**DEPARTMENT ADMINISTRATIVE ORDER NO. 22-06**
**Series of 2022**

**SUBJECT: THE NEW TECHNICAL REGULATION CONCERNING THE MANDATORY PRODUCT CERTIFICATION OF VAPORIZED NICOTINE AND NON-NICOTINE PRODUCTS**

***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,*** the World Trade Organization (WTO) defined **Standard** as "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**." (emphasis supplied)

***WHEREAS,*** the WTO defined **Technical Regulation** as "a document which lays down product characteristics for their related processes and production methods, including the applicable administrative provisions, with which **compliance is mandatory**." (emphasis supplied)

***WHEREAS***, Executive Order (E.O.) No. 106, s. 2020 entitled "Prohibiting the Manufacture, Distribution, Marketing and Sale of Unregistered and/or Adulterated Electronic Nicotine/Non-Nicotine Delivery Systems, Heated Tobacco Products and Other Novel Tobacco Products,

Amending Executive Order No. 26 (S. 2017) and for other Purposes", in its Section 2 provides that devices forming components of ENDS/ENNDS or HTPs shall be subject to the product standards imposed by the Department of Trade and Industry and the FDA, in accordance with RA Nos. 7394 and 11467.

***WHEREAS***, in accordance with Section 4 of EO 106, "The entry/importation of unregistered or adulterated ENDS/ENNDS, HTPs, or components thereof is hereby prohibited. For this purpose, the FDA and DTI are hereby directed to coordinate with the Bureau of Customs in the formulation of ENDS/ENNDS, HTPs, and their components into the Philippine Market."

***WHEREAS***, EO 913, Series of 1983, vests with the DTI the adjudicatory powers such as to conduct arbitration, conciliation, mediation, formal investigation; imposition of administrative penalties; and issue cease-and-desist orders, seizures, preventive measures and other similar orders in case of violation of trade and industry laws including those relating to the BPS' Certification Schemes;

***NOW THEREFORE***, pursuant to EO 106, RA 4109, RA 7394, RA 11467, Series of 1967, EO 913, Series of 1983 and EO 292, Series of 1987, the following Technical Regulation governing the BPS Mandatory Product Certification Schemes for Vaporized nicotine and non-nicotine products is hereby prescribed and promulgated for the compliance, information, and guidance of all concerned.

## Rule 1. OBJECTIVE

This DAO aims to strictly ensure that vaporized nicotine and non-nicotine products to be manufactured, distributed, or sold in the Philippines meet the specified requirements prescribed by this Technical Regulation.

## Rule 2. SCOPE

This DAO prescribes the Technical Regulations for the mandatory certification of vaporized nicotine and non-nicotine products, whether locally manufactured or imported, as follows:

2.1 **Vapor product system**;

2.2 **Vapor product device**; and

2.3 **Heated tobacco product system**

## Rule 3. DEFINITION OF TERMS

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

3.1. **Attestation** – issuance of a statement of conformity based on a decision following review of an audit report, that fulfillment of specified requirements has been demonstrated. [1]

3.2. **Audit** – a systematic, independent and documented process for obtaining audit evidence, and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. [2]

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[1] *ISO/IEC 17000*
[2] *ISO 19011:2011*

3.3. **Audit criteria** – set of policies, procedures or requirements used as a reference against which audit evidence is compared. [3]

3.4. **Base Model** – one that represents a set of generic characteristics of a group of products.

3.5. **Batch Number** - a unique identifying number or set of letters and numbers assigned to a production/lot batch of products.

3.6. **BPS** – Bureau of Philippine Standards of the DTI.

3.7. **BPS Recognized Conformity Assessment Body (CAB)** – the CAB (inspection body, testing laboratory, or certification body) duly recognized by BPS to have the scope and competence to conduct activities relevant to the requirements set forth by BPS, to include but not limited to, CABs accredited by the PAB, CABs recognized by BPS under the Association of South East Asian Nations Mutual Recognition Arrangement (ASEAN MRA), Asia-Pacific Economic Cooperation (APEC) MRA and other regional and bilateral MRAs entered into by the Government of the Philippines through the DTI. BPS shall issue Recognition Certificate upon completion of all requirements for application for recognition.

3.8. **Cartridge** – e-liquid refill with or without vaporising chamber. [4]

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

3.10. **Certificate of Conditional Release** – a document issued to an importer allowing the temporary release of goods from Custom's custody, upon compliance with the BOC and BPS requirements, while awaiting BPS decision on the issuance of SOC.

3.11. **Certificate of Exemption** – a document issued to importer of vaporized nicotine and non-nicotine products that are not within the scope of PNS AFNOR XP D90-300 and PNS BSI PAS 88500.

3.12. **Claim** – information declared by client. [5]

3.13. **Confirmation** – an action, declaration, document, or statement that corroborates, ratifies, verifies, gives formal approval, or assures the validity of something.[6]

3.14. **Conformity** – fulfillment of a requirement.[7]

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

3.16. **Determination** – include assessment activities such as testing, measuring, inspection, design appraisal, assessment of services, and auditing to provide

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[2] *ISO 19011:2011*
[3] *Ibid*
[4] *PNS AFNOR XP D90-300-1:2019*
[5] *ISO 19011:2011*
[6] *ISO/IEC 17029*
[7] *Webster's New World Law Dictionary*

information regarding the product requirements as input to the review and attestation functions.

3.17. **DTI** – Department of Trade and Industry

3.18. **Electrical accessories** – auxiliary items with a specified electrical function that can be attached to or removed from a tobacco heating device[8] and vapor product device

3.19. **EU No. 10/2011** - Commission Regulation (EU) on plastic materials and articles intended to come into contact with food.

3.20. **EU No. 20/1245** - Commission Regulation (EU) amending and correcting EU No. 10/2011 on plastic materials and articles intended to come into contact with food.

3.21. **Evaluation** – systematic examination of the extent to which a product, process, or service fulfills specified requirements.[9]

3.22. **Generic Model** – refers to a model which critical components and materials composition such as mechanical, electrical, functional characteristics are similar with its base model.

3.23. **Heated Tobacco Product (HTP)** – specific combination of heated tobacco and non-tobacco materials consumed or depleted through single or multiple use with a tobacco heating device.[10] Also referred to as Heated Tobacco Product Consumables or Heat-Not-Burn-Product Consumables.

3.24. **Heated Tobacco Product System (HTP System)** – shall refer to a HTP Consumable and HTP Device that are intended to be used together as a system.

3.25. **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.[11] This may include inventory and sampling.

3.26. **Inspection body** – a body that performs inspection.[12]

3.27. **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.

3.28. **ISO 9001** – Quality Management Systems – Requirements

3.29. **ISO/IEC 17000** – Conformity assessment – Vocabulary and general principles

3.30. **ISO/IEC 17020** – Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

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[8] *PNS BSI PAS 8850:2022*
[9] *ISO/IEC 17000*
[10] *PNS BSI PAS 8850:2022*
[11] *ISO/IEC 17020*
[12] *ISO/IEC 17020*

3.31. **ISO/IEC 17029** – Conformity assessment – General principles and requirements for validation and verification bodies.

3.32. **ISO/IEC 17065** – Conformity assessment – Requirements for bodies certifying products, processes and services.

3.33. **ISO 19011** – Guidelines for Auditing.

3.34. **Mouthpiece** - part of the electronic cigarette that is in contact with the mouth.[13]

3.35. **Overall Migration Limit** - maximum permitted amount of non-volatile substances released from a material or article into food simulants. [14]

3.36. **PAB** – Philippine Accreditation Bureau of the DTI.

