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Kiwa Manual

for the Kiwa NSF/ANSI 61 product certificate for
drinking water system components

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Validation

This version of the manual replaces the version of 5 August 2014 and has been validated by the responsible Division Director of Kiwa on 27 May 2016.

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1 Introduction

1.1 General

This manual includes all relevant requirements which are used by Kiwa as the basis for the issue and maintenance of a certificate for drinking water system components used for transport or treatment and /or production of drinking water, based on NSF/ANSI 61.

This manual is used by Kiwa in conjunction with the Kiwa-Regulations for Product 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 the clause 7 of ISO/IEC 17065.

1.2 Field of application / scope

This manual, covering the NSF/ANSI 61, is intended to certify products, components, or materials that come into contact with drinking water or treatment products or both, giving minimum health effect requirements for the chemical contaminants and impurities that are indirectly imparted to the drinking water. This manual does not establish performance, taste and odour, or microbial growth support requirements for drinking water system products, components, or materials.

Remark: point of use drinking water treatment devices are not covered by this manual.

1.3 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.

IQC scheme (IQCS):

a description of the quality inspections carried out by the supplier as part of his quality system.

Product:

products, components or materials that come into contact with drinking water, as defined and covered by NSF/ANSI 61.

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:

for this manual "testing" is the following:

All necessary testing to ensure that the product shall meet the requirements as stated with this manual.

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 and/or functional requirements,
- production Process Assessment,
- assessment of the quality system and the IQC-scheme,
- assessment on the presence and functioning of the remaining procedure.

3.2 Granting the quality declaration

After finishing the pre-certification tests the results are presented to the person deciding on granting of the certificate. This person evaluates the results and decides whether the certificate can be granted or additional data and/or tests are necessary.

4 Product Requirements

4.1 General

This chapter contains the requirements that products defined as drinking water system components, have to fulfil. These requirements are part of the technical specification of the products, as included in the certificate.

4.2 Requirements to avoid deterioration of the quality of the drinking water

The products shall meet the requirements laid down in NSF/ANSI 61. This means that de procedure according to NSF/ANSI 61 for obtaining a recognised quality declaration has to be concluded with positive results.

The test methods described in NSF/ANSI 61 are applicable.

4.3 Installation instructions

The supplier shall provide installation instructions 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 specific installation guidelines.

4.4 Protection of products during transport and storage

When applicable, the products shall be protected during storage and transport to prevent contamination of all parts intended to come in contact with drinking water. See for information Annex II: "Guidance for prevention of contamination during transport and storage".

5 Marking

5.1 General

The products shall be marked with following indelible marks and indications:

- name or logo of the manufacturer;
- data or code indicating the date of production;
- type indication

5.2 Certification mark

After concluding a Kiwa certification agreement the certified products shall, beside the marks indicated in the respective standards, be indelible marked with:

the words **KIWA NSF/ANSI 61** ¹⁾

or the logo ¹⁾



The minimum required marking on the packaging of the products (for instance bags) shall be:

- K15007;
- Manufacturer's or suppliers name and trade mark or identification mark;
- Production code.

¹⁾ If not possible the marking shall be on the smallest packaging

6 Requirements with respect to the quality system

This chapter contains the requirements which have to be met by the supplier's quality system.

6.1 Manager of the quality system

Within the supplier's organizational structure an employee must have been appointed who is in charge of managing the supplier's quality system.

6.2 Internal quality control/quality plan

The supplier 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 producer;
- 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 Procedures and working instructions

The supplier 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.

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⁾	2 x year ³⁾
Installation instructions	4.3	X	X	2 x year
Protection during transport and storage	4.4	X	X	2 x year
Marking	5	X	X	2 x 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.

7.2 Inspection of the quality system

The quality system will be checked by Kiwa on the basis of the IQC scheme.

The inspection contains at least those aspects mentioned in the Kiwa Regulations for Product Certification.

