OPCW

Technical Secretariat

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NOTE BY THE DIRECTOR-GENERAL

STATUS OF LABORATORIES DESIGNATED FOR THE ANALYSIS OF BIOMEDICAL SAMPLES

1. The Conference of the States Parties (hereinafter "the Conference") at its First Session established the conditions under which laboratories may seek designation for the analysis of authentic samples (C-I/DEC.60, C-I/DEC.61, C-I/DEC.62, and C-I/DEC.65, all dated 22 May 1997), and at its Fifth Session (C-V/6, dated 19 May 2000) mandated the Executive Council (hereinafter "the Council") to take a decision regarding guidelines on the designation of laboratories for such analysis. The Council took that decision at its Twentieth Session (EC-XX/DEC.3, dated 28 June 2000). Additional guidelines on the designation of laboratories for the analysis of authentic samples were adopted by the Conference at its Twentieth Session (C-20/DEC.4, dated 2 December 2015).

2. In addition to the existing designation scheme set out in the decisions mentioned above, with effect from 2016 the Director-General may designate laboratories for the analysis of authentic biomedical samples (C-20/DEC.5, dated 2 December 2015). Such designations will be assessed and issued separately from the existing mechanism for the designation of laboratories for the analysis of environmental samples. Proficiency tests for biomedical samples will be referred to as the "Official OPCW Biomedical Proficiency Tests" (BioPTs). Laboratories may be designated for the analysis of either biomedical samples or environmental samples, or for both.

3. When designating laboratories for the analysis of authentic biomedical samples, and in accordance with C-20/DEC.5 and C-1/DEC.61, the Director-General takes into account whether:

   (a) the laboratory has implemented a quality assurance system in accordance with internationally recognised standards (for example, ISO[1] 17025 or equivalent);

   (b) the laboratory has obtained accreditation by an internationally recognised accreditation body for the tasks for which it is seeking designation;

   (c) the laboratory regularly participates and performs successfully in the last two BioPTs conducted by the OPCW; and

[1] ISO = International Organization for Standardization.

(d) the laboratory has achieved a performance rating of either two As or one A and one B in the last two BioPTs.

4. The Director-General will designate a laboratory for the analysis of authentic biomedical samples following its third BioPT if the laboratory satisfies the criteria set out in paragraph 3 above.

5. A laboratory must participate in every biomedical proficiency testing programme conducted once per calendar year, unless the additional guidelines in C-20/DEC.4 are applicable.

6. If a designated laboratory performs unsuccessfully in a proficiency test it may be temporarily suspended, but retain designated status, or it may have its designated status withdrawn, according to the guidelines in EC-XX/DEC.3. When this happens, the laboratory, also in accordance with EC-XX/DEC.3, will no longer be selected by the Director-General to receive and analyse authentic samples from the OPCW. However, it may perform other tasks, as set out in C-I/DEC.67 (dated 22 May 1997). Unsuccessful performance resulting in temporary suspension includes:

(a) having a score of C, D, or F (other than a false positive identification) in a single BioPT; or

(b) having a score of two Bs in the last two BioPTs.

7. In line with the guidelines contained in the Annex to EC-XX/DEC.3, any designated laboratory whose designation has been withdrawn or any laboratory that has been temporarily suspended may regain its designated status once it demonstrates that it again fulfils the criteria set out in paragraph 3 above.

8. Following the completion of the Third Official OPCW Biomedical Proficiency Test, the Director-General wishes to inform Member States of current status of the laboratories designated for the analysis of authentic biomedical samples. Seventeen laboratories from 13 Member States have been designated (see the list in Annex 1).

