BUREAU OF
PRODUCT
STANDARDS

IMPLEMENTING GUIDELINES FOR ISSUANCE OF
PS QUALITY CERTIFICATION MARK LICENSE FOR
PNS 103: 1987 SPECIFICATION FOR
MEDICAL GRADE OXYGEN IN CYLINDERS

Pursuant to Republic Act 4109, Republic Act 7394, Executive Order No. 913 series
of 1983, Executive Order No. 101 series of 1967, Department Administrative Order No. 1,
series of 1997 and its future amendments and PNS 103:1987, the following implementing
guidelines is hereby issued for the information, guidance and compliance of all
manufacturers and/or refillers and other concerned stakeholders.

1.0 SCOPE

These guidelines specify the rules and regulations in the implementation of

2.0 DEFINITION OF TERMS

For the purpose of this implementing guidelines, the following definitions shall apply:

2.1 BPS - Bureau of Product Standards

2.2 DTI - Department of Trade and Industry

2.3 PS Quality and/or Safety Certification Mark License - Document issued by
BPS to a company authorizing its use of the PS Quality and/or Safety
Certification Mark on the products.

2.4 Manufacturer/Refiller - An entity engaged in the manufacture or refill of
medical grade oxygen in cylinders.

2.5 Wholesaler/Dealer/Retailer - An entity engaged in the sale of medical grade
oxygen.

2.6 Licensee - Manufacturer or refiller granted by BPS a License to use the PS
Quality Certification Mark License.

2.7 Test Samples – medical grade oxygen in cylinders picked out at random
from the batch either from the production line or warehouse.

2.8 Batch - group of the same products made on the same production line using
the same lot of materials during one production shift.

3.0 AUTHORITIES AND RESPONSIBILITIES OF THE DTI

3.1 In addition to the duties specified in DAO 1, series of 1997, BPS shall:

3.1.1 Inform licensees of any changes in the standard.
3.1.2 Maintain and disseminate a registry of PS Mark License Holders for medical grade oxygen.

3.1.3 Coordinate with the DTI Regional/Provincial Offices in the implementation of this implementing guidelines, especially in the conduct of factory and product audits relative to the BPS' Product Certification Mark Schemes.

3.1.4 Conduct final evaluation of all factory and product assessment reports and other relevant recommendations of the DTI Regional/Provincial Offices.

3.1.5 Issue, deny, or revoke licenses based on findings under clause 3.1.4.

3.1.6 Coordinate with DTI Regional or Provincial Offices and the DTI Office of Legal Affairs in identifying and implementing appropriate legal action against manufacturers and/or assemblers violating the above-stated laws, rules and regulations, department administrative orders, this implementing guidelines, the requirements of the specific standard, its implementing memoranda and circular.

3.2 DTI Regional/Provincial Offices

3.2.1 Conduct factory and product assessments on companies applying for PS Certification Mark License.

3.2.2 Conduct market monitoring and enforcement of Philippine National Standards.

3.2.3 Take legal action against violators of the standard, these implementing guidelines and other DTI rules and regulations.

4.0 APPLICATION FOR PS CERTIFICATION MARK LICENSE

4.1 Manufacturers and/or refillers of medical grade oxygens shall apply to BPS, through the DTI Regional/Provincial Offices, for the Philippine Standard (PS) Quality and/or Safety Certification Mark License.

4.2 Application forms for PS Certification Mark License shall be available for Php 300.00. Check payments shall be payable to DTI.

4.3 Application forms shall be completely filled-up by the applicant-company and duly notarized.

4.4 Application for PS Certification Mark License shall be filed in triplicate together with the following documents:

4.4.1 Articles of Incorporation or Business Name and Sub-Contracting Agreement, if any.
4.4.2 Quality Manual (Controlled Copy)
4.4.3 Brief description of manufacturing process
4.4.4 Listing 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 official receipts.

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

4.4.6 Copies of labels, markings and logos etc. as per requirements of specific standard.

4.4.7 Vicinity map of the factory.

4.5 Incomplete application forms and attachments shall not be processed accordingly.

5.0 FACTORY ASSESSMENT

5.1 After filing the duly accomplished application form, the applicant shall be informed by BPS/DTI Regional / Provincial Offices of the schedule of assessment.

