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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 designates the laboratories for the analysis of authentic biomedical samples following the second 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 Second 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; the list of them is annexed hereto.

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,<br>Academy of Military Medical Sciences | China |
| 3. | The Laboratory of Analytical Chemistry,<br>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 | The Netherlands |
| 9. | Chemical Analysis Laboratory, CB Department,<br>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 RATIING OF DESIGNATED LABORATORIES IN OFFICIAL BIOMEDICAL PROFICIENCY TESTS

| | State Party | Laboratory | 1st BioPT | 2nd BioPT |
|---|---|---|---|---|
| | | | 2016 | 2017 |
| 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 |
| 5. | France | DGA Maîtrise NRBC, Département d'analyses chimiques | A | A |
| 6. | Germany | Bundeswehr Institute of Pharmacology and Toxicology | A | A |
| 7. | India | Vertox-Biochemistry Division, Defence Research and Development Establishment | A | A |
| 8. | Iran (Islamic Republic of) | Defence Chemical Research Laboratory | A | F |
| 9. | Netherlands | TNO Defence, Security and Safety | A | A |
| 10. | Republic of Korea | Chemical Analysis Laboratory, CB Department, Agency for Defence Development | A | A |
| 11. | Russian Federation | Laboratory for the Chemical and Analytical Control of Military Research Centre | A | A |
| 12. | Russian Federation | Laboratory of Chemical Analytical Control and Biotesting, Research Institute of Hygiene, Occupational Pathology and Human Ecology (RIHOPHE) | A | A |
| 13. | Singapore | Verification Laboratory, Defence Medical and Environmental Research Institute, DSO National Laboratories | A | A |
| 14. | Sweden | Swedish Defence Research Agency (FOI) | A | A |
| 15. | United Kingdom of Great Britain and Northern Ireland | Defence Science and Technology Laboratory, Chemical and Biological Systems, Porton Down | A | A |
| 16. | United States of America | Centers for Disease Control and Prevention | B | A |
| 17. | United States of America | Edgewood Chemical and Biological Forensic Analytical Center | A | A |
| 18. | United States of America | Lawrence Livermore National Laboratory | A | A |

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