Audit plan / program

Certification requirements
The initial audit will be performed according to the applicable guideline(s). In case the conditions give reason, the plan may be changed in mutual consultation. When we do not receive any reaction to the plan 2 days before the audit, we assume the audit plan can be followed. The contact person will make sure that the persons involved are available and will provide a room in which the auditor(s) can write their report at the end of the day.

Initial audit

Audit plan

Name activity	Attendies and location	Standard requirements
Opening meeting	All employees concerned; meeting room	-
Assessment of the Quality documents	Quality Manager; meeting room	As set in the applicable guideline(s), Kiwa regulations and indicated in the model IQC-scheme
Assessment of hygienic aspects	Responsible employee	Clause 4.2.1 of the applicable guideline(s)
Production tour (IQC assessment) Consisting of • receiving inspection, • production process (machining, assembly etc.), • internal transport and storage, • final inspection and test facilities • calibration of measuring equipment	Employees responsible for the Quality of production and facilities	As set in the applicable guideline(s), regulations and model IQC-scheme
Assessment of handling of (customers) complaints	Responsible employee	As set in the applicable guideline(s) and Kiwa regulations
Reporting	Auditor(s), meeting/reporting room	-
Closing meeting	All employees concerned; meeting room	

Objectives of the audit
During the above audit, Kiwa will verify whether all requirements concerning the production facility are conform the requirements as set in the applicable guideline(s)

Hereby Kiwa will verify whether:
- the quality system and the manual comply with the requirements of the applicable guideline(s), Kiwa regulations and indicated in the model IQC-scheme
- the quality system has been sufficiently implemented in order to ensure that manufactured products continuously comply with the functional requirements included in the guideline(s);
- the implementation of the defined processes and documentation of the quality system was demonstrated;
- the quality system is effective;

Audit plan / program

surveillance audits

In contradiction to the initial audit the surveillance audits are not necessarily to be announced, but may be unannounced. Therefore the audit plan may not be communicated beforehand.
However, each audit will be executed according the following plan and frequencies.

Audit plan

Name activity	Attendies and location	Standard requirements
Opening meeting	All employees concerned; meeting room	-
Results of previous assessment(s)	Responsible employee(s); meeting room	Applicable guideline(s)
Assessment of hygienic aspects	Responsible employee	Clause 4.2.1 of the applicable guideline(s)
Production tour (IQC assessment) • receiving inspection, • production process (machining, assembly etc.), • internal transport and storage, • final inspection, • calibration of measuring equipment • marking • handling of non-complying products • corrective actions	Employees responsible for the Quality of production and facilities	As set in the applicable guideline(s), regulations and model IQC-scheme
Assessment of handling of (customers) complaints	Responsible employee	As set in the applicable guideline(s) and Kiwa regulations
Verification of end product	Responsible employee	Test matrix as included in the guideline(s)
Reporting	Auditor(s), meeting/reporting room	-
Closing meeting	All employees concerned; meeting room	

Frequencies

The following frequencies are followed:

- each visit
  - Results of previous assessment(s)
  - Assessment of hygienic aspects
  - Marking
  - Corrective actions
- at least once per year
  - receiving inspection,
  - production process (machining, assembly etc.),
  - final inspection,
  - Assessment of handling of (customers) complaints
- at least once per 3 year
  - internal transport and storage,
  - calibration of measuring equipment
  - handling of non-complying products

For the verification of the end product the test matrix as included in the Kiwa evaluation guideline shall be followed.

Objectives of the audit

During the above audits, Kiwa will verify whether all requirements concerning the production facility are conform the requirements as set in the applicable guideline(s) and what has been included in the Kiwa certificate(s).

Hereby Kiwa will verify whether:

- the quality system and the manual continuously comply with the requirements of the applicable guideline(s), and Kiwa regulations
- the quality system has been sufficiently implemented in order to ensure that manufactured products continuously comply with the functional requirements included in the guideline(s) and replicates what has been included in the IQC-scheme(s),
- the implementation of the defined processes and documentation of the quality system was demonstrated;
- the quality system is effective.