Annex 1: List of Laboratories Designated for the Analysis of Authentic Biomedical Samples

Annex 2: Performance Rating of Designated Laboratories in Official Biomedical Proficiency Tests

Annex 1

LIST OF LABORATORIES DESIGNATED FOR THE ANALYSIS OF AUTHENTIC BIOMEDICAL SAMPLES

	Laboratory	State Party
1.	Defence Science and Technology Group	Australia
2.	Laboratory of Toxicant Analysis, Academy of Military Medical Sciences	China
3.	Laboratory of Analytical Chemistry, Research Institute of Chemical Defence	China
4.	Finnish Institute for Verification of the Chemical Weapons Convention (VERIFIN)	Finland
5.	DGA Maîtrise NRBC, Département d'analyses chimiques	France
6.	Bundeswehr Institute of Pharmacology and Toxicology	Germany
7.	Vertox-Biochemistry Division, Defence Research and Development Establishment	India
8.	TNO Defence, Security and Safety	Netherlands
9.	Chemical Analysis Laboratory, CB Department, Agency for Defence Development	Republic of Korea
10.	Laboratory for the Chemical and Analytical Control of Military Research Centre	Russian Federation
11.	Laboratory of Chemical Analytical Control and Biotesting, Research Institute of Hygiene, Occupational Pathology and Human Ecology (RIHOPHE)	Russian Federation
12.	Verification Laboratory, Defence Medical and Environmental Research Institute, DSO National Laboratories	Singapore
13.	Swedish Defence Research Agency (FOI)	Sweden
14.	Defence Science and Technology Laboratory, Chemical and Biological Systems, Porton Down	United Kingdom of Great Britain and Northern Ireland
15.	Centers for Disease Control and Prevention	United States of America
16.	Edgewood Chemical and Biological Forensic Analytical Center	United States of America
17.	Lawrence Livermore National Laboratory	United States of America

Annex 2

PERFORMANCE RATING OF DESIGNATED LABORATORIES IN OFFICIAL BIOMEDICAL PROFICIENCY TESTS

	State Party	Laboratory	2nd BioPT	3rd BioPT
			2017	2018
1.	Australia	Defence Science and Technology Group	A	A
2.	China	Laboratory of Toxicant Analysis, Academy of Military Medical Sciences	A	A
3.	China	Laboratory of Analytical Chemistry, Research Institute of Chemical Defence	A	A
4.	Finland	Finnish Institute for Verification of the Chemical Weapons Convention (VERIFIN)	A	A[2]
5.	France	DGA Maîtrise NRBC, Département d'analyses chimiques	A	A
6.	Germany	Bundeswehr Institute of Pharmacology and Toxicology	A	A[2]
7.	India	Vertox-Biochemistry Division, Defence Research and Development Establishment	A	A
8.	Netherlands	TNO Defence, Security and Safety	A	A[2]
9.	Republic of Korea	Chemical Analysis Laboratory, CB Department, Agency for Defence Development	A	A[2]
10.	Russian Federation	Laboratory for the Chemical and Analytical Control of Military Research Centre	A	A
11.	Russian Federation	Laboratory of Chemical Analytical Control and Biotesting, Research Institute of Hygiene, Occupational Pathology and Human Ecology (RIHOPHE)	A	A
12.	Singapore	Verification Laboratory, Defence Medical and Environmental Research Institute, DSO National Laboratories	A	A

[2] Laboratory was not a test participant but was awarded an "A" performance rating based on the criteria in decision C-20/DEC.4.

	State Party	Laboratory	2nd BioPT	3rd BioPT
			2017	2018
13.	Sweden	Swedish Defence Research Agency (FOI)	A	A[2]
14.	United Kingdom of Great Britain and Northern Ireland	Defence Science and Technology Laboratory, Chemical and Biological Systems, Porton Down	A	A[3]
15.	United States of America	Centers for Disease Control and Prevention	A	A
16.	United States of America	Edgewood Chemical and Biological Forensic Analytical Center	A	A
17.	United States of America	Lawrence Livermore National Laboratory	A	A

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[3] Laboratory requested a withdrawal from the test without penalty after receiving samples. Withdrawal was granted by the OPCW.