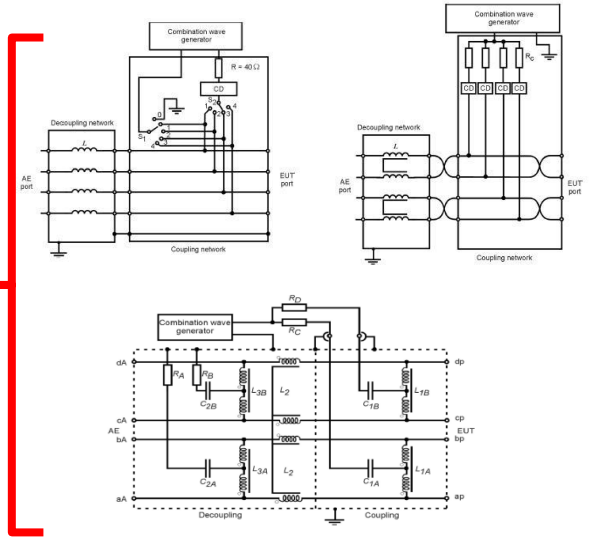
The test level is applied on shields with a 2 Ω generator source impedance and with the 18 µF capacitor (see 6.2.3).

b) Shields grounded at one end:

– the test shall be carried out according to 7.4 or 7.5 (see Figure 4) because the shield does not provide any protection against surges induced by magnetic fields.

NOTE 2 In this case, surge testing is not applied to the shield.

For EUTs which do not have metallic enclosures, the surge is applied directly to the shielded cable at the EUT side.



> IEC 61000-4-5 changes in Ed.3:2014-05

Selection of the test levels (depending on the installation conditions)

Table B.1 – Power ports: selection of the test levels (depending on the installation class)

Installation class	Test levels (kV)							
	AC power supply and a.c. I/O External ports *		AC power supply and a.c. I/O Internal ports *,d		DC power supply and d.c. I/O External ports *		DC power supply and d.c. I/O Internal ports *,d	
	Coupling mode		Coupling mode		Coupling mode		Coupling mode	
	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground
0	NA	NA	NA	NA	NA	NA	NA	NA
1	NA	0,5	NA	NA	NA	NA	NA	NA
2	0,5	1,0	NA	NA	NA	NA	NA	NA
3	1,0	2,0	1,0	2,0	NA	NA	NA	NA
4	2,0 b	4,0 b	2,0 b	4,0 b	2,0 b	4,0 b	2,0 b	4,0 b
5	c,b	c,b	2,0 b	4,0 b	2,0 b	4,0 b	2,0 b	4,0 b

* No test is advised if the cable length is shorter than or equal to 10 m.

b Where the port is always intended to be used with specified primary protection, testing is performed with the primary protection in place to ensure coordination with the protection elements. If primary protection is required to protect the interface but not provided, testing is also performed at the maximum let through level of the specified primary protection and with a typical primary protector.

c Depends on the class of the local power supply system.

d The testing of intra-system ports is generally not required.

Table B.2 – Circuits/lines: selection of the test levels (depending on the installation class)

Installation class	Test levels (kV)											
	Unsymmetrical operated circuits/lines *,c,*				Symmetrical operated circuits/lines *,c,*				Shielded circuits/lines *,d,*			
	External port		Internal port		External port		Internal port		External port		Internal port	
	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground	Line-to-line	Line-to-ground	Line-to-line	Shield-to-ground	Line-to-line	Shield-to-ground
0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
1	NA	NA	NA	0,5	NA	NA	NA	0,5	NA	NA	NA	NA
2	NA	NA	0,5	1,0	NA	NA	NA	1,0	NA	NA	NA	0,5
3	NA	NA	1,0	2,0	NA	NA	NA	2,0	NA	NA	NA	2,0
4	2,0 b	4,0 b	2,0 b	4,0 b	NA	4,0 b	NA	4,0 b	NA	4,0 b	NA	4,0 b
5	2,0 b	4,0 b	2,0 b	4,0 b	NA	4,0 b	NA	4,0 b	NA	4,0 b	NA	4,0 b

* No test is advised for data connections intended for cables shorter than 10 m.

b Where the port is always intended to be used with specified primary protection, testing is performed with the primary protection in place to ensure coordination with the protection elements. If primary protection is required to protect the interface but not provided, testing is also performed at the maximum let through level of the specified Primary protection and with a typical primary protector.

c Line-to-line surges (transverse) may occur in networks where SPDs (surge protective devices) with connection to ground are used for protection. Such surges are outside the scope of this standard. This phenomenon can however be simulated by applying common mode surges through the defined primary protection elements.

d The testing of ports connecting to antennas is outside the scope of this standard.

* The testing of intra-system ports is generally not required.

The surges (and generators) related to the different classes are as in the following:

Classes 1 to 5: **1,2/50µs** (8/20µs) for ports of power lines, short-distance signal circuits/lines and local area networks (e.g. Ethernet, Token Ring, etc.) and similar networks

Classes 4 to 5: **10/700µs** (5/320µs) for symmetrical communication lines intended to interconnect widely dispersed systems via such means as direct connection to multi-user telecommunications networks lines typically >300 m in length.

> IEC 61000-4-5 changes in Ed.3:2014-05

Conclusion

- → Only one waveform/pulse specifications for verification/calibration of the equipment according to IEC 61000-4-5 Ed.3:2014-05.
- → Generator output to be verified through a 18uF capacitor.
- → Based on a clear definition of current ranges and tolerances for the CDNs the use of high-current
  CDNs for low current DUTs is restricted.
- → Waveform/pulse verification and compliance to specification is now also mandatory for CDNs for signal/data, interconnection and communication lines.

> IEC 61000-4-5 changes in Ed.3:2014-05

Still confused but on a higher level?

Any questions or comments?

emtest MILMEGA TESEQ

Thank you for listening !!

AMETEK COMPLIANCE TEST SOLUTIONS

OBSERVATIONS ON THE USE OF RISK MANAGEMENT FOR THE IEC 60601 SERIES

Consumer and Retail

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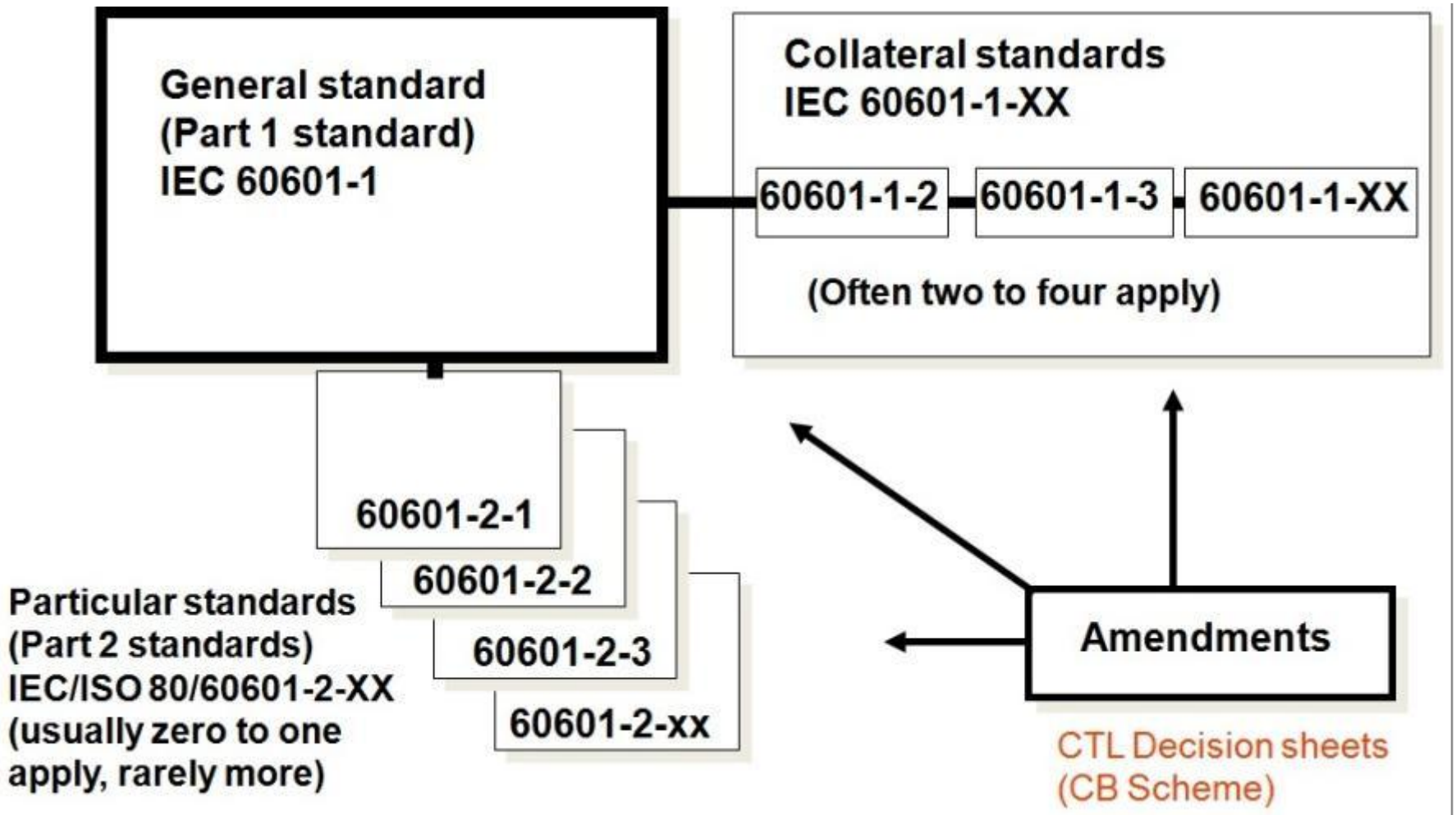
revision: 2015-02-10

AGENDA

- Common problems with Risk Management files.
- Essential Performance explained.
- Where Risk Management is useful.
- The significant Risk Management requirements in IEC 60601-1 3rd edition + Amendment 1.

IEC 60601 SERIES STRUCTURE



PROBLEMS WITH OLDER DEVICES CERTIFIED TO 60601, 2ND EDITION

- Conversion to 3rd edition for the EU.
- Often little to no RM performed.
  - Post-production monitoring a good starting point.
- If RM performed just to meet the 3rd edition standard provides less value.

COLLATERAL & PARTICULAR REQUIREMENTS STANDARDS

- Often not considered in the RM process.
- Particular standards (60601-2-x and 80601-2-x) have Essential performance for critical care devices
  - e.g. infant incubators and ICU devices.
  - In some cases make collateral standards mandatory.
- There are about 60 Particular Requirements standards
  - Examples include patient monitors, imaging equipment, endoscopes, hospital beds

COLLATERAL & PARTICULAR REQUIREMENTS STANDARDS

- Collateral standards (60601-1-x)
  - IEC 60601-1-2 Electromagnetic disturbances
    - emphasized use of RM in especially the new 4th edition
  - IEC 60601-1-3 Radiation protection in diagnostic X-ray equipment
    - heavy use of RM
  - IEC 60601-1-6 Usability
    - RM is the core requirement
  - IEC 60601-1-8 tests and guidance for alarm systems
    - alarms are characterized via risk management

COLLATERAL & PARTICULAR REQUIREMENTS STANDARDS

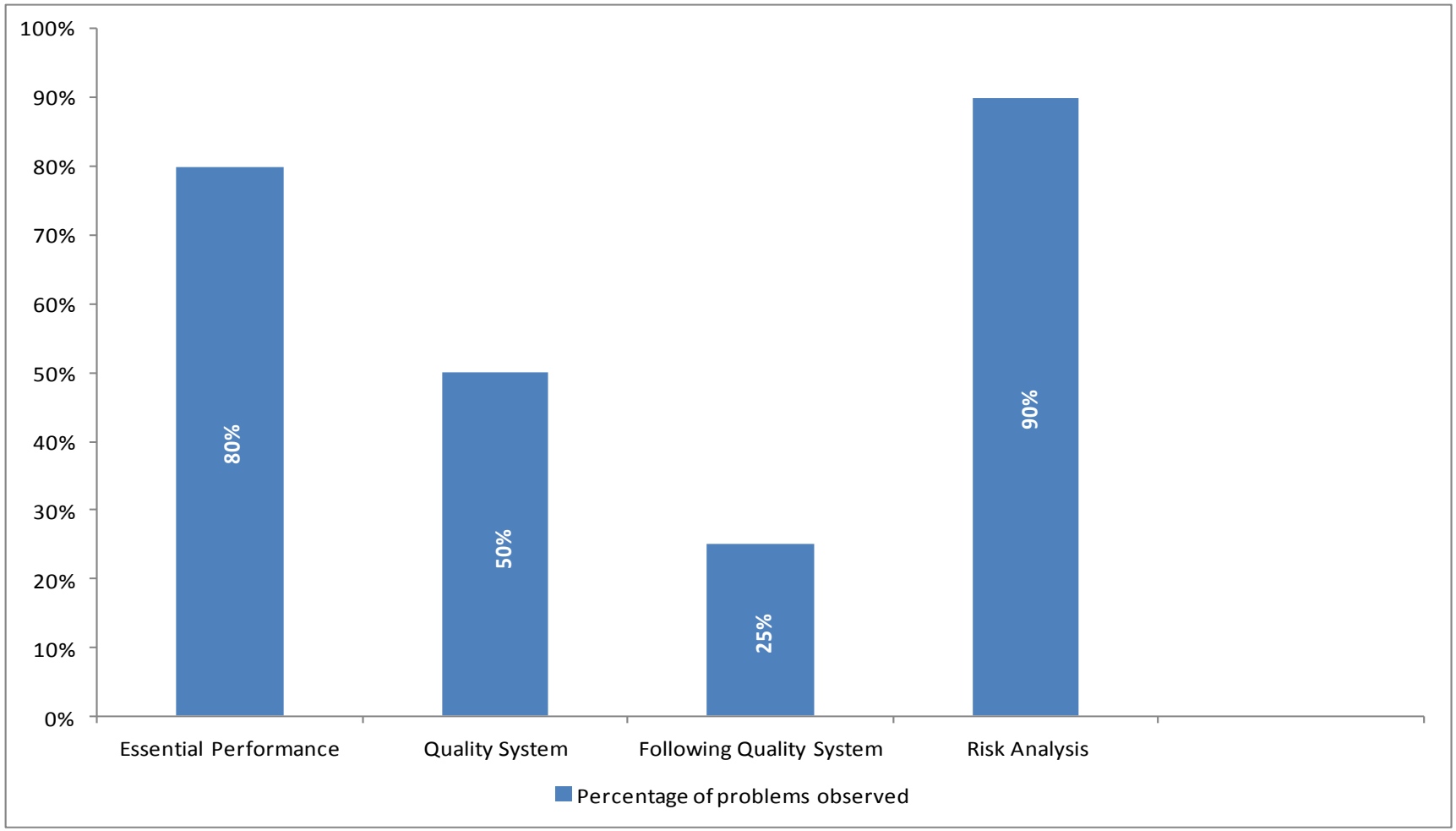
- Collateral standards (60601-1-x)
  - IEC 60601-1-9 environmentally conscious design
    - RM for impacts to health and environment
  - IEC 60601-1-10 development of physiologic closed-loop controllers
    - RM is the core requirement
  - IEC 60601-1-11 home healthcare environment
    - RM for usability and environment of use
  - IEC 60601-1-12 devices used in the emergency medical services environment
    - RM relating to environment of use

COLLATERAL & PARTICULAR REQUIREMENTS STANDARDS

- General requirement standards: main standard and Collaterals standards
  - Include no specific Essential Performance
  - Heavy on Risk Management

- Particular Requirement standards:
  - Essential Performance ranges from no specifics to several EP criteria
  - Little to a lot of Risk Management

RM DEFICIENCIES AND RELATED QMS DEFICIENCIES



DESIGN REVIEWS INCLUDING RISK MANAGEMENT

- Better informed of the RM and hardware requirements.
- This is really the best last chance to start a more complete RM file.
  - Can be included as part of a thorough design review.
  - Our experience has shown that most do not understand the level of RM detail the 60601 standards and especially the 60601-1 Test Report Form require.
  - Simply following the Examples of Hazards in Annex E of ISO 14971 will produce a Risk Analysis that is too general and of less use.

DESIGN REVIEWS

- Risk Analysis is not comprehensive.
  - 60601 series requires certain items to be addressed via Risk Management.
    - Most, but not all, relate to electric shock, energy, and mechanical hazards.
    - Risk Management also is essential for the things 60601 does a poor job addressing: new technologies, new methods of care, particle radiation, etc.