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

3.38. **PNS 2133-1:2018 (IEC 60335-1:2016, MOD)** – Household and similar electrical appliances – Safety – Part 1: General Requirements

3.39. **PNS AFNOR XP D90-300-1:2019** – Electronic cigarettes and e-liquids - Part 1: Requirements and test methods for vaporized nicotine and non-nicotine products

3.40. **PNS AFNOR XP D90-300-2:2019** - Electronic cigarettes and e-liquids - Part 2: Requirements and test methods for e-liquids.

3.41. **PNS AFNOR XP D90-300-3:2019** – Electronic cigarettes and e-liquids – Part 3: Requirements and test methods for emissions.

3.42. **PNS BSI PAS 8850:2022** - Non-combusted tobacco products - Heated tobacco products and electrical tobacco heating devices – Specification

3.43. **PNS IEC 60950-1:2015** – Information technology equipment - Safety - Part 1: General requirements

3.44. **PNS IEC 62368-1:2021** – Audio/video, information and communication technology equipment - Part 1: Safety requirements

3.45. **PNS IEC 61558-1:2021** – Safety of transformers, reactors, power supply units and combinations thereof - Part 1: General requirements and tests

3.46. **PNS IEC 62133:2015** – Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

3.47. **PNS IEC 62680-3:2019** – Universal serial bus interfaces for data and power - Part 3: USB battery charging specifications.

3.48. **Product Certification** – the provision of impartial third-party attestation that fulfillment of specified requirements has been demonstrated. [15]

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[13] *PNS AFNOR XP D90-300-1:2019*
[14] *Commission Regulation (EU) No 10/2011*
[15] *ISO/IEC 17065*

3.49. **PS License** – authority given by BPS to a local/foreign manufacturer, authorizing the use of the PS Certification Mark on its product.

3.50. **Review** – verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfillment of specified requirements. [16]

3.51. **Sampling** – a method of getting a representative sample of a product according to a specified procedure.

3.52. **Serial Number** - unique number or string of characters in a series and used as a means of identification of a product.

3.53. **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.

3.54. **Statement of Confirmation (SOC)** – a document stating that the imported vaporized nicotine and non-nicotine products was sourced from a manufacturer with a valid PS License and that the imported electronic cigarette product from said manufacturer complies with specified requirements after undergoing inspection and verification and should contain the batch or serial number and manufacturing date of the imported electronic cigarette.

3.55. **Surveillance** – a systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity.[17]

3.56. **Tank** - part of the vaporizing chamber designed to take the e-liquid. [18]

3.57. **Technical Regulation** - a document which lays down product characteristics for their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.

3.58. **Test Report** – a document that presents test results and other information relevant to a test.

3.59. **Testing Laboratory** – a laboratory that 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.

3.60. **Third Party** – a body that is independent of the organization that provides the product/service and is not the user of the product/service (testing, inspection, and sampling). [19]

3.61. **Tobacco Heating Device** - electrical device providing the source of heat required to directly or indirectly heat a heated tobacco product (HTP) without combustion of the heated tobacco. [20]

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[16] *ISO/IEC 17000*
[17] *Ibid*
[18] *PNS AFNOR XP D90-300-1:2019*
[19] *ISO/IEC 17000*
[20] *PNS BSI PAS 8850:2022*

3.62. **Trade name** – any registered name or designation identifying or distinguishing an enterprise

3.63. **Vaporized Nicotine and Non-Nicotine Products (VNP)** - shall refer to the category of products used in both HTP System and Vapor Product System which are novel consumer goods that generate a nicotine-containing or non-nicotine containing aerosol without combustion.

3.64. **Vapor Product System** - shall refer to the specific combination consisting of the Vapor Product Refill and Vapor Product Device which, based on the information made available to the consumer by the provider, are intended to be used together. Also referred to as Electronic Nicotine/Non-Nicotine Delivery System (ENDS/ENNDS)

3.65. **Vapor product device** – used to transform an e-liquid into an inhalable aerosol [21] that user mimics the act of smoking. Refillable or disposable, rechargeable or not, regardless of the model of the vaporizing device. Also referred to as electronic cigarette device or vape.

3.66. **Vapor product refill** – liquid or gel consumable intended for transformation into an aerosol and then inhaled with an electronic cigarette.[22] Non-tobacco may or may not contain nicotine. Also referred to as e-liquid or juice.

3.67. **Verification** – confirmation of a claim, through the provision of objective evidence, that specified requirements have been fulfilled.[23]

3.68. **Warehouse** – secured premises built purposely for storage of products and to preserve the quality and integrity of the same.

## Rule 4. THE PHILIPPINE STANDARD (PS) SAFETY AND QUALITY CERTIFICATION MARK LICENSING SCHEME

The PS Safety and Quality Certification Mark Licensing Scheme (PS Licensing Scheme for brevity) shall be available to both local and foreign manufacturers selling or distributing vaporized nicotine and non-nicotine products, in the Philippine market. The License to use the PS Certification Mark shall be granted to a company found to be compliant with the requirements. To ensure compliance of the certified products, regular surveillance activities as per existing DTI rules shall be conducted as follows, as may be applicable:

4.1 Local companies holding a valid PS license;

4.1.1 Annual system and product audit at the factory; and
4.1.2 Random product audit at the warehouse/market.

4.2 Foreign companies holding a valid PS license;

4.2.1 Annual system and product audit at the factory; and
4.2.2 Regular product audit per shipment.

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[21] *PNS AFNOR XP D90-300-1:2019*
[22] *Ibid*
[23] *ISO/IEC 17029*

## Rule 5. DOCUMENTARY REQUIREMENTS AND PROCEDURES FOR THE PS LICENSING SCHEME

### 5.1 Application for PS License shall be supported by the following:

5.1.1 Duly accomplished application form, subscribed and sworn to by the applicant, or his duly authorized management representative. In case of an overseas applicant, the application form shall be duly authenticated by the Philippine Consulate in the country where the manufacturing plant to be audited is located. The requirement of authentication may be waived subject to reciprocity arrangements between the Philippines and the exporting country;

5.1.2 For a sole proprietorship: Business Name Registration and permit issued by the local government unit having jurisdiction over it;

For a corporation or partnership: SEC Registration and Articles of Incorporation/Partnership and By-Laws, submitted once, unless an amendment has been made; or

In case of an overseas applicant, the local branch or representative office/agency shall also provide the equivalent foreign document stated herein, whichever is applicable.

5.1.3 Latest Income Tax Return or latest audited financial statement, and certification of an accountant on the net worth of the business, submitted once unless an amendment has been made within the current year;

5.1.4 Quality Management System (QMS) Manual covering the product being applied for PS License, including the description of the product/s' production/manufacturing process;

5.1.5 Product Identification Traceability Procedure including process flow, materials and process control and drawings, among others;

5.1.6 List of test and measuring equipment with nominal capacities and serial numbers at each inspection point and final product testing together with the evidence of ownership, such as but not limited to Official Receipts;

5.1.7 Brief description of equipment maintenance and calibration program for all testing and measuring equipment with their corresponding calibration certificates;

5.1.8 Copies of labels, markings, and logos as per requirements of specific standard and this Technical Regulation;

5.1.9 Vicinity map of the factory; and

5.1.10 Oath of undertaking to abide by the Terms and Conditions of the License, respectively signed by the manufacturer/ local office or agent/ importer.

