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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 Canada and any of the EEA EFTA States;

Medical Devices

- 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 concerned on the basis of requirements of that 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 Canada and any of the EEA EFTA States;
- The design, development and testing of a two-way alert system (see guidance in Attachment 4);
- The establishment of contact points between Regulatory/Designating Authorities and CABs of the Parties;
- The participation in information exchange meetings with particular focus on conformity assessment and vigilance, including participation in staff training sessions. The exchange of staff will also be encouraged; and
- h) During the confidence-building programme, where one Party has developed sufficient confidence in the evaluation methods and results of the other, it may at its own discretion, establish the relevant document of compliance permitting market access for its own jurisdiction based on the evaluation reports of another Party without the full submission.

Participation in activities referenced under c) and d) should be understood as means to provide, on an exemplary basis, supplementary evidence in relation to the process of designation and surveillance of CABs.

## 6.3 Budget

Each of the Parties to the MRA will be responsible for the costs of its participation in the confidence building activities.

## 6.4 End of Transition Period

No later than 18 months after the entry into force of this Agreement, the Joint Sectoral Group shall proceed to a joint evaluation of the experience gained. This evaluation will cover the adequacy of the confidence building programme, the capabilities of Regulatory/Designating Authorities and the capabilities of the designated Conformity Assessment Bodies.