OPCW **Conference of the States Parties**

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DECISION

DESIGNATION OF LABORATORIES FOR THE ANALYSIS OF AUTHENTIC BIOMEDICAL SAMPLES AND GUIDELINES FOR THE CONDUCT OF BIOMEDICAL PROFICIENCY TESTS

The Conference of the States Parties,

Recalling that at its First Session the Conference of the States Parties (hereinafter "the Conference") adopted the following decisions (all dated 22 May 1997): "Proficiency Testing Leading to the Certification of Designated Laboratories" (C-I/DEC.60); "Criteria for the Designation of Laboratories by the OPCW" (C-I/DEC.61); "Criteria for Acceptable Performance of Laboratories in Proficiency Testing" (C-I/DEC.62); and "Criteria for the Conduct of OPCW/PTS Proficiency Testing" (C-I/DEC.65);

Recalling further that the Executive Council (hereinafter "the Council"), mandated by the Conference at its Fifth Session (paragraph 21.4 of C-V/6, dated 19 May 2000), adopted the "Guidelines on the Designation of Laboratories for the Analysis of Authentic Samples" (EC-XX/DEC.3, dated 28 June 2000) to be taken into account by the Director-General in relation to the designation of laboratories for the analysis of authentic samples;

Recognising that, pursuant to subparagraph 56(b) of Part II of the Verification Annex to the Chemical Weapons Convention (hereinafter "the Verification Annex"), the Director-General has the responsibility to certify the laboratories designated to perform different types of analysis;

Noting that, in accordance with paragraph 17 of Part XI of the Verification Annex, samples of importance in the investigation of alleged use of chemical weapons include biomedical samples from human or animal sources;

Recognising further that differences in the characteristics of biomedical and other types of samples and in the methods of their analysis and reporting of the results require departures from the existing mechanisms established by the Conference and the Council;

Reaffirming the need to maintain a high level of proficiency and analytical capabilities of laboratories designated for the analysis of authentic samples transferred off-site in accordance with the relevant provisions of the Chemical Weapons Convention; and

Noting also the recommendation of the Council on this matter at its Eightieth Session (EC-80/DEC.4, dated 8 October 2015);

Hereby:

Decides that, in relation to the designation of laboratories for the analysis of authentic biomedical samples and the conduct of biomedical proficiency tests, the Director-General will take into account the guidelines annexed hereto.

Annex:

Designation of Laboratories for the Analysis of Authentic Biomedical Samples and Guidelines for the Conduct of Biomedical Proficiency Tests

Annex

DESIGNATION OF LABORATORIES FOR THE ANALYSIS OF AUTHENTIC BIOMEDICAL SAMPLES AND GUIDELINES FOR THE CONDUCT OF BIOMEDICAL PROFICIENCY TESTS

Designation of laboratories

1. Currently, the OPCW proficiency tests focus on the analysis of samples with concentrations of chemicals relevant to the aim of the test as they are typically encountered in environmental samples. These tests will continue to be organised by the Technical Secretariat (hereinafter "the Secretariat") in accordance with the existing guidelines relating to the subject matter as adopted by the Conference in decisions C-I/DEC.60, C-I/DEC.61, C-I/DEC.62, and C-I/DEC.65 and by the Council in decision EC-XX/DEC.3, subject to any further decisions by the Conference or the Council. These tests will continue to be referred to as the "Official OPCW Proficiency Tests".

2. In addition to the existing designation scheme set out in the decisions mentioned in paragraph 1 above, from 2016 onward the Director-General may designate laboratories for the analysis of authentic biomedical samples. Such designation will be assessed and issued separately from the existing mechanism for the designation of laboratories for the analysis of other authentic 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 other authentic samples, or for both.

3. In line with the existing guidelines contained in C-I/DEC.61 on the designation of laboratories by the OPCW, the following requirements for designation will be taken into account by the Director-General:

   (a) the laboratory has implemented a quality assurance system according to internationally recognised standards (e.g. ISO[1] 17025 or ISO 15189);

   (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 at least one BioPT per year; and

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

4. In addition to the guidelines set out in C-I/DEC.61, the guidelines contained in the Annex to EC-XX/DEC.3 will apply to BioPTs, with the exception of subparagraph 2(b). It is the intention of the Secretariat to organise one BioPT per year.

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[1] ISO = International Organization for Standardization.

5. The Director-General may provisionally designate 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. Obtaining a rating of A for assisting the OPCW in either sample preparation or evaluation of the test will not lead to a provisional designated status. From the second BioPT onward, the criteria set out in subparagraphs 3(c) and 3(d) above must be satisfied to either obtain or maintain designated status.

6. Laboratories are encouraged to ensure at the earliest possible time that their scope of accreditation includes all methods relevant to the analysis of authentic biomedical samples. Until further notice by the Secretariat, non-accredited analytical methods will be accepted as long as the scope of accreditation includes the handling and documentation of samples, including appropriate respective procedures for chain of custody and chain of evidence. The Secretariat may decide to make accredited methods mandatory based on its assessment of the overall progress of the laboratories towards the application of accredited methods.