## 5.2 PS License Application Process

5.2.1 Each PS License application shall be factory, plant or site-specific and importer, local office or agent-specific.

5.2.2 For foreign manufacturers, only one local importer per license shall only be allowed. As such, when another local importer wants to import the same product from the same foreign manufacturer, a separate PS License application shall be filed.

5.2.3 Conduct of Factory and Product Audit

5.2.3.1 Upon submission and confirmation of the completeness and compliance of the documentary requirements, an assessment of the Quality Management System's conformity to PNS ISO 9001 and product specifications' conformity to specific applicable version of PNS shall be conducted;

5.2.3.2 Audit shall be undertaken by either the BPS, DTI Regional/Provincial Office (RO/PO), or BPS-recognized auditing bodies based on established audit procedure. Only recognized auditing bodies in the BPS official list may be designated as auditors; and

5.2.3.3 During the audit, samples shall be drawn for all model per brand of the product to be certified for the purpose of in-plant and independent testing. Independent testing shall be conducted only by BPS-recognized testing laboratory.

5.2.3.4 If there are non-conformities noted during the audit, the auditors shall inform the company and require them to undertake corrective actions. The auditors shall accomplish the non-conformity report for the non-conformities observed which shall be acknowledged by the company's authorized representative.

5.2.3.5 The company shall implement and complete the corrective actions within three (3) months for initial audit and one (1) month for surveillance and product inclusion audit. If the company fails to implement the corrective actions within the specified period, it should be a cause for denial of PS application or suspension of the PS License.

5.2.4 If the applicant is a foreign-based manufacturer, the application shall, for purposes of accountability, be made and filed by its local branch or representative office or representative agency who must be duly registered in accordance with Philippine laws;

5.2.5 The PS License shall only be issued upon satisfactory evaluation of the results of factory audit and determination of product conformance to the specific PNS based on pertinent test reports;

5.2.6 If the evaluation of the factory audit report showed unsatisfactory results, the PS License shall not be issued. Only after the re-assessment and subsequent product compliance shall the BPS issue the PS License;

5.2.7 The PS License shall be effective from the date of issuance and with full force and effect for a period of three (3) years, subject to the surveillance audits prescribed herein. PS License can be suspended, withdrawn or cancelled at any time for cause and after due process;

5.2.8 For renewals, the PS License holder must, through written notice, coordinate with BPS or the DTI RO/PO for a schedule of the re-certification audit at least six (6) months before the expiration date. Otherwise, the PS License shall be considered expired immediately after the end period of its validity.

5.2.9 In case of changes materially affecting the PS License and/or license holder's ability to comply with BPS product certification requirements, the license holder shall inform BPS in writing within one (1) month prior to the date the changes will take effect. Otherwise, appropriate action shall be undertaken by BPS.

5.2.9.1 Changes may include, but shall not be limited to, change in management or business name; transfer of plant site; modification of product design and/or specifications. Product audit may be necessary subject to the approval of BPS

5.2.9.2 A PS License may be transferred from one importer to another only after the receipt of written request from the foreign manufacturer, current importer, and the new importer.

## Rule 6. FILING / PROCESSING OF APPLICATION FOR STATEMENT OF CONFIRMATION OR IMPORT COMMODITY CLEARANCE FOR IMPORTED VAPORIZED NICOTINE AND NON-NICOTINE PRODUCTS

6.1. The importer shall apply for either Statement of Confirmation (SOC) for PS certified vaporized nicotine and non-nicotine products or Import Commodity Clearance (ICC) for non-PS certified vaporized nicotine and non-nicotine products on a per shipment per Bill of Lading/Airway Bill basis. The duly accomplished and subscribed application form shall be supported by the following:

6.1.1 For sole proprietorship registered with DTI, the application shall be accomplished and signed by the owner and filed by the owner or by a duly authorized representative by virtue of a notarized Special Power of Attorney (SPA); or

For Corporation/Partnership registered with SEC, the application shall be accomplished and signed, and filed by any officer or organic employee, duly authorized by virtue of a notarized board/partnership resolution or Secretary's Certificate;

6.1.2 Packing List;

6.1.3 Commercial Invoice;

6.1.4 Bill of Lading;

6.1.5 Summary of the production batch/lot/serial numbers;

6.1.6 DTI Business Registration Certificate for sole proprietorship or Latest SEC Registration Certificate and Articles of Incorporation/Partnership for corporation/partnership;

6.1.7 List of distributors/retailers with their complete addresses and contact details;

6.1.8 Proof of ownership or contract of lease of warehouse;

6.1.9 Import Entry (may be submitted later prior to release of the certificate);

6.1.10 Surety Bond; and

6.1.11 Copy of PS License for SOC applications

6.2. The application for SOC/ICC shall be processed as follows:

6.2.1 **Application for Statement of Confirmation (SOC)**

6.2.1.1 The applicant shall submit the duly accomplished and subscribed application form and requirements to the BPS.

6.2.1.2 Upon receipt of the application and complete requirements, a Certificate of Conditional Release shall be issued, subject to the conditions stated therein.

6.2.1.3 Product inspection shall be conducted by the BPS, DTI RO/PO or the BPS-recognized inspection body at the declared warehouse in accordance with the applicable provisions hereof. The original inspection report shall be sent directly to the BPS by the BPS-recognized inspection body within two (2) working days from the date of inspection.

6.2.1.4 If inspection shows that the product shipped is consistent with the importation documents (e.g. quantity, product description, markings, etc.), SOC shall be issued by the BPS Bureau Director or his duly designated representative. Otherwise, a Show Cause Order shall be issued and the provisions hereto shall apply.

6.2.1.5 The BPS shall have the prerogative to require sampling and testing to verify the consistent conformance of the product to the standard as amended/updated as well as the compliance of the manufacturer to the provisions of this Order and other applicable rules and regulations.

6.2.2 **Application for Import Commodity Clearance (ICC)**

6.2.2.1 Processing of applications under this scheme replaces the ICC Scheme under DAO 5:2008, subject to the requirements and transitory provision stated herein.

6.2.2.2 The applicant shall submit the duly accomplished and subscribed application form and requirements to the BPS.

6.2.2.3 Upon receipt of the application and complete requirements, a Certificate of Conditional Release shall be issued, subject to the conditions stated therein.

6.2.2.4 Product inspection and drawing of samples shall be conducted by the BPS, DTI RO/PO or the BPS-recognized inspection body at the

declared warehouse in accordance with the applicable provisions hereof. The original inspection report shall be sent directly to the BPS by the BPS-recognized inspection body within two (2) working days from the date of inspection.

6.2.2.5 If inspection shows that the product shipped is consistent with the importation documents, the issuance of ICC shall be recommended subject to the satisfactory result of testing. Otherwise, a Show Cause Order shall be issued and the provisions hereto shall apply.

6.2.2.6 The drawn samples shall be submitted by the applicant to the BPS-recognized testing laboratory within three (3) working days from the date of inspection and sampling for the conduct of testing.

6.2.2.7 If the result of the test shows conformance, the ICC shall be issued by the BPS Bureau Director or his duly designated representative. Otherwise, the provisions under Rule 9.3.3 of this Order shall apply.

6.3. The importer shall inform BPS in writing if there are any revisions in the information provided in the application and seek approval of such prior to the conduct of inspection and/or verification. Otherwise, appropriate action shall be undertaken by BPS.

**Rule 7. INSPECTION/ AUDIT AND SAMPLING**

7.1 Inspection/audit and sampling shall be conducted by the BPS, DTI RO/PO or the BPS-recognized auditing body/inspection body in accordance with existing BPS Audit, Inspection and Sampling Procedure.

