



ASSESSMENT TOOL FOR LICENSING A LABORATORY FOR DRINKING WATER ANALYSIS

Name of Laboratory: _____

Address: _____

Number & Address

Barangay/ Municipality

Province/City

Region

Contact No./Fax No./E-mail Address: _____

Application for: Initial
 Renewal

Accreditation No: _____ Date Issued: _____
 Expiry Date: _____

GENERAL INFORMATION:

Name of Owner or Governing Body (if corporation): _____

Name of Head of Laboratory: _____

Classification according to:

Ownership: Government Private

Institutional Character: Institution-Based Freestanding

Service Capability¹: Bacteriological Analysis Chemical Analysis
 Physical Analysis Radiological Analysis

Instructions:

- (1) Encircle (+) if item indicated is present, and (-) if item indicated is absent/ present but non-functional.
- (2) All items with (*) shall be posted in a conspicuously designated area.
- (3) Regulatory Officers will use this checklist during inspection/ monitoring prior to issuance of accreditation (initial/ renewal).

¹ Refer to Annex A – List of Parameters for Each Service Capability

² Philippine Nuclear Research Institute (PNRI) regulated



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STANDARDS	REFERENCE	FINDINGS		REMARKS
		INSPECTION	MONITORING	
1. <u>MANAGEMENT STANDARDS</u> 1.1 <u>APPLICATION DOCUMENTS</u> All application documents shall be valid and properly filled up. 1.1.1 <u>Documentary Requirements:</u> 1.1.1.1 List of Personnel ❗ Name ❗ Position ❗ Status: P-Permanent/ T-Temporary ❗ Educational attainment ❗ PRC registration number and validity (where applicable) ❗ Training ❗ Signature 1.1.1.2 List of Equipment/Instruments ❗ Name of equipment ❗ Date acquired with proof of purchase ❗ Quantity ❗ Functional status 1.1.1.3 Floor Layout ❗ Properly labeled areas with appropriate scale to include spatial relationship with adjacent areas if present.	AO No. 2006 – 0024	(+) (-)	(+) (-)	



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<p>1.1.1.4 Certificates and Permits</p> <p>The laboratory shall comply with the following certificates and permits, which shall be valid and current. They shall be filled up and posted conspicuously at the reception area.</p> <ul style="list-style-type: none"> ! DTI/ SEC registration * (for private lab) ! Enabling Act (for national government lab) ! Board Resolution (for local government lab) ! Proof of qualification for the *: <ul style="list-style-type: none"> • Head of Laboratory • Analyst ! Proof of ownership of the premises (valid and notarized to include location map) <p>1.1.1.5 Self –Assessment Tool</p> <ul style="list-style-type: none"> ! Properly accomplished and completed 		(+) (-)	(+) (-)	
<p>1.2 <u>MANAGEMENT RESPONSIBILITY</u></p> <p>The Laboratory shall be managed effectively, efficiently and in accordance with its mission, vision and objectives.</p> <p>1.2.1 <u>Mission, Vision and Objectives</u> *:-</p> <p>1.2.1.1 Mission, vision and objectives shall be in accordance with PD 856</p>	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-)	(+) (-)	



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1.2.2 Management/ Staff Meetings: 1.2.2.1 Held at least twice a year or as needed. 1.2.2.2 Documented minutes of the meeting (reflecting the date, time, attendance, agenda, and action taken) shall be present and properly filed <u>within</u> the lab.		(+)	(-)	(+)	(-)	
1.2.3 Continuing Program for Staff Development and Training: 1.2.3.1 There shall be a written continuing program on staff development and training. 1.2.3.2 Proof of training through certificates, memos, written reports, budgetary allocations, etc.		(+)	(-)	(+)	(-)	
1.2.4 Procedures for handling complaints and client feedback: 1.2.4.1 There shall be a written protocol for handling complaints/ client feedback. 1.2.4.2 Forms for complaints/ client feedback 1.2.4.3 Suggestion box and/ or equivalent, visible to clients 1.2.4.4 Records of complaints/ client feedback and actions taken		(+)	(-)	(+)	(-)	



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<p>1.3 <u>MANPOWER</u></p> <p>Personnel and practices shall be in place to ensure the achievement of the mission of the laboratory.</p> <p>1.3.1 <u>Staffing Pattern:</u></p> <p>1.3.1.1 Organizational chart *</p> <ul style="list-style-type: none"> ! Organizational chart shall be clearly structured indicating the names with pictures and designation. ! There shall be a minimum of three (3) laboratory personnel for each service capability³. ! There shall be a minimum of five (5) laboratory personnel for multi-service capability. <p>1.3.1.2 Duties and responsibilities</p> <ul style="list-style-type: none"> ! There shall be documented duties and responsibilities of all personnel reflecting lines of authority, accountability, communication, and interrelationship. ! Managerial and technical personnel shall have authority and resources needed to perform duties and responsibilities. 	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	

³ When the head of the laboratory is not a registered chemist, there shall be a minimum of four (4) laboratory personnel for chemical/ physical analysis.



