

PLENARY SESSION

Requirements addressed to economic operators/non-verifiable requirements

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'verification document'

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3. The standard contains provisions which unfairly privilege one economic operator or a group of economic operators by not being technically neutral enough (e.g. IPRs are included or a specification arbitrarily matches the products of one/a few manufacturers only).

EC-EY Checklist

4.1 (i) A requirement, provision or piece of guidance is addressed to 'economic operators', (ii) the 'neutrality principle' is not respected, OR (iii) a requirement, provision or piece of guidance addresses inappropriate conditions for placing on the market (or service provision)
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What does this mean?

- ▲ Avoid to create conditions for unfair competition
- ▲ Technological Neutral & Performance based
- ▲ Neutrality principle
- ▲ Conformity assessment guidance to be followed
- ▲ Attention not to discriminate SME's

- ▲ Each individual product shall comply to the legislation



IR 3

- ▲ Statistical methods such as 80-80 rules (EMC standardization)
- ▲ Instructions on WHO has to perform a test
 - ▲ This should not be addressed in a standard
 - ▲ Legal 'conformity assessment modules' may exist

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6. The standard claims to cover a certain legal requirement while giving the economic operator a choice that is not provided for by the legislator and thus suggesting that it is permissible to circumvent the requirement.

EC-EY Checklist

4.5 Contains a non-specific or non-verifiable requirement, provision or piece of guidance, leaving it to a manufacturer or another standard user to decide how to apply

What does this mean?

- ▲ Tests need to be defined in order to ensure that the specifications are correctly and coherently applied and met
- ▲ Tests shall not contain clauses allowing manufacturers to determine (or deviate from agreed) requirements



[...] During and after the test, the apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a permissible **performance level specified by the manufacturer** when the apparatus is used as intended. [...]

[...] the manufacturer shall declare, for inclusion in the test report, **his own specification for an acceptable level of performance or degradation of performance** during and/or after the immunity tests[...]



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Thank You

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