

#### MALDIVES FOOD AND DRUG AUTHORITY

Ministry of Health Male', Maldives

## **Terms of Reference**

# PARTICIPATION of NATIONAL HEALTH LABORATORY IN A PROFICIENCY TESTING SCHEME ACCREDITED TO ISO/IEC 17043

## 19 May 2019

#### 1. Introduction

National Health Laboratory (NHL) is a division of Maldives Food and Drug Authority (MFDA) with the main mandate of safety, quality control and hygiene verification of food and pharmaceuticals. NHL is divided into two main sections namely, Chemistry and Microbiology laboratories. The matrices tested include water, food and swabs and brought from food establishments, factories and resorts etc. and pharmaceuticals.

NHL has been accredited to the international standard ISO/IEC 17025 since December 2008. For the maintenance of its accreditation status it is compulsory to assure quality of tests. To fulfill this obligation of ISO/IEC 17025;2007, NHL intends to participate in a Proficiency Testing (PT) scheme.

Thus this "Terms of Reference" (TOR) has been developed to find a suitable PT provider/ program.

## 2. Scope and Objectives

The objective of this TOR is to find a competent PT provider/program accredited to the international standard ISO/IEC 17043 for NHL to participate for the assurance of the quality of tests.

The chosen party should provide PT services including but not limited to the following:

- 1. Send PT samples to NHL
- 2. Evaluate the test results by comparing the test results with assigned or nominal value or harmonized value obtained with all participating laboratories in the program
- 3. Provide a report for the score of NHL's test result

The details of the parameters for which PT are required are included in the list 1 attached. Testing of the PT samples will be carried out at NHL.

### 3. Requirements / Qualifications

- 3.1. The PT providers intending to offer PT services to NHL shall have the following qualifications and requirements.
  - a) The PT provider offering the PT services must be accredited to the standard ISO/IEC 17043.
  - b) The program shall **cover all the tests in the list 1 attached** and in the given ranges.
  - c) The PT provider must have at least 3 years' experience of providing to PT and must be currently engaged in the service.
  - d) The PT program must have at least 5 laboratories participating in its program.
  - e) Submission of test results should be available via electronic method or electronic correspondence.

- f) Time for the submission of results should allow sufficient time for transport of the sample/ material, processing and testing. The time taken for processing and testing for different parameters are included in the list 1.
- g) A schedule of the PT program for a year should be available prior to the start of the year's program.
- h) Provision of transport/courier services for the sample materials to NHL.
- i) Reports of evaluation of the test results shall be available via electronic media.
- Statistical method used for the evaluation of each test result must be sent along with each report.
- k) Full charges for one year program/cycle should be stated.
- 3.2. Documents to prove conformance to the points numbered 3.1 a), b), c) and d) of above criteria should be submitted along with proposals and proof to show conformance to the rest of the criteria should be submitted either by submitting relevant documents or statements in the proposals. Submissions without these documents and statements will be cancelled. Proposals submitted by parties not conforming to the above criteria will be cancelled.

## 4. Submission of applications

- 4.1. Interested qualified parties should submit a quotation for charges of PT services inclusive of :
  - a. Prices of the PT pack for the tests in US Dollars
  - b. Charges for courier/delivering the PT materials (for each test or pack of test ) for each round of the test parameter to the following address:

National Health Laboratory,

Maldives Food and Drug Authority

Ministry of Health

Roashanee Building, Sosun Magu,

Male' 20184

Republic of Maldives

c. Time allowed for postage and testing.

Quotations /proposals not stating the above will be cancelled. Any other charges that would incur must be included.

- 4.2. In addition to the quotation interested parties should submit:
  - a) A copy of the accreditation certificate to ISO 17043.
  - b) Schedule of the PT program
  - c) Criteria used to evaluate and decide acceptable test results
  - d) Brief profile
  - e) List of clients/ laboratories which had participated in the past 3 years.
  - f) Details of ways to submit test results and sending reports of evaluation of test results
  - g) Payment conditions
  - h) Any other terms and conditions subject to the process
  - i) Contact details including full address, email address and phone numbers with country codes

Proposals/ quotations not accompanying the above documents/ information except for 4.2.(h) will be cancelled.

5. <u>Selection: An appropriate party shall be chosen by evaluating the quotations/proposals using the</u> following grading system.

Price: 80 (Eighty) points; the highest point will be given to the least quoted party and the rest will be graded by ratio.

Experience: 20 (Twenty) points; External documents stating the duration of proficiency testing scheme. The longest duration gets the highest point and the rest will be graded by ratio.

- **6. Duration**: All required test rounds to be covered within a year of start date.
- 7. Contact: Thooma Adam/ Maldives Food and Drug Authority

Republic of Maldives.

8. <u>Deadline for submission:</u>

Interested parties are to submit signed quotations and other required documents on or before the official time of  $23^{rd}$  May 2019 to

Maldives Food and Drug Authority, Ministry of Health, Roashanee Building, Sosun Magu, Male' 20184

Electronic versions of the quotations and documents can be emailed to <a href="maileo:nhl@health.gov.mv">nhl@health.gov.mv</a> before the above due date. Late submissions cannot be considered under any circumstances.

List 1- Details of parameters for which PT is required.

