

**Global Harmonization Task Force
Study Group 4 „Regulatory Auditing“**

**Quality Systems Auditing for Multi-
Purpose Inspections: Experience &
Practical Advice-Giving**

Europe

Markus Zobrist, PhD, Inspector, SWISSmedic

Chair GHTF SG4

Auditing Experience in Europe

European Union (EU) European Free Trade Association (EFTA)

- 1 New Approach Regulation in Europe**
- 2 Requirements for Conformity Assessment Bodies**
- 3 Audit programme**
- 4 Audits done by Notified Bodies for CE-Marking**
- 5 Conclusions**

New Approach Regulation for Medical Devices in Europe

⇒ **Essential Requirements listed in EU-Directives**
(Corresponding to GHTF „Essential Principles“)

⇒ **Use of harmonized Standards**
(to fulfill Essential Requirements)

⇒ **Conformity Assessment Procedures**
(Available for each class or group of products/devices)

⇒ **Separation
of functions**



Conformity Assessment



Market Surveillance

New Approach Regulation for Medical Devices in Europe

- ⇒ **Conformity Assessment Bodies (79 NBs for Europe)**
(Notified Bodies available for a procedure, a group or type of devices)

- ⇒ **Competent Authorities for the Market Surveillance**
(Approval of clinical trials, Vigilance System, checking products on the market, notification of products,)

- ⇒ **Designating Authorities**
(Designating Notified Bodies and exercising surveillance)

Requirements for Conformity Assessment Bodies (CABs)

②

in Europe: Notified Bodies (NBs)

Criteria for NB (as in SG4 N28, ISO/IEC 17021 + ISO 19011)

- legal responsibility
- impartiality + independence
- financing + liability
- competence, due professional care
- confidentiality
- quality management

...

Requirements for Conformity Assessment Bodies (CABs)

②

Designation and Monitoring of NB in Europe

- Designating Authority
- MEDDEV 2.10-2 Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices,
http://ec.europa.eu/enterprise/medical_devices/meddev/index.htm
- MEDDEV 2.10-2 includes requirements of GHTF SG4 N28
- Cooperation of Designating Authorities for harmonizing practice:
Notified Bodies Operations Group (NBOG)



Requirements for Conformity Assessment Bodies (CABs)

②

Voluntary co-operation scheme of NB in Europe

- Need for harmonization of good practice
- European Association of Notified Bodies for Medical Devices Practice Guides
TEAM-NB Recommendations
<http://www.team-nb.org>