DESIGN REVIEWS

- Risk Analysis is not comprehensive.
  - Need help? Annex E of ISO 14971: 2007 *Examples of hazards, foreseeable sequences of events and hazardous situations* is a good place to start.
    - These are examples of Hazards and may be too general to make for designing a safer electrical device.
  - Examine and complete the Risk Management tables that have “14971 clause mapping” tables in the 60601 Test Report Forms.
    - Without using 60601 as a Risk Management tool, completing the tables in the Test Report Forms becomes an exercise in paperwork, not one that produces a safer device.

ESSENTIAL PERFORMANCE (4.3)

- What happens when there is not a Part 2 standard to dictate essential performance?
  - Go back to the definition. Your RM exercise may point to EP criteria.
  - Definition: *Performance of a clinical function, other than that related to Basic Safety, where loss or degradation beyond the limits specified by the Manufacturer results in an unacceptable Risk.*

- All applicable fault condition testing cannot be identified without identifying Essential Performance in the RMF.
  - Conversely, all fault conditions that should not be considered cannot be adequately justified without the RMF.

ESSENTIAL PERFORMANCE

- There may be more EP criteria than in 60601.
  - Start with the indications for use.
  - Many manufacturers don't consider EP when planning their 60601 testing.
    - Often there is weak justification that there are no EP, even for critical care devices.
- Some lower risk devices may not have any EP.
- Decisions made for EP may affect the test house's review of software per Clause 14 of IEC 60601-1.

ESSENTIAL PERFORMANCE

- An example of EP criteria from IEC 60601-2-27 for electrocardiographic monitoring equipment:

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	201.11.8
Protection against depletion of battery	201.11.8.101
ESSENTIAL PERFORMANCE of ME EQUIPMENT	201.12.1.101
Electrosurgery interference	202.6.2.101
Time to alarm for heart rate ALARM CONDITIONS	208.6.6.2.103
TECHNICAL ALARM CONDITIONS indicating inoperable ME EQUIPMENT	208.6.6.2.104

RISK MANAGEMENT (4.2)

- A risk management process according to ISO 14971 shall be performed.

  meaning. . .

- Certification to IEC 60601-1 not possible without compliance with ISO 14971.

- IEC 60601-1 is intended to serve as a tool in the risk management process.

  - The manufacturer must have a policy for establishing acceptable risks and acceptance of residual risks.

RISK MANAGEMENT (4.2)

- The requirements of this standard, referring to inspection of the Risk Management File, are considered to be satisfied if the manufacturer has:
  - established a risk management process
  - established acceptable levels of risk
  - shown that the residual risks are acceptable (according to the policy for determining acceptable risk)

- Downside to the concept of Risk:
  - More work to be done before sending device to the test house.
  - Sometimes less concrete requirements in standard.
  - More work to be done by the test house.
  - It is practically useless to the manufacturer if it is used to meet the 60601 standard after the device has been designed, rather than make a better device.

- Upside to the concept of Risk:
  - Reduces the uncertainty of the safety of the device.
  - Greater design flexibility.
  - Provides Objective Evidence when using the “escape clause” of 4.5.

WHERE IS RM USEFUL WITH RESPECT TO 60601?

- There are some key areas with respect to 60601 where Risk Management is helpful.
  - The generic “Complies with IEC 60601-1” in the Risk Analysis is not helpful where there is more than one means of addressing the requirement.
- Having a checklist of the RM requirements in 60601-1 can save time.
- *Manufacturers’ RM files are much stronger in the areas of cleaning and sterilization, wear & tear, markings and manuals, and use of the device.*

WHERE IS RM USEFUL WITH RESPECT TO 60601?

- Electrical Insulation: Operator vs. Patient Protection
  - Is the device being over-engineered?
- Patient Applied Part type
  - What level of patient isolation is needed?
- High integrity components
  - Should any components be fail safe?

WHERE IS RM USEFUL WITH RESPECT TO 60601?

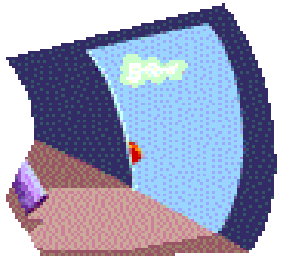
- Spillage test
  - Where? How much? How long? Should the device have a standard ingress protection rating?

- Maximum temperature of Patient Applied Parts
  - Heat supplied to patient intentional?
  - Risk management needs to define the use of the applied part, duration of contact, area of contact, blood perfusion, etc.

WHERE IS RM USEFUL WITH RESPECT TO 60601?

- Alarms – does IEC 60601-1-8 apply?
  - Alarm or information signal?
  - Alarm priority
- Does PEMS (software) affect Basic Safety or Essential Performance?

ESCAPE CLAUSE (4.5)



- Alternative means of addressing a risk are acceptable, provided that the manufacturer can justify through through “scientific data or clinical opinion or comparative studies” that the Residual Control measure or alternate test is at least as low as if the standard’s requirement of addressing that particular Risk had been applied.
  - This takes effort for the manufacturer to do, so using the escape clause is not as simple a matter as it may have been in the previous edition of 60601.

Can SGS provide any help during the Risk Analysis ?

Other than as it relates to the 60601 standards, no…

DESIGN REVIEWS & ISO 14971 (APPLICATION OF RISK MANAGEMENT)

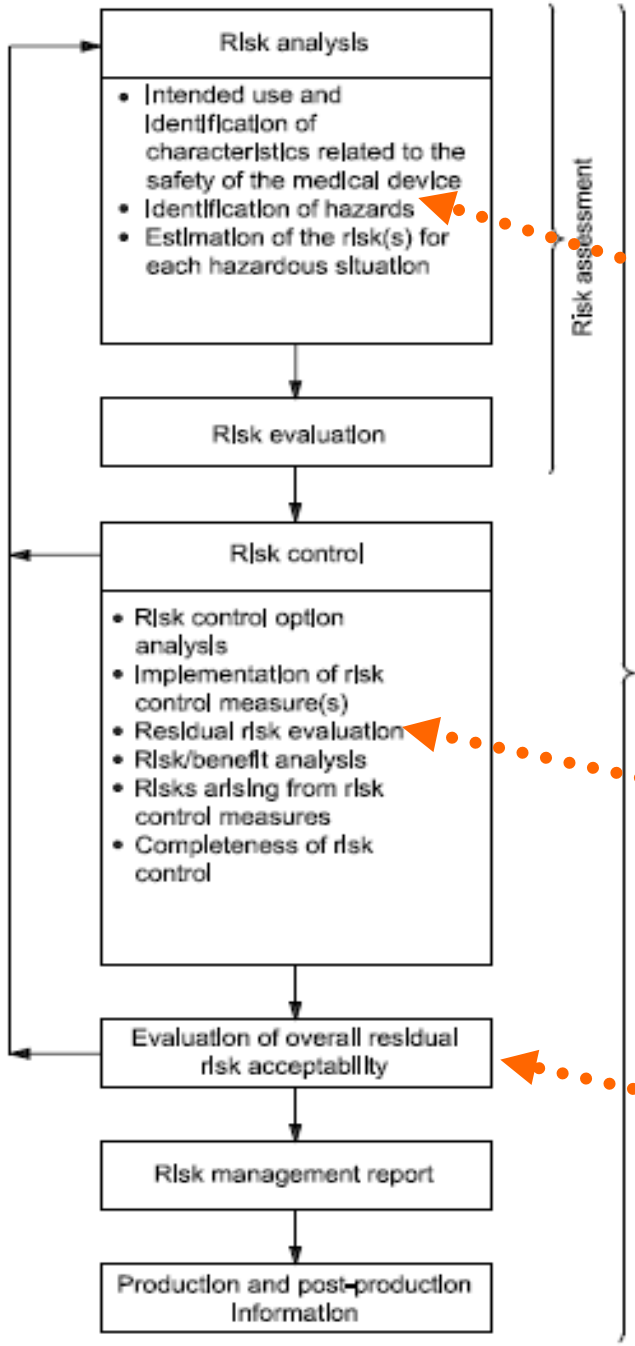


Figure 1 — A schematic representation of the risk management process

Identification of hazards (4.3 of 14971)

Test house input during design review?

Examination of old reports for similar devices?

Residual risk evaluation (6.4 of 14971)

Testing to 60601-1 & examination of results, particularly SFCs.

Additional aspects of the ISO 14971 process (clauses 7 to 9) are handled by SSC.

EXPECTATIONS – WHAT IS NEEDED TO SATISFY 60601 RM REQUIREMENTS?

- The device specific Risk Analysis.
  - Essential Performance considered.
  - Software considerations in the Risk Analysis where SW affects either Basic Safety or Essential Performance.
- The RM Process documents.
- The test houses request their customers to fill out the RM tables in the 60601 test report forms or a custom check list in order to save time (and the customer money).

TABLE FOR RM PROCESS DOCUMENTS

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT		
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
3.2		Adequate Resources	
3.2		Assignment of qualified personnel	
3.2		Policy for determining criteria for risk acceptability	
3.3		Qualification of personnel	
3.4		Risk management plan	
3.5		Risk management file	
4.1		Risk analysis process	
…			
4.4		Estimation of the risk(s) for each hazardous situation	
5		Risk evaluation	
6.1		Risk reduction	
…			
6.7		Completeness of risk control	
7		Evaluation of overall residual risk acceptability	
8		Risk management report	
Supplementary Information:			

EXPECTATIONS – WHAT DO WE NEED?

- There will be parts of the RMF that are closely examined, and parts that are not.
  - The parts that we will need right away will be the parts that relate to 60601.
  - We will eventually need to examine the rest to ensure 14971 is met.

TYPICAL RM REQUIREMENTS IN 60601

9.8.3.1	RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General		
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result - Remarks**	**Verdict**
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

11.1.2.2	RM RESULTS TABLE: Applied parts not intended to supply heat to patient		
Clause of ISO 14971	**Document Ref. in RMF (Document No. & paragraph)**	**Result – Remarks**	**Verdict**
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
Supplementary information:			

EXPECTATIONS – WHAT WE DO NOT NEED

- ISO 14971 as part of a quality systems certification.
  - Being certified to ISO 14971 is not bad, but it does not exempt the safety test lab from having to verify 14971 is being followed for the specific medical device.
- Observed problems with the RM process are uncommon.
  - Exception may be with manufacturers that certify to 60601, but don't make medical devices by the definition of the regulatory authorities.
  - Devices such as carts, gas & electrical pendants, sports medicine.

HAZARD EXAMPLES FROM 14971, ANNEX E

- While by no means complete, how do the typical examples from Annex E of 14971 fit into common RM requirements in IEC 60601-1?
  - 60601-1-x & 60601-2-x standards will add to the ISO 14971 list.
  - The manufacturer must also add & subtract hazards depending on the device.
  - Taking 60601 RM requirements into account will leaves less important design considerations to chance.

ELECTROMAGNETIC ENERGY

- Line voltage
  - *No specific RM requirements.*

- Leakage currents
  - *8.3 - Classification of APPLIED PARTS*
  - *8.4.2 - ACCESSIBLE PARTS including APPLIED PARTS*
    - **Accessible vs. patient applied parts often not given enough thought.**
  - *8.5.2 - Separation of PATIENT CONNECTIONS*
    - **Often not considered.**
- Electromagnetic fields
  - *17 - Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS*

RADIATION ENERGY

- Ionizing radiation
  - *10.1.2 - ME EQUIPMENT Intended to produce diagnostic or therapeutic X-radiation*

- Non-ionizing radiation
  - *No specific RM requirements.*

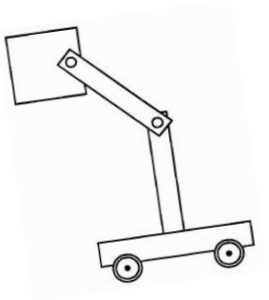
THERMAL ENERGY

- High temperature
  - *11.1 - Excessive temperatures in ME EQUIPMENT*
  - *11.2.2.1 - RISK of fire in an OXYGEN RICH ENVIRONMENT*

- Low temperature
  - *11.1.2.2 - APPLIED PARTS not intended to supply heat to a PATIENT*
    - **Risk management needs to define the use of the applied part, duration of contact, area of contact, blood perfusion, etc.**
  - *Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation*

MECHANICAL ENERGY

9 - PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS



- Gravity
  - Falling
  - Suspended masses
  - *Table 19 & 9.8 - HAZARDS associated with support systems*
    - **Overload factors often not considered.**

- Vibration
  - *Table 19 & 9.6 - Acoustic energy (including infra- and ultrasound) and vibration*
    - **Cycle time often not considered.**
- Stored energy
  - *9.7 - Pressure vessels and parts subject to pneumatic and hydraulic pressure*

MECHANICAL ENERGY

9 - PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS

- Moving parts
  - *Table 19 & 9.2 - HAZARDS associated with moving parts*
    - **Body part access and their dimensions often not considered.**
- Torsion, shear and tensile force
  - *Table 19*
  - *9.2 - HAZARDS associated with moving parts*
  - *9.8 - HAZARDS associated with support systems*
- Moving and positioning of patient
  - *9.2 - HAZARDS associated with moving parts*
  - *9.4 - Instability HAZARDS*

MECHANICAL ENERGY

9 - PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS

- Acoustic energy
  - ultrasonic energy
  - infrasound energy
  - sound
  - *Table 19 & 9.6.2.2 - Infrasound and ultrasound energy*

- High pressure fluid injection
  - *Table 19 & 9.7 - Pressure vessels and parts subject to pneumatic and hydraulic pressure*

BIOLOGICAL

- Bacteria
- Viruses
- Other agents (e.g. prions)

- Re- or cross-infection
  - *15.3.7 - Environmental influences*
  - *11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS*
    - *The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the affects of multiple cleanings.*
  - *11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS*

CHEMICAL

- Exposure of airway, tissues, environment or property, e.g. to foreign materials:
  - acids or alkalis
  - Residues
  - Contaminates
  - additives or processing aids
  - cleaning, disinfecting or testing agents
  - degradation products
  - medical gasses
  - anesthetic products
    - *11.6.8 - Compatibility with substances used with the ME EQUIPMENT*

BIOCOMPATIBILITY

- Constituents, e.g.:
  - allergenicity/irritancy
  - Pyrogenicity
    - *11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS*

SGS Life Sciences group provides services in this area.
SGS does not conduct animal studies.

FUNCTION

- Incorrect or inappropriate
- output or functionality
- Incorrect measurement
- Erroneous data transfer
- Loss or deterioration of function
  - *12.4.4 - Incorrect output*
  - *14 - PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)*
    - **Clause 14 evaluation required if software affects the Basic Safety or Essential Performance of the equipment.**

USE ERROR

- Attentional failure
- Memory failure
- Rule-based failure
- Knowledge-based failure
- Routine violation
  - Usability standard, IEC 60601-1-6

LABELLING

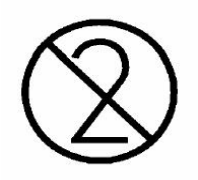
- Incomplete instructions for use
- Inadequate description of performance charact
- Inadequate specification of intended use
- Inadequate disclosure of limitations
  - *7.9.2.2 - Warning and safety notices*
  - *7.9.2.4 - Electrical power source*
  - *7.9.2.5 - ME EQUIPMENT description*
  - *7.9.2.15 - Environmental protection*
  - *7.9.3.2 - Replacement of fuses, POWER SUPPLY CORDS and other parts*

OPERATING INSTRUCTIONS

- Inadequate specification of accessories to be used with the medical device
- Inadequate specification of pre-use checks
- Over-complicated operating instructions
  - 7.1.1, 12.2, & 16.2 - USABILITY of the identification, marking and documents
  - Usability standard, IEC 60601-1-6

WARNINGS

- Of side effects



- Of hazards likely with re-use of single-use medical devices

SPECIFICATION OF SERVICE AND MAINTENANCE

- 4.4 - EXPECTED SERVICE LIFE
- 11.2.2.1 - RISK of fire in an OXYGEN RICH ENVIRONMENT
- 15.2 - Serviceability

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WHEN YOU NEED TO BE SURE

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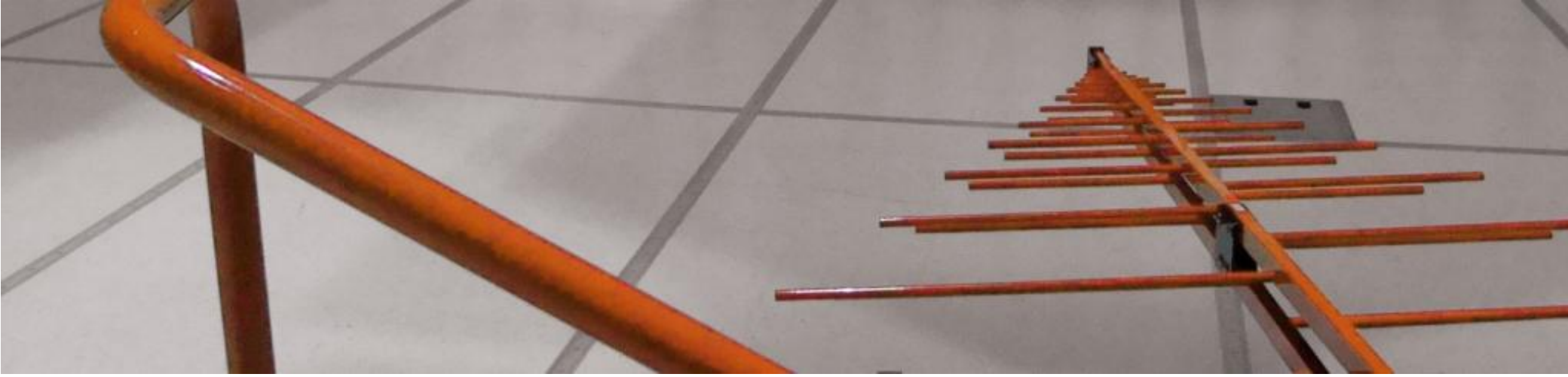

EN 55032

THE REPLACEMENT OF EN 55022 AND EN 55013

Consumer and Retail

David Schram, Director, EMC

WHEN YOU NEED TO BE SURE

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AGENDA

- Quick review of EN 55022
- Quick review of EN 5013
- Overview of EN 55032

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 55022

December 2010

ICS 33.100.10

Supersedes EN 55022:2006 + A1:2007 + A2:2010

English version

Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement

(CISPR 22:2008, modified)

Appareils de traitement de l'information - Caractéristiques des perturbations radioélectriques - Limites et méthodes de mesure (CISPR 22:2008, modifiée)

Einrichtungen der Informationstechnik - Funkstöreigenschaften - Grenzwerte und Messverfahren (CISPR 22:2008, modifiziert)

EN 55022:2010/AC:2011

- As the title suggests, EN 55022 applies to Information Technology Equipment (ITE), which is any equipment:
  - a) which has a primary function of either (or a combination of) entry, storage, display, retrieval, transmission, processing, switching, or control, of data and of telecommunication messages and which may be equipped with one or more terminal ports typically operated for information transfer;
  - b) with a rated supply voltage not exceeding 600 V.
  - It includes, for example, data processing equipment, office machines, electronic business equipment and telecommunication equipment.

