OPCW **Technical Secretariat**

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NOTE BY THE DIRECTOR-GENERAL

STATUS OF THE 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 (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 the analysis of authentic samples. The Council took this 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 in paragraph 1 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 the following into account:

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

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

   (c) whether the laboratory regularly participates and performs successfully in every BioPT conducted by the OPCW; and

[1] ISO = International Organization for Standardization.

(d) whether 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 provisionally designates the laboratories for the analysis of authentic biomedical samples following the first BioPT if the laboratory satisfies the criteria set out in subparagraphs 3(a) and 3(b) above and has achieved a performance rating of A in the first test (C-20/DEC.5).

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 B 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 First Official OPCW Biomedical Proficiency Test, the Director-General wishes to inform Member States of the laboratories designated for the analysis of authentic biomedical samples. Seventeen laboratories from 14 Member States have been designated; the list of them is annexed hereto.

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

Annex

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.	Defence Chemical Research Laboratory	Iran (Islamic Republic of)
9.	TNO Defence, Security and Safety	Netherlands
10.	Chemical Analysis Laboratory, CB Department, Agency for Defence Development	Republic of Korea
11.	Laboratory for the Chemical and Analytical Control of 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, Chemical and Biological Systems, Porton Down	United Kingdom of Great Britain and Northern Ireland
16.	Edgewood Chemical and Biological Forensic Analytical Center	United States of America
17.	Lawrence Livermore National Laboratory	United States of America

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