7.2 If inspection/audit and sampling cannot be conducted within the prescribed period, the concerned DTI RO/PO or the BPS-recognized Inspection Body shall inform the BPS in writing of the reason/s thereof within sixteen (16) working hours upon receipt of the notice to conduct inspection. Under justifiable reasons, inspection and sampling may be re-scheduled, otherwise, appropriate action shall be undertaken.

7.3 **Sampling Size**

To determine the specific number of samples for vaporized nicotine and non-nicotine products the table below shall apply:

| Product | Samples per set | |
|---|---|---|
| | **Independent testing** | **In-plant testing** |
| Vapor product device | 2 vapor product devices | 1 vapor product device |
| Vapor product system | 4 vapor product devices, ≤ 110 ml product refills[24] | 1 vapor product device |
| Heated tobacco system | 60 heated tobacco products[25], 62 tobacco heating devices | 5 tobacco heating devices |
| Electrical accessory | 2 pieces per electrical accessory | NA |

[24] *Number of refills (ex. bottle, pods, cartridge) may be drawn to suffice the quantity of liquid required*
[25] *Average test samples shall be randomly selected for multiple/different type of heated tobacco products*

7.3.1 For ICC or SOC application (if necessary), two (2) sets of samples for independent testing of vaporized nicotine and non-nicotine products per model per brand shall be randomly drawn from the shipment at the importer's warehouse.

The first set shall be sent to the BPS-recognized testing laboratory for testing. The second set shall be kept by the importer as reserved samples.

7.3.2 For PS initial, surveillance or recertification, or inclusion audits, one (1) set of samples for in-plant testing of vaporized nicotine and non-nicotine products and two (2) sets of samples for independent testing of vaporized nicotine and non-nicotine products per model per brand, shall be randomly drawn from the manufacturer's production line, or warehouse.

The first set of samples shall be subjected for in-plant testing at the manufacturer's plant and shall be witnessed by the BPS-designated auditor/s. The second set shall be sent to the BPS-recognized testing laboratory for independent testing upon satisfactory result of the in-plant test. The third set shall be kept by the manufacturer as reserved samples for re-testing, if necessary.

7.3.3 For generic model, one (1) piece shall be drawn and be sent together with its base model to the BPS-recognized testing laboratory for actual verification purposes.

7.3.4 For PS applications, drawing of samples of the generic models for independent testing may be waived upon confirmation that it is similar to the declared base model based on the definition under Rule 3.22 of this Order through actual verification by the product auditor during the conduct of factory audit.

7.3.5 If upon verification of the BPS-recognized testing laboratory or the product auditor that the claimed generic model did not conform to the definition as stated in Rule 3.22 of this Order, complete set of samples shall be drawn and full product testing shall be required.

7.3.6 A set of samples shall include the vaporized nicotine and non-nicotine products together with the corresponding product information manual and individual product packaging.

7.3.7 If the product includes electrical accessories, the applicant shall be required to submit two (2) sets per electrical accessory per vaporized nicotine and non-nicotine products.

The first set shall be sent to the BPS-recognized testing laboratory for independent testing upon satisfactory result of the in-plant test. The second set shall be kept by the applicant as reserved samples.

## 7.4 Sampling Procedure

7.4.1 The BPS, DTI RO/PO, BPS-recognized auditing/inspection body, the PS applicant/license holder, and ICC applicant's authorized representative shall ensure that the drawn samples are traceable to the particular serial/lot/batch or shipment where they were drawn.

7.4.2 Test samples drawn shall be packed/sealed and signed in the presence of authorized representatives from BPS, DTI RO/PO or BPS-recognized auditing/inspection body who shall ensure that the Request for Test form is properly filled-up and signed by the manufacturer or importer.

7.4.3 The auditor or the inspector shall ensure that the Request for Test form together with the drawn samples is directly submitted to the BPS-recognized testing laboratory within three (3) working days from the date of audit/inspection and furnish BPS with a copy thereof within three (3) working days from submission. For foreign-based PS License holders/applicants, the auditor shall ensure that the samples drawn shall be shipped to the BPS-recognized testing laboratory within three (3) working days from the date of audit.

7.4.4 The BPS-recognized testing laboratory shall document properly the receipt of the product samples to include but not limited to taking pictures of the following:

7.4.4.1 Request for Test; and

7.4.4.2 Packaging of the samples as submitted and received

7.4.5 For PS initial audits and ICC applications, all brands, and models of the vaporized nicotine and non-nicotine products that will be covered by the PS license or ICC certificate shall be sampled.

7.4.6 For PS surveillance audit, at least one-third (1/3) of the brands, types, and models covered by the scope of the existing license shall be sampled or verified per surveillance audit. Any brands, types, and models that did not undergo sampling/testing or verification during the validity of the license shall be dropped from the scope of recertification.

**Rule 8. PRODUCT TESTING**

8.1. The drawn samples shall be tested by the BPS Testing Laboratory or other BPS-recognized testing laboratory.

8.2. The following Philippine National Standards (PNS) shall be used as references to determine the conformance of the vaporized nicotine and non-nicotine products covered in this Technical Regulation to the necessary requirements prescribed therein:

| Product | Reference Standard/s |
|---|---|
| Vapor product device | PNS AFNOR XP D90-300-1:2019 |
| Vapor product system | PNS AFNOR XP D90-300-1:2019,<br>PNS AFNOR XP D90-300-2:2019, and<br>PNS AFNOR XP D90-300-3:2019 |
| Heated tobacco system | PNS BSI PAS 8850:2022 |

8.3. The following Philippine National Standards (PNS) shall be used as references to determine the conformance of the electrical accessories (if any) covered in this Technical Regulation to the necessary requirements prescribed therein:

| Electrical Accessory | Reference Standard |
|---|---|
| All electrical accessories | PNS IEC 60950-1:2015 or<br>PNS IEC 62368-1:2021 |
| Adapters, external power supplies | PNS IEC 61558-1:2021 |
| Rechargeable batteries | PNS IEC 62133:2015 |
| USB chargers | PNS IEC 62680-3:2019 |

8.4 For vapor product device and system, conformance to the migration testing requirements shall be verified through the test methods prescribed by Commission Regulation (EU) No 10/2011 and Commission Regulation (EU) No 20/1245.

Overall migration limit is **10 mg per milligrams per square decimeter** and shall be performed with the following test conditions:

| Component | Contact temperature | Contact time | Food Simulant |
|---|---|---|---|
| Mouthpiece | 70 °C | 2 hours | Water |
| Tank | 70 °C | 2 hours | Ethanol 10% |

8.5. In addition to the parameters prescribed under the aforementioned reference PNS, the BPS Testing Laboratory or other BPS-recognized testing laboratory shall conduct test to verify that embossed/engraved/printed markings are legible and durable. Compliance shall be checked by inspection and by rubbing the marking by hand for 15 seconds with a piece of cloth soaked with water and again for 15 seconds with a piece of cloth soaked with petroleum spirit. After all the tests, the marking shall be clearly legible. It shall not be easily possible to remove marking plates nor shall they show curling. Result of the test on marking shall form part of the test reports to be submitted to the BPS.