EN 55022:2010/AC:2011

- ITE is subdivided into two categories denoted class A ITE and class B ITE.
  - Class B ITE is a category of apparatus which satisfies the class B ITE disturbance limits.
  - Class B ITE is intended primarily for use in the domestic environment and may include:
    - equipment with no fixed place of use; for example, portable equipment powered by built-in batteries;
    - telecommunication terminal equipment powered by a telecommunication network;
    - personal computers and auxiliary connected equipment.

EN 55022:2010/AC:2011

- Class A ITE is a category of all other ITE which satisfies the class A ITE limits but not the class B ITE limits.
- Such equipment should not be restricted in its sale but the following warning shall be included in the instructions for use:

Warning

This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

EN 55022:2010/AC:2011

- Tests within
  - Conducted Emissions on mains
  - Conducted Emissions on telecom ports
  - Radiated Emissions, 30-1000 MHz
  - Radiated Emissions, 1000-6000 MHz

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 55013

June 2013

ICS 33.100.10

Supersedes EN 55013:2001 + A1:2003 + A2:2006, EN 55013:2001/IS1:2009

English version

Sound and television broadcast receivers and associated equipment - Radio disturbance characteristics - Limits and methods of measurement

(CISPR 13:2009, modified)

Récepteurs de radiodiffusion et de télévision et équipements associés - Caractéristiques des perturbations radioélectriques - Limites et méthodes de mesure (CISPR 13:2009, modifiée)

Ton- und Fernseh-Rundfunkempfänger und verwandte Geräte der Unterhaltungselektronik - Funkstöreigenschaften - Grenzwerte und Messverfahren (CISPR 13:2009, modifiziert)

EN 55013:2013

- EN 55013 applies to the generation of electromagnetic energy from
  - Sound and television receivers
    - Appliances intended for the reception of sound broadcast and similar services for terrestrial, cable and satellite transmission, digital and analog
  - Similar transmissions
  - Associated equipment
    - Equipment intended to be connected directly to sound or television broadcast receivers or generate or reproduce audio or visual information
  - Excludes ITE, but telecommunications ports must be tested according to EN 55022

EN 55013:2013

- Not categorized into classes like 55022. The limits are comparable to Class B
- Tests include:
  - Disturbance voltage at mains terminals (aka conducted emissions)
  - Disturbance voltage at the antenna terminals
  - Disturbance voltage at the RF output
  - Disturbance power
  - Radiated disturbance (aka radiated emissions)
  - Radiated power (for home satellite receivers)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 55032

May 2012

ICS 33.100.10

English version

Electromagnetic compatibility of multimedia equipment - Emission requirements
(CISPR 32:2012)

Compatibilité électromagnétique des équipements multimédia - Exigences d'émission (CISPR 32:2012)

Elektromagnetische Verträglichkeit von Multimediageräten und -einrichtungen - Anforderungen an die Störaussendung (CISPR 32:2012)

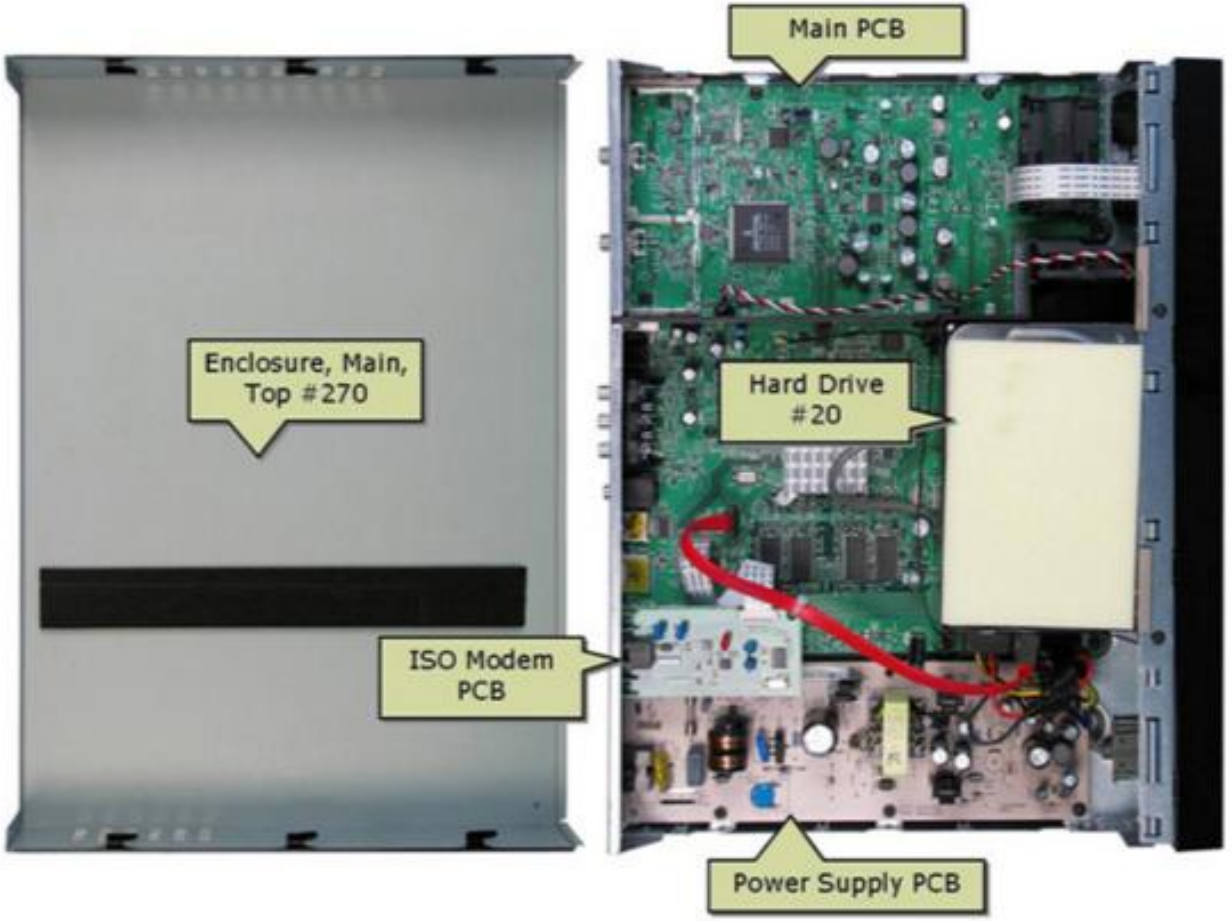
55032:2012/AC:2013

- Why do we need a new standard?
  - Audio and ITE equipment have different uses
  - Historically different designs
  - But designs have converged to the point where it is difficult to discern the difference
    - ITE equipment routinely incorporates Audio / Video ports
    - A/V equipment routinely use digital techniques in design
  - Now we have an EMC standard for multimedia equipment which covers both

STEREO RECEIVER

STEREO RECEIVER

SET TOP BOX


Main PCB
Enclosure, Main, Top #270
Hard Drive #20
ISO Modem PCB
Power Supply PCB

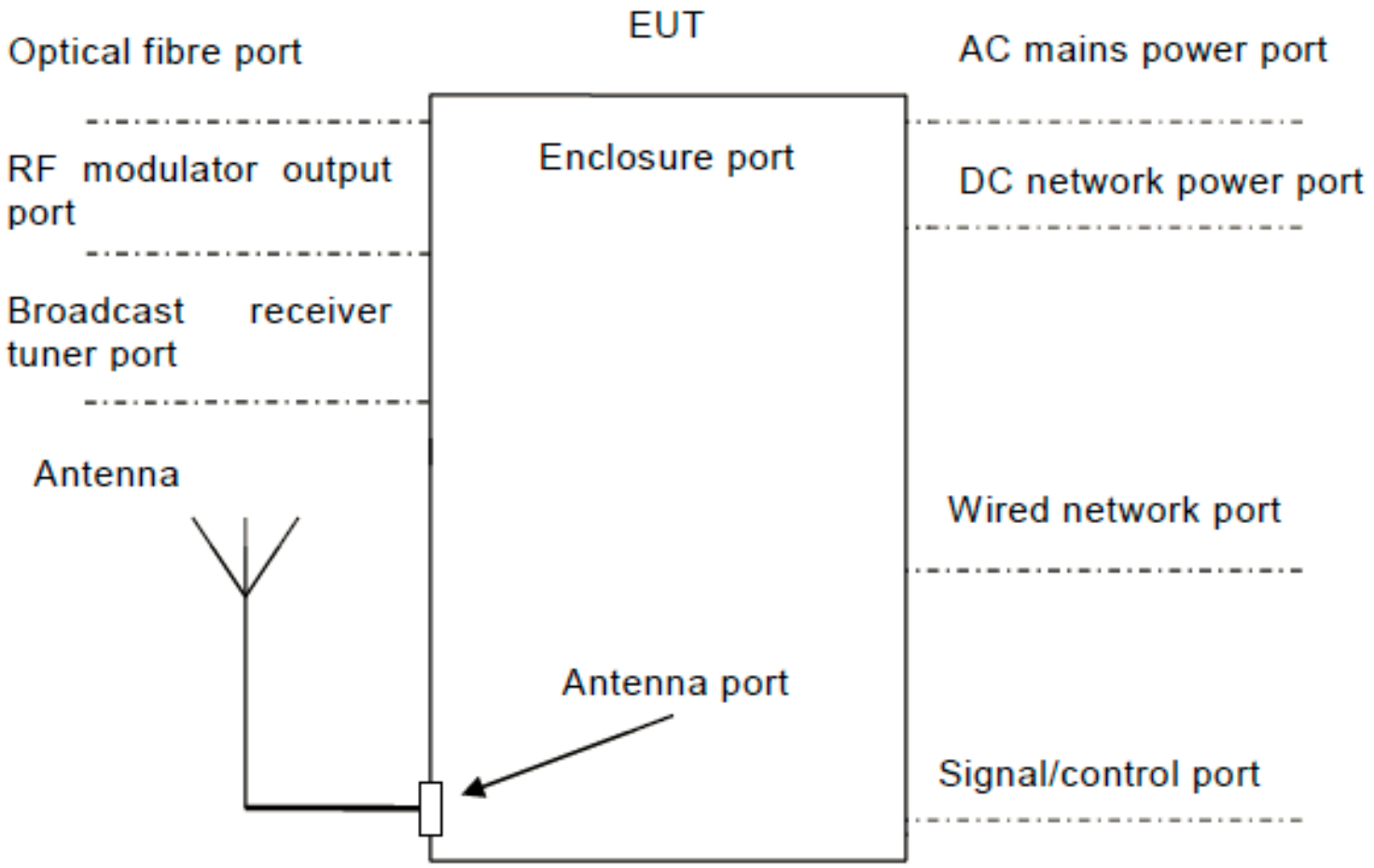
PC MOTHERBOARD

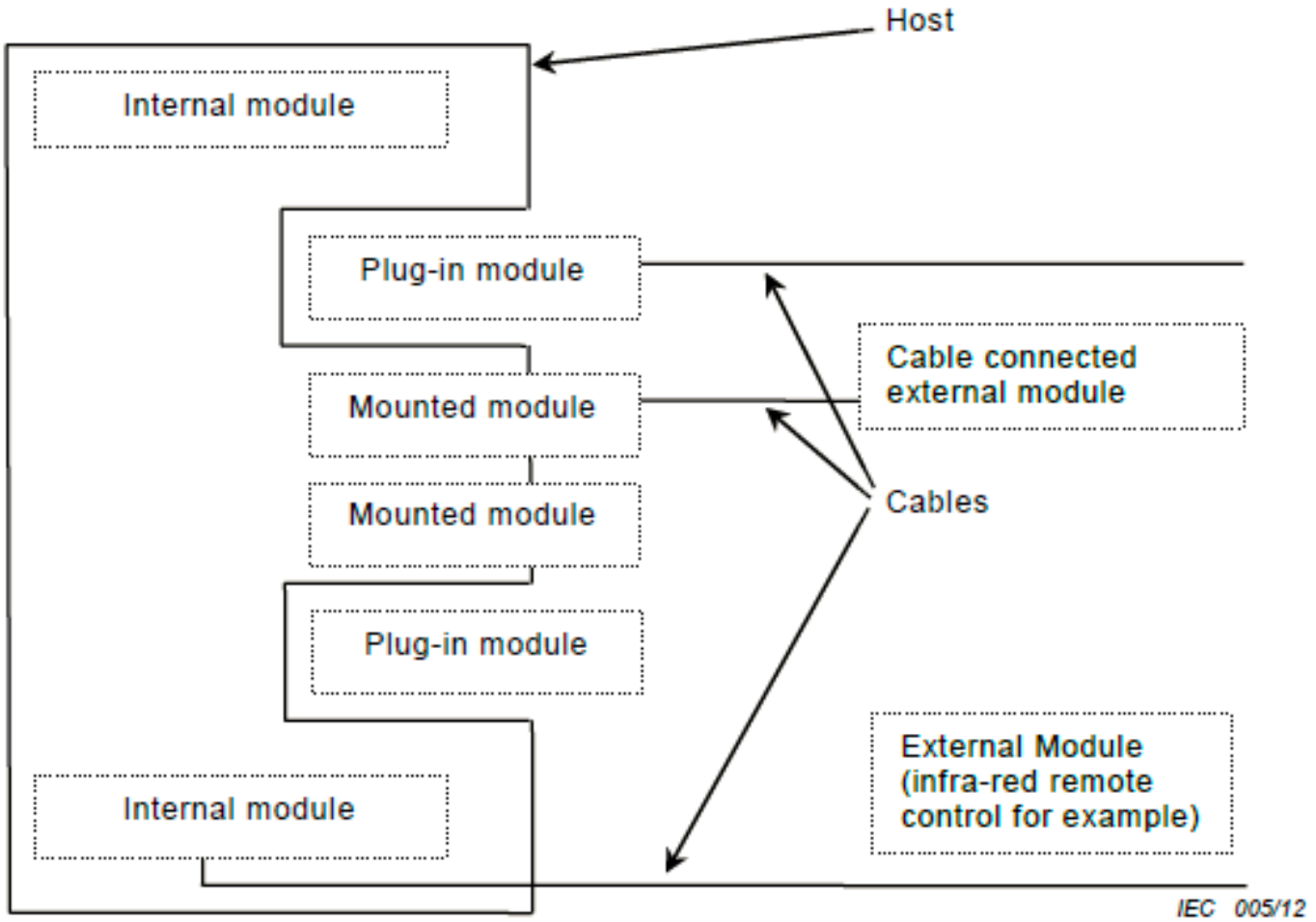
55032:2012/AC:2013

- Equipment within the scope of CISPR 13 or CISPR 22 is within the scope of this publication.
- MME intended primarily for professional use is within the scope of this publication.
- This standard defines Class A equipment and Class B equipment associated with two types of end-use environment.

