

MEMORANDUM CIRCULAR NO. 21-33

Series of 2021

SUBJECT : Establishment of Product Risk Assessment Guidelines for a Smart Regulatory Process in the Bureau of Philippine Standards

WHEREAS, the Department of Trade and Industry (DTI) is the economic catalyst that enables innovative, competitive, job generating, inclusive business, and empowers consumers;

WHEREAS, pursuant to such mandate, the DTI is empowered under Executive Order (EO) 292, Series of 1987 otherwise known as the "Administrative Code of 1987" to protect consumers from trade malpractices and from substandard or hazardous products;

WHEREAS, the DTI Bureau of Philippine Standards (BPS) [formerly known as Bureau of Product Standards] is mandated by Republic Act (RA) 4109 to perform standards development, certification, testing, policy formulation, and monitoring functions;

WHEREAS, EO 101, Series of 1967 empowers the BPS to promulgate, subject to the approval of the DTI Secretary, such rules and regulations for the marking of goods standardized by the BPS and for other purposes;

WHEREAS, such BPS mandates are reiterated in RA 7394 or the "Consumer Act of the Philippines" wherein it states that, "*it shall be the duty of the State to develop and provide safety and quality standards for consumer products, including performance or use-oriented standards, codes of practice and methods of tests; to assist the consumer in evaluating the quality, including safety, performance and comparative utility of consumer products; to protect the public against unreasonable risks of injury associated with consumer products; to undertake research on quality improvement of products and investigation into causes and prevention of product related deaths, illness and injuries; and to assure the public of the consistency of standardized products*";

WHEREAS, consistent with its mandates, the BPS implements the Mandatory Product Certification Schemes to ensure that products posing considerable risks on consumers' life, health, and safety are certified as conforming to the relevant safety and/or quality requirements prior to distribution in the Philippine market;

WHEREAS, a product is included in the BPS List of Products Under Mandatory Certification through the issuance of a technical regulation prescribing the administrative and technical requirements for the implementation of mandatory certification of the concerned product;

WHEREAS, according to the Philippine Good Regulatory Principles launched by the Anti-Red Tape Authority (ARTA), regulators should take an evidence-based approach to determining and managing risks involved at every stage of the regulatory cycle;

WHEREAS, establishing a systematic product risk assessment procedure as part of the BPS' process of introducing technical regulations is necessary for the harmonized understanding between the stakeholders on the risk-based certification scheme requirements prescribed in the proposed technical regulations;

WHEREFORE, foregoing premises considered, these guidelines are hereby issued for guidance of all concerned:

1. OBJECTIVE

This Memorandum Circular aims to establish a systematic Product Risk Assessment Guidelines to ensure that the certification requirements stipulated in the technical regulations of BPS are based on the risk level of the product as identified and agreed through a transparent, participatory, and evidence-based process.

2. SCOPE

This Memorandum Circular shall apply to all products proposed to be included in the BPS' List of Products under Mandatory Certification and those that are covered by an existing technical regulation proposed to be updated or revised.

3. DEFINITION OF TERMS

For purposes of this Guidelines, the following definitions shall apply:

Audit – a systematic, independent and documented process for obtaining objective evidence, and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. ¹

BPS – Bureau of Philippine Standards of the DTI

Certification Body – third party conformity assessment body operating a certification scheme.

Conformity Assessment Body (CAB) – a third party inspection body, testing laboratory and certification body operating within its scope of competence.

Conformity – fulfillment of a requirement.²

DTI – Department of Trade and Industry

International Standard – a standard developed under the WTO principles for international standards development such as those developed by international bodies like the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), International Telecommunication Union (ITU) and those developed by foreign standards bodies under these principles.

Harm – physical injury or damage to the health of people or damage to property or the environment.³

Hazard – potential source of harm.³

ISO – International Organization for Standardization

¹ ISO 19011:2011

² ISO 9000:2015

³ ISO/IEC Guide 51



IEC - International Electrotechnical Commission

Inspection – examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements, or, on the basis of professional judgment, with general requirements.⁴ This includes inventory and sampling.

Inspection body – a body that performs inspection.⁴

PNS ISO/IEC 17067 – Fundamentals of product certification and guidelines for product certification schemes

Philippine National Standards (PNS) – Standards promulgated by the BPS.

Product Certification – the provision of impartial third-party attestation that fulfillment of specified requirements has been demonstrated.⁵

Product Certification Scheme – certification system related to specific products to which the same specified requirements, specific rules and procedures apply.

