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NOTE BY THE DIRECTOR-GENERAL

DESIGNATION OF LABORATORIES FOR THE ANALYSIS OF AUTHENTIC SAMPLES: RETENTION OF DESIGNATION STATUS

1. In his statement to the Third Session of the Conference of the States Parties, the Director-General informed Member States that he has designated seven laboratories to carry out the analysis of authentic samples (paragraph 34 of C-III/DG.2, dated 16 November 1998).

2. Any laboratories which may qualify for designation in the future will be designated by the Director-General accordingly. In accordance with his above-mentioned statement, the Director-General will, when designating laboratories for the analysis of authentic samples in accordance with C-I/DEC.61 and C-I/DEC.65, both dated 22 May 1997, take into account the following:

   (a) the validity of the quality system and accreditation (C-I/DEC.61) considering the quality system and standards used (ISO/IEC Guide 25, EN 45001, or equivalent), as well as the accreditation body, the accreditation validity period, and the scope of the accreditation. It should be confirmed that a proper quality system is in place, and that the scope of the accreditation is relevant to the analysis of chemical warfare agents and related compounds, i.e. that the laboratory has been accredited for the tasks for which it is seeking designation[1]; and

   (b) successful performance in the OPCW's Official Inter-Laboratory Proficiency Testing Programme. A combined rating of three maximum scores (three As), or two As and one B, shall be regarded as successful performance in proficiency tests (see subparagraph 4(d) of C-I/DEC.65) required for laboratories seeking designation for the analysis of authentic samples.

[1] See C-I/DEC.61, "Criteria for the Designation of Laboratories by the OPCW", and C-I/DEC.67, "Scope of Activities of Designated Laboratories and the Role and Status of Other Laboratories".

3. In accordance with the Director-General's earlier statements on this subject, successful laboratories should, however, bear in mind that, in order to retain their designated status, they will need to demonstrate their continued proficiency by participating successfully in at least one proficiency test per year (EC-IX/DG.7*, paragraph 26, and EC-XII/DG.5, paragraph 21).

4. During the year 1998, in order to retain designation, designated laboratories must demonstrate that they have maintained their capabilities once, either as a regular participant, or as the laboratory supporting the Technical Secretariat in preparing the test samples or in evaluating the test results, in a proficiency test organised by the Technical Secretariat.

5. Starting from the year 1999 for those laboratories that have, or will have been, designated for the analysis of authentic samples, the following will apply:

   (a) the criteria (quality system, accreditation and successful performance in proficiency tests) for retaining the designation shall be defined in the same terms as the criteria for seeking designation. A designated laboratory must keep the Technical Secretariat informed of any changes in its accreditation status;

   (b) in order to retain designation, designated laboratories will have to demonstrate that they have maintained their capabilities once a year in a proficiency test organised by the Technical Secretariat. Should two such tests be conducted in a given year, designated laboratories should participate on one occasion. If only one test per year is conducted, the capabilities necessary to retain designation must be demonstrated, either by participating as a regular participant, or as the laboratory supporting the Technical Secretariat in preparing the test samples or evaluating the test results (provided that the requirements set forth in subparagraph 5(c) of C-I/DEC.65 are met). Although it is the intention of the Technical Secretariat to organise two tests per year in the future, the Technical Secretariat may, due to the timing of the Fifth Official Proficiency Test, be able to conduct only one test in 1999. The problem of retaining designation by participating solely as the laboratory supporting the Technical Secretariat in preparing the test samples or evaluating the test results could be solved, however, should the preparation of test samples and the evaluation of test results be conducted on a contractual basis by a reputable commercial laboratory, or by laboratories capable of fulfilling the requirements set out in C-I/DEC.65 and in the OPCW Standard Operating Procedures for the preparation of test samples[2] and for evaluation of results[3] of OPCW proficiency tests. The Technical Secretariat intends to pursue this option in the future;

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[2] Annex 2 to PC-XI/B/WP.6 as noted by Working Group B of the Preparatory Commission in PC-XI/B/12, subparagraph 3.5(i), and as amended in PC-XII/B/7.

[3] Note by the Director-General, "Revised Standard Operating Procedure for Evaluation of the Results of OPCW Proficiency Tests", S/46/98, 21 April 1998.

(c) the designation of a designated laboratory will be withdrawn should there be either a substantial change in its accreditation status, or should its performance deteriorate, as follows:

(i) a substantial change in accreditation status. Loss of accreditation or a change in its scope implying inadequate analytical capabilities in the analysis of chemical warfare agents and related compounds will be regarded as a substantial change;

(ii) failure to participate once a year in a proficiency test organised by the Technical Secretariat (see paragraph 3 and subparagraph 5(b) above);

(iii) an unsuccessful performance as a regular participant in the proficiency tests. A rating of C, D or Failure; or a second B in their last three consecutive tests (i.e. ABB or BAB) will be regarded as unsuccessful performance;

(iv) an unsuccessful performance in the proficiency tests when preparing the test samples or evaluating the results[4]; and

(v) an unsatisfactory performance in the analysis of control samples distributed by the OPCW. When it comes to the off-site analysis of authentic samples (i.e. sample, control sample, and blank, when available) false positive identifications and failure to identify the chemicals present shall be regarded as unsatisfactory performance;

(d) any designated laboratory whose designation has been withdrawn may be redesignated once it has provided adequate proof that it again meets the criteria set out in C-I/DEC.61 and C-I/DEC.65. Depending on the reason for the withdrawal of the designation, the laboratory in question should take the following action:

(i) it should provide the Technical Secretariat with adequate information to enable it to confirm the validity of its quality system and accreditation (see subparagraph 2(a) to this Note); and/or

(ii) it should demonstrate its capabilities successfully in three consecutive tests in the OPCW's Official Inter-Laboratory Proficiency Testing Programme (see subparagraph 2(b) to this Note).

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[4] See C-I/DEC.65, subparagraph 5: "(a) laboratories preparing the samples shall be credited with a maximum performance rating of A (see table) for one proficiency test if the test samples meet the requirements of the "Standard Operating Procedure (SOP) for Preparation of Test Samples for OPCW/PTS Proficiency Tests"; (b) laboratories evaluating the analytical results shall be credited with a maximum performance rating of A (see table) for one proficiency test if the evaluation meets the requirements of the "Standard Operating Procedure (SOP) for Evaluation of Results of OPCW/PTS Proficiency Tests"."