OPCW Technical Secretariat

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NOTE BY THE DIRECTOR-GENERAL

STATUS OF LABORATORIES DESIGNATED FOR THE ANALYSIS OF AUTHENTIC 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-I/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/IEC 17025[1] 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] Standard ISO/IEC 17025 of the International Organization for Standardization/International Electrotechnical Commission.

(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 eighth 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 Eighth Official OPCW Biomedical Proficiency Test, the Director-General wishes to inform States Parties of the current status of the laboratories designated for the analysis of authentic biomedical samples. A total of 19 laboratories from 14 States Parties have been designated (see Annex 1). The performance ratings of these laboratories can be found in Annex 2.

Annexes:

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 Analyse Chimique	France
6.	Bundeswehr Institute of Pharmacology and Toxicology	Germany
7.	Biomedical Verification Division, Defence Research and Development Establishment	India
8.	Defense Chemical Research Laboratory (DCRL)	Iran (Islamic Republic of)
9.	TNO Defence, Safety and Security	Netherlands
10.	Chemical Analysis Laboratory, CBR Directorate, Agency for Defense Development	Republic of Korea
11.	Laboratory for the Chemical and Analytical Control of the Military Research Centre	Russian Federation
12.	Laboratory of Chemical Analytical Control and Biotesting, Research Institute of Hygiene, Occupational Pathology and Human Ecology (RIHOPHE)	Russian Federation
13.	Verification Laboratory, Defence Medical and Environmental Research Institute, DSO National Laboratories	Singapore
14.	Swedish Defence Research Agency, FOI	Sweden
15.	Defence Science and Technology Laboratory, Porton Down	United Kingdom of Great Britain and Northern Ireland
16.	Centers for Disease Control and Prevention	United States of America
17.	Combat Capabilities Development Command (DEVCOM), Chemical Biological Center (CBC), Forensic Analytical Laboratory	United States of America
18.	Lawrence Livermore National Laboratory	United States of America
19.	U.S. Army Medical Research Institute of Chemical Defense	United States of America

Annex 2

PERFORMANCE RATING OF DESIGNATED LABORATORIES IN OFFICIAL BIOMEDICAL PROFICIENCY TESTS

	Laboratory	**State Party**	**7th BioPT**	**8th BioPT**
			2022	**2023**
1.	Defence Science and Technology Group	Australia	A	A
2.	Laboratory of Toxicant Analysis, Academy of Military Medical Sciences	China	A	B
3.	Laboratory of Analytical Chemistry, Research Institute of Chemical Defence	China	A	B
4.	Finnish Institute for Verification of the Chemical Weapons Convention (VERIFIN)	Finland	A	A
5.	DGA Maîtrise NRBC, Département Analyse Chimique	France	A	A
6.	Bundeswehr Institute of Pharmacology and Toxicology	Germany	A	A
7.	Biomedical Verification Division, Defence Research and Development Establishment	India	A	A
8.	Defense Chemical Research Laboratory (DCRL)	Iran (Islamic Republic of)	A	A
9.	TNO Defence, Safety and Security	Netherlands	A	A
10.	Chemical Analysis Laboratory, CBR Directorate, Agency for Defense Development	Republic of Korea	A	A
11.	Laboratory for the Chemical and Analytical Control of the Military Research Centre	Russian Federation	A	A
12.	Laboratory of Chemical Analytical Control and Biotesting, Research Institute of Hygiene, Occupational Pathology and Human Ecology (RIHOPHE)	Russian Federation	A	A
13.	Verification Laboratory, Defence Medical and Environmental Research Institute, DSO National Laboratories	Singapore	A	A
14.	Swedish Defence Research Agency, FOI	Sweden	A	A
15.	Defence Science and Technology Laboratory, Porton Down	United Kingdom of Great Britain and Northern Ireland	A	A

	Laboratory	**State Party**	**7th BioPT**	**8th BioPT**
			2022	**2023**
16.	Centers for Disease Control and Prevention	United States of America	A	A
17.	Combat Capabilities Development Command (DEVCOM), Chemical Biological Center (CBC), Forensic Analytical Laboratory	United States of America	A	A
18.	Lawrence Livermore National Laboratory	United States of America	A	A
19.	U.S. Army Medical Research Institute of Chemical Defense	United States of America	A	A

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