

- (c) For scientific technical evaluations, an inter-comparison exercise which would consist of parallel evaluations (double blind evaluations), made by the Conformity Assessment Body in each territory, of a manufacturer's technical submission against the requirements of the intended market for that device, will be undertaken. Full reports and recommendations shall be exchanged for comparison. A certificate of compliance can be issued by the body responsible for the relevant market during this inter-comparison study. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different medium to high-risk technologies with the involvement of each Party's Regulatory/Designating Authorities and CABs. Additional evidence with respect to the competency of Regulatory/Designating Authorities or CABs can be requested by either Party;
- (d) For quality systems assessments, an inter-comparison exercise which would consist of the participation of Regulatory/Designating Authorities in audits carried out by CABs of the other Party on the basis of requirements of the other Party. Audit management, methods and reports will be compared. The inter-comparison study should take place on a sampling basis comprising a sufficient number of cases spread over the range of different technologies with the involvement of each Party's Regulatory/Designating Authorities and CABs. Additional evidence with respect to the competency of Regulatory/Designating Authorities or CABs can be requested by either Party;