5.2 DTI/BPS duly authorized representative shall visit the applicant company’s factory/plant with the aim of ascertaining that:

5.2.1 The quality management system of the applicant company complies with the requirements of DAO 1:1997.

5.2.2 The finished product under the processors existing conditions conforms to the requirements of PNS 103:1987 whichever is applicable.

5.2.3 The manufacturer/refiller shall have the following minimum test and measuring equipments:

5.2.3.1 Gas Chromatograph or Orsat Apparatus
5.2.3.2 Calibrated Gas Detector with accessories or infrared analyzer
5.2.3.3 Oil free Teflon diaphragm type vacuum pump
5.2.3.4 Pressure Gauge

6.0 PRODUCT ASSESSMENT

6.1 Sampling

A duly authorized DTI/BPS representative shall take three (4) cylinders to be subjected for testing; One (1) cylinder to be tested in-plant witnessed by a duly authorized DTI/BPS representative, and the other one (1) cylinder to be sent to BPS Testing Center or to BPS accredited or recognized testing laboratories for independent test. Three cylinders shall remain with the company in the event of failure in the independent test. It is understood that independent testing shall be conducted only upon the satisfactory results of in-plant test.
6.1.1 Test sample(s) shall be taken randomly either in the production or warehouse.

6.1.2 Test sample(s) for independent test shall be packed/sealed and signed in the presence of DTI/BPS representative and shall be shipped within ten (10) working days to the BPS Testing Center or to BPS accredited/recognized testing laboratory/ies by the manufacturer and/or refiller. BPS Testing Center shall issue acknowledgement of receipt of test samples.

6.1.3 The authorized DTI/BPS representative shall ensure that Request for Test form is properly filled-up and signed.

6.1.4 Prior to testing, there shall be no preparation, modification or adjustment, special quality control, testing or assembly procedure in any manner on a test sample or any parts and sub-assemblies thereof, that is not normally performed during production and assembly.

6.2 Testing

6.2.1 Test shall be done by BPS Testing Center or BPS accredited/recognized testing laboratory in accordance with the requirements of PNS 103: 1987. The following parameters shall be tested during the independent check.

- Purity
- Specific Impurities
  - Carbon Dioxide
  - Carbon Monoxide
  - Nitric Oxide & Nitrogen Dioxide
  - Water
- Odour

6.2.2 The official testing laboratory for medical grade oxygen samples shall be the Bureau of Product Standards Testing Center (BPSTC) and/or BPS accredited or recognized testing laboratories.

6.2.3 All test results shall be held strictly confidential by the BPSTC or BPS recognized/accredited laboratory/ies concerned. Copies furnished to the companies are for product certification purposes only.

6.3 Disposition of samples

6.3.1 After the cylinder has been tested, it will be returned to the manufacturer and/or refiller. The testing laboratory shall not be liable for whatever damage sustained by the test samples during transport and testing. Upon receipt of notice of disposal of test samples, the manufacturer and/or refiller arranges within one (1) month time to pick up the samples at BPS Testing Center. Otherwise, BPS shall dispose
the samples in a manner deemed appropriate, under existing accounting and auditing rules.

6.3.2 Samples that failed to comply with the requirements of PNS 103:1987 may be stored at the concerned test laboratory for reference purposes, in the event that the manufacturer and/or assembler contest the results of tests.

6.4 Non-compliance

6.4.1 Four samples per brand must have been tested by BPS or BPS recognized/accredited laboratory/ies before a declaration can be made that the product does not conform to the requirements of PNS 103: 1987.

6.4.2 If in the determination of BPS the first sample fails, the next three samples from the same lot shall be tested. If the retest passed, the lot is declared as conforming to the requirements of PNS 103: 1987.

6.4.3 If in the determination of BPS, both tests failed to conform to the requirements of PNS 103:1987, the manufacturer/refiller will be advised by DTI/BPS to undertake remedial measures.

6.4.4 Only after reassessment and subsequent product compliance shall the manufacturer and or assembler be allowed by BPS to market his product.