Warning: This equipment is compliant with Class A of CISPR 32. In a residential environment this equipment may cause radio interference.

EN 55032:2012/AC:2013

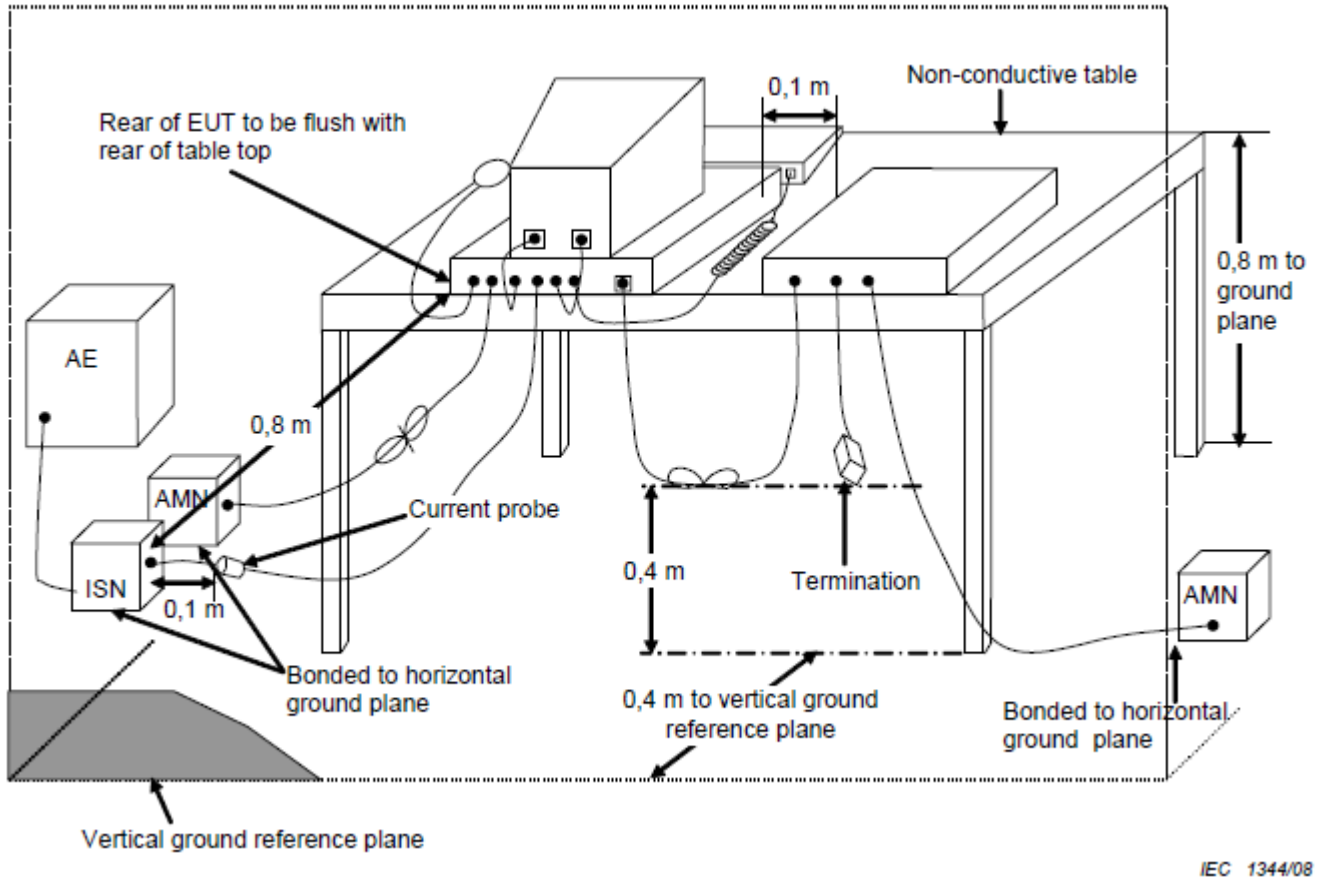



Host
Internal module
Plug-in module
Mounted module
Mounted module
Plug-in module
Internal module
Cable connected external module
Cables
External Module (infra-red remote control for example)
IEC 005/12

