**Medical Devices** 

## Attachment 3

## PHASES AND ELEMENTS OF A CONFIDENCE BUILDING PROGRAM

- A. REVIEW AND EVALUATION OF ELEMENTS OF CONFORMITY ASSESSMENT (EXCHANGE OF DOCUMENTATION)
  - 1. Legislative and Regulatory Requirements and Scope
    - Empowering legislation and regulations including authority to enforce laws and regulations, powers given to evaluators and auditors, authority to remove violative products from the market, etc.
    - Suitable controls on conflict of interest
  - 2. Regulatory Directives and Policies
    - Procedures for determining competency of evaluators/auditors
    - Enforcement policies/guidelines/procedures
    - Codes of conduct/ethics
    - Training/certification policies/guidelines
    - Alert/crisis management policies/procedures/guidelines
    - Organizational structure, including roles, responsibilities and reporting relationships
  - 3. Quality Audit Management, Methodology and Practices
    - Scope/details of operating standards, etc.
    - Auditor qualifications, numbers, training, quality assurance, contracting, etc.
  - 4. Scientific Technical Evaluation Methodology and Practices
    - Scope/details of operating standards, etc.
    - Evaluator qualifications, numbers, training, quality assurance, contracting, etc.