

maintenance program supporting the continued operation of the MRA. The Group will include representatives of Health Canada and of the Competent Authorities of the EEA EFTA States and will be co-chaired by a representative of Canada, on the one hand, and a representative of the EEA EFTA States, on the other.

6. TRANSITION PERIOD

6.1 Time Frame

The confidence-building period will commence upon the signing of the MRA and is expected to be completed within 18 months.

6.2 Confidence Building Programme

At the beginning of the transitional period, the Joint Sectoral Group will elaborate a joint confidence building programme (guidance provided in Attachment 3). The implementation of this program shall establish the capability of Canada, on the one hand, and each of the EEA EFTA States, on the other, to perform conformity assessments in compliance with the requirements and procedures of the other Party concerned. The evidence shall provide practical relevance to the decisions regarding the operational phase.

The confidence building programme should include the following actions and activities:

- a) The organization of seminars aiming to inform Regulatory/Designating Authorities and Conformity Assessment Bodies on each Party's regulatory system, procedures and requirements;
- b) The conduct of workshops aiming to provide, for Regulatory/Designating Authorities, a common understanding and exchange of information regarding requirements and procedures for the designation and surveillance of Conformity Assessment Bodies (CABs);
- 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