#	Parameter	Matrix	Number of rounds	Time taken for				
			(at least)	processing and testing				
FOOD CHEMISTRY								
1.	Moisture	Food	Once in a year	3 days				
2.	Ash content	Food	Once in a year	3 days				
3.	Total nitrogen	Food	Once in a year	3 days				
4.	Sodium	Food	Once in a year	3 days				
5.	Chloride	Food	Once in a year	3 days				
6.	Arsenic	Fish	Once in a year	8 days				
7.	Cadmium	Fish	Once in a year	8 days				
8.	Mercury	Fish	Once in a year	8 days				
9.	Protein	Food	Once in a year	3 days				
10.	Fibre	Food	Once in a year	3 days				
11.	Peroxide Value	Oil	Once in a year	3 days				
12.	Iodine value	Oil	Once in a year	3 days				
13.	Total Volatile Nitrogenous Base (TVB-	Fish	Once in a year	3 days				
	N)							
14.	Total sugars	Food	Once in a year	3 days				
15.	Acidity / acid value	Food	Once in a year	3 days				
16.	Histamine	Fish	Twice in a year	2 days per round				
17.	Lead	Food	Once in a year	8 days				
18.	Mercury	Food	Once in a year	8 days				
19.	Cadmium	Food	Once in a year	8 days				
	W	ATER CHEMIS	TRY					
20.	Sodium	Water	Twice in a year	4 days per round				
21.	Potassium	Water	Twice in a year	4 days per round				
22.	pH	Water	Twice in a year	1 day per round				
23.	Electrical Conductivity	Water	Twice in a year	1 day per round				
24.	Sodium	Sea Water	Once in a year	4 days per round				
25.	Potassium	Sea Water	Once in a year	4 days per round				
26.	рН	Sea Water	Once in a year	1 day per round				
27.	Electrical Conductivity	Sea Water	Once in a year	1 day per round				
28.	Chloride	Water	Once in a year	1 day				
29.	Calcium	Water	Once in a year	2 days				
30.	Magnesium	Water	Once in a year	2 days				
31.	Alkalinity	Water	Once in a year	2 days				
32.	Total Hardness	Water	Once in a year	2 days				
33.	Phosphorus	Water	Once in a year	2 days				
34.	Fluoride	Water	Once in a year	2 days				
35.	Sulphate	Water	Once in a year	2 days				
36.	Nitrite	Water	Once in a year	2 days				
37.	Nitrate	Water	Once in a year	2 days				
38.		Water	Once in a year	2 days				
39.	Total Organic Carbon	Water	Once in a year	2 days				
40.	Colour	Water	Once in a year	1 day				
41.	Turbidity	Water	Once in a year	1 day				

42.	Cadmium	Water	Once in a year	2 days
43.	Lead	Water	Once in a year	2 days
44.	Iron	Water	Once in a year	2 days
45.	Manganese	Water	Once in a year	2 days
46.	Aluminum	Water	Once in a year	2 days
47.	Zinc	Water	Once in a year	2 days
48.	Copper	Water	Once in a year	2 days
49.	Nickel	Water	Once in a year	2 days
50.	Chromium	Water	Once in a year	2 days
51.	Mercury	Water	Once in a year	3 days
52.	Chromium	Sea Water	Once in a year	3 days
53.	Mercury	Sea Water	Once in a year	3 days
54.	Barium	Water	Once in a year	2 days
55.	Boron	Water	Once in a year	3 days
56.	Arsenic	Water	Once in a year	3 days
57.	Selenium	Water	Once in a year	2 days
58.	Silver	Water	Once in a year	2 days
59.	Lithium	Water	Once in a year	2 days
60.	Cobalt	Water	Once in a year	2 days
61.	Tin	Water	Once in a year	2 days
62.	Cyanide	Water	Once in a year	2 days
63.	Biological Oxygen Demand (BOD)	Water	Once in a year	7 days
64.	Chemical Oxygen Demand (COD)	Water	Once in a year	3 days
65.	Suspended solids	Water	Once in a year	1 day
66.	Total Dissolved Solids	Water	Once in a year	1 day
67.	Oil and grease	Water	Once in a year	3 days
68.	Taste and Odour	Water	Once in a year	3 days
		D MICROBIO		
69.	Enumeration – Coagulase positive staphylococcus	Food	Twice in a year	3 days
70.	Enumeration – Escherichia coli	Food	Twice in a year	3 days
71.	Enumeration – Coliforms	Food	Once in a year	2 days
72.	Enumeration- Aerobic Plate Count	Food	Once in a year	3 days
73.	Detection test - Listeria monocytogenes	Food	Once in a year	5 days
74.	Detection test - Salmonella spp.	Food	Once in a year	5 days
75.	Detection test - Staphylococcus	Food	Once in a year	5 days
	aureus			
76.	Detection test - Vibrio parahaemolyticus	Food	Once in a year	3 days
77.	Enumeration- Clostridium perfringens	Food	Once in a year	2 days
78.	Enumeration- sum of yeast and mould	Food	Once in a year	6 days
79.	Enumeration- Bacillus cereus	Food	Once in a year	3 days
80.	Enumeration- Aerobic plate count	Swab	Once in a year	3 days
81.	Enumeration - Enterobacteriaceae	Food	Once in a year	3 days
82.	Enumeration- Aerobic plate count	Milk	Once in a year	3 days
83.	Enumeration – Escherichia coli	Milk	Once in a year	3 days
84.	Enumeration – Coagulase positive staphylococcus	Milk	Twice in a year	3 days
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WATER MICROBIOLOGY							
85.	Total Coliforms	Water	Twice in a year	2 days			
86.	Escherichia coli	Water	Twice in a year	2 days			
87.	Enterococci	Water	Twice in a year	3 days			
88.	Clostridium perfringens	Water	Twice in a year	2 days			
89.	Colony counts (22°C/ 3days and 37°C/	Water	Twice in a year	4 days			
	2days)						
90.	Pseudomonas aerogenosa	Water	Once a year	5 days			