Audit Programme

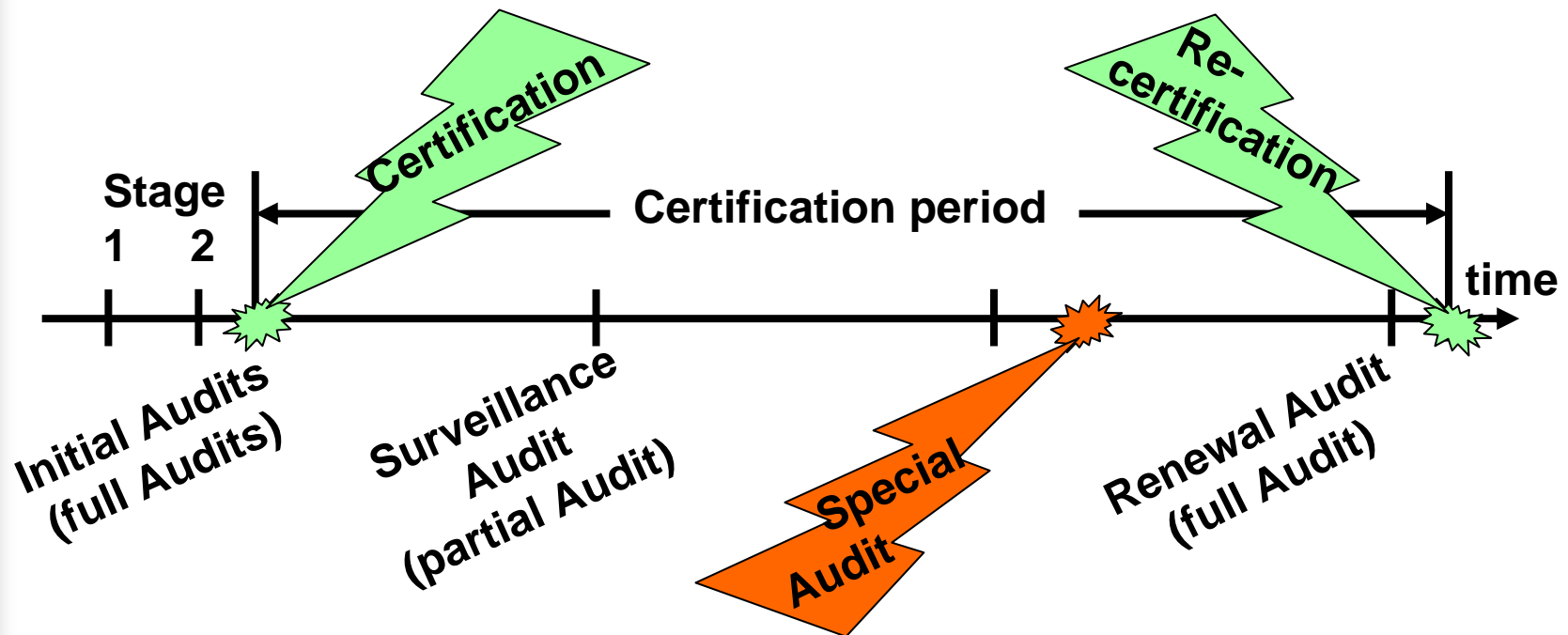
③

Use of Guidelines + Standards for Auditing

- **GHTF SG4 (99) 28:** Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements (**currently in revision**)
- **ISO 19011:** Guidelines for quality and/or environmental management systems auditing:
- **ISO/IEC 17021:** Conformity assessment — Requirements for bodies providing audit and certification of management systems

Audit programme

Audit programme covering the auditing activities within a certification period from 3 to 5 years, example:

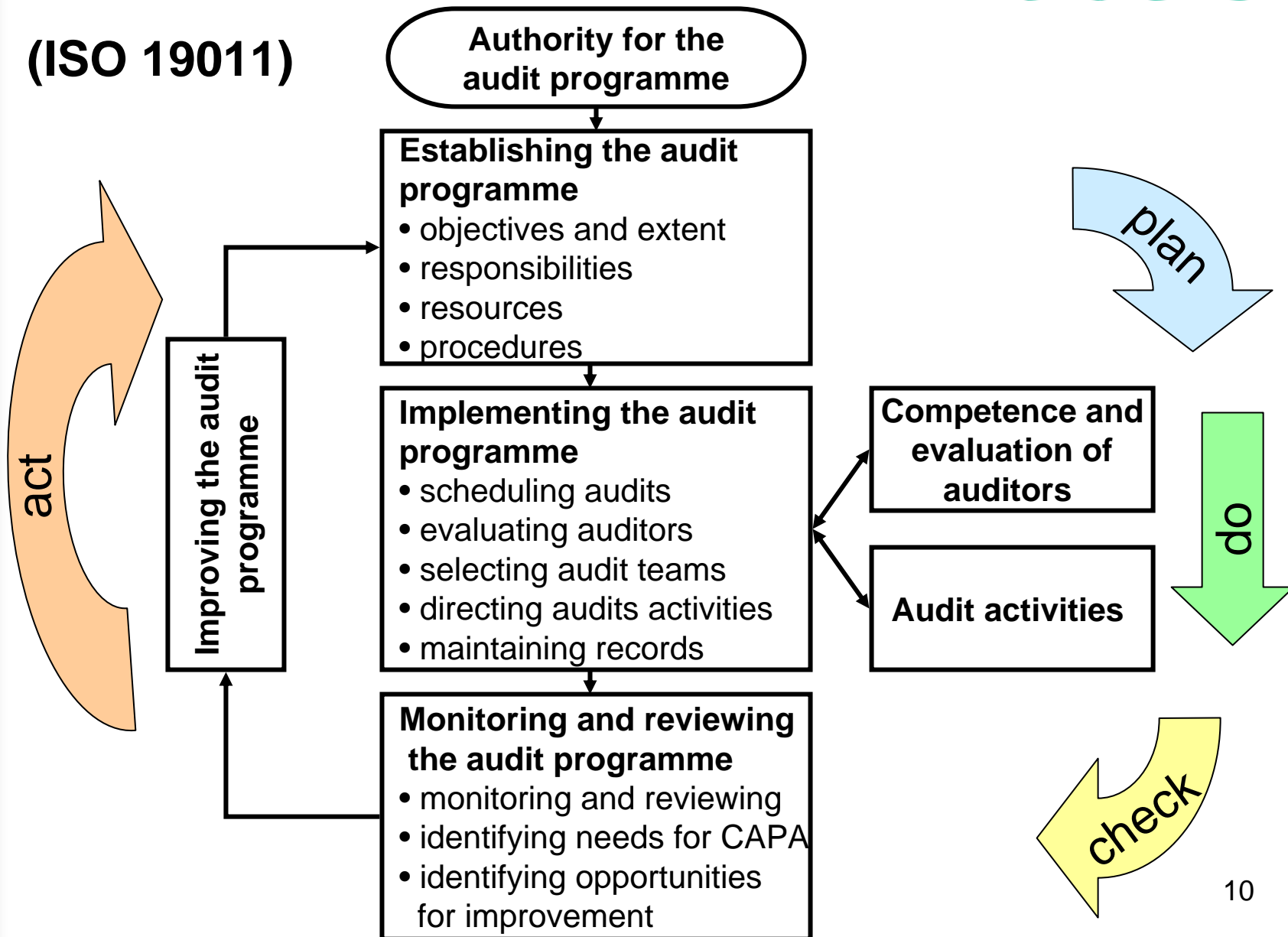


Audit programme

3



(ISO 19011)



