Manual K15006
15 September 2023

Kiwa Manual

for the Kiwa NSF/ANSI/CAN 60 product certificate
for drinking water treatment chemicals

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Validation
This version of the manual replaces the version of 01 November 2020 and has been validated by the responsible Division Director of Kiwa on 15 September 2023

Trust
Quality
Progress

Contents

1 Introduction

1.1 General

This manual includes all relevant requirements which are employed by Kiwa when dealing with applications for the issue and maintenance of a certificate for products used for drinking water treatment chemicals, based on NSF/ANSI/CAN 60.

This manual is used by Kiwa in conjunction with the Kiwa Regulations for Certification. These regulations detail the methods used by Kiwa for conducting the necessary investigations prior to issuing the product certificate and the methods of external control.

For the performance of its certification work, Kiwa is bound to the requirements as included in EN-ISO/IEC 17065 “Conformity assessment - Requirements for bodies certifying products, processes and services”.

This manual replaces the manual K15006, dated 2020-11-01. The quality declarations issued and based on that manual will not lose their validity.

Description of the changes:
- Addition of the product requirement shelf life, section 4.5;
- Addition of the quality requirement for process water, section 6.5

1.2 Field of application / scope

This manual, covers the Drinking Water Treatment Chemicals — Health Effects of the NSF/ANSI/CAN 60. The products are intended to be used for treatment and / or production of water intended for human consumption. It describes the characteristics of the product and specifies the requirements of the product and gives reference to the analytical methods e.g. when the product is a chemical substance.
Drinking water treatment chemicals and other chemical products that are directly added to water and are intended and not intended to be present in the finished water are covered by this scope.

Chemicals covered by this scope include, but are not limited to, coagulation and flocculation chemicals, softening, precipitation, sequestering, pH adjustment, and corrosion / scale control chemicals, disinfection and oxidation chemicals, miscellaneous treatment chemicals, and miscellaneous water supply chemicals.

Contaminants produced as by-products through reaction of the treatment chemical with a constituent of the treated water are not covered by this scope.
Acknowledging the fact that indigenous microorganisms may be present in drinking water, products resulting in the intentional introduction of microorganisms for the treatment of drinking water are excluded from the scope.

This scope does not establish performance or taste and odor requirements for drinking water treatment chemicals.

1.3 Acceptance of test reports provided by the supplier

If the supplier provides reports from test institutions or laboratories to prove that the products meet the requirements of this evaluation guideline, the supplier shall prove that these reports have been drawn up by an institution that complies with the applicable accreditation standards, namely:

- NEN-EN-ISO/IEC 17020 for inspection bodies;
- NEN-EN-ISO/IEC 17021-1 for certification bodies certifying systems;
- NEN-EN-ISO/IEC 17025 for laboratories;
- NEN-EN-ISO/IEC 17065 for certification bodies certifying products.

Remark:
This requirement is considered to be fulfilled when a certificate of accreditation can be shown, issued either by the Board of Accreditation (RvA) or by one of the institutions with which an agreement of mutual acceptance has been concluded by the RvA. The accreditation shall refer to the examinations as required in this evaluation guideline. When no certificate of accreditation can be shown, Kiwa shall verify whether the accreditation standard is fulfilled.

1.4 Quality declaration

The quality declarations to be issued by Kiwa are described as Kiwa product certificates.

2 Terms and definitions

In this manual the following terms and definitions are applicable:

Supplier:
the party that is responsible for ensuring that the products meet and continue to meet the requirements on which the certification is based.

Manufacturer
the party that is responsible for the production of the products on which the certification is based.

IQC scheme (IQCS) :
a description of the quality inspections carried out by the supplier as part of his quality system.

Product:
Drinking Water Treatment Chemicals.

Chemicals:
for this manual with “chemical” is meant all water treatment products covered by NSF/ANSI/CAN 60.

Product requirements:
requirements made specific by means of measures or figures, focusing on (identifiable) characteristics of products and containing a limiting value to be achieved, which limiting value can be calculated or measured in an unequivocal manner.

Pre-certification tests:
tests in order to ascertain that all the requirements recorded in the manual are met.

Inspection tests:
tests carried out after the certificate has been granted in order to ascertain whether the certified products continue to meet the requirements recorded in the manual.