8.6. **In-plant Test**

8.6.1 Under the PS Licensing Scheme, the manufacturer shall demonstrate its capability to manufacture products consistently conforming to the requirements of the relevant PNS and this Technical Regulation. For this purpose, the manufacturer shall have the capability to conduct the following minimum test parameters under the reference PNS stated in Rule 8.2 herein using its own inspection, measuring, and testing equipment to be witnessed by the auditor during the conduct of factory audit:

8.6.1.1 **Vapor product device**

8.6.1.1.1 Tests for Mechanical Risks
8.6.1.1.2 Tests for Thermal Risks

8.6.1.2 **Heated tobacco system**

8.6.1.2.1 Tests for Electrical Safety - Under PNS BSI PAS 8850, electrical safety test is conducted through the use of IEC 60335-1. Minimum test parameters to be conducted in-plant shall be as follows:

a. Marking and instructions
b. Protection against access to live parts
c. Power input and current
d. Heating
e. Mechanical strength

8.6.2 The manufacturer shall establish a system to ensure the full and consistent compliance of its finished products to the requirements of the relevant PNS and this Technical Regulation.

8.7. Considering the regular updating of standards, the latest edition of the PNS shall be used as reference. It is understood that future amendments of the PNS used in this Order shall be effective 24 months after its promulgation to provide ample time to all stakeholders to adjust and conform to the new requirements, if any.

8.8. The original test reports shall be sent directly to the BPS by the BPS-recognized testing laboratory together with the pictures of samples as received, pictures of samples showing the required markings, and copy of the Request for Test.

8.9. The BPS reserves the right to be present at any point of the certification process.

**Rule 9. EVALUATION OF RESULTS**

9.1. The test reports shall be evaluated based on the requirements of the relevant standards and this Technical Regulation.

9.2. The PS License and ICC Certificate shall only be issued upon determination of compliance to the safety and performance requirements of the vaporized nicotine and non-nicotine products and its electrical accessories (if any).

9.3. If the drawn samples failed the required tests, the BPS shall:

9.3.1. **For PS application**

9.3.1.1. For new and extension of the scope applications, inform the applicant of the result and direct the same to undertake corrective measures otherwise, the application shall be denied.

If corrective measure was undertaken, applicant shall submit propose corrective measures. If approved another product audit shall be conducted.

9.3.1.2. For PS surveillance/recertification, inform the applicant of the result and suspension/cancellation order in accordance with Rule 18.2 and Rule 18.3 of this Order. BPS shall give order to submit the reserved samples for testing otherwise, if the applicant refused to submit the reserved samples and opted to undertake corrective measures, a Product Recall Order shall be required in accordance with Rule 15 of this Order.

If corrective measure was undertaken, applicant shall submit propose corrective measures. If approved another product audit shall be conducted.

If the reserved samples passed the testing, the suspension/ cancellation order shall be lifted otherwise the suspension/ cancellation order shall be maintained and Product Recall Order shall be required in accordance with Rule 15 of this Order.

The suspension/cancellation order shall only be lifted upon the compliance of the applicant to this Order and the conformance of the product to the relevant Philippine National Standard.

9.3.2. **For SOC application**

9.3.2.1. Considered as surveillance activity, the provisions of Rule 9.3.1.2 shall apply.

9.3.3. **For ICC application:**

9.3.3.1. Inform the applicant of the result and present the following options:

9.3.3.2. Submit the reserved samples for testing;

9.3.3.3. Undertake remedial or corrective measures subject to actual inspection, verification, inventory, and re-sampling (if necessary) by the BPS, DTI RO/PO, or the BPS-recognized inspection body;

9.3.3.4. Export the shipment back to the country of origin, at its own expense, subject to inventory and inspection by an authorized DTI/BPS representative prior to the exportation. Export documents (i.e. Bill of Lading and Import Entry or any other document that will serve as proof that the non-compliant products arrived at the country of origin) shall be submitted by the applicant to the BPS; or

9.3.3.5. Destroy the non-conforming products in accordance with existing rules and regulations, at its own expense, and to be witnessed by a duly authorized DTI/BPS representative. Inspection and inventory shall be conducted by the DTI/BPS representative prior to the actual destruction.

9.3.4. **For rejected shipment, lot or batch:**

9.3.4.1. Notwithstanding the acceptance of the shipment/batch, any non-conforming lots found during inspection and/or testing, whether forming part of the sample or not, shall be rejected.

9.3.4.2. The importer or manufacturer at its own expense, shall either export to the country of origin or destroy the non-conforming product in the presence of DTI authorized representative and other relevant government agencies/authorities in accordance with existing ru0les and regulations within ninety (90) days from the notice of rejection of shipment, lot or batch.

**Rule 10. DISPOSAL OF SAMPLES**

10.1. Tested samples which complied with the requirements of the standard as well as the unused samples shall be retrieved by the manufacturer and/or importer within fifteen (15) days from receipt of notice of retrieval from the concerned testing laboratory, copy BPS. If the importer/manufacturer fails to claim the samples after the said period, the testing laboratory shall, with due notice to BPS and the manufacturer and/or importer, dispose the samples in a manner deemed appropriate in accordance with existing accounting and auditing rules.

10.2. Samples which fail to comply with the specified requirements shall be stored for at least six (6) months in the laboratory to ensure their availability in the event the importer/manufacturer contests the result of the test including those subject of litigation.

## Rule 11. MARKING REQUIREMENTS

For traceability and verification purposes, the required markings for manufactured or imported vaporized nicotine and non-nicotine products shall be available at all times for verification by the BPS, FTEB, DTI RO/PO, and their authorized representatives.

The required markings and information shall comply with their relevant PNS, Consumer Act of the Philippines (Republic Act No. 7394) and the following:

### 11.1 Embossed/engraved/printed on the device

11.1.1 Model Name;
11.1.2 Brand Name or Trade Name; and
11.1.3 Serial or Batch Number

### 11.2 Individual packaging of the device

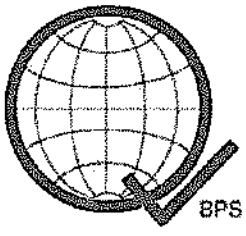
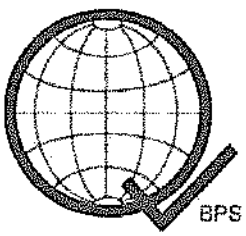
11.2.1 Model Name;
11.2.2 Trade Name;
11.2.3 Serial or Batch Number;
11.2.4 Manufacturing date; and
11.2.5 PS or ICC Mark, as applicable.

**Philippine Standard (PS) Certification Mark Logo**

11.2.5.1 For vapor product system and heated tobacco product system certified as conforming to the safety and performance requirements, the design of the PS Mark shall be in accordance with Figure A.

11.2.5.2 For vapor product device certified as conforming to the safety requirements, the design of the PS Mark shall be in accordance with Figure B.

The PS Mark affixed on a product or its package may be enlarged or reduced to an appropriate size provided that its dimensions conform to specifications in Figure A or Figure B.

| | |
|---|---|
|  CERTIFIED Product Safety and Quality License No. Q-XXXX |  CERTIFIED Product Safety License No. Q-XXXX |
| **Figure A** | **Figure B** |

### 11.3 Product Information Manual

11.3.1 Technical Specifications of the vaporized nicotine and non-nicotine products;
11.3.2 Detailed diagram of the device showing all part;
11.3.3 Material composition of the device;
11.3.4 Shall comprise of how to use, handle, and maintain its electrical accessories, if any;
11.3.5 Original and replacement electrical accessories shall mention their operating characteristics and their compatibility, and
11.3.6 Shall be written in an official language (English or Filipino)

### 11.4 Embossed/engraved/printed on the electrical accessory

11.4.1 Model Name;
11.4.2 Brand Name or Trade Name; and
11.4.3 Serial or Batch Number

## Rule 12. TERMS AND CONDITIONS OF THE PS LICENSE

The PS License holders and importers shall abide by the following terms and conditions:

12.1. Consistently abide by RA 4109, EO 133: 1987, EO 913: 1983 and RA 7394 and their implementing rules and regulations, and orders which the BPS issues in pursuance with its authority under the law.

