Recommendations to list CABs in Attachment 2 of this Annex shall be made by participating Designating/Regulatory Authorities, listed in Attachment 1, to the Joint Sectoral Group on the basis of the results of the confidence building programme. Conformity Assessment Bodies that have been accepted by the Joint Sectoral Group will be listed in Attachment 2 with an indication of their specific conformity assessment expertise and the fields of medical device technologies for which they are recognized. The corresponding Regulatory/ Designating Authority responsible for a CAB will also be listed in Attachment 2. Proposals to limit the recognition of capabilities of CABs should be based on objective evidence and documented. The Joint Sectoral Group may recommend that a CAB not be listed in Attachment 2, provided there is documented evidence demonstrating its lack of capabilities. Excluded CABs may apply for reconsideration of their status once the necessary corrective measures have been taken and confirmed.

Where no agreement on any of the above matters has been reached in the Joint Sectoral Group, the matter will be referred to the Joint Committee under the Framework Agreement.

The Parties shall enter into the operational phase provided that there is representation of each Party's CABs in Attachment 2.

The Sectoral Annex will also be re-examined at the end of the transitional period to take account of the regulatory evolution of each Party. Consideration shall be given to a single submission/evaluation/quality systems assessment which simultaneously satisfies the requirements of each jurisdiction.

7. OPERATIONAL PHASE

7.1 General Obligations

The provisions of this Section will apply only to conformity assessment carried out in the respective territories of Canada, on the one hand, and of each of the EEA EFTA States, on the other, by Conformity Assessment Bodies recognized under this Sectoral Annex.

The EEA EFTA States and Canada agree that, for medical devices covered by this Annex, each Party will recognize the conclusions of the conformity assessment carried out by another Party and the certificate of compliance granted by the Conformity Assessment Body of another Party, without further re-assessment.

For evaluation against the requirements of each EEA EFTA State, Health Canada, Conformity Assessment Bodies designated by Canada or other Conformity Assessment Bodies recognized as competent by an EEA EFTA State shall establish the conclusions of completed conformity assessments as referred to in the Active Implantable Medical Device and the Medical Device Directives, and issue the appropriate certificate of compliance. The responsible authorities