Risk – the combination of the probability of occurrence of harm and the severity of that harm.³

Standard - a document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory.⁶

Technical Regulation – a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.⁶

Testing Laboratory – a laboratory which measures, examines, or determines the characteristics of performance of material or products. It may also be a laboratory that calibrates inspection, measuring and test equipment.

4. PRODUCT RISK ASSESSMENT

4.1 The Product Risk Assessment shall be conducted for all products proposed to be covered under the BPS Mandatory Product Certification Schemes. This shall also be applicable for products that are already included in the BPS List of Products Under Mandatory Certification but will be proposed for the updating or revision of an existing technical regulation.

4.2 The Product Risk Assessment shall be conducted through the Product Risk Assessment Committee established for each product category which shall include, but not limited, to the following:

³ ISO/IEC Guide 51

⁴ ISO/IEC 17020

⁵ ISO/IEC 17065

⁶ WTO Agreement on Technical Barriers to Trade

Electrical and Electronic Products	Building and Construction Materials	Chemical and Other Consumer Products
A. Household appliances B. Lamps and related products C. Wiring devices D. Electric wires and cables E. Consumer electronics	F. Steel products G. Cement products H. Sanitary wares & ceramic tiles I. Plastic pipes J. Glass products K. Wood products	L. Automotive products M. Chemical products N. Other consumer products

4.3 The BPS may create new product categories for new products not covered in section 4.2 herein, if necessary.

4.4 The BPS shall initiate the assembly of the concerned Product Risk Assessment Committee prior to the preparation of the draft technical regulation. A representative from the BPS Standards Conformity Division shall be assigned for each Committee to provide administrative assistance, monitor the risk assessment activity, and ensure that the proceedings of the discussion are consistent with the requirements of these Guidelines and other applicable BPS rules and regulations.

4.5 The results of the risk assessment activity shall be documented and upon agreement of the Committee, a report shall be submitted to the BPS Director. The report shall include, but not limited to, the following:

4.5.1 The determined risk level (Low, Medium, or High) of the product as agreed by the Committee

4.5.2 The risk calculation documentation and results

4.5.3 Minutes of the meeting/s conducted

4.5.4 Attendance sheet/s

4.5.5 Photo, audio, and/or video documentation of the meeting

5. ESTABLISHMENT OF PRODUCT RISK ASSESSMENT COMMITTEES

5.1. A Product Risk Assessment Committee shall be composed of representatives from the following:

5.1.1 Inspection/Auditing Body

5.1.2 Testing Laboratory of the subject product

5.1.3 Suppliers (manufacturer/importer of the subject product)

5.1.4 Professional organization

5.1.5 Government agency with mandate related to the subject product

5.1.6 Consumer organization

5.2 The BPS shall provide the qualification criteria for each of the Committee member, the nomination and approval procedure, and the terms and conditions of the designation of the Committee Members. These shall form part of the Quality Management System of the BPS Standards Conformity Division.

5.3 The Product Risk Assessment Committee shall nominate a Chair to preside the meetings. The duties and responsibilities of the Chair and the members of the Committee shall be established through the Quality Management System of the BPS Standards Conformity Division.

5.4 The Product Risk Assessment Committee shall ensure that the risk assessment activity is conducted with objectivity and impartiality at all times.

6. RISK CALCULATION

6.1 The level of risk of a product can be obtained by using the formula below.

$$R = C \times P$$

Where:

- R** = risk score of a product
- C** = the consequence of non-compliance
- P** = the probability of occurrence of harm
- x** = multiplication sign

6.2 The Consequence of Non-Compliance (C) refers to the severity of the harm that a product may cause to the consumer if the said product is faulty or non-conforming to the relevant standards. The determination of C shall be in accordance to the following:

6.2.1 The hazards innate to the subject product shall be categorized to the following hazard types:

- 6.2.1.1 Electric;
- 6.2.1.2 Extreme temperature;
- 6.2.1.3 Fire and/or explosion;
- 6.2.1.4 Mechanical;
- 6.2.1.5 Chemical and toxicity;
- 6.2.1.6 Radiation; and
- 6.2.1.7 Other identified hazards not covered by any of the above

6.2.2 For each hazard type, the following factors shall be identified:

- 6.2.2.1 The product's properties that are likely to cause an injury to the consumer;
- 6.2.2.2 The possible scenario/s that the consumer will possibly experience in using the product that might lead to an injury; and
- 6.2.2.3 The potential injuries that the consumer might get in case the identified scenario occurred

6.2.3 Each of the potential injury identified shall be assessed and rated based on the severity of the injury, as follows:

Severity of injury	Score
Slight injury	1
Moderate	2
Serious	3
Very Serious	4
Fatal	5