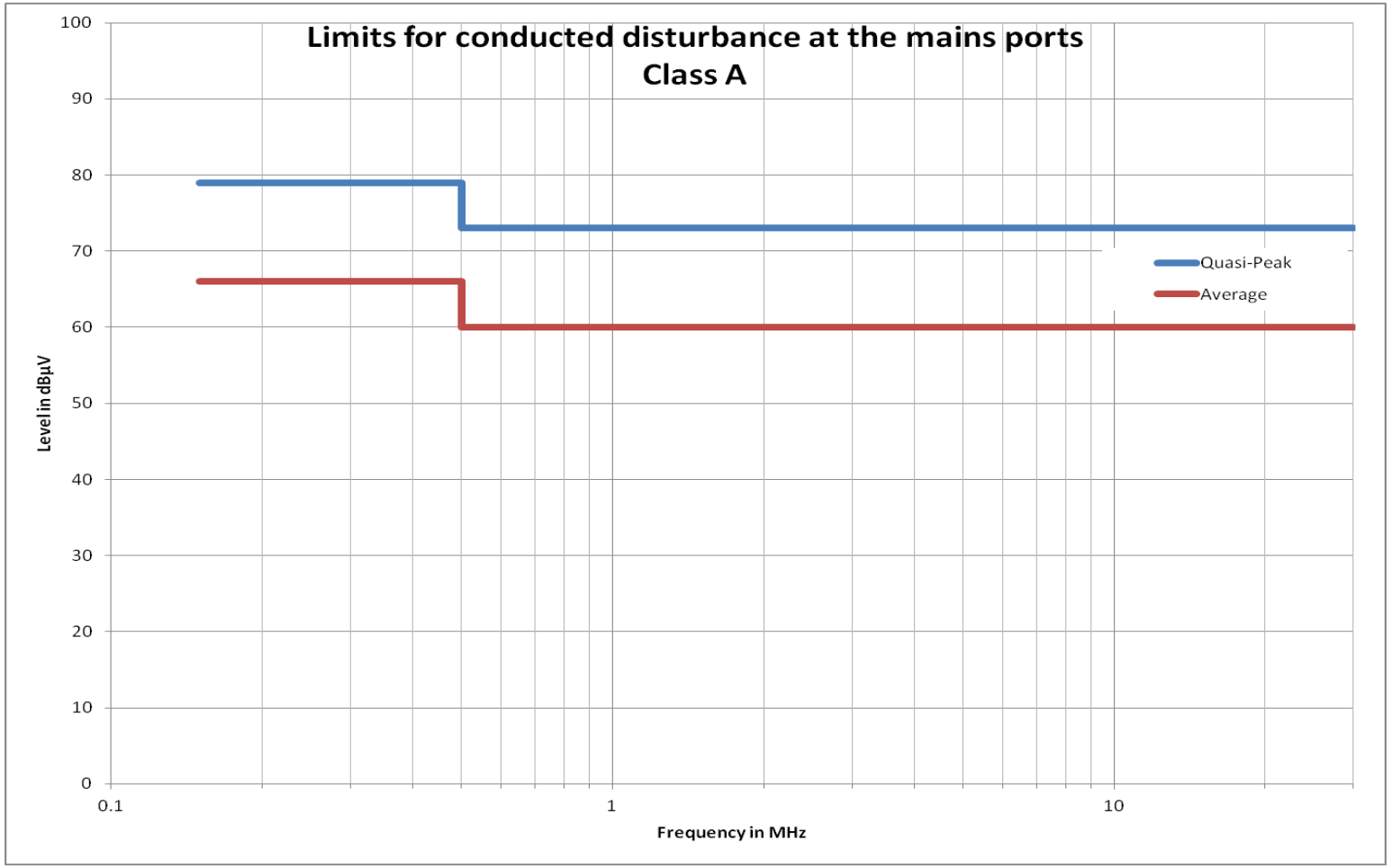
EN 55032:2012/AC:2013

- Conducted Emissions

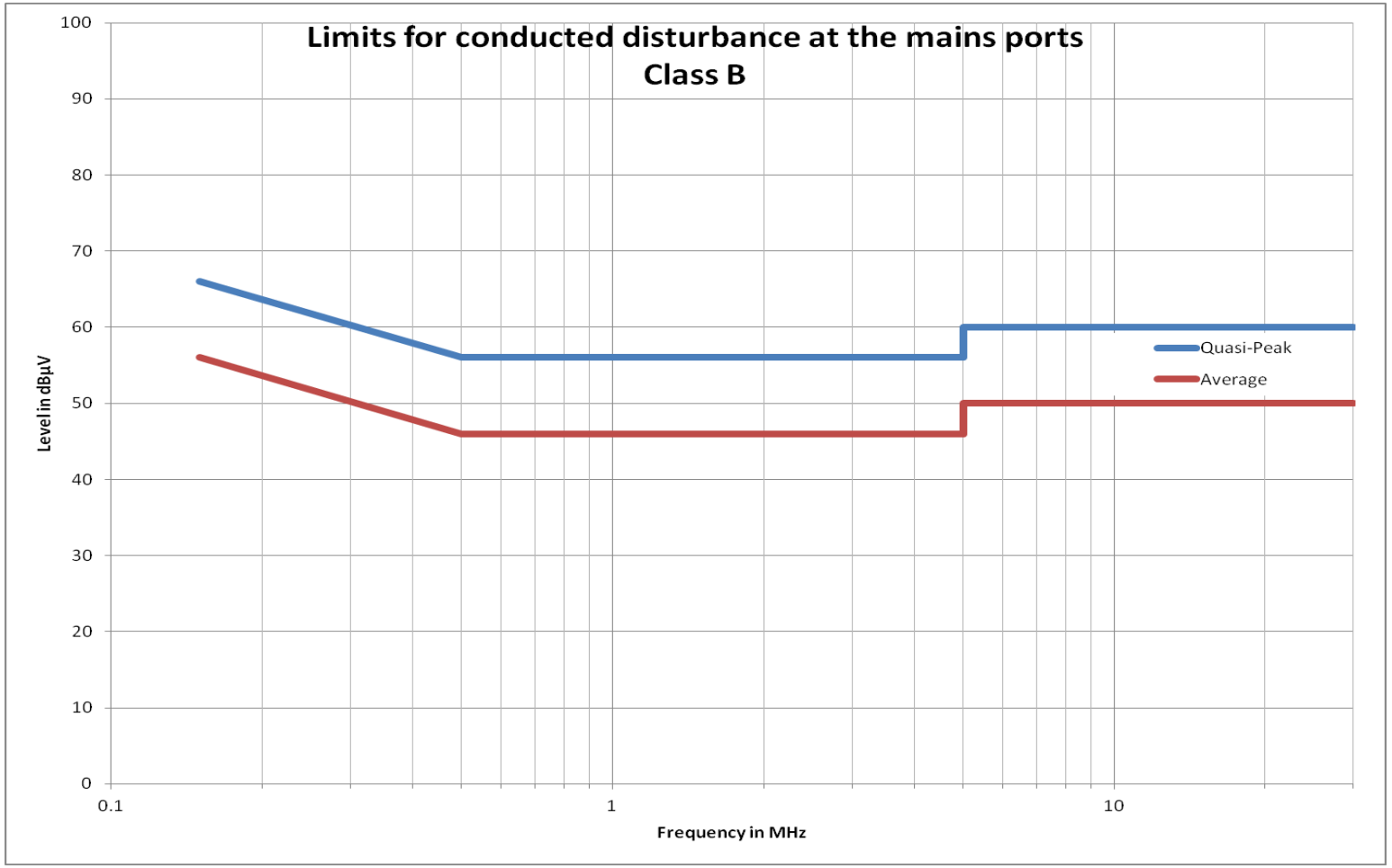
EN 55032:2012/AC:2013



EN 55032:2012/AC:2013



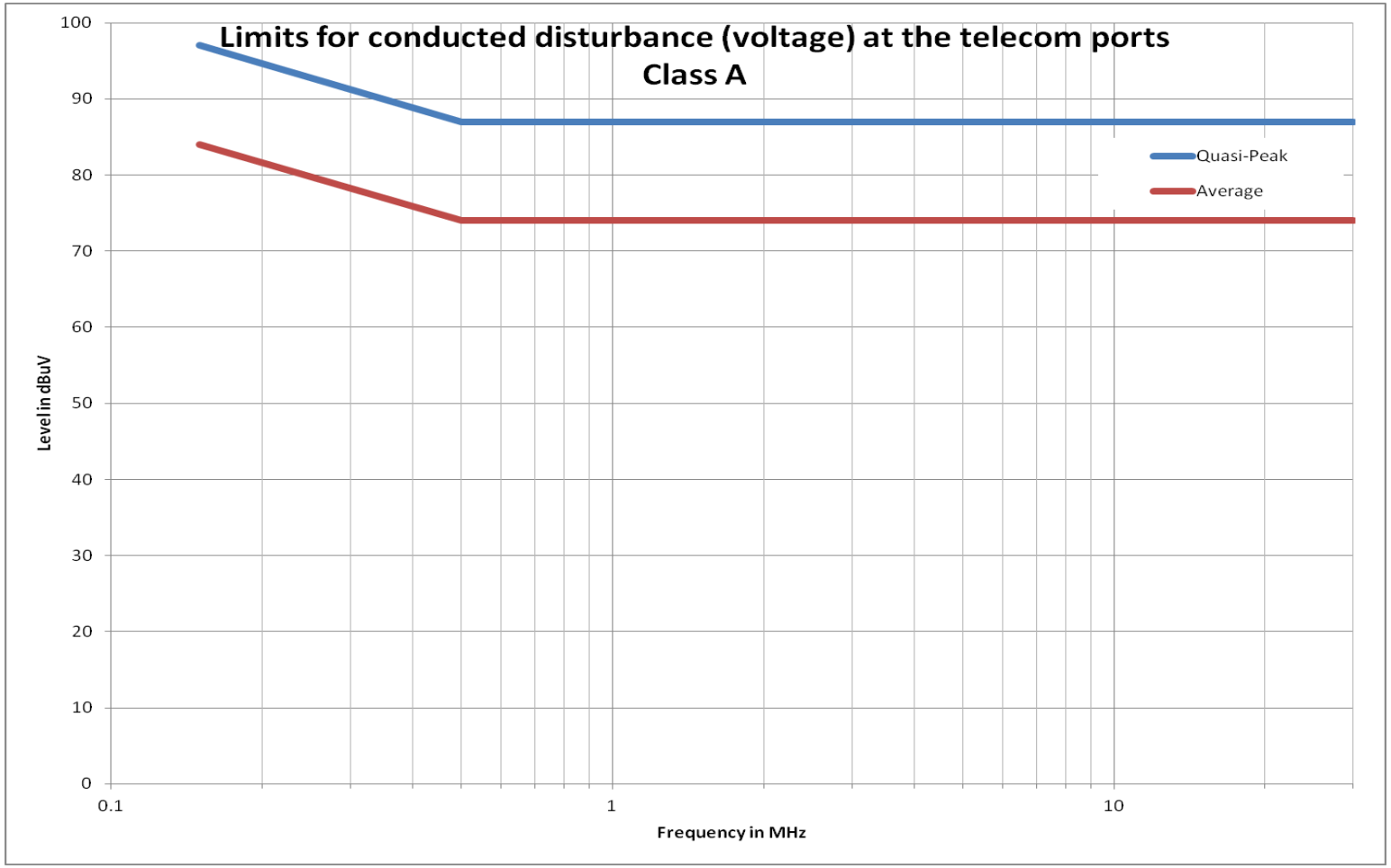
EN 55032:2012/AC:2013



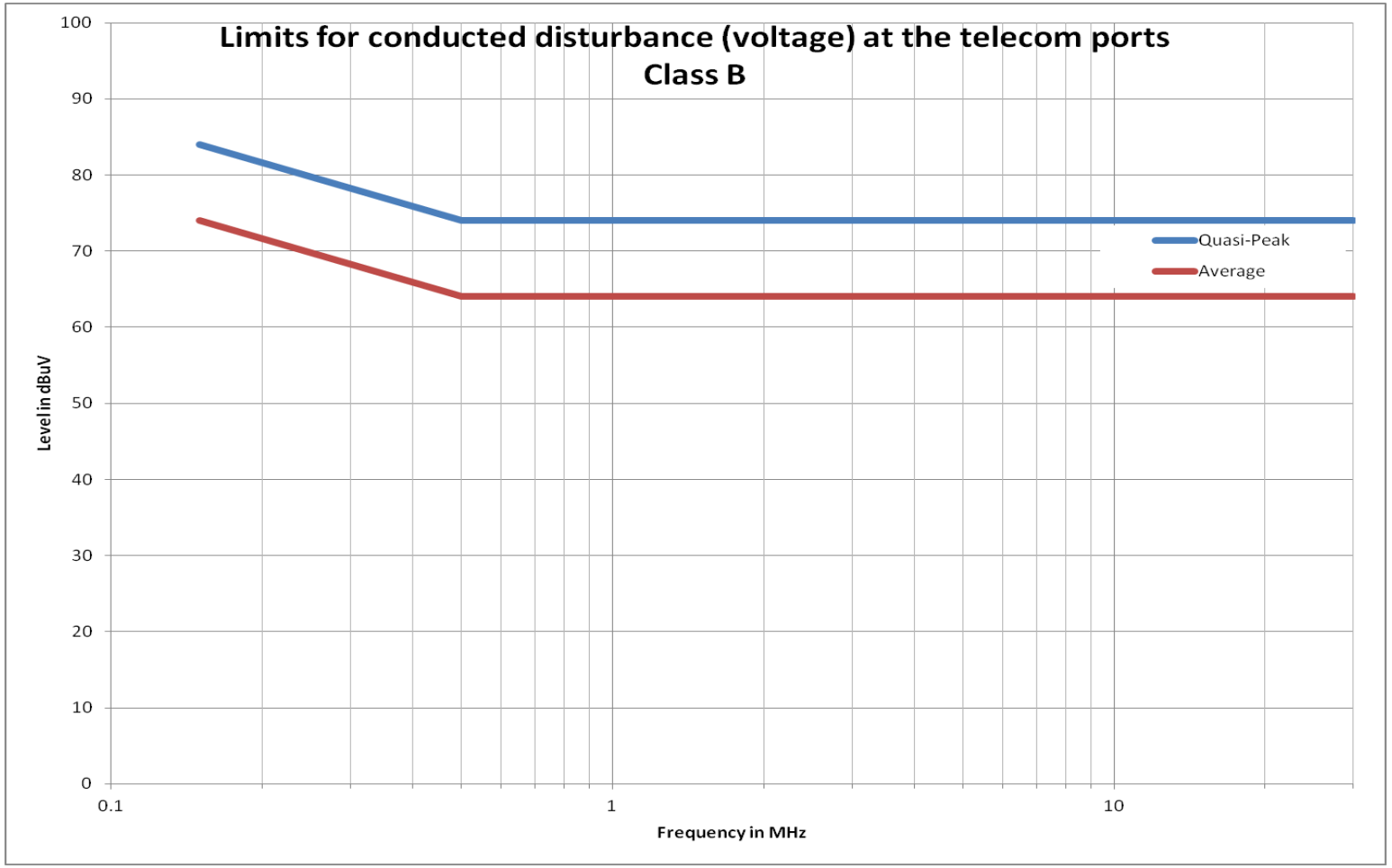
EN 55032:2012/AC:2013

- Asymmetric mode conducted emissions
  - Formerly telecom port conducted emissions
- Applicable to
  - Wired network ports
  - Optical fiber ports with metallic shield or tensions members
  - Antenna ports

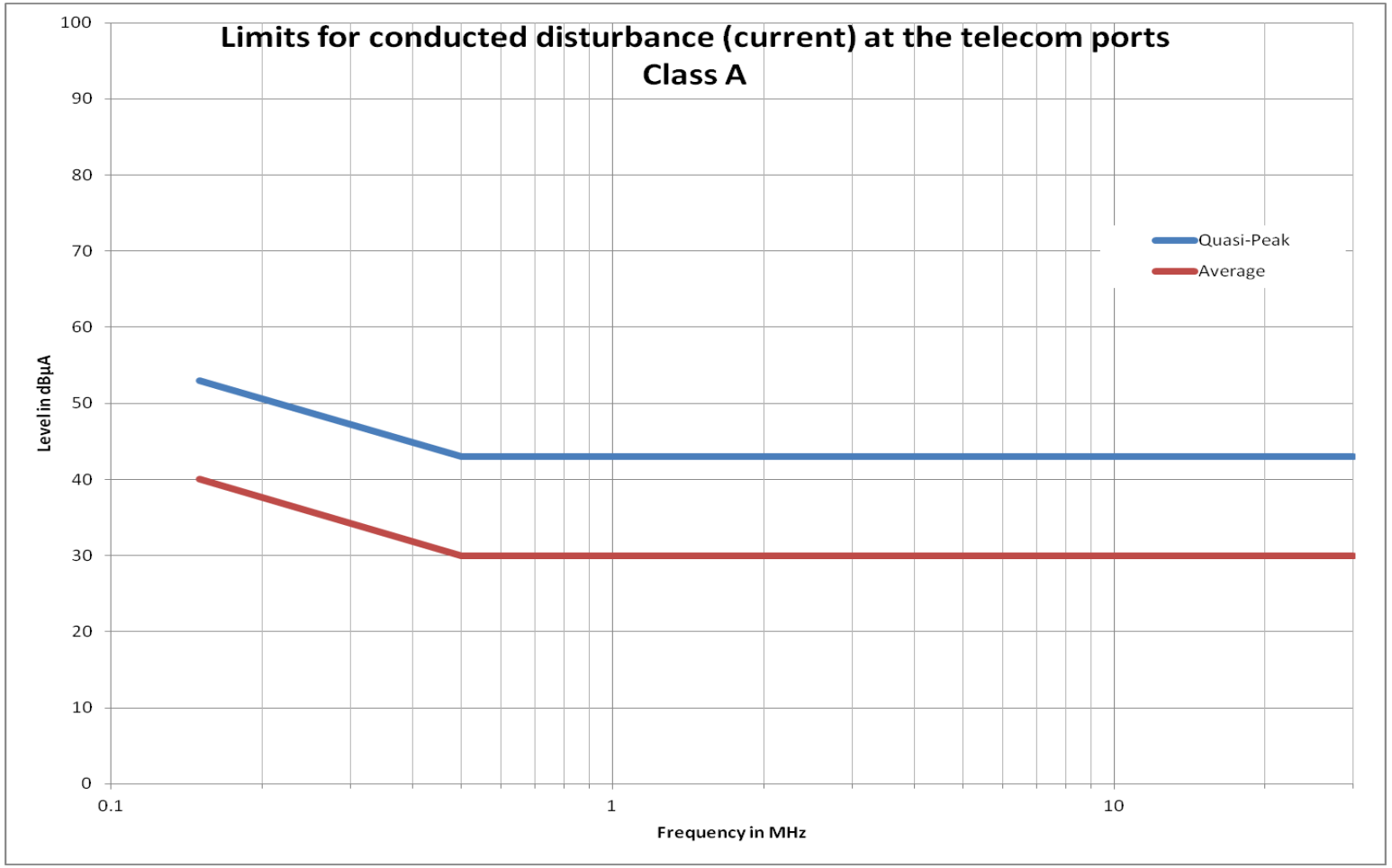
EN 55032:2012/AC:2013



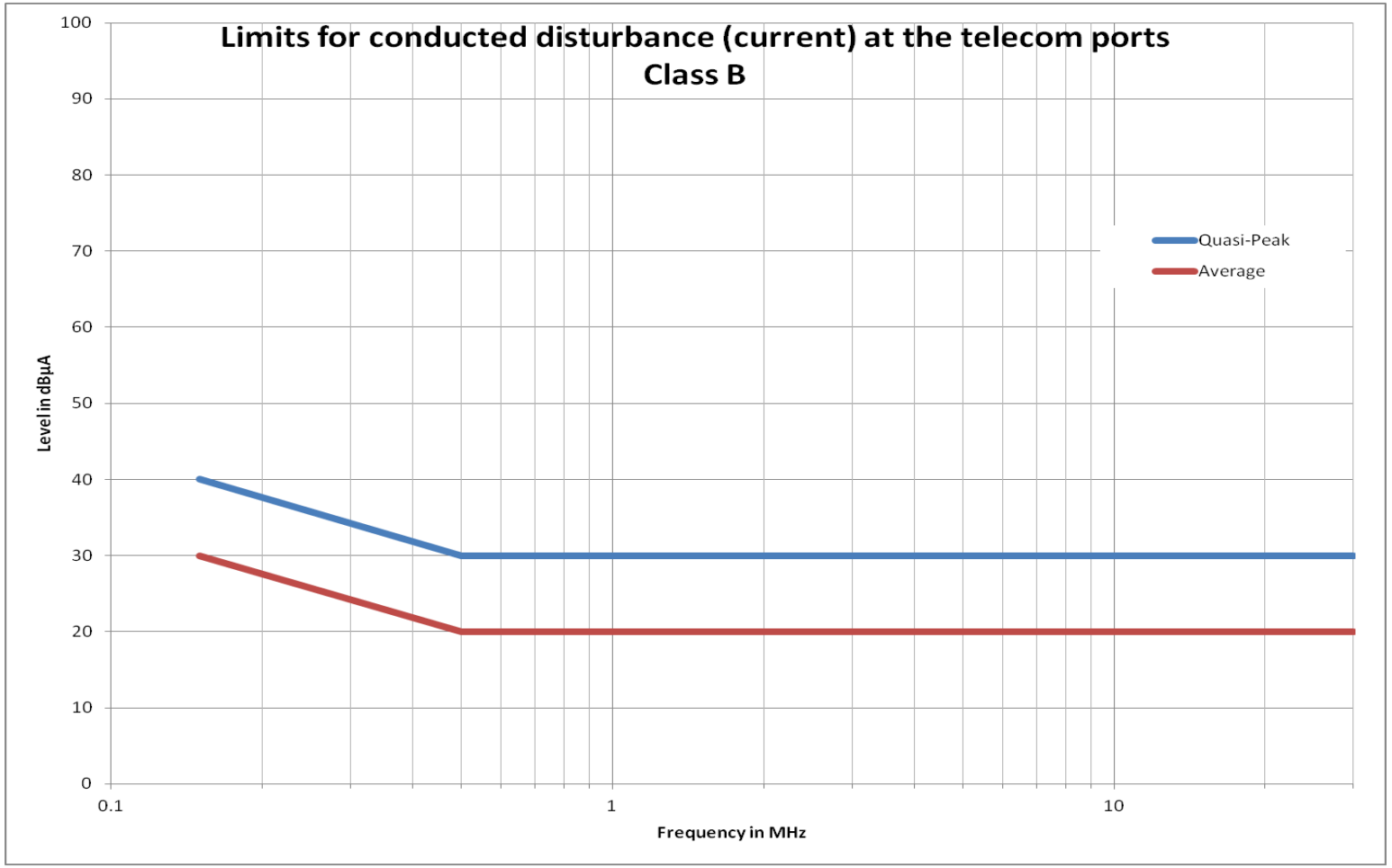
EN 55032:2012/AC:2013



EN 55032:2012/AC:2013



EN 55032:2012/AC:2013



EN 55032:2012/AC:2013

- Conducted differential voltage emissions
- Applicable to
  - TV broadcast receiver tuner ports with an accessible connector
  - RF modulator output ports
  - FM broadcast receiver tuner ports with an accessible connector

EN 55032:2012/AC:2013

Table clause	Frequency range MHz	Detector type/ bandwidth	Class B limits dB(μV) 75 Ω			Applicability
			Other	Local Oscillator Fundamental	Local Oscillator Harmonics	
A12.1	30 – 950	For frequencies ≤1 GHz Quasi Peak/ 120 kHz	46	46	46	See a)
	950 – 2 150		46	54	54	
A12.2	950 – 2 150		46	54	54	See b)
A12.3	30 – 300		46	54	50	See c)
	300 – 1 000				52	
A12.4	30 – 300	For frequencies ≥1 GHz Peak/ 1 MHz	46	66	59	See d)
	300 – 1 000				52	
A12.5	30 – 950		46	76	46	See e)
	950 – 2 150			n/a	54	

a) Television receivers (analogue or digital), video recorders and PC TV broadcast receiver tuner cards working in channels between 30 MHz and 1 GHz, and digital audio receivers.

b) Tuner units (not the LNB) for satellite signal reception.

c) Frequency modulation audio receivers and PC tuner cards.

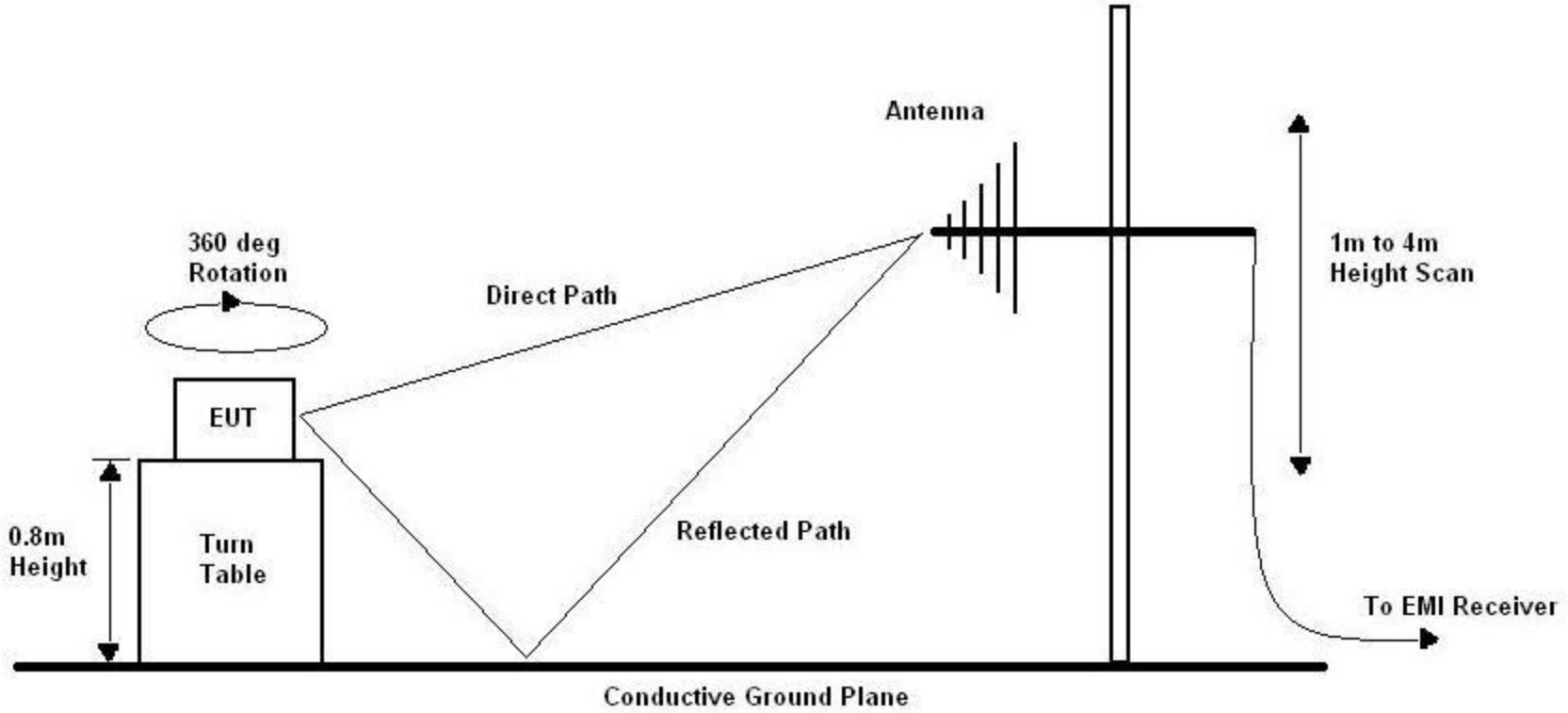
d) Frequency modulation car radios.

e) Applicable to EUTs with RF modulator output ports (for example DVD equipment, video recorders, camcorders and decoders etc.) designed to connect to TV broadcast receiver tuner ports.