8 Agreements on the implementation of certification

8.1 General

Beside the requirements included in this manual, also the general rules for certification as included in the Kiwa Regulations for Product 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 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 directions for conducting inspections and the aspects to be audited,
- the measurements to be taken by Kiwa in case of Non Conformities,
- measurements 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:

- certification assessors: they are in charge of carrying out the pre-certification tests and assessing the inspectors' reports;
- site assessors: they are in charge of carrying out external inspections at the supplier's works;
- decision-makers: 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 following qualification requirements have been set for the subject matter of this manual (see table 2):

Table 2 – Qualification requirements of certification staff.

ISO/IEC 17065	Certification Assessor	Site Assessor	Decision maker
Education - general	<ul style="list-style-type: none"> • Technical higher-level professional education • Internal training certification and Kiwa policy • Training auditing 	<ul style="list-style-type: none"> • Intermediate-level professional education • Internal training certification and Kiwa policy • Training auditing 	<ul style="list-style-type: none"> • Higher level professional education • Internal training certification and Kiwa policy • Training auditing
Education - specific	<ul style="list-style-type: none"> • for manual relevant technical education • specific studies and training (know-how and skills) 	<ul style="list-style-type: none"> • for manual relevant technical education • specific studies and training (know-how and skills) 	<ul style="list-style-type: none"> • not applicable.
Experience - general	<ul style="list-style-type: none"> • 1 year of relevant work experience with at least 4 pre certification tests of which one carried out independent under supervision 	<ul style="list-style-type: none"> • 1 year of relevant work experience with at least 4 inspections of which one carried out independent under supervision 	<ul style="list-style-type: none"> • 4 year of relevant work experience with at least 1 year in certification
Experience - specific	<ul style="list-style-type: none"> • Detailed knowledge of the manual and 4 certification tests carried out on the basis of the manual or similar 	<ul style="list-style-type: none"> • Detailed knowledge of the manual and 4 inspections carried out on the basis of the manual or similar 	<ul style="list-style-type: none"> • general knowledge of the manual

The level of education and the experience of the certification staff involved should be demonstrably recorded.

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:

- decision makers: qualification of 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 at regular intervals to check whether the supplier complies with his obligations. The frequency of audits amounts at least two audits on site per year for suppliers with a quality management system (in accordance with 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 is not certified against ISO 9001, the frequency of the audits on site may be increased to at least four per year.

Inspections shall at least refer to:

- the suppliers IQC-scheme and the results obtained from inspections carried out by the supplier,
- the correct way of marking of certified products
- complying with required procedures.

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

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 61	Drinking Water System Components – 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
ISO 9001	Quality management systems - Requirements
ISO/IEC 17021-1	Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements
ISO/IEC 17065	Conformity assessment - Requirements for bodies certifying products, processes and services

I Model IQC Scheme

Inspection subjects	Inspection aspects	Inspection method	Inspection frequency	Inspection registration
Raw materials or materials supplied: - recipe sheets - incoming goods inspection raw materials	- Recipe according annex product agreement -		Each delivery	Entry control document
Production process, production equipment, plant: - procedures - working instructions - equipment - release of product	- tuning parameters - maintenance aspects	- adjustments machine - maintenance scheme - measuring - visual evaluation	- continuously - continuously - start up new product	- "digital" - work sheet - inspection document
Finished-products	- soundness -etc	- visually - measuring - etc	- continuously - etc	End control documents
Measuring and testing equipment - measuring equipment - calibration	- proper functioning - accuracy within the range of measurement	- during usage - records of non-conformities	- continuously - 1 x year	- end control document - calibration document
Logistics - internal transport - storage - Preservation - packaging - identification	- circumstances in practise - comparison with order	- comparison with procedure - visual inspection	- continuously	- keep logistical procedures up to 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 water distribution ¹⁾ and need substantial efforts to clean the system.

b) Protection of the used products

The primary task in this case is “prevention” and secondary is also important the preparation of the main for the actual drinking water transport.

For all products coming from the production location, until installation in the drinking water system the same “preventive” measurements shall be taken ²⁾, to prevent pollution. Therefore 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 combination of packaging and closing the pipe/fitting ends.