12.2. Ensure that the certified product conforms at all times to a specific standard as amended/updated and its implementing rules and regulations.

12.3. Warrant that it has the authority to use the brand name, trade name and trademarks indicated in the application form.

12.4. Be held liable for any damages that its product might cause to their consumers.

12.5. The Product Certification Mark shall not be affixed on any products not covered by the license issued by BPS.

12.6. Establish and maintain systems of product recall and of addressing complaints filed by its clients or customers concerning its certified products, and shall maintain records thereof.

12.7. Give duly-authorized representatives of the BPS or DTI RO/PO or, in the case of foreign companies, BPS or BPS-recognized CABs, full access to the premises where the certified product is manufactured/assembled/stored; to relevant equipment, records, personnel and subcontractors for purposes of investigating complaints or evaluating consistency of compliance with the requirements of this technical regulation;

12.8. Maintain a record of all complaints made known to it, relating to compliance with certification requirements and make these records available to BPS or its authorized representative/s when requested; take appropriate action with respect to such complaints and any deficiencies found affecting such product's conformance to the requirements for certification; and, document the action taken, subject to verification by the BPS or its authorized representative/s.

12.9. Submit itself to surveillance activities to ensure consistent compliance with the BPS requirements of the Product Certification Scheme.

12.10. In case of subcontracts, shall assume full responsibility for its sub-assemblies', semi-finished and finished products' conformance to the specific requirements.

12.11. Inform BPS in writing of any changes that will materially affect its PS License and its ability to comply with BPS product certification requirements within one (1) month prior to the date the change will be made, such as, but not limited to change in management, business name, addition of brand name, modification of product's designs and specifications and/or transfer of plant site.

12.11.1. If the change involves addition of brand name and modification in the product's design or specifications, BPS shall facilitate the conduct of appropriate product certification activity;

12.11.2. In case of transfer of plant site, BPS, DTI RO/PO, or BPS-recognized auditing bodies shall conduct factory and product audit at the new site.

12.12. Pay the applicable fees and other charges as billed or stipulated by BPS, its duly recognized inspection and/or certification bodies.

12.13. Any incorrect references to the certification scheme; misleading use of PS License, SOC, or any other mechanisms indicating that a product is certified found in documentation or publicity materials or any breach hereof, shall be a ground for the issuance of Show Cause Order.

12.14. Traders or retailers in possession of covered products whose PS Licenses have expired or have been suspended, recalled, withdrawn, revoked or cancelled shall be notified in writing of such suspension, recall, withdrawal, revocation or cancellation.

12.15. Upon suspension, recall, withdrawal, cancellation or revocation of the PS License, the holder shall discontinue the manufacture and/or use of covered products including advertising materials relevant thereto and shall take action as may be required by the BPS.

12.16. Agrees that all information stated in the application shall be treated as proprietary and regarded as confidential except for those information indicated in the PS License and Certificate which is considered public document. The confidential information shall not be disclosed to any third party without prior consent, unless required by the law.

12.17. The PS License is non-transferable.

Any infractions of the foregoing shall be a ground for the suspension, withdrawal or cancellation of the license.

**Rule 13. TERMS AND CONDITIONS OF THE SOC/ICC APPLICATION/CERTIFICATE**

The SOC/ICC applicants and holders shall abide by the following terms and conditions:

13.1. Consistently abide by RA 4109, EO 133: 1987, EO 913: 1983 and RA 7394 and their implementing rules and regulations, and orders which the BPS issues in pursuance with its authority under law.

13.2. Give duly-authorized representatives of the BPS or DTI RO/PO or BPS-recognized inspection bodies full access during working hours to the declared warehouse for the purpose of inspection, sampling and inventory.

13.3. SOC/ICC Applicant shall abide by the conditions stipulated in the Certificate of Conditional Release issued by BPS.

13.4. Ensure that the certified product conforms at all times to applicable standard as amended/updated and its implementing rules and regulations.

13.5. Be held liable for any damages that its product might cause to their consumers.

13.6. The ICC stickers shall not be affixed on any products not covered by the ICC Certificate issued by BPS.

13.7. The SOC, and ICC Certificate shall not be used in any misleading manner.

13.8. Establish and maintain a system of product recall and of addressing complaints filed by its clients or customers concerning its certified products, and shall maintain records thereof.

13.9. Pay the applicable fees and charges as billed or stipulated by BPS, DTI RO/PO, and/or BPS-recognized inspection bodies and /or BPS-recognized testing bodies.

13.10. Agrees that all information stated in the application shall be treated as proprietary and regarded as confidential except for those information indicated in the SOC/ICC Certificate which is considered public document. The confidential information shall not be disclosed to any third party without prior consent, unless required by the law.

Any infractions of the foregoing shall constitute sufficient grounds for the institution of administrative sanctions/fines against the SOC/ICC applicant/holder.

**Rule 14. REQUIREMENTS IN CASE OF NON-CONFORMANCE**

For covered vaporized nicotine and non-nicotine products that do not conform to the requirements of BPS rules and regulations/guidelines, the following provisions, on a per shipment basis, shall apply:

14.1. A SHOW CAUSE ORDER shall be issued by BPS or DTI-RO/PO giving the PS License holder or the importer opportunity to explain within fifteen (15) days from receipt why its Surety Bond shall not be forfeited in favor of DTI and/or why a formal charge shall not be filed. This may include a CEASE AND DESIST ORDER addressed to the owner/manager or the authorized representative of the company concerned, to refrain from supplying, distributing, selling or displaying for sale the products subject thereof until such time that the Show Cause Order is lifted.

14.2. If the explanation to the Show Cause Order is not acceptable, the BPS or DTI-RO/PO shall direct the manufacturer and/or importer concerned to submit a sworn affidavit undertaking to do the following as directed whichever is applicable:

14.2.1 Permanently cease and desist from manufacturing, supplying, distributing, selling or displaying for sale the non-conforming products subject thereof;

14.2.2 Effect a full product recall to account such products that are already in circulation through publication in a newspaper of national circulation, giving the public a minimum of thirty (30) days from the second publication within which to return subject products. The product recall shall specify the basis or ground therefor. The manufacturer/importer/distributor shall keep BPS informed in writing on the progress of the recall. Such publication shall include a NOTICE warning the public that the product subject thereof is not compliant with the safety requirement; and

14.2.3 Recognize BPS authority to forfeit the Surety Bond.

**Rule 15. PROCEDURES AND REQUIREMENTS FOR PRODUCT RECALL**

After the product is declared by the BPS to be non-conforming, the BPS shall immediately notify the manufacturer and/or importer. The manufacturer and/or importer shall within fifteen (15) days from receipt of notice implement product recall in accordance with the following:

15.1. The recall order shall be published in a newspaper of general circulation for at least two (2) consecutive Saturdays/Sundays;

15.2. The layout, content, font and size of the recall order shall be prescribed by the BPS;

15.3. The recall period shall be for a minimum of thirty (30) days from date of the second publication;

15.4. Proof of publication of the recall orders shall be submitted to the BPS or the DTI RO/PO;

15.5. Inventory of the recalled products shall be submitted to BPS or DTI RO/PO;

15.6. Recalled products shall be condemned, destroyed, or otherwise disposed of in accordance with applicable rules on disposal issued by the DTI, Department of Budget and Management, and Commission on Audit.