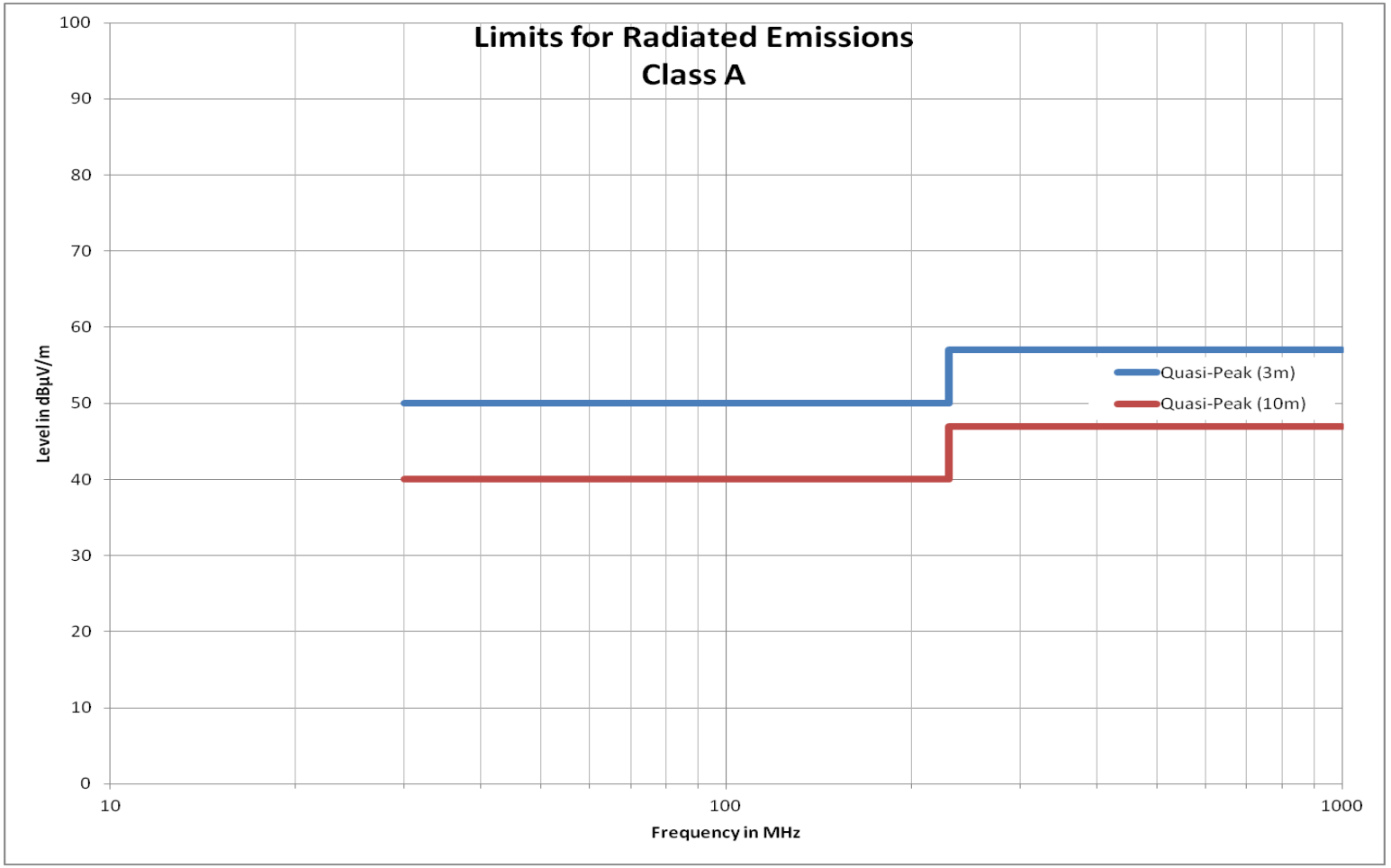
EN 55032:2012/AC:2013

- Radiated Emissions

EN 55032:2012/AC:2013



EN 55032:2012/AC:2013



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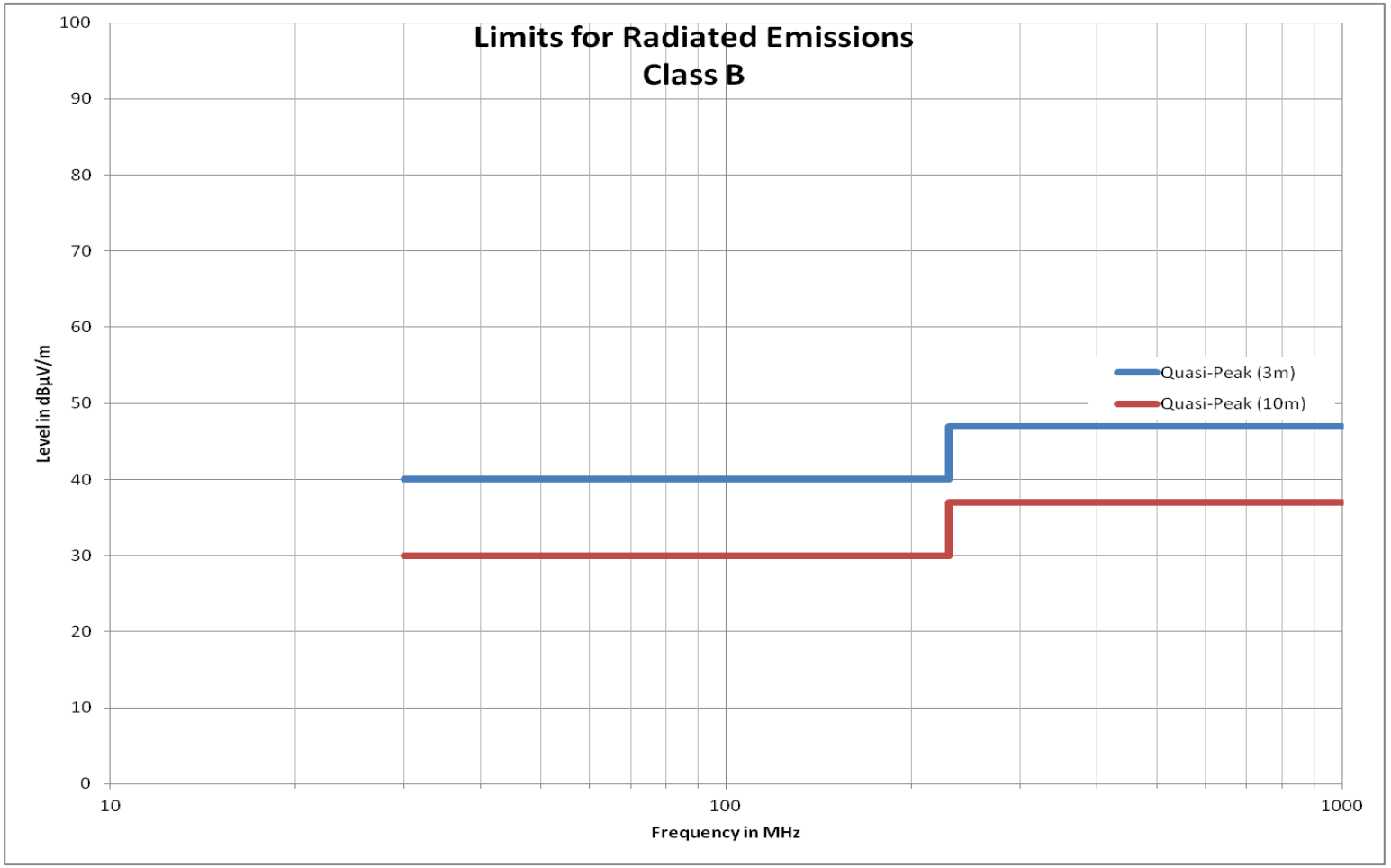
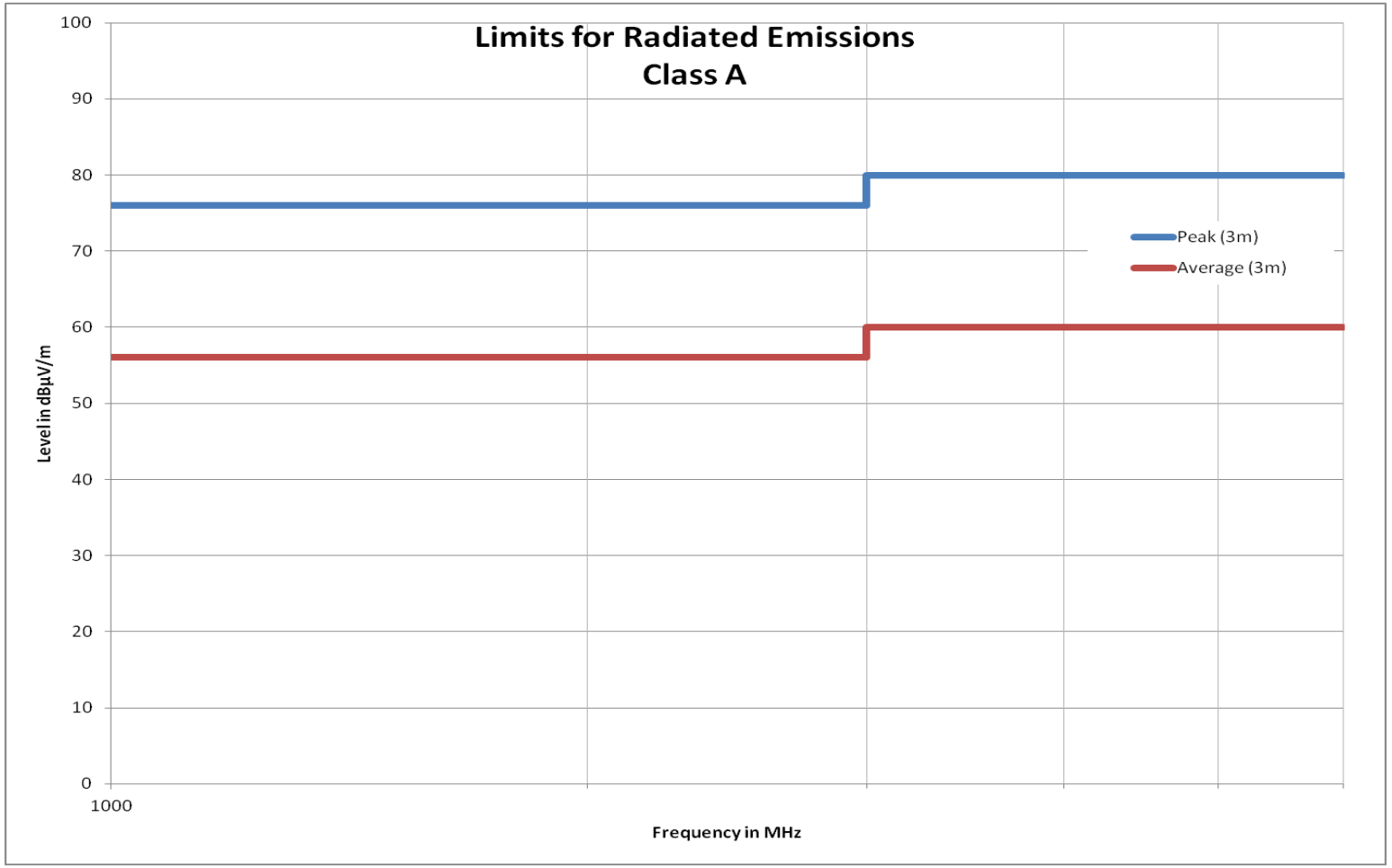
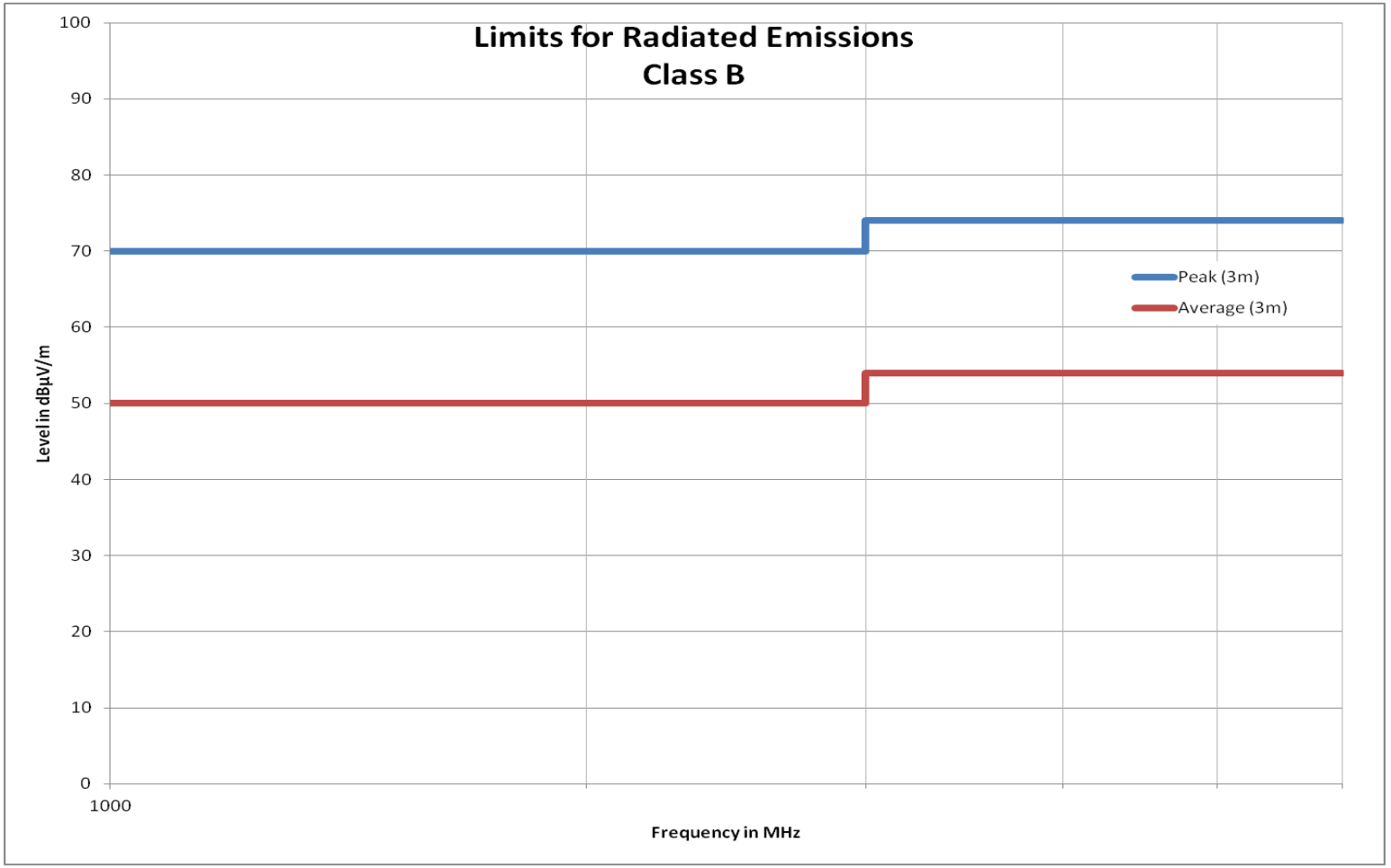


EN 55032:2012/AC:2013



EN 55032:2012/AC:2013



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WHEN YOU NEED TO BE SURE

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RESTRICTED AND DECLARABLE SUBSTANCES

Consumer and Retail

Kenneth Stanvick, Director, Restricted Subtances Testing Services

WHEN YOU NEED TO BE SURE

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AGENDA

- EU RoHS Update
- EU REACH Update
- Questions?

DIRECTIVE 2011/65/EU (ROHS2)

- Addition of 4 new substances – DEHP-BBP-DBP-DIBP (all currently listed as SVHCs in REACH)
  - April 1 2016 ECHA filed Restriction proposal Annex XV for the 4 substances
- Maximum Concentration Value shall not exceed 0.1% weight per homogeneous material for these 4 new substances

DIRECTIVE 2011/65/EU (ROHS2)

- Addition of 4 new substances – DEHP-BBP-DBP-DIBP (all currently listed as SVHCs in REACH)
  - Effective 7/22/2019 for categories 1 thru 7, 10 and 11
  - Effective 7/22/2021 for categories 8 and 9
  - Many companies are asking their suppliers to declare the presence of these substances today

DIRECTIVE 2011/65/EU (ROHS2)

- Exemption review activity
  - Categories 1 thru 7, and10
  - RoHS 2 requires that exemptions listed in Annex III listed as of 7/21/2011 shall be reviewed by 7/21/16
  - Categories 8 and 9 exemptions shall be reviewed by 7/21/2018 unless a shorter period is specified

DIRECTIVE 2011/65/EU (ROHS2)
EXEMPTIONS UNDER REVIEW

Pack	Exemptions being reviewed	Request	Stakeholder Consultation Period	Final Report Expected
7	Lead - Cadmium	Renewals -Edit	4/24/2015 to 6/19/2015	September 2015
8	Lead	New	3/13/2015 to 12/12/2015	Mid December 2015
9	Multiple Substances (29)	Renewals	6/10/2015 to 3/09/2016	March 2016
10	Cadmium	Re-Evaluation	8/25/15 to 4/24/2016	April 2016
11	Pb	New	12/19/2015	September 2016

http://rohs.exemptions.oeko.info/index.php?id=163

ROHS ENFORCEMENT ACTIVITY EXAMPLE

- UK National Measurement Office
  - Higher Priced Toys Purchasing Project
    - 40% failure rate for RoHS and or Battery Directive
    - See article – April 15 2015 SGS Safeguards
    - Higher Priced Toys 2014 RoHS Report https://www.gov.uk/government/uploads/system/uploads/atta...)