Remark: The test matrix contains a summary showing what tests Kiwa will carry out in the pre-certification stage and in the event of inspections as well as showing the frequency with which the inspection tests will be carried out.

Product certificate:
a document, in which Kiwa declares that a product may, on delivery, be deemed to comply with the product specification recorded in the product certificate.

Testing:
all necessary testing, done to ensure that the product shall meet the requirements as stated with this manual.

Certification mark
a protected trademark of which the authorization of the use is granted by Kiwa, to the supplier whose products can be considered to comply on delivery with the applicable requirements.

Shelf life:
the shelf life is defined: the amount of time that a properly packaged and stored product will last without undergoing chemical or physical changes.

3 Procedure for granting the quality declaration

3.1 Pre-certification tests

The pre-certification tests to be performed are based on the (product) requirements as included in this manual including the test methods and contain, depending on the nature of the product to be certified:

- type testing to determine whether the products comply with the product requirements,
- production Process Assessment;
- assessment of the quality system and the IQC-scheme,
- assessment on the presence and functioning of the remaining procedure.
- if applicable, assessment of the warehouse(s) when:
  - There is a risk that products have limited shelf life and/or are particularly sensitive to handling damage and so may no longer be in conformity before they are sold, or;
  - there is the risk that products may lose their traceability from manufacture to being first sold e.g. be wrongly labelled and packaged by the manufacturer if ready manufactured products are delivered in bulk from subcontractors and broken down into smaller lots for sale.
- if applicable, assessment of the sales office when complaints, use of certification logos or other aspects cannot be (fully) assessed at the production location, e.g. when the production location is not part of the organization of the certificate holder.

3.2 Investigation into the product and/or performance requirements

Kiwa will investigate to be certified products against the certification requirements as stated in the manual.
The necessary samples will be drawn by or on behalf of Kiwa.

3.3 Production process assessment

When assessing the production process, it is investigated whether the manufacturer is capable of continuously producing products that meet the certification requirements.
The evaluation of the production process takes place during the ongoing work at the manufacturer.
The assessment also includes at least:

- The quality of raw materials, half-finished products and end products;
- Internal transport and storage.

3.4 Contract assessment

If the supplier is not the manufacturer of the products to be certified, Kiwa will assess the agreement between the supplier and the manufacturer.
This written agreement, which is available for Kiwa, includes at least:

- Accreditation bodies, scheme managers and Kiwa will be given the opportunity to observe the certification activities carried out by Kiwa or on behalf of Kiwa at the manufacturer;
- The scope of the certified products;
- The relevant certification requirements (e.g factory production control requirements);
- A notification from the company to the certificate holder in event of changes to the relevant production process or product.

3.5 Granting the quality declaration

After finishing the initial investigation, the results are presented to the Decision maker (see 8.2) deciding on granting the certificate. This person evaluates the results and decides whether the certificate can be granted or if additional data and/or tests are necessary.

4 Product Requirements

4.1 General

This chapter contains the requirements that products, defined as drinking water treatment chemicals, have to fulfil.

4.2 Requirements to avoid deterioration of the quality of drinking water

The products shall meet the requirements laid down in NSF/ANSI/CAN 60.
This means that de procedure according to NSF/ANSI/CAN 60 for obtaining a recognised quality declaration has to be concluded with positive results. Under the provisions of this Standard,
a product shall not contribute any contaminant to drinking water in excess of the contaminant's SPAC.

The test methods described in NSF/ANSI/CAN 60 are applicable.

4.3 Instructions for use

The supplier shall provide instructions of use where applicable. A reference to these instructions shall be made at or near to the packaging. The instructions must contain specific information with regard to storage, safety, transport, processing temperature and use. The primary reason for providing this information is to contribute to the awareness of the importance of hygienic work as a 'prevention measure'.

4.4 Protection of products during transport and storage

The supplier must have a procedure in place that protects the products in such way, that the hygiene is ensured during storage and transport. Appropriate, effective measures shall be made to control access to products at all points of manufacturing, blending, diluting, packaging, repackaging, storage, shipping and handling, and to provide the manufacturer and the purchasing user of product with the ability to detect tampering.

