ANNEX VI

Functions and duties of laboratories

PART III

Designated laboratories in Member States

1. The competent authority of a Member State shall designate only laboratories for diagnostic services pursuant to Article 57 that fulfil the following requirements. They must:

   (a) undertake to notify, without delay, the competent authority whenever a laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

   (b) undertake to participate in comparative tests (ring-tests) of diagnostic procedures arranged by the national reference laboratory;

   (c) operate and be assessed and accredited in accordance with the following European Standards account being taken of the criteria for different testing methods laid down in this Directive:

      (i) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;

      (ii) EN 45002 on ‘General criteria for the assessment of testing laboratories’;

      (iii) EN 45003 on ‘Calibration and testing laboratory accreditation system — General requirements for operation and recognition’.

2. The accreditation and assessment of testing laboratories referred to in paragraph 1(c) may relate to individual tests or groups of tests.

3. The Member States may designate laboratories which do not comply with the requirements referred to in point 1(c)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided that the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. The competent authority shall cancel the designation where the conditions referred to in this Annex are no longer fulfilled.