ROHS2 UNINTENDED CONSEQUENCES

- Article 2(2)
  - Without prejudice to Article 4(3) and 4(4), Member States shall provide that EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with this Directive, may nevertheless continue to be made available on the market until 22 July 2019.

ROHS2 UNINTENDED CONSEQUENCES

- Secondary market problem
  - non-compliant products that have been placed on the market between January 2013 and July 2019, have to be put off the market and cannot be resold or refurbished after 22 July 2019 (no secondary market operations would be possible)
- Spare parts
  - Products legally placed on the market cannot be repaired with non compliant parts, no repair as manufactured, after 22 July 2019

ROHS2 UNINTENDED CONSEQUENCES

- Solutions under review
  - **Simplifying the existing RoHS directive**
    1. a comprehensive scope exclusion for pipe organs to be listed among the exclusions in Article 2(4),
    2. the transformation of the Article 2(2) transitional period until 22 July 2019 for products newly in scope into a proper compliance requirement in Article 4(3) by the same date;

ROHS2 UNINTENDED CONSEQUENCES

- Solutions under review
  - **Simplifying the existing RoHS directive**
    3. a new spare part provision for all products newly in scope other than those already covered in current Article (4), in order to allow the repair of products (placed on the Union market before the RoHS 2 requirements applied to its product category) with compatible spare parts.

ROHS2 UNINTENDED CONSEQUENCES

- Solutions under review
  - **Alternative policy approaches**
    4. an amendment of Article 2(2) to exclude only Category 8 and Category 9.
    5. The incorporation of Article 2(2) into Article 4(3) with the 21.7.2017 as compliance date, allowing secondary market operations for non-conforming products newly placed on the market before 22 July 2017
       - Foreseen Adoption Q2 2016

EU REACH

- EU REACH
  - Registration Evaluation Authorization of Chemicals
  - Substances of Very High Concern list contains 168 substances today
  - SVHC list added to every 6 months
  - Must be disclosed if greater than 0.1% of the weight of the “article” they are part of

- EU REACH
  - Substances move from SVHC list to Authorization list - 64 entry numbers today
    - Each entry may represent a substance, a mixture or a group of substances
  - Substances move from Authorization list to no use allowed – banned status
  - REACH has an “open scope” versus RoHS 10 categories today – 11th added 7/22/2019

EU REACH

- Disagreement in regards to definition of an “article”
- Background
  - ECHA guidance document published April 20 2011**7(2) ‘Notification of SVHCs in Articles’**
  - Notification by producer or importer required if an SVHC is:
    - > 0.1% in article and
    - Total quantity of SVHC is > 1 tonne per producer or importer per year
- Applies to entre product

EU REACH

- Background
  - REACH Article 3(3), an article is defined as an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

EU REACH

- Background
- Article 33 '**Duty to communicate information on substances**
  - supplier of an article containing an SVHC on the Candidate List in a concentration of more than 0.1% shall provide the recipient of the article with sufficient information, available to the supplier, to allow the safe use of the article, including, as a minimum, the name of the SVHC

EU REACH

- Background
- July 2013 dissenting EU/EEA members publish Guidance for Suppliers of Articles document reaffirming their view that
  - Once an “article” always an “article

- http://www.kemi.se/en/global/broschyrer/guidance-for-suppliers-of-articles.pdf

EU REACH

- Court of Justice of the European Union Ruling
  - September 10 2015 supported the view of the 7 EU/EEA dissenting Members
  - “Once an article always an article” definition clarified
  - Complex articles, example finished products, contain many simple articles, example components, enclosures, fasteners
  - http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-09/cp150100en.pdf

EU REACH “ARTICLE” EXAMPLE

Example	Item	Description	Trigger Limit
Coated Cable		The cable is for professional use and consists of a core of copper wire with a PV C coating. The copper wire is an article before production of the cable, while the PV C is a liquid mixture	The PVC coating contains BBP but the coating was a mixture before production of the cable. The first article that contains BBP is the cable. . Thus, in this case the 0.1% limit should be applied to the whole cable.

EU REACH “ARTICLE” EXAMPLE

Example	Item	Description	Trigger Limit
Printed t- shirt		The t-shirt has a print. The raw material for the print is delivered to the production site as liquid paint in different colors.	The paint was a mixture and not an article before production of the T-shirt. The first article that contains DEHP is the T-shirt. Thus, in this case the 0.1% limit with respect to the DEHP content has to be applied to the T-shirt with the print.

EU REACH “ARTICLE” EXAMPLE

Example	Item	Description	Trigger Limit
Hole mounted capacitor		Hole mounted capacitor. It is covered by a plastic layer made from a polymer mixture with additives and is later on soldered or glued to a PCB	The covering plastic layer has never existed as an individual article. The trigger limit must thus be applied to the whole article; i.e. the capacitor.

EU REACH

- Call to Action
  - “Simple articles” such as the t-shirt example will continue to be reported as was previously done
    - Weight % of any SVHC contained within will be calculated using the total weight of the “simple article” the t-shirt

EU REACH

- Call to Action
  - “Complex articles”, made up of many “simple articles” will need to be reported differently
  - A “complex article” containing an SVHC will be calculated for each “simple article”, SVHC Weight %, contained in the complex article
    - Do not use the total weight of the “complex article” to determine the weight % for determining SVHC reporting limit
  - “Complex articles” may have thousands of “simple articles” contained within

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WHEN YOU NEED TO BE SURE

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GB 31421 – MEETING CHINA'S NEW BATTERY STANDARD

Consumer and Retail

Jody Leber, Manager, Battery Safety

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GENERAL

As of August 1st 2015 GB 31241 replaced GB/T 18287 as the new safety standard for batteries and cells used in portable electronic equipment in China. Many manufacturers have been struggling with the importation and language barriers to gain approval to this new standard. Although many requirements are based on IEC 62133 there are variations and additional construction and testing requirements. The intent of this presentation is to assist manufacturers to ensure their batteries and cells can successfully be imported and meet the new standard. We will discuss compliance strategies, documentation requirements, testing and the future for battery certification in China.

GENERAL

This presentation will cover the following items:

- Background
- Evaluation
- Testing
- Reporting

BACKGROUND

The requirements in China for electronic equipment are typically the mandatory CCC mark. In the case of batteries the mark CCC mark is not applicable since batteries are not specified in the CCC list. However, Portable electronic equipment such as ITE and AV (Laptops, Mobile Phones, and portable DVD Players) that are specified will require the batteries used in those devices be tested to GB 31421. We actually suggest testing all batteries regardless of the end product to reduce the risk of confiscation by customs

BACKGROUND

There are currently three options available for the batteries:

1. Self-Declare: The manufacturer may perform the tests or contract anyone else to do the testing and create a Declaration of Conformity. We do not suggest this option as China has a history of stopping products at the border and confiscating them.

2. GB 31421 Report from Government Laboratory: In this case samples will be sent to an accredited lab in China and all evaluation and testing will be performed there. We suggest this as the preferred option. Not only will it satisfy the current requirements, but the test report may be used for up to one year to apply for official certification if it becomes mandatory. Compliance with GB 31421 may be stated on the product, but no references to CQC.

BACKGROUND

3. Full CQC Certification: The option follows the same path as the GB 31421 Report from Government Laboratory with the addition of factory inspections and allows use of the CQC mark.

EVALUATION

The evalaution and component requirements are very similar to IEC 62133 CB Scheme. The following items must be approved as shown.

Packs

- Cells: Cells must be certified to GB 31421 or tested. Nominal Voltage and Capacity are specified in the report.
- PWB: UL 796 Standard for Printed-Wiring Boards is acceptable. Flammability and Temperature rating are specified in the report. (Not consistent with various)
- Fuse: UL 248 Low-Voltage Fuses is acceptable. Voltage and opening current are specified in the report.

EVALUATION

- PTC: UL 1434 Thermistor-Type Devices is acceptable. Voltage and opening current are specified in the report.
- Wire: UL 758 Appliance Wiring Material is acceptable. Gauge, Flammability and Temperature are specified in the report. (Not consistent with various)
- Enclosure: UL 94 Tests for Flammability of Plastic Materials for Parts in Devices and Appliances is acceptable (Not consistent with various)
- PCM: This has been specified but only described with a flammability rating.
- FET: Has been included in some reports, but not others.
- Control IC: Has been included in some reports, but not others.

Cells

- Anode Material
- Cathode Material
- Electrolyte

MARKINGS

The following is a summary of the specific requirements.

- Battery Name and Model: Must be in Chinese
- Upper Charging Voltage: Must be in Chinese
- Warning: Must be in Chinese
- Manufacturer: Must be in Chinese
- Nominal Voltage and Capacity: Must be in Chinese
- Do Not Wash: Only if exempting the test

Cells (30)

- Capacity (Common Failure)
- External Short Circuit at 20 °C
- External Short Circuit at 55 °C
- Overcharge (3 x Maximum Charging Current)
- Over Discharge
- Low Pressure
- Temperature Cycling
- Vibration
- Shock

TESTING

- Drop
- Crush
- Impact
- Thermal Abuse
- Projectile

Battery (40)

- Low Pressure
- Temperature Cycling
- Vibration
- Shock
- Drop
- Stress Relief
- High Temperature
- Washing
- Flame Retardant

TESTING

- Overvoltage
- Overcurrent
- Undervoltage
- Overload
- External Short Circuit
- Reverse Charging
- ESD

PCM (0)

- Overvoltage
- Overcurrent
- Undervoltage
- Overload
- Short Circuit
- High Voltage

REPORTING

The report will be provided in Chinese.

The important part is the Chinese Government Laboratory stamp which authenticates the report.

Unless full certification is pursed, it will be up to the manufacturer to ensure quality system requirement and control of critical components is maintained.

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INTERNATIONAL TYPE APPROVAL

Consumer and Retail

Janet Gavidia, Program Manager, International Type Approval

WHEN YOU NEED TO BE SURE

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OVERVIEW

- Step 1 – Key items to take into account at design/mfg stage

- Step 2 – Introduction: What is International Type Approvals
  - What is it and what does it mean to me
  - Type Approval Schemes (RF, EMC, Safety, Energy, Efficiency)
  - Flowchart

- Step 3 – Solutions from SGS
  - International Type Approval Services in US and globally (our solutions)
  - SGS Global (who we are and what we do)

DESIGN CONSIDERATIONS

- What is Products intended use, product classification?
- Target Markets – US or Global?
- Why does it matter?

- Depending on how you classify/describe a product it may impact your compliance
- Example: Medical Wireless Tablet
- Medical: Class A
- Wireless Portion: Class B

Whether a product is tested to Class A or B limits for emissions will be determined by where the product will be marketed and/or used. Class B emission limits apply to residential environments: Class A emission limits apply to commercial, industrial and all other environments.

DEMONSTRATING COMPLIANCE

If we look at examples for EU Compliance

- **Medical Device with radio:**
  - RF--EN 302 291 or EN300 328
  - EMC--EN301 489
  - Safety--EN 60601-1-2: 2001
- Medical Device without a radio
  - EMC - CISPR11/EN55011
  - EN60601
- EN55011 vs EN55022 have same limits but **different classifications**
  - EN55011 class A is **10dB more relaxed** from EN55022 class B
- EN55011 comes in from medical requirement but is for RF energy vs. EN55022 which is for RF communication
- ITE device with radio
  - RF--EN 300 330
  - EMC--EN301 489-3
  - Safety--EN 60950
- ITE device without radio
  - EMC--EN 55022
  - EMI -- EN 55024
  - Safety--EN 60950
- Also US FCC would be impacted 15.109 (b) vs 15.209 [6-10 dB] different 15.209 more stringent

USING PROPER CLASSIFICATIONS TO AVOID POTENTIAL TEST FAILURES

- Class A = commercial environment
- Class B = residential environment
- Definitions for commercial environment is a grey area, vary from country by country

FCC 15.209	intentional radiators, emission limits are stricter then 15.109(B) class A
EN 55011 -CISPR 11	EMC for ISM devices, defines class A and class B. EN 55011 class B limits are stricter then FCC 15.109(B) class A
EN 55022-CISPR 22	EMC for ITE devices, defines class A and class B. EN 55022 class B limits are stricter then FCC 15.109(B) class A
EN 301489-1	EMC for RF devices, based on EN55022 class A (telecom centres) and class B (general) limits, class B limits are stricter then FCC 15.109(B) class A

STANDARDS STRUCTURE

- Generic Standards: are based on the applicable product environments (such as *Residential* or *Industrial*) rather than product type, and are to be utilized when no applicable product family standards are available

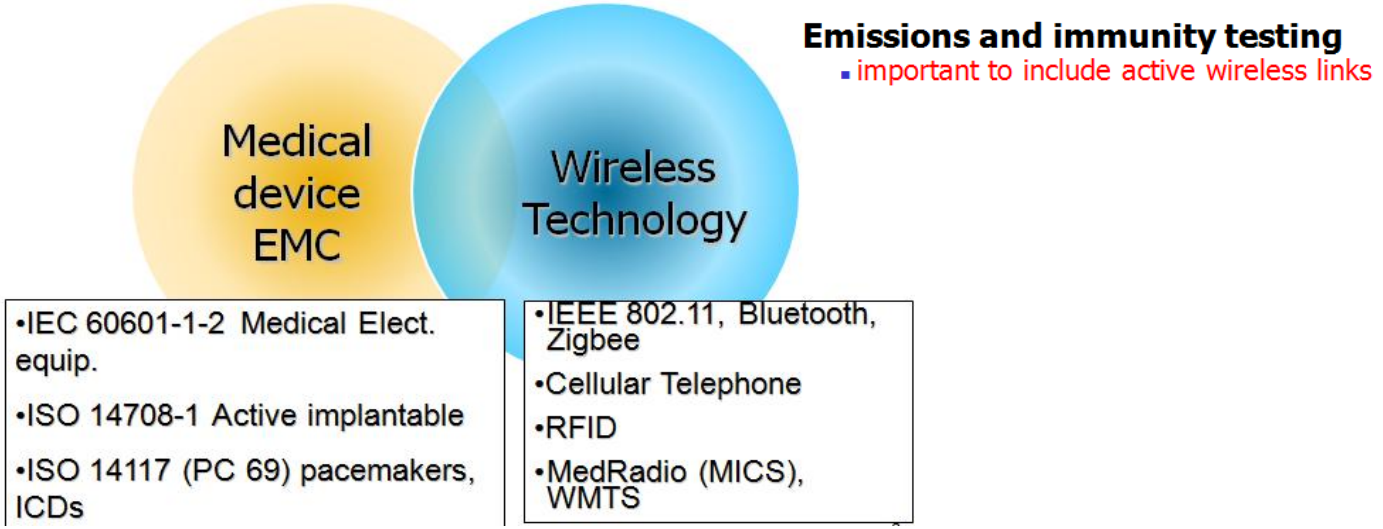
  - Product Family: are specific to the type or class of product, think: medical electrical

  - Product: specific to the product being tested, think: electrocardiographs

Basic standard (general and fundamental rules)	EN61000-4-x (IEC61000-4-x)	EMC- testing and measurement techniques
Generic standard (for equipment in a specific environment)	EN61000-6-3 (IEC61000-6-3)	Generic Emission Standard for commercial, residential and industrial environment
	EN61000-6-1 (IEC61000-6-1)	Generic Immunity Standard for commercial, residential and industrial
Product Standard (for a specific product family)	EN55022 (CISPR22)	ITE equipment
	EN55014 (CISPR14)	Household appliances
	EN300 330	Electromagnetic compatibility and radio spectrum matters (ERM) ;SRD Short range devices;

IMPORTANCE OF PROPER STANDARD SELECTION

- In a presentation by FDA they highlighted the important key aspects to pay close attention to and standard selection was one area



From: CRDH Presentation Toward Safe and Effective Wireless Medical Device and Systems

IDENTIFYING YOUR TARGET MARKETS

- Recommend to list out your intended countries
- Develop a Compliance Plan in order to map out proper strategy, order of testing, and what tests can be leverage in what country
- Electrical Safety
- May want to consider CB scheme
  - You would want to know ahead of time so you can inform test house that you want all national deviations included –to avoid local testing

Test Plan

Priority	Country	Standard	Action	Note
1	US	FCC	Fcc Verification	Based on existing FCC grant #-M2B
1	Canada	Industry Canada RSS210	No action ?	Based on exsiting IC approval# -B2
	Europe	EN301 489-1, EN301 489-17; EN300 328		Client needs to provide Copy of CE DoC+ test reports to verify that standards are to latest
	Chile	SUBTEL		Leverage FCC/ CE Reports + approvals to secure Chile Approval
	Egypt	NTRA		Leverage CE Reports + approvals to secure Egypt Approval
	India	Regulatory Authority of India		Leverage FCC/ CE Reports + approvals to secure India Approval

INTRODUCTION – INTERNATIONAL TYPE APPROVALS (ITA)

- When selling your products globally there are many items to take into account

Mandatory Requirements

- Legal Regulations enforced

Vs.