4.5 Shelf life

If applicable, the shelf life of the product is according to the manufacturers own declaration.
The manufacturer has to prove the fulfilment of the declared shelf life by duration tests or by other relevant evidence.
The declaration and prove shall be inspected during the yearly inspection visits (see chapter 7).

5 Marking

5.1 General

The products or documentation shipped with the product, have to be marked with following minimum indelible marks and indications:

- Product trade name;
- Certificate number;
- Suppliers or manufacturers name and address;
- “Net weight”;
- “Lot number”;
- “Maximal usage dose of the product”.

For extensive marks according to NSF/ANSI/CAN 60 standard: see certificate

5.2 Certification mark

After concluding a Kiwa certification agreement, the certified products shall be indelible marked on the packaging[1)] with the following certification marks:

or in words

KIWA NSF/ANSI 60

[1)] If not possible, the marking shall be on the delivery receipt.

Remark:
for bulk transport (in lorries) use one of both certification marks for the expedition document.

6 Requirements with respect to the quality system

This chapter contains the requirements which have to be met by the suppliers and/or manufacturers quality system.

6.1 Manager of the quality system

Within the suppliers and/or manufacturers organizational structure an employee must have been appointed who is in charge of managing the quality system.

6.2 Internal quality control/quality plan

The supplier and/or manufacturer shall have an internal quality control scheme (IQC scheme) which is applied by him.

The following must have been demonstrably recorded in this IQC scheme:

- what aspects are checked by the supplier and/or manufacturer;
- according to what methods such inspections are carried out;
- how often these inspections are carried out;
- in what way the inspection results are recorded and kept.

This IQC scheme should at least be an equivalent derivative of the model IQC scheme as shown in annex I.

6.3 Control of test and measuring equipment

The supplier and/or manufacturer shall verify the availability of necessary test and measuring equipment for demonstrating product conformity with the requirements in this manual.
When required the equipment shall be kept calibrated (e.g recalibration at interval).
The status of actual calibration of each equipment shall be demonstrated by traceability through an unique ID.
The supplier and/or manufacturer must keep records of the calibration results.
The supplier and/or manufacturer shall review the validity of measuring data when it is established at calibration that the equipment is not suitable anymore.

6.4 Procedures and working instructions

The supplier and/or manufacturer shall be able to submit the following:

- procedures for:
    - dealing with products showing deviations;
    - corrective actions to be taken if non-conformities are found;
    - dealing with complaints about products and/or services delivered;
- the working instructions and inspection forms used.

6.5 Hazard assessment procedures for process water

If the finished product contains water supplied by a public water system, the manufacturer shall have procedures in place that identify steps to be taken when utilities issue warnings, such as a boil water alert, do not drink, or do not use order.
If the finished product contains water sourced through other than a public water system, the manufacturer shall have procedures that periodically monitor the water for chemicals of concern.
The procedure shall also specify treatment of the source water, or preclude its use, when significant quality changes may introduce unacceptable levels of contaminants to the product.

6.6 Other requirements

The supplier shall be able to submit the following:

- the organisation’s organogram;
- qualification requirements of the personnel concerned.

7 Summary of tests and inspections

This chapter contains a summary of the following tests and inspections to be carried out in the event of certification:

- pre-certification tests;
- inspection tests as to toxicological requirements and product requirements;
- inspection of the quality system.

The frequency with which Kiwa will carry out inspection tests is also stated in the summary.

7.1 Test matrix

In table 1 the test matrix is given.

Table 1 – Test matrix.

Description of requirement	Manual clause	Tests within the scope of:		
		Pre-certification	Supervision by Kiwa after granting of certificate[1)]	
			inspection[2)]	frequency (no./year)
Requirements to avoid deterioration of the quality of the drinking water	4.2	X	X[3) 4)]	1x year
Instructions for use	4.3	X	X	1x year
Protection during transport and storage	4.4	X	X	1x year
Shelf life	4.5	X	X	1x year
Marking	5	X	X	1x year
Requirements with respect to the quality system	6	X	X	1x year

1) In case the product or production process changes significantly, it must be determined whether the performance requirements are still met.
All product characteristics that can be determined within the visiting time (maximum 1 day) are determined by the inspector or by the supplier in the presence of the inspector. In case this is not possible, an agreement will be made between the certification body and the supplier about how the inspection will take place.