- 6.2.4 The highest severity score among all the identified injuries shall be assigned as the Consequence of Non-Compliance (C) that will be used in the risk calculation.
- 6.3 The Probability of Non-Compliance (P) shall be determined using the form provided in Annex A. The result of the assessment using Annex A shall be assigned as the Probability of Non-Compliance (P) in the risk calculation.
- 6.4 The level of risk of a product shall be based on the calculated Risk Score (R) as determined using the formula in clause 6.1, and shall be assigned as follows:

Level of Risk	Risk Score
High Risk	14.1 – 25.0
Medium Risk	5.1 – 14.0
Low Risk	0.1 – 5.0

7. CERTIFICATION SCHEMES BASED ON THE RISK LEVEL OF THE PRODUCT

- 7.1 To ensure that the requirements to be prescribed in the technical regulations of the BPS concerning its Mandatory Product Certification Schemes are based on the risk level of the specific product and that the corresponding certification schemes are aligned to those prescribed in PNS ISO/IEC 17067, the following shall be applicable:
- 7.1.1 For products identified as High Risk, a certification scheme aligned with the Scheme Type 5 described in PNS ISO/IEC 17067 shall be required by the BPS in its technical regulation. The type of surveillance activities and the frequency by which they will be conducted shall vary depending on the risk score of the product. If the risk assessment calculation yields a score falling within the higher range of the risk score for High Risk, i.e. with risk score of 19.6 to 25.0, the BPS shall consider to implement a more frequent surveillance activity.
- 7.1.2 For products identified as Medium Risk, the Scheme Type 1b based on PNS ISO/IEC 17067 shall be required by the BPS in its technical regulation.
- 7.1.3 For products identified as Low Risk, the Scheme Type 1a based on PNS ISO/IEC 17067 shall be required by the BPS in its technical regulation.

8. REVIEW OF RISK ASSESSMENT RESULTS

To ensure the continuous appropriateness of the risk assessment results, monitoring and review of the risk scores shall be conducted every five (5) years or as the need arises.

9. SEPARABILITY CLAUSE

If any term or provision of this Order should be declared illegal or invalid by a court of competent jurisdiction, the remaining terms and provisions thereof shall remain unimpaired and in full force.

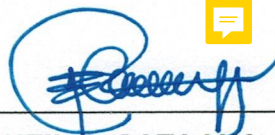
10. EFFECTIVITY

This Memorandum Circular shall be effective immediately after its publication in a newspaper of general circulation, a copy of which shall be submitted to the UP Office of National Administrative Register.

For the information and guidance of those concerned.

Done in the City of Makati this 21st day of Sept. in the year 2021.

Recommended by:



NEIL P. CATAJAY
Director, BPS

Approved by:



ATTY. RUTH B. CASTELO
Undersecretary, CPG

Determination of the Probability of Non-Compliance (P)

To determine P, the following factors identified to affect the likelihood of occurrence of non-compliance shall be rated with 1, 3, or 5, whichever will apply to the product being subjected to risk assessment. The average rating shall be determined as the P to be used in the risk calculation.

Factor	Rating
1. Safety/quality issue/s or concern/s about the product. <ul style="list-style-type: none"> • 1 = There are no reported issue/concern regarding the product. • 3 = There is a known issue on the quality of the product but the issue does not considerably affect the safety aspect of using the product. • 5 = There is a known safety and/or quality concern on the product as evidenced by reports/complaints from consumers, or as shown in the news or other media platforms 	
2. The technology used in the design and manufacture of the product <ul style="list-style-type: none"> • 1 = The technology is widely-used in the industry and has been established for a significant period of time. • 3 = The technology is relatively new but is already adopted and used within the industry • 5 = The technology is new and there is no sufficient study or evidence to ensure that the product manufactured using this technology will conform to the relevant standard/s 	
3. Availability of the product in the market <ul style="list-style-type: none"> • 1 = The product is exclusively sold by one supplier • 3 = The product is sold in several stores • 5 = The product can be easily purchased in the market 	
4. Consumer's demand for the product <ul style="list-style-type: none"> • 1 = The product is not commonly purchased by majority of consumers • 3 = The product is popular but is considered a non-essential item • 5 = The product is an essential item used by the majority of 	
5. The frequency of the use of the product by the consumers <ul style="list-style-type: none"> • 1 = The product is not commonly used in the household or in the daily activities of the consumers • 3 = The product is commonly used in the household but the time of exposure to the product is not a significant portion of the consumer's regular activities • 5 = The product is commonly used in most households and the period of exposure or usage of the product is a significant portion of the consumer's daily activities 	
P = Average of the ratings	