15.7. The manufacturer and/or importer shall compensate parties availing of the recall order.

**Rule 16. FEES, CHARGES, BOND REQUIREMENT AND OTHER EXPENSES**

16.1. All corresponding fees, charges, costs, and other related expenses shall be for the account of manufacturer/importer.

16.2. Fees and charges to be paid by the applicant in accordance with Annex A shall be as follows:

16.2.1. Application Fee;

16.2.2. Audit/inspection fees;

16.2.3. Transportation/travelling expenses, and board and lodging costs of auditor/s and inspector/s during audit/inspection, subject to existing rules and regulations or third-party provision;

16.2.4. Processing Fee of Statement of Confirmation/Import Commodity Clearance on imported products (non-refundable, payable upon releasing of the application on per product, per shipment, per Bill of Lading/Airway Bill basis, assessed by the BPS based on the amount declared in the Invoice);

16.2.5. PS License fee for manufactured products;

16.3. For imported vaporized nicotine and non-nicotine products, a Surety Bond amounting to One Hundred Fifty Thousand Pesos (PhP 150,000.00) shall be posted on a per shipment, per Bill of Lading/Airway Bill basis.

16.4. Any violation of the terms and conditions of the Product Certification Scheme shall, upon notice, result in the *motu proprio* forfeiture of the bond based on the non-conformity or non-compliance stated herein.

**Rule 17. SHOW CAUSE ORDER AND BOND FORFEITURE**

17.1 A Show Cause Order shall be issued against a manufacturer or importer who fails to comply with legal and technical requirements or whose product/s failed to conform to such requirements, unless the manufacturer or importer can justify under oath that the non-conformity is correctible and/or the non-compliance is negligible.

17.2 A Cease and Desist Order may be issued simultaneously with the Show Cause Order directing the manufacturer and/or importer to refrain from manufacturing, selling, distributing or disposing the products in any manner.

17.3 Any violation of the Terms and Conditions of the Certificate of Conditional Release and/or provisions of this Order shall, upon notice, result in *moto proprio* forfeiture of the Surety Bond.

17.4 Pending resolution of the Show Cause Order involving a particular shipment, applications filed after the issuance of the Show Cause Order by the same importer may be processed, provided, a sworn undertaking to abide by the decision on said Show Cause Order shall be submitted prior to the issuance of the necessary Certificate/License for succeeding application/s.

**Rule 18. SUSPENSION, WITHDRAWAL, AND CANCELLATION OF PS LICENSE**

18.1 A duly issued PS License shall be suspended, recalled, withdrawn, cancelled or revoked based on any of the following grounds:

18.1.1 That the product bearing the PS Mark failed to conform to the requirements of a specific PNS as amended/updated;

18.1.2 That licensee failed to comply with monitoring, surveillance or enforcement notices/directives/orders;

18.1.3 That the licensee failed to comply with the terms and conditions of the license;

18.1.4 That the licensee made false statements or alterations in connection with its application for or re-certification of the license;

18.1.5 That the licensee violated any of the provisions of this Order;

18.1.6 That an Order of Execution vis-à-vis a decision finding the licensee liable for violation of a trade and industry law/s or rules and regulations directing BPS to suspend/cancel or revoke the PS License issued in favor of said licensee;

18.2 The license shall be suspended, recalled, withdrawn, cancelled or revoked after the BPS Director has served the licensee a notice of his intention to do so, stating therein the grounds for the contemplated action, granting the licensee the opportunity to be heard within fifteen (15) days from the date of notice.

18.3 If there is a final finding that a product does not conform to the specified technical requirements, the license shall, upon mere notice be immediately suspended, withdrawn, recalled, cancelled or revoked.

Notwithstanding the preceding provisions, the BPS Director may direct that a Formal Charge be filed against the party concerned pursuant to EO 913 Series of 1983, DAO No. 7, Series of 2006 and DAO No. 2, Series of 2007 and /or its future amendments.

**Rule 19. COMPLAINTS/APPEAL HANDLING PROCESS**

19.1 BPS shall implement a system of handling complaints/appeals related to the product certification process.

19.2 Remedies for the action or decision of a BPS personnel/chief/director relative to an application for PS License/SOC/ICC shall be the following:

19.2.1 In case of denial of the PS License/SOC/ICC application, the applicant may file a motion for reconsideration with the BPS Director within ten (10) working days from receipt of the letter of denial. No second motion for reconsideration shall be allowed;

19.2.2 In case of suspension, recall, withdrawal, cancellation or revocation of the PS License, a motion for reconsideration may be filed with the BPS Director by the licensee within ten (10) working days from receipt of the notice. No second motion for reconsideration shall be allowed.

19.3 In case the motion for reconsideration is denied, an appeal may be filed with the DTI Secretary within fifteen (15) calendar days from receipt of denial of the motion for consideration. The appeal shall be based solely on grounds of grave abuse of discretion amounting to lack or excess of jurisdiction committed by the official who rendered the decision.

19.4 The filing of a Motion for Reconsideration shall suspend the period to file an appeal.

**Rule 20. PROHIBITED ACTS**

The following acts are hereby declared prohibited, in addition to those listed in DAO No. 2, Series of 2007 and its future amendments, viz:

20.1 Use of the Product Certification Mark in any misleading manner;

20.2 Manufacture or production of covered products after the license is expired, suspended, withdrawn or cancelled;

20.3 Sale, offer for sale using over the counter or on-line mode or any form of advertisement of any vaporized nicotine and non-nicotine products not complying with the particular technical regulation or corresponding standard;

20.4 Non-compliance, neglect or resistance to effect the product recall as directed by BPS;

20.5 Misrepresentations, misleading or unauthorized statements and/or claims made in the application, letters/replies/forms in relation to product certification. Such include unauthorized reproduction of product certification documents, or any part thereof;

20.6 Submission of falsified documents or forging the signature of the Bureau Director or its designated representative; and

20.7 Non-compliance or failure to comply with the provisions hereof.

**Rule 21. PENALTIES OR SANCTIONS**

The following shall be imposed upon any manufacturer, importer, recognized testing laboratory/facility, or any other person or entity found in violation of any provision hereof after due process, as may be appropriate:

21.1 Administrative fine as per existing DTI Rules and Regulations/Department Administrative Orders and EO 913.

21.2 Cancellation or revocation of PS License pursuant to a final and executory decision rendered by an administrative agency or the regular courts.

21.3 Cancellation or revocation of recognition issued by the BPS.

21.4 Watch-listing and/or blacklisting of importers/manufacturers.

21.5 Any other sanctions or penalties as provided under existing DTI rules and regulations.

**Rule 22. ISSUANCE OF GUIDELINES/PROCEDURES**

BPS may issue such procedural guidelines as may be necessary in the implementation of this Order.

**Rule 23. REPEALING CLAUSE**

All provisions of existing Department Administrative Orders, circulars, and guidelines inconsistent with this Administrative Order are hereby repealed subject to the transitory provisions below.

## Rule 24. 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.

## Rule 25. TRANSITORY PROVISIONS

25.1 All manufacturers of vaporized nicotine and non-nicotine products covered in this Order may apply for voluntary certification using Rule 8 of this Order, procedures and requirements prescribed within eighteen (18) months after the date of effectivity of this Order.

25.2 All manufacturers and/or importers of vaporized nicotine and non-nicotine products shall be required to undergo the mandatory product certification procedures (PS or ICC certification) eighteen (18) months after the date of effectivity of this Order.