7. In line with the guidelines contained in the Annex to EC-XX/DEC.3, a laboratory designated for the analysis of authentic biomedical samples will lose its designated status under any of the following conditions:

   (a) failure in a BioPT due to a false-positive identification of a test chemical;

   (b) failure to correctly analyse control samples issued by the Secretariat together with authentic biomedical samples;

   (c) failure to participate in at least one BioPT per year;

   (d) loss of accreditation by the laboratory covering activities of biomedical sample analysis and/or sample handling and chain of custody/chain of evidence procedures; or

   (e) failure to regain full status of designation while being temporarily suspended.

8. In line with the guidelines contained in the Annex to EC-XX/DEC.3, should a designated laboratory perform unsuccessfully in a BioPT, the laboratory will be temporarily suspended but will not lose its designated status. It may not analyse authentic samples. However, it may perform other tasks as defined in the Annex to Conference decision 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 false positive identification) in a single BioPT; or

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

9. 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.

10. The processes of achieving, maintaining, and potentially losing designated status for the analysis of authentic biomedical samples and of other authentic samples shall be treated as being independent of each other.

11. The results of each BioPT and the status of designation of laboratories after each test will be published in individual Notes by the Secretariat.

12. These guidelines will be the primary reference for the designation of laboratories for the analysis of authentic biomedical samples and for the conduct of BioPTs. Unless otherwise specified, the relevant sections of the previous Conference and Council decisions relating to the designation of laboratories for the analysis of authentic samples will be used as references with necessary changes.

Guidelines for the conduct of the Official OPCW Biomedical Proficiency Tests

13. In line with the guidelines contained in the Annex to C-I/DEC.60, the BioPTs will be open to all laboratories in Member States seeking to become designated laboratories for the analysis of authentic biomedical samples.

14. In line with the guidelines contained in the Annex to C-I/DEC.60, the BioPT samples will be provided by the Secretariat free of charge to all participating laboratories. The cost of participation, including sample analysis, as well as the costs of sample preparation and evaluation of test results, where applicable, will be borne by the participating laboratory or the Member State concerned. The BioPT sample preparation and the evaluation of test results will be the responsibility of the Secretariat; however, either may be contracted out or provided by a Member State on a cost-free basis.

15. The Secretariat, in close cooperation with the external accreditation body, will at the earliest possible time expand its scope of accreditation under ISO 17043 to include the BioPT so that such tests may be carried out under its ISO 17043 accreditation.

16. The basis for the conduct of the BioPT will be formed by a set of quality controlled standard operating procedures of the Secretariat. Any changes or additions to the BioPT criteria will be compiled and distributed by the Secretariat in the form of a new release of quality documents to all concerned laboratories, following the current practice of the Proficiency Testing Programme (S/315/2002, dated 27 August 2002). The respective current set of quality documents will be made available to all interested Member States upon request.

17. The evaluation of test results will follow the criteria and guidelines set forth in the latest set of quality documents. In line with the guidelines contained in subparagraph 4(d) of the Annex to C-I/DEC.65 and subparagraph 3(b) of the Annex to EC-XX/DEC.3, the performance rating of test participants will be determined as follows:

Identification of chemicals	**Failure of test**	**Performance Rating**
Laboratory identifies all chemicals		A
Laboratory identifies all but one chemical		B
Laboratory identifies more than half of the chemicals		C
Laboratory identifies less than half of the chemicals		D
	Laboratory reports a false-positive identification of a chemical or engages in collusion or falsification of test results	Failure (F) leading to a loss of designation
	Laboratory reveals confidential information in the report or fails to submit a report within the test period	Failure ($F^{\dagger}$) without loss of designation

18. In line with the guidelines contained in the Annexes to C-I/DEC.65 and EC-XX/DEC.3, the OPCW Laboratory may prepare the test samples and either conduct an evaluation of the test results alone or delegate this task to designated laboratories acting as assisting laboratories for either sample preparation or evaluation, respectively. Requirements and criteria for both activities are covered by work instructions that are part of the set of quality documents. Assisting laboratories will be awarded a performance rating of A if their fulfilment of the task was satisfactory and meets all requirements of the respective work instruction. Laboratories cannot use the performance rating for preparing samples or evaluating test results in more than one of their last two consecutive BioPTs (i.e. laboratories must participate in at least one out of two tests as regular participants).

19. In line with the guidelines contained in the Annex to C-I/DEC.65, the Secretariat will inform the test participants before the test of the purpose and scenario of the test. After completion of the test by the participating laboratories, the Secretariat has the responsibility to evaluate the results of the test in accordance with the respective quality documents.

20. Any laboratory that fails to return the results of a BioPT within the test period will fail that test unless it informs the Secretariat of its intention to withdraw before the end of the test and also provides a satisfactory explanation.

21. In line with the guidelines contained in the Annex to C-I/DEC.62, in case of errors (false positives and negatives) as revealed in the final test report issued by the Secretariat, each concerned laboratory will take immediate remedial action. The laboratories in question must submit a full report stating the cause of the problem and any remedial actions taken before the next BioPT. Failure to submit such a report will result in the laboratory in question being banned from participation in any further BioPTs until an acceptable report is received by the Secretariat.

22. These guidelines will be the primary reference for the conduct of BioPTs. Unless otherwise specified, the relevant sections of the previous Conference and Council decisions relating to the conduct of the Official OPCW Proficiency Tests will be used as references with necessary changes.

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