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1.3.2 <u>Personnel Records:</u> All records shall be within the laboratory premises.				
1.3.2.1 Curriculum vitae ❗ Personal background ❗ Education ❗ Experience & Training		(+)	(-)	
1.3.2.2 Job description ❗ Detailed description of tasks, responsibilities and accountabilities		(+)	(-)	
1.3.2.3 Health status ❗ Medical/ health certificate		(+)	(-)	
1.3.2.4 List of Personnel Designation		(+)	(-)	
1.3.3 <u>Policies For Hiring, Orientation and Promotion:</u>				
1.3.3.1 There shall be a written policy for hiring, orientation and promotion for all levels of personnel.		(+)	(-)	
1.3.4 <u>Policies For Violation/ Suspension/ Termination:</u>				
1.3.4.1 There shall be a written policy for violation/ suspension/ termination for all levels of personnel.		(+)	(-)	



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1.4 DOCUMENT AND RECORDS The laboratory shall maintain records in a manner that allows reconstruction of all activities, easy retrieval and minimum retention. 1.4.1 Document Control: 1.4.1.1 There shall be a written policy to control all documents that form part of its quality system both internal and external and shall ensure the following: <ul style="list-style-type: none"> ! Availability of the authorized editions of documents ! Periodic review and revision of the documents ! Removal of invalid or obsolete documents ! All hand amendments clearly marked, initialed and dated ! Copies of the SOP Manual available at the bench or work area ! Work instructions of the SOP match the SOP Manual 1.4.2 Control of Records: 1.4.2.1 There shall be a written policy for handling of quality and technical records, including but not limited to: <ul style="list-style-type: none"> ! Records maintenance ! Security and confidentiality ! Protection and back-up ! Audit trail ! Corrections/ alterations 1.4.2.2 Records shall be legible, stored and readily retrievable in suitable environment to prevent damage, deterioration and loss. 1.4.2.3 All observations, data and calculations shall be recorded.	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	



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<p>2. TECHNICAL STANDARDS</p> <p><u>PERSONNEL</u></p> <p>The laboratory shall ensure personnel performing specific tasks are qualified on the basis of education, training, experience and/ or demonstrated skills, and appropriate supervision is provided when staff is being trained.</p> <p>It shall ensure personnel are employed or contracted, and contracted personnel are supervised, competent and work in accordance with the quality system.</p> <p>It shall maintain current job descriptions for managerial, technical and key support staff.</p> <p>2.1.1 <u>Head of the Laboratory:</u></p> <p>2.1.1.1 Proof of qualification</p> <ul style="list-style-type: none"> ! PRC ID, if applicable ! PRC Board Certificate * ! PSP Certificate (Clinical Pathology) * ! PAM Registration * ! Certificate of Training in Laboratory Management * ! Record of Work Experience (minimum of 3 years) in the theory and practice of water analysis <p>2.1.1.2 Proof of employment (appointment/ contract)</p>	<p>AO No. 2006 – 0024; PNS ISO/IEC 17025</p>	<p>(+) (-)</p> <p>(+) (-)</p>	<p>(+) (-)</p> <p>(+) (-)</p>	



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<p>2.2 <u>PHYSICAL PLANT</u></p> <p>Adequate facility shall be in place for the safe and efficient operation of the laboratory.</p> <p>2.2.1 <u>Floor Area:</u></p> <p>2.2.1.1 Work Area</p> <ul style="list-style-type: none"> ! The work area shall correlate with the volume and type of analysis to be undertaken including provision for periods of peak workload. ! It shall have a minimum of twenty (20) square meters of work area for free-standing laboratories. ! It shall have sufficient <ul style="list-style-type: none"> • Counter top for sample processing • Storage cabinet for equipment, instruments, reagents and supplies • Sink with strong water supply for cleaning and sterilizing • Fume hoods for handling of acids and organic chemicals • Containment facility for bacteriological analysis <p>2.2.2 <u>Utilities:</u></p> <p>2.2.2.1 The laboratory shall be housed in a permanent building with adequate power supply, water supply, and ventilation.</p> <ul style="list-style-type: none"> ! There shall be adequate running water in the work area. ! Air conditioning unit may be used for improved ventilation. 	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	