25.3 All vaporized nicotine and non-nicotine products that are already distributed or offered for sale in the local market or remaining inventories at the manufacturer's plant or warehouse prior to the effectivity of mandatory certification shall apply for a certification within twelve (12) months after the date of mandatory certification. The application shall be supported by the following:

25.3.1 Summary of Products being applied for Certificate of Exemption listed in accordance to the format provided in Annex B.
25.3.2 Any documentary proof that the products are locally manufactured or imported prior to the effectivity of this Order (e.g. Production Records, Import Entry, Bill of Lading, Notice of Arrival, etc.)

Certificate of Exemption and corresponding mark shall be issued upon satisfactory result of evaluation.

25.4 To ensure strict compliance, monitoring and enforcement shall be conducted thirty (30) months after the date of effectivity of this Order. After this period, only vaporized nicotine and non-nicotine products bearing a valid PS Mark, ICC stickers or other BPS-issued certification mark shall be sold, offered for sale or distributed in the local market. All non-compliant products shall be subjected to the following:

25.4.1 First Offense – Notice of Violation shall be issued but retailers/distributors shall only be advised to pull-out the items from the selling area.

25.4.2 Second Offense onwards – Notice of Violation shall be issued subject to the regular adjudication process.

25.5 In the absence of a BPS-recognized testing laboratory, the PS License applicants/holders shall nominate a testing laboratory accredited by an accreditation body signatory to ILAC/APAC MRA to conduct the product testing as per Rule 8 of this Order.

25.6 Meanwhile, in lieu of product testing under the Import Commodity Clearance Certification Scheme, the importers shall warrant that the vaporized nicotine and non-nicotine products they import into the country conform to the relevant

Philippine National Standards through the following:

25.6.1 Importers shall submit supplier's/manufacturer's declaration of conformity on a per shipment per Bill of Lading/Airway Bill basis;

25.6.2 Copy of valid test report for each energy vaporized nicotine and non-nicotine products issued within one (1) year from the date of issuance by a testing laboratory accredited by an accreditation body signatory to ILAC/APAC – MRA; and

25.6.3 Copy of valid ISO 9001 Certificate of the manufacturer

25.7 It is understood that the requirements stated in Rules 25.5 and 25.6 of this Order shall cease to be implemented once a BPS-recognized testing laboratory is available.

**Rule 26. EFFECTIVITY**

This Order shall take effect upon fifteen (15) days after its publication in a national newspaper of general circulation, a copy of which shall be submitted to the UP Office of National Administrative Register.

Done in the City of Makati this 15th day of June in the year 2022.

**Recommended by:**

**NEIL P. CATAJAY**
Director
Bureau of Philippine Standards

per DO 22-60

**ATTY. RUTH B. CASTELO**
Undersecretary
Consumer Protection Group

**Approved:**

**RAMON M. LOPEZ**
Secretary

*ANNEX A*

## TABLE 1: SCHEDULE OF FEES AND CHARGES FOR BPS PS LICENSING

| | PARTICULARS | FEE | PAYABLE TO |
|---|---|---|---|
| 1 | Application Form | Php 300.00 | DTI |
| 2 | Quality Manual Review | Php 5,000.00 | |
| 3 | Pre-Audit / Audit / Surveillance Audits per Man-Hour (Payable within 15 days after billing) as per size of establishment based on Table 1A | | |
| 3.1 | Micro | Php 100.00 or as charged by Designated Auditing Body | DTI / Designated Auditing Body |
| 3.2 | Small | Php 300.00 or as charged by Designated Auditing Body | |
| 3.3 | Medium | Php 400.00 or as charged by Designated Auditing Body | |
| 3.4 | Large | Php 500.00 or as charged by Designated Auditing Body | |
| 4 | Original License Fee* (Payable within 15 days after billing) | | |
| 4.1 | Micro | Php 5,000.00 | DTI |
| 4.2 | Small | Php 7,500.00 | |
| 4.3 | Medium | Php 10,000.00 | |
| 4.4 | Large | Php 12,500.00 | |
| 5 | Annual License Fee* (Payable within 15 days after billing) | | |
| 5.1 | Micro | Php 2,500.00 | DTI |
| 5.2 | Small | Php 3,750.00 | |
| 5.3 | Medium | Php 5,000.00 | |
| 5.4 | Large | Php 6,250.00 | |
| 6 | Transportation | As per arrangement (if necessary) | DTI / Designated Auditing Body |
| 7 | Hotel Accommodation | As per arrangement (if necessary) | DTI / Designated Auditing Body |
| 8 | Testing Fee | As charged by Designated Testing Laboratory | BPS-Recognized Testing Laboratory |
| 9 | Freight Charges of Samples | As charged by Freight Forwarder | Freight Forwarder |
| 10 | Market Sample | As per Official Receipts / Sales Invoice | Manufacturer/Importer |

## TABLE 1A: SIZE OF ESTABLISHMENT

| SIZE OF ESTABLISHMENT | ASSETS |
|---|---|
| Micro | Up to Php 3,000,000.00 |
| Small | Php 3,000,001.00 up to Php 15,000,000.00 |
| Medium | Php 15,000,001.00 up to Php 100,000,000.00 |
| Large | Over Php 100,000,000.00 |

## TABLE 2: SCHEDULE OF FEES AND CHARGES FOR THE IMPORT COMMODITY CLEARANCE (ICC) AND STATEMENT OF CONFIRMATION (SOC)

| PARTICULARS | FEE | PAYABLE TO |
|---|---|---|
| Application Fee | Php 300.00 | DTI |
| Processing Fee (depends on the value of the batch being applied for SOC/ICC) | | |
| Invoice/batch value up to **Php 500,000.00** | Php 5,000.00 | DTI |
| Invoice/batch value from Php 500,001.00 to Php 1,000,000.00 | Php 7,500.00 | |
| Invoice/batch value above **Php 1,000,000.00** | Php 10,000.00 | |
| Inspection Fee | As charged by the DTI / BPS Designated Inspection Body | DTI / Designated Inspection Body |
| Transportation | As per arrangement (if necessary) | DTI / Designated Inspection Body |
| Testing Fee | As charged by the BPS-Recognized Testing Laboratory | BPS-Recognized Testing Laboratory |
| Freight charges of samples | As charged by Freight Forwarder | Freight Forwarder |
| Market sample | As per Official Receipts/Sales Invoice | Manufacturer/Importer |
| ICC sticker | Php 1.56 per piece (subject to change as notified by the BPS) | DTI |

Notes:

- *Original and Annual License Fees depend on the size of establishment as stipulated on Table 1A herein.*
- *The Schedule of Fees and Charges in this DAO were adopted from DAO 04:2008 and DAO 05:2008.*

*ANNEX B*

**Application for Certificate of Exemption for Vaporized Nicotine and Non-Nicotine Products Manufactured and Distributed in the Market prior to the Mandatory Certification prescribed under DAO 22-___, Series of 2022**

Applicant Company: ☐ Local Manufacturer ☐ Importer

Name of Applicant Company:_____ Date: _____

Office Address: _____

Product: _____

Product Details:

| Type/ Model | Manufacturing Date *(if locally manufactured)* | Date of Arrival inthe Philippines *(if imported)* | Name of Manufacturer *(if imported)* | Country of Origin *(if imported)* | Value of Product (in PhP) | Store/Warehouse Address where the products are stored | Batch/Serial Nos. | Quantity |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

**Declared by:**

**Total = _____**

_____

Name and Signature of Company Representative