Client or Market Driven

- Marketing need (but not legally required); Differentiation from competition

Customs & Enforcement

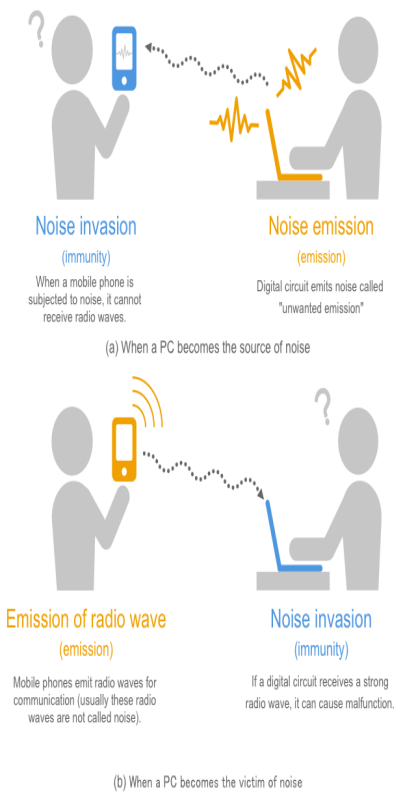
PURPOSE OF APPROVALS - MANDATORY

- **Spectrum Usage and Interoperability:**
  - Ensure frequency of operation remains within defined limits
  - Remains within transmit power
  - Is received correctly
- **EMC:** ensure that
  - Electromagnetic disturbance generated by equip does not exceed a level which prohibits equip from operating as intended.
  - Equip has a level of immunity against electromagnetic disturbance when operated.
- **Safety:** to evaluate the potential of the device for
  - Shock hazards
  - Fail safe characteristics
  - Flammability
- **Add. Requirements:** other countries may impose
  - Energy efficiency
  - SAR testing

MARKET DRIVEN AND ENFORCEMENT

- Market surveillance authorities (e.g. EU)
- Complaint from competitors or public
- Custom searches and non-conformity
- Random audits
- Penalties for putting non-compliant products into marketplace ranges form fines to imprisonment

INTRODUCTION CONTINUED



- Need for Mandatory Regulations
  - Reduce product liability, ensure safety
  - Reduce/eliminate interference
  - If wireless to ensure product operates in designated frequencies

- The task of testing and certifying for global markets is challenging indeed
  - Identifying applicable requirements
  - Regulations varying country by country, numerous agencies
  - Diff test set ups, testing to national test standards
  - Language barriers, figuring out the right regulatory agency

CONTRIBUTING MARKET DRIVERS

- Wired and Wireless connectivities are regulated in over **180 countries** around the globe and still evolving
- Customs Agency activities increasing, with more countries who are controlling product at the point of entry
- Market Surveillance Enforcement

- Market compliance arm of the Regulatory Agencies
- Cooperation with Customs Agency
- Check product in marketplace

TYPE APPROVAL SCHEMES – VARY BY PRODUCT AND COUNTRY

- Main Types of Approvals:
  - Radio Frequency-RF
  - Electromagnetic
  - Electrical Safety
  - Energy Efficiency

- Approval Schemes

Self Declaration	→	EU R&TTE Directive, EMC Directive
Type Approval	→	USA, Canada FCC or Industry Canada
Product Safety Approvals	→	Argentina-IRAM India - BIS China - CCC
Complex Type Approvals	→	Requiring in-country testing and/or factory inspections

ADDITIONAL TYPE APPROVAL REQUIREMENTS

- In the Manual – compliance statements may apply, varies country to country
- Local labeling requirements

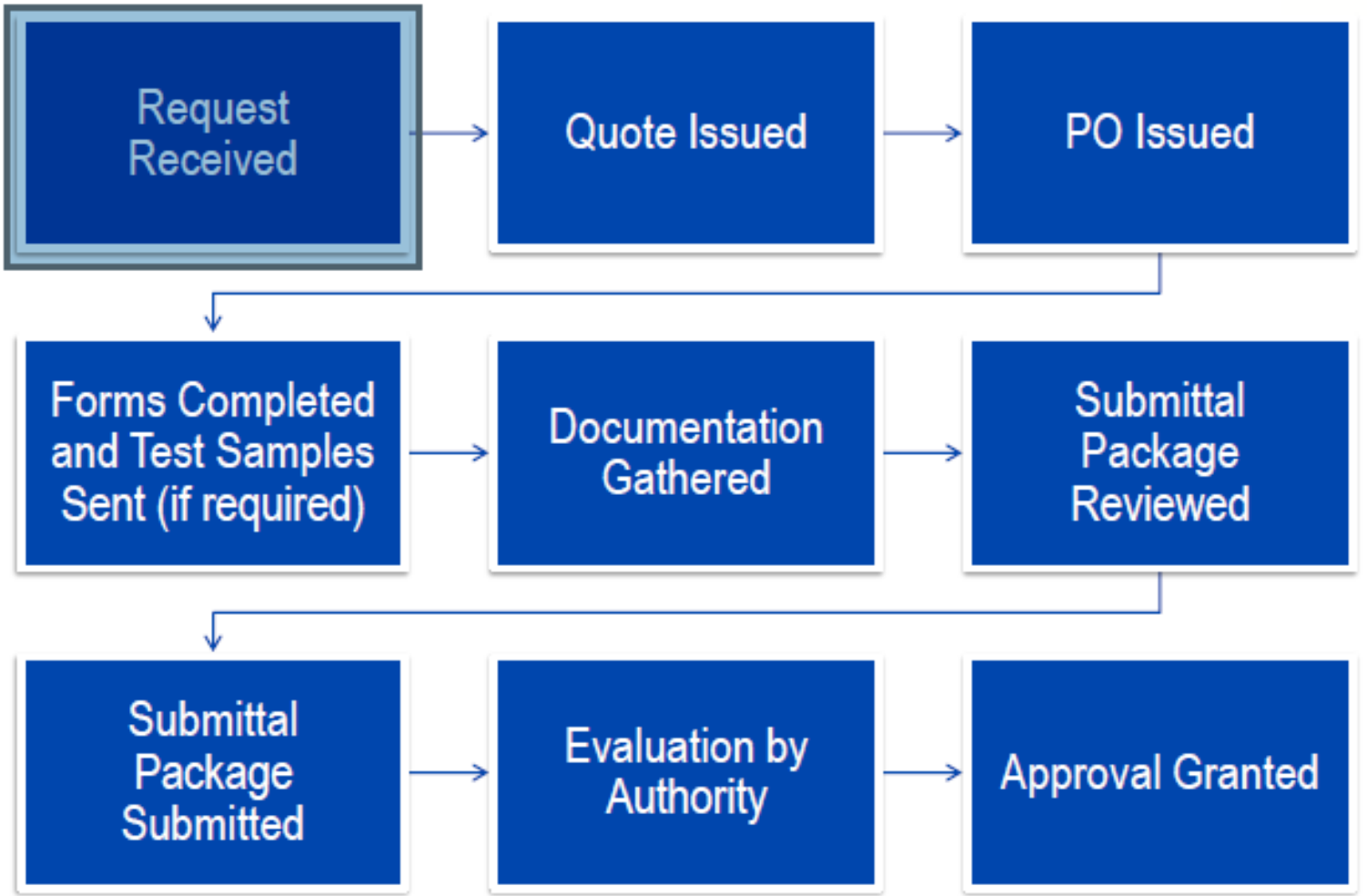
Brazil

ANATEL
Agência Nacional de Telecomunicações

Este equipamento opera em caráter secondário, isto é, não tem direito a protecão contra interferencia prejudicial, mesmo de estacões do mesmo tipo, e não pode causar interferencia a sistemas operando em caráter primário.

Korea Regulatory Statement—
당해 무선설비는 운영 중 전파혼신 가능성이 있음
Possible radio wave interference during operation of concerned radio equipment.

TYPICAL PROCESS



CHALLENGES MANUFACTURERS MUST OBTAIN ANSWERS TO

- The varying laws and regulations (Medical, Safety, EMC, Radio, Telecom, Environmental, Hygienic, Energy Efficiency, Packaging, Markings and Labeling, etc.) applicable to equipment
- What standards, testing programs and methodologies are used?
- Are samples required for in-country testing or for verification purposes? Should these be supplied as in standard commercial configuration or must they be specially prepared or configured as for samples for wireless equipment?
- What frequencies are allowed? Indoor/Outdoor use? What's the local voltage, or plug type?

INTERNATIONAL TYPE APPROVAL – CRADLE TO GRAVE SOLUTIONS

- **Requirement Solutions**
  - Identification of which requirements apply to your product and whether one or multiple certification schemes are required
  - Advice on manual and/or label requirements
- **Testing Solutions**
  - Technical requirement identification
  - Accredited and/or government designated laboratories for product testing worldwide
- **Global Solutions Local Expertise**
  - Around the globe, there are specific country requirements that your products need to comply with before importation. With accredited locations worldwide, and global approvals in over 150 countries
- **Cradle to Grave Solutions**
  - Ensure products can meet global requirements
  - Perform pre-compliance checks to ensure there are no surprises once the product design is locked
  - Help formulate your regulatory strategy
  - Manage all of the required testing, both domestically and international
  - Determine if re-testing is required due to product changes
  - Assist in managing renewals or recertifications
- **SGS offers the benefit of local experts that understand the necessary requirements to help support your needs**

SGS TOTAL MARKET ACCESS SOLUTIONS

- 45 countries

- Total solution including Safety, EMC, Energy Efficiency & Telecom Approvals

- 180 countries

- Wireless solution including RF and Telecom Approvals

- *Type Approval is simply a demonstration that specified requirements relating to a product have been fulfilled*

OUR SERVICES

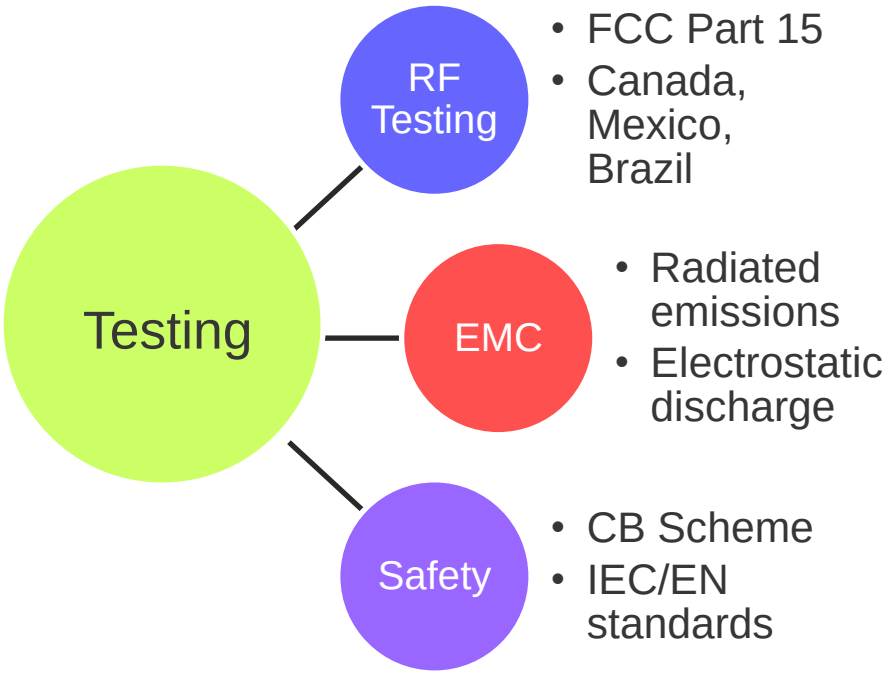
- Certification Services:
  - Safety Approvals
  - EMC Approvals
  - Energy Efficiency
  - RF Approval
  - Telecom Approval
  - MED Approval
- Consultancy Services:
  - Approval Roadmaps, test plans
  - Regulation training
  - Support client to build up regulation information database
- Value Added Services:
  - Dedicated program manager
  - By request educational supplier seminar

TESTING AND CERTIFICATION HIGHLIGHTS

Certification Highlights:

- **SGS Taiwan:** Bluetooth SIG Accredited BQTF & Radio Certification Body Status
- **SGS Japan:** Has Certification Body Status
- **SGS Offices:** Are an RTTE Notified Body can issue an NB opinion
- **SGS China:** Accredited by China government
- **SGS US:** Can test for US, Canada, Europe, AU/NZ, Singapore, Taiwan, Korea, Japan, Vietnam, Hong Kong

Testing Highlights:



MOST REQUESTED COUNTRIES

Americas
- Argentina
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- Ecuador
- Mexico
- Venezuela

Caribbean
- Dominican Republic
- Jamaica
- Trinidad and Tobago

Europe
- Russia
- Serbia
- Ukraine

Africa
- Nigeria
- South Africa

Middle East
- Egypt
- Israel
- Saudi Arabia
- Oman
- UAE
- Kazakhstan

India – Asia – Pacific
- Australia
- China
- India
- Japan
- Korea
- Malaysia
- New Zealand
- Philippines
- Singapore
- Taiwan
- Thailand

SGS AT A GLANCE

Nº1
WORLD LEADER

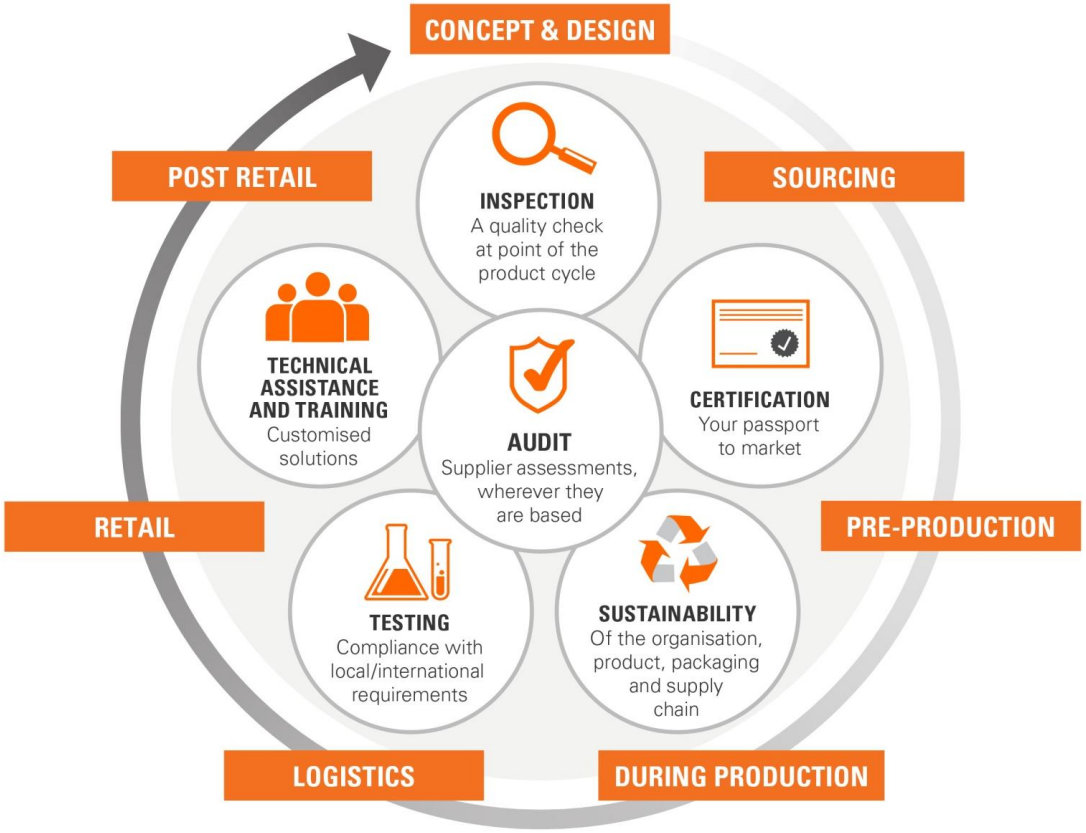
85,000
EMPLOYEES

1,800
OFFICES AND LABORATORIES

14
GLOBAL INDUSTRIES

GLOBAL SERVICE LOCAL EXPERTISE

SOLUTIONS FOR THE ENTIRE PRODUCT LIFE CYCLE



- Depending on your product and if you are an integrator, reseller or manufacturer you will want to take testing and compliance into account as early as possible in order to minimize the degree of costly rework or potential redesign.

CONCLUSION

- In a fast moving global market place the challenge to meet regulatory requirements in your markets remains a barrier
- By working with a reliable compliance partner manufacturers can minimize risk and get the support and assistance needed to navigate the sea of requirements
- Our experts in compliance management will help you make the right choices so you can get your product tested and certified quickly and professionally

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THANK YOU FOR COMING