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2.2.3 <u>Waste Facility:</u> 2.2.3.1 There shall be a written policy for laboratory waste management following universal guidelines. 2.2.3.2 There shall be an implementation plan. 2.2.3.3 There shall be an inventory of waste chemicals including estimate concentration, means of disposal/ or containment, and frequency of disposal.		(+) (-)	(+) (-)	
2.2.4 <u>Housekeeping:</u> 2.2.4.1 There shall be a written policy for laboratory housekeeping following universal guidelines. 2.2.4.2 The laboratory shall be kept clean, dust-free, odor-free, safe and secured. 2.2.4.3 There shall be a written program for vermin control.		(+) (-)	(+) (-)	
2.2.5 <u>Personnel Safety:</u> 2.2.5.1 There shall be a written policy for safety of personnel following universal guidelines. 2.2.5.2 Personnel safety devices such as safety gloves, safety glasses, laboratory gowns, and face masks, shall be available when appropriate.		(+) (-)	(+) (-)	



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<p>2.3 <u>EQUIPMENT, INSTRUMENTS, REAGENTS AND SUPPLIES</u></p> <p>Necessary equipment, instruments, reagents and supplies shall be in place for the safe and efficient operation of the laboratory.</p> <p>2.3.1 <u>Equipment/Instruments:</u></p> <p>2.3.1.1 There shall be functional and operational equipment/ instruments.</p> <p>2.3.1.2 There shall be a readily available inventory of equipment/ instruments.</p> <p>2.3.1.3 There shall be a written program for preventive/ corrective maintenance of equipment/ instruments.</p> <p>2.3.1.4 There shall be a written program for calibration of equipment designed and operated so that calibrations and measurements are traceable to the International System of Units (SI Units).</p>	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-) (+) (-) (+) (-) (+) (-)	(+) (-) (+) (-) (+) (-) (+) (-)	
<p>2.3.2 <u>Reagents/Supplies:</u></p> <p>2.3.2.1 There shall be appropriate reagents/ supplies to perform the water analysis.</p> <p style="padding-left: 20px;">! The reagents/ supplies shall conform to the requirements of NRL, PNSDW, AWWA, APHA, and WPCF.</p> <p>2.3.2.2 There shall be a readily available inventory of reagents/ supplies.</p> <p>2.3.2.3 There shall be a written program for calibration of volumetric laboratory wares designed and operated so that calibrations and measurements are traceable to the International System of Units (SI Units).</p>		(+) (-) (+) (-) (+) (-)	(+) (-) (+) (-) (+) (-)	



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<p>2.4 ANALYTICAL METHODS</p> <p>The laboratory shall use appropriate methods and procedures for all calibrations and tests.</p> <p>2.4.1 Method Selection:</p> <p>2.4.1.1 The laboratory shall select analytical methods that are appropriate for the analyte and sample matrix based on the current PNSDW and the latest locally available Standard Method for the Examination of Water and Waste Water, AWWA, APHA, WPCF that produce the appropriate quantitative levels⁵.</p> <p>2.4.2 Uncertainty of Measurement:</p> <p>2.4.2.1 There shall be written procedures for estimating uncertainty of measurement.</p>	AO No. 2006 – 0024; PNS ISO/IEC 17025	(+) (-)	(+) (-)	
<p>2.4.3 Calculations and Data Transfers:</p> <p>2.4.3.1 The laboratory shall ensure calculations and data transfers are checked in a systematic manner.</p>		(+) (-)	(+) (-)	

⁵ Refer to Annex C – Minimum Equipment, Reagent and Laboratory Ware for Specific Test



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<p>2.4.4 <u>Method Validation:</u></p> <p>2.4.4.1 Modification of analytical methods is allowed provided that these are validated and approved by the NRL prior to its use.</p> <p>2.4.4.2 The laboratory shall validate</p> <ul style="list-style-type: none"> ! Non-standard methods ! Laboratory designed/ developed methods ! Standard methods outside their intended scope ! Amplifications and modifications of standard methods ! Confirm that the methods are fit for the intended use <p>2.4.4.3 The laboratory shall ensure the range and accuracy of the values obtainable from validated methods are relevant based on:</p> <ul style="list-style-type: none"> ! Uncertainty of the results ! Limit of detection ! Limit of quantification ! Selectivity of the method ! Linearity ! Limit of repeatability and/ or reproducibility ! Robustness against external influences and/ or cross-sensitivity against interference from the matrix of the sample 		(+) (-)	(+) (-)	
<p>2.4.5 <u>Policies for Outsourcing of Tests:</u></p> <p>2.4.5.1 The laboratory shall conform to the guidelines for outsourcing of tests set by the NRL.</p> <p>2.4.5.2 The laboratory shall attach the results of the tests outsourced from other accredited laboratories to the principal test results/ reports.</p>		(+) (-)	(+) (-)	



