Sectoral Annex Medical Devices

## 5. Evaluation and Auditing Reports

- Scope and format of reports
- Content requirements
- Storage, retrieval and access to reports
- Scope and format of abbreviated reports, conclusions of conformity assessment and certificates

## 6. Auditing and Evaluation Procedures

- Audit and Evaluation strategy (type, scope, scheduling, focus, notification, risk)
- Pre-audit or evaluation preparation/requirements
- Methodology (access to and review of firm's files and databases, collection of evidence, data review, sample collection, interviews)
- Post audit and evaluation activities (procedures for report issuance, follow-up, decision making)
- Collection/storage of and access to data

## 7. Auditing and Evaluation Performance Standards

 Frequency/number, quality and timeliness of reports, norms/frequency/procedures for re-audit or re-evaluation and corrective action

## 8. Enforcement Powers and Procedures

- Provision of written notices of violations to firms
- Non-compliance management procedures/mechanisms (recall, suspension, quarantine of products, certificate revocation, seizure, prosecution)
- Appeal mechanisms
- Other measures to promote voluntary compliance by firm