7.0 COMPLIANCE AND RESPONSIBILITIES OF THE PS LICENSEE

7.1 Compliance

7.1.1 When the results of factory and/or product assessments show conformity to the requirements specified in this implementing guidelines, PS Quality and/or Safety Certification Mark license will be issued to the manufacturer and/or refiller. Terms and condition of the license shall be governed by the provision of Department Administrative Order No. 1 Series of 1997, “Revised Rules Concerning the Philippine Standards (PS) Quality and/or Safety Certification Mark Scheme”.

7.2 Responsibilities of the PS Licensee

7.2.1 The licensee shall observe and abide by the provisions of R.A. 4109, E.O. 913, Series of 1983, E.O. 133, Series of 1987, R.A. 7394, DAO 1.1997 and their implementing rules and regulations and shall comply with any and all other directives and orders which the BPS may issue in pursuance with its authority under the law.

7.2.2 Every licensee shall ensure that his product, for which a license has been issued, conforms at all times to the requirements of PNS...
103:1987. For this purpose, he shall maintain to the satisfaction of BPS, a system of quality control including inspection and testing.

7.2.3 The licensee shall give the duly authorized representative(s) of the BPS or DTI Regional/Provincial Offices or in the case of foreign companies by BPS officially recognized counterparts National Standards Bodies, inspection and/or certification bodies, access during working hours to the premises where certified product is manufactured, for the purpose of evaluating materials, production processes, finished articles, quality assurance facilities, records and others in accordance with DAO 1:1997.

7.2.4 The licensee shall be subject to at least once a year audit to ensure consistent compliance with the BPS requirements on Philippine Standard (PS) Quality and/or Safety Certification Mark Scheme.

7.2.5 As part of the annual surveillance audit and wherever possible, samples of the certified product shall be drawn from the market in coordination with the company representative. Cost of samples drawn from the market shall be shouldered by the company. Upon the option of the BPS, samples may be drawn at the factory site when appropriate.

7.2.6 In cases of subcontracts, it is understood that the licensee shall assume full responsibility for the quality of sub-assemblies, semi-finished products of its subcontractor(s).

7.2.7 The licensee shall inform BPS in writing of any change of management, business name, brand and/or transfer of plant site. In the case of transfer of plant, notice must be made within one (1) month after such transfer is accompanied. For change or addition of brand name, DTI/BPS shall be notified for the necessary product audit.

7.2.8 Upon transfer of plant site, the license shall be deemed valid only after factory and product audit at the new site by BPS or DTI Regional/Provincial Office or in case of foreign companies by BPS officially recognized counterpart National Standard Bodies, inspection and/or certification bodies.

7.2.9 The licensee shall pay the applicable fees and charges as billed or stipulated by BPS or DTI Regional/Provincial Offices or BPS officially recognized counterpart National Standards Bodies, inspection and/or certification bodies.

7.2.10 The license to use the PS Quality and/or Safety Mark is non-transferable.

7.2.11 Any infraction of these implementing guidelines shall constitute sufficient grounds for the institution of administrative sanctions/fines against a licensee, which will include suspension, withdrawal,

7.2.12 Mention or an indication must be made in advertisements and other promotional materials of the licensee that its medical grade oxygens are certified under BPS’ PS Certification Mark Scheme.

8.0 PS CERTIFICATION MARK

8.1 The design of the PS Certification Mark shall be in accordance with the Attached Illustration.

8.2 The PS Mark shall be affixed on the portable fire extinguisher covered by the PS Certification Mark License.

8.3 The PS Certification Mark License shall not be used on any medical grade oxygen in a misleading manner.

8.4 The PS Mark shall be permanently fixed on the product, or in its packaging, whichever is practical covered by the corresponding PS Certification Mark License, in order to avoid its misuse.

8.5 The company shall use the PS logo corresponding to the PS License (to addressed PS Quality/PS Safety).

9.0 MONITORING

9.1 BPS / DTI Regional/Provincial Offices shall at any time monitor and inspect medical grade oxygens in the market for conformance to the requirements of PNS 103:1987. If the products are found not conforming to the standard, DTI/BPS shall make appropriate action or impose the necessary legal actions in accordance with the relevant laws, rules and regulations.

10.0 EFFECTIVITY

10.1 These guidelines shall take effect immediately.

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JESUS L. MOTOOMULL
Director

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Date

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