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<p>2.5 SAMPLING</p> <p>There shall be a system for receiving, accessioning, collection and disposal of sample.</p> <p>2.5.1 Sample Collection:</p> <p>2.5.1.1 There shall be written procedures for collection of sample at sampling location.</p> <p>2.5.1.2 The laboratory shall ensure client-requested deviations, additions or exclusions from the documented sampling procedures are recorded and communicated to the appropriate personnel.</p> <p>2.5.1.3 There shall be written procedures for recording sample data and operations.</p> <ul style="list-style-type: none"> ! Sampling procedure used ! Identification of the sample ! Environmental conditions ! Diagrams (or equivalent) to identify sampling location 	PNS ISO/IEC 17025	(+) (-)	(+) (-)	



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<p>2.5.2 Handling of Sample:</p> <p>2.5.2.1 There shall be written procedures for the management of sample to ensure protection of integrity of the sample and the interests of the laboratory and client.</p> <ul style="list-style-type: none"> ! Receipt ! Handling ! Protection ! Storage ! Retention and/ or disposal <p>2.5.2.2 There shall be a system for identifying sample for calibration and/ or test.</p> <p>2.5.2.3 The laboratory shall ensure abnormalities or deficiencies on sample received are recorded.</p> <ul style="list-style-type: none"> ! If there is doubt about the suitability of the sample, or it does not conform to description provided, or the test/ calibration is not specified, the laboratory shall ensure that the client is contacted and the instructions are recorded. <p>2.5.2.4 There shall be appropriate facilities to maintain the integrity of the sample and the protection of the secured sample and records.</p>		(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	
		(+) (-)	(+) (-)	



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<p>2.6 REPORTING THE RESULTS</p> <p>Results shall be reported accurately, clearly, unambiguously and objectively, and in accordance with specific instructions in the methods.</p> <p>2.6.1 Test Results/ Reports:</p> <p>2.6.1.1 All observations, data and calculations shall be recorded.</p> <p>2.6.1.2 There shall be logbooks and/or worksheets that include:</p> <ul style="list-style-type: none"> ! Date of the test ! Name of analyst ! Analyte ! Sample details (source, date and time of sampling, sample code) ! Test observations ! All rough calculations ! Relevant instrument traces ! Relevant calibration data <p>2.6.1.3 Test results/ reports shall include, but not limited to, the following information</p> <ul style="list-style-type: none"> ! Date of the test ! Client details (name, address, contact number) ! Name and signature of analyst ! Name and signature of laboratory head/ certifying officer ! Analyte ! Sample details (source if available, date and time of sampling, sample code) ! Method used ! Test results ! PNSDW values, if applicable 	<p>AO No. 2006 – 0024; PNS ISO/IEC 17025</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>	<p>(+) (-)</p> <p>(+) (-)</p> <p>(+) (-)</p>	



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2.7 <u>QUALITY ASSURANCE PROGRAM</u> The laboratory shall prepare and adopt a quality assurance program to establish, maintain and improve the quality of data generated by the laboratory.	AO No. 2006 – 0024; PNS ISO/IEC 17025				
2.7.1 <u>Internal Quality Assurance:</u>					
2.7.1.1 The laboratory shall have written procedures on quality control for monitoring validity of tests and calibrations.		(+)	(-)	(+)	(-)
<ul style="list-style-type: none"> ! Regular use of certified reference materials ! Replication using the same or different methods ! Retesting or recalibration of samples ! Correlation of results for different characteristics of a sample ! Recording of results so as trends are detectable and statistical techniques may be applied to the reviewing of the results where practicable 					
2.7.1.2 The laboratory shall conduct an internal quality audit at least once a year.		(+)	(-)	(+)	(-)
2.7.1.3 All quality control charts shall be displayed in a conspicuous place in the laboratory.		(+)	(-)	(+)	(-)
2.7.2 <u>External Quality Assurance:</u>					
2.7.2.1 The laboratory shall participate in proficiency testing programs.		(+)	(-)	(+)	(-)
<ul style="list-style-type: none"> ! Certificate of Participation in EQAS 					
2.7.2.2 It shall maintain a record of receipt of samples for EQAS from NRL.		(+)	(-)	(+)	(-)
2.7.2.3 It shall submit a record of results to NRL.		(+)	(-)	(+)	(-)
2.7.2.4 It shall keep a record of corrective action taken when evaluation of performance is below satisfactory.		(+)	(-)	(+)	(-)



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Name of Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[] For issuance of Certificate of Accreditation as Laboratory for Drinking Water Analysis.

Validity from _____ to _____

[] Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

[] Non-Issuance: Specify reason/s. _____

Inspected by:

Printed Name	Signature	Position/Designation
_____	_____	_____
_____	_____	_____
_____	_____	_____

Received by:

Signature _____

Printed Name _____

Position/Designation _____

Date _____



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Name of Laboratory: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

For issuance of Notice of Violation

Non- Issuance of Notice of Violation

Others (Specify)

Monitored by:

Printed Name

Signature

Position/Designation

Received by:

Signature _____

Printed Name _____

Position/Designation _____

Date _____