2) This aspect is compared with the for this aspect ascertained acceptance parameters on the basis of the IQC inspection (indirect by means of direct related parameters).

3) Sampling and testing to verify the IQC of the manufacturer; this activity is performed once a year or, if in combination with other drinking water approvals, once every three years.

4) Products that are unavailable for testing by the Kiwa for more than three years from the last test date cannot be considered compliant with the NSF/ANSI/CAN 60 standard.

7.2 Inspection of the quality system

The quality system of the supplier and/or manufacturer will be checked by Kiwa on the basis of the IQC scheme.
The inspection contains at least those aspects mentioned in the Article 6 of this manual.

8 Agreements on the implementation of certification

8.1 General

Beside the requirements included in this manual, the general rules for certification as included in the Kiwa Regulations for Certification apply.

These rules are in particular

- the general rules for conducting the pre-certification tests, to be distinguished in:
    - the way suppliers are to be informed about how an application is being handled,
    - how the test are conducted,
    - the decision to be taken as a result of the pre certification tests.
- the general rules for conducting inspections and the aspects to be audited,
- the measures to be taken by Kiwa in case of Non Conformities,
- measures taken by Kiwa in case of improper Use of Certificates, Certification Marks, Pictograms and Logos,
- terms for termination of the certificate,
- the possibility to lodge an appeal against decisions of measurements taken by Kiwa.

8.2 Certification staff

The staff involved in the certification may be sub-divided into:

- Hygienic Evaluator (**HE**): they are in charge of carrying out the analytical summaries, evaluation test results and assessing the laboratory results;
- certification assessors (**CAS**): they are in charge of carrying out the certification advice, preparing certification documents and assessing the inspectors' reports;
- site assessors (**SAS**): they are in charge of carrying out external inspections at the supplier's works;
- decision-makers (**DM**): they are in charge of taking decisions in connection with the pre-certification tests carried out, continuing the certification in connection with the inspections carried out and taking decisions on the need to take corrective actions.

8.2.1 Qualification requirements

The qualification requirements consist of:

- qualification requirements for personnel of a certification body which satisfies the requirements EN ISO / IEC 17065, performing certification activities (see table 2)

Education and experience of the concerning certification personnel shall be recorded demonstrably.

Table 2 – Qualification requirements of certification staff.

Technical competences	Hygienic Evaluator	Certification Assessor	Site Assessor	Decision maker
Education - specific	• Higher professional working level (HBO) in technical area and competences. • Internal training certification and Kiwa policy • Training auditing	• Technical training at MBO (vocational) level and MBO competences Internal training certification and Kiwa policy • Training auditing	• Technical training at MBO (vocational) level and MBO competences Internal training certification and Kiwa policy • Training auditing	• Higher professional working level (HBO) in technical area and competences. Internal training certification and Kiwa policy • Training auditing
	• for manual relevant technical education • specific studies and training (know-how and skills)	• for manual relevant technical education • specific studies and training (know-how and skills)	• for manual relevant technical education • specific studies and training (know-how and skills) • Kiwa basic course witness testing	• not applicable
Experience – specific	• A minimum of 1 year experience in manufacturing, testing, inspection and/or the installation business.	• A minimum of 1 year experience in manufacturing, testing, inspection and/or the installation business.	• A minimum of 1 year experience in manufacturing, testing, inspection and/or the installation business. • Qualification for relevant scheme • witness of testing	• 4 year of relevant work experience with at least 1 year in certification
	• 3 correctly performed independent hygienic evaluations, checked and reviewed by qualified employees (for an additional scheme, number is reduced to one)	• 3 correctly performed independent product evaluations, checked and reviewed by qualified employees (for an additional scheme, number is reduced to one)	• 3 coached inspections • 1 independent inspection	• general knowledge of the manual

8.2.2 Qualification

The qualification of the Certification staff shall be demonstrated by means of assessing the education and experience to the requirements mentioned before. In case staff is to be qualified on the basis of deflecting criteria, written records shall be kept.

The authority to qualify staff is dedicated to:

- Product manager: qualification of hygienic evaluator, certification assessors and site assessors,
- Management of Kiwa: qualification of decision makers.

