

Regulatory Comparison and Measured-Margin Verification

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1. Comparison-record fields

First establish the specific product, use, configuration and target market. Identify applicable regulatory requirements, adopted or referenced standards, precise clauses and official sources. All applicable requirements must be met, and core parameters must have reliable measured evidence exceeding the corresponding regulatory requirement. Self-selected values without a regulatory basis, general scores or voluntary evaluation benchmarks do not automatically establish performance beyond regulatory requirements.

2. Interpreting numerical results

Upper limits, lower limits, intervals, classes, qualitative findings and non-detects are assessed according to the original provisions. Apply any decision rule specified by the standard or method. If a reliable margin cannot be established, simple subtraction cannot justify an award.

3. Core performance and complete compliance

At least one meaningful, quantifiable core parameter identified in advance must reliably exceed its requirement, while all other applicable requirements are satisfied. There is no self-imposed uniform 10% margin, no scoring and no offsetting one failure with another advantage.

4. Meet all applicable requirements first

The product, use, configuration and market must be accurate. All mandatory items must be present, with no unresolved failures. Favourable results elsewhere cannot offset omissions or safety problems.

5. Identify core comparison parameters in advance

At least one quantifiable core parameter directly relevant to principal use, quality or safety must show a reliable margin. The comparison is identified before verification to prevent retrospective selection of unrelated favourable data.

6. Compare according to the direction of the requirement

A lower result may show a margin against an upper limit, and a higher result against a lower limit.

Intervals and performance classes follow the original requirements. A pass/fail result without comparable data does not, by itself, establish performance above the requirement.

7. Comparable methods, conditions and units

Compare under the same clause and method. Retain conditions, values, units, uncertainty and applicable decision rules. Unresolved measurement differences and rounding must not be treated as advantages.

8. Explain the data without overstating it

Method example: where a limit is no greater than 10 and the measured result is 6, the numerical difference is 4, or 40% below the limit. This does not mean that the product is 40% safer. A non-detect retains its detection limit and must not be described as zero content.

9. Findings limited to verified parameters

Retain the standard, edition, clause, report page and measured result together. Exceeding a standard on one parameter does not establish leadership in every aspect of performance. Each market must satisfy the conditions separately.

10. Records, administration and correction

For matters covered by this document, records must retain the application or case number, specific product and market, version used, documents and page references, responsible personnel, material dates, reasons and formal notices. Personal information and trade secrets are handled according to access permissions. Questions about a record may be raised through correction, complaint or reconsideration channels available to an entitled applicant. Submission alone does not alter an existing decision or licence. The outcome is determined by the formal notice and current record.

11. Effective date, application and version control

Version 2.0 of this document is published and takes effect on 19 October 2026. It applies to relevant matters formally submitted after that date. Existing applications retain their original snapshot and rules. Material changes are notified separately and handled under transitional arrangements; new conditions are not retrospectively inserted into historical decisions. Website and downloadable texts must agree. Superseded versions identify their replacement, and name or wording corrections are recorded separately from substantive amendments.