Audits done by Notified Bodies for CE-Marking

Contractual relationship between the manufacturer and the Notified Body

- valid for at least a complete certification period
- defining the EU conformity assessment procedure (CAP)
- defining sites to be included for certification
- defining product range
- may include CAP for other regions if the NB is a designated CAB for that purpose (eg. Registrar for Canada, Taiwan ...)
- may include voluntary certification for ISO 9001

Audits done by Notified Bodies for CE-Marking

Planning

- requesting + receiving information from the manufacturer/auditee:
the current quality manual, persons responsible, on products, on processes, on changes
- allocation of resources (audit team)
- planning of the details of the audit:
which auditor audits what – when – where,
needing which partner of the auditee

Audits done by Notified Bodies for CE-Marking

Preparing

- auditors review the quality manual
- experts of the auditing are aware of applicable standards
- audit plan arranged with auditee
- details of audit plan include:
 - opening meeting
 - for each process audited: times, names of auditors, location, responsible persons/function of the auditee
 - auditors' review
 - closing meeting

Audits done by Notified Bodies for CE-Marking

Auditing process on site (technique)

- auditors use detailed checklists (derived from the clauses of ISO 13485 and other applicable standards)
- use of checklists also to cover specific regulatory requirements
- no systematic retention of copies of documents of procedures, etc.) by auditors on all instances they note as non-compliance

Audits done by Notified Bodies for CE-Marking

Auditing process on site (levels of depth)

- auditors verify that process required are established and that they are designed to fulfill the requirements (for all process in case of a full audit)
- auditors verify systematically that processes are carried on according to the QMS, procedures and standards the auditee claims to fulfill
- auditors verify that the records exist and are retained as required
- auditors may sample the quality data to verify that the data is “sound”

Audits done by Notified Bodies for CE-Marking

Auditing time spent on site, aspects considered

- the requirements of the relevant management system standards;
- size and complexity
- technological and regulatory context
- outsourcing
- the results of any prior audits
- number of sites and multi-site considerations

ISO/IEC 17021 clause 9.1.4 requires a documented procedure for determining the audit time, and a justification recorded for the time planned for each audit

Audits done by Notified Bodies for CE-Marking

Communication of non-compliance

- lead auditor must explain levels of findings at the opening meeting
 - major non-conformities (preventing certification or continuation of certification)
 - other non-conformities
 - recommendations for improvement
- all non-compliances must be communicated as soon as the facts are clear and at the closing meeting
- recommendations may be communicated also later in the audit report

Audits done by Notified Bodies for CE-Marking



Reporting

according to the requirements of ISO 19011 clause 6.6.1

- audit objectives
- audit scope, particularly identification of the organizational and functional units or processes audited and the time period covered
- identification of the audit client (auditee/manufacturer)
- identification of audit team leader and members
- dates and places where the on-site audit activities were conducted
- audit criteria, audit findings and audit conclusions

Audits done by Notified Bodies for CE-Marking



Reporting

The audit report may also include or refer to the following, as appropriate:

- audit plan, list of auditee representatives
- summary of the audit process, including the uncertainty and/or any obstacles encountered that could decrease the reliability of the audit conclusions
- confirmation that the audit objectives have been accomplished within the audit scope in accordance with the audit plan
- any areas not covered, although within the audit scope
- any unresolved diverging opinions
- recommendations for improvement, if specified in the audit objectives
- agreed follow-up action plans, if any
- confidentiality statement, distribution list for the audit report

Audits done by Notified Bodies for CE-Marking



Reporting

- ⇒ **use of the reports in the CE-certification process within the auditing organization**
- ⇒ **reports need to be complemented/rewritten in order to be used for other certification schemes in other jurisdictions**
- ⇒ **1 report usable for various certification schemes**



Conclusions

Effective Auditing (using up-to-date audit strategy)

- top down approach widely applied
- fully process oriented auditing?
- risk based auditing strategy applied?
- is the GHTF subsystem approach applied?

⇒ **Remaining potential for improvement in applying:**

GHTF SG4 N30 R20:2006: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy”

Conclusions

Tool needed to facilitate multi-purpose auditing

- to allow the use of a single audit report...
- ⇒ **need to harmonize the requirements for the audit report content for regulatory purposes:**

**GHTF SG4 N33 R15:2007 (final document)
Guidelines for Regulatory Auditing of Quality
Management Systems of Medical Device Manufacturers
– Part 3: Regulatory Audit Reports**

Thank you for your attention
and for your support of SG4's work!