8.3 Report Pre certification tests

Kiwa records the results of the pre certification tests in a report. This report shall comply with the following requirements:

- completeness: the reports verdicts about all requirements included in the manual,
- traceability: the findings on which the verdicts have been based shall be recorded traceably,
- basis for decision: the decision maker shall be able to base his decision on the findings included in the report.

8.4 Decision for granting the certificate

The decision for granting the certificate shall be made by a qualified decision maker which has not been involved in the pre certification tests. The decision shall be recorded traceable.

8.5 Nature and frequency of external inspections

Kiwa shall carry out audits on site at the supplier and/or manufacturers at regular intervals to check whether the supplier and/or manufacturer complies with his obligations. The frequency of audits amounts to at least one audit on site per year for suppliers with a quality management system (in accordance with EN-ISO 9001) for their production, which has been certified by an acknowledged body (in accordance with ISO/IEC 17021-1) and where the IQC scheme forms an integral part of the quality management system. In case the production of the supplier or manufacturer is not certified against EN-ISO 9001, the frequency of the audits on site may be increased to at least two per year.

Inspections shall at least refer to:

- the product requirements;
- the production process;
- the suppliers or manufacturers IQC scheme and the results obtained from inspections carried out by the supplier or manufacturer;
- the correct way of marking certified products;
- compliance with required procedures;
- handling complaints about products delivered.

The results of each inspection shall be traceably recorded in a report.

8.6 Non conformities

When the certification requirements are not met, measures are taken by Kiwa in accordance with the sanctions policy as written in the Kiwa Regulation for Certification.
The Sanctions Policy is available through the “News and Publications” page on the Kiwa website "Kiwa Regulation for Certification"

9 Titles of standards

9.1 Public law rules

In table 3 the public rules that have to be fulfilled are listed.

Table 3 – Public law rules (the latest version is valid).

Standard	Title
NSF/ANSI/CAN 60	Drinking water treatment chemicals – Health Effects

9.2 Standards / normative documents

In table 4 the relevant normative documents (standards) for this manual are listed.

Table 4 – For this manual relevant normative documents (standards). (the latest version is valid).

Standard	Title
EN-ISO 9001	Quality management systems – Requirements
NEN-EN ISO/IEC 17020	Conformity assessment - General criteria for the operation of various types of bodies performing inspection
NEN-EN ISO/IEC 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems
NEN-EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
NEN-EN ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services

I - Model IQC Scheme (example)

<table>
<tr><td><u>IQC-schedule</u>
<u>INTERNAL QUALITY PLAN</u></td><td>Manufacturer / supplier:
Production location address:</td><td>Number of appendices:</td></tr>
<tr><td colspan="3"><u>Field(s) of application</u>
<u>According Evaluation Guideline(s)</u></td></tr>
<tr><td colspan="2"><u>Number of production shifts:</u></td><td rowspan="3"><u>Quality manual, procedures and working instructions</u>
Is the Quality Management System (QMS) certified according to ISO 9001[1)]?

If yes, by which certification body:

If yes, is the certification body accredited for the particular scope of certification?

In case the QMS is <u>not</u> certified according to ISO 9001:
• Working instructions, test instructions and procedures are documented as follows:
• The following procedure for dealing with <u>complaints</u> applies:
• The following procedure for <u>nonconformity review</u> applies:

<u>Hazard assessment procedures for process water</u>
If the finished product contains water supplied by a public water system, the manufacturer should have procedures in place that identify steps to be taken when utilities issue warnings, such as a boil water alert, do not drink, or do not use order: yes/n.a.

If the finished product contains water sourced through other than a public water system, the manufacturer should have procedures that periodically monitor the water for chemicals of concern.
(The procedure shall also specify treatment of the source water, or preclude its use, when significant quality changes may introduce unacceptable levels of contaminants to the product): yes/n.a.</td></tr>
<tr><td colspan="2"><u>Quality Control</u>
Total number of employees in QC department :
Number of QC-operators per shift :

If no QC-inspections are carried out during night shifts, state the QC procedure(s)/instruction(s) to be followed: yes, documented in:QM</td></tr>
<tr><td colspan="2"><u>Inspection and test records</u>
All records shall be maintained for a minimum of 15 years.</td></tr>
<tr><td colspan="2"><u>Specific agreements/comments/explanations</u></td><td>Signature of the manufacturer/supplier:

Date :</td></tr>
</table>

Calibration of measuring and test equipment

Applicable procedure(s) nr(s):

Equipment to be calibrated	Calibration aspect	Calibration method	Calibration frequency	Calibration file (name and location)

B. Raw material and additives

Applicable procedure(s) nr(s):

B.1 Receipt

For each delivery of raw material or additives data with respect to dates, manufacturers, types and quantities are recorded as follows:

B.2 Entry control

Type of raw material	Inspection aspect	Inspection method	Inspection frequency	Registration file (name and location)

C. Batch release tests per machine (including in-process and finished product testing)

Applicable procedure(s) nr(s):

Production process(es):

Type of product	Type of test	Test method	Test frequency	Registration file (name and location)

D.	**Process verification tests** Applicable procedure(s) nr(s):			
Type of product	Type of test	Test method	Test frequency	Registration file (name and location)
E.	**Control of nonconforming and/or rejected products** Applicable procedure(s) nr(s):			
E.1	**Method of registration**			
E.2	**Method of identification**			
E.3	**Method of nonconformity review and disposition**			
F.	**Inspection with regard to packaging, storage and transportation of the finished product** Applicable procedure(s) nr(s):			
Inspection aspects		Inspection method	Inspection frequency	Registration file (name and location)
F.1	**Packaging/storage/ transportation/shelf life etc**			

Raw materials list **(not required to fill-out this appendix in case reference can be made to other Kiwa certification agreement)**	**Appendix I** Date: ……

I.1 The product is built-up of the following raw materials:

a) In case of products made from ready-made raw materials: listing of name and/or unique code of the raw material(s);

b) In case of products made from own compounded raw materials: reference to raw material/compound sheets which are (only) available at the production location and which have to be authenticated by Kiwa (e.g. by the Kiwa inspector);

c) In case of composed products (e.g. plastics fitting body, with separate nut, clamp ring and rubber sealing ring): of each part a specification according to a) or b) (whatever applicable).

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List of technical drawings			**Appendix II** Date:……..
Drawing title and number	Drawing date	Drawing title and number	Drawing date

II - Guidance for prevention of contamination during transport and storage

a) Importance of a hygienic operation

The impact of pollution can have big consequences for the treatment and / or production of water intended for human consumption[1)] and need substantial efforts to clean the system.

b) Protection of the used products

The primary task in this case is “prevention”.

For all products coming from the production location, until use in the drinking water system, the same “preventive” measurements shall be taken [2)], to prevent pollution.
Therefore suppliers and/or manufacturers shall have a procedure how to prevent pollution of certified (drinking water) products during production, transport and storage.

c) Requirements for the protection of products

For all preventive (protective) actions taken to protect the products against pollution it is important that the protection will last for the complete process of storage, transport and again storage.

remark :
[1)] mostly this is a microbiological contamination coming from the surrounding area on macro- and micro scale (like dust, but also feces and dead beasts.
[2)] “protection” is the closing of packaging.

III – Model certificate (example)

CERTIFICATE

Product certificate
Kxxxxx/0x

kiwa

Issued			
Replaces	-		
Page	*1 of 1*		

Drinking water treatment chemicals – health effects according to NSF/ANSI/CAN 60

STATEMENT BY KIWA
With this product certificate, issued in accordance with the Kiwa Regulations for Product Certification, Kiwa declares that legitimate confidence exists that the product:

Name product

supplied by

Name customer

as specified in this product certificate and marked with the Kiwa NSF/ANSI 60 mark in the manner as indicated in this product certificate may, on delivery, be relied upon to comply with Kiwa evaluation guideline Manual K15006 for "drinking water treatment chemicals – health effects according to **NSF/ANSI/CAN 60**", dated dd-mm-yyyy.

Name director
Kiwa

Publication of this certificate is allowed.
Advice: consult www.kiwa.nl in order to ensure that this certificate is still valid.

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ANAB ACCREDITED PRODUCT CERTIFICATION

Company Name and address customer Phone e-mail website etc.			

Certification process consists of initial and regular assessment of:
- **quality system**
- **product**