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Guide to Certification

for the Kiwa UK Certificate for

- Thermostatic Mixing Valves (Type 2 TMV and Type 3 TMV)
- Tempering valves

Preface

This Guidance document has been created to explain the requirements of certification and inparticular the requirements of certification and testing to ISO 17065 and ISO 17025.

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1 Introduction

General

This Guidance document has been created to explain the requirements of certification and inparticular the requirements of certification and testing to ISO 17065 and ISO 17025. This document explains the requirements of certification to a 1+ scheme as defined by the Construction Products Regulations (CPR). This document explains the difference between other certification schemes which are operated to lower levels of certification such as levels 2 and 3 as defined in the CPR.

Overview.

This document is to aid manufacturers, suppliers, users etc. to the requirements of Certification Schemes in particular to explain the Kiwa UK Certification Scheme for Type 2 TMV, Type 3 TMV and Tempering valves which is a 1+ System as referred to under the CPR. The current system used in the UK for the acceptance of these products is an Attestation of Conformity Level 3, and it's important that manufacturers, suppliers and users' understand the difference between the levels of acceptance defined by the CPR.

2 Definitions

What is Product Certification?

Product certification or product qualification is the process of certifying that a certain product has passed performance tests and quality assurance tests, and continues to meet the qualification criteria stipulated in contracts, regulations, or specifications (typically called "certification schemes" in the product certification industry). This means that the manufacturer's products are independently assessed to ensure that the products, materials of construction and the manufacturing processes meet the requirements of the certification scheme.

What is the Certification process?

A product might be verified to comply with a specification or stamped with a specification number. This may not, by itself, indicate that the item is fit for any particular use. The person or group of persons who own the certification scheme (i.e., engineers, trade unions, building code writers, government, industry, etc.) have the responsibility to consider the choice of available specifications, choose the correct ones, set qualification limits, and enforce compliance with those limits. The end users of the product have the responsibility to use the item correctly. Products must be used in accordance with their listing for certification to be effective.

In many instances, prior to applying for certification, a product supplier will send a product to a testing laboratory (some certification schemes require the product to be sent out for testing by the product certifier instead). When the product to be certified is received at the testing laboratory, it is tested in accordance with the laboratory's internal procedures and with the methods listed in the test standards specified by the certification scheme. The resulting data collected by the testing laboratory, is then forwarded either back to the manufacturer, or directly to the product certifier.

The product certifier then reviews the product supplier's application information, including the testing data. If the certifier's evaluation concludes that the test data shows that the product meets all required criteria as listed in the certification scheme, and the decision maker(s) of the product certifier concur with the evaluation, then the product is deemed "certified" and is listed in a directory which the Product certifier is required to maintain. ISO/IEC 17065 requires that the final decision to grant or not grant certification be made only by a person or group of persons not involved in the evaluation of the product.

Products often need periodic re-certification, also known as surveillance. This requirement is typically identified within the certification scheme that the product is certified to. Certification bodies may require product suppliers to perform some sort of surveillance activity, such as collecting sample products from the marketplace for testing, in order to maintain their "listed" or "certified" status. Other examples of Surveillance activities include surprise audits of the manufacturing plant, supervision of the manufacturing and/or testing process, or a simple paperwork submittal from the supplier to the product certifier to ensure that the certified product has not changed. Other causes for recertification may include complaints issued against the product's functionality which would require removal from the marketplace, and expiration of the original certification. These lists of examples are by no means exhaustive.
Some certification schemes, or the product certifiers which operate those Schemes, may require that the product supplier operate a Quality Management System registered to ISO 9000, or that the testing be performed by a laboratory accredited to ISO 17025 and additionally may be required to undertake additional requirements for the laboratory to be accepted by the Certifier. The decision to set these requirements is most often made by the person or group which owns the Certification Scheme.

What is a Certification Mark?

Certified products are typically endorsed with a certification mark provided by the product certifier. Issuing of a certification mark is at the discretion of the individual product certifier. ISO 17065 does not require the product certifier to offer a certification mark in the event that a certificate is offered. When certification marks are issued and used on products, they are usually easy to see and enable users to

track down the certification listings to determine the criteria that the product meets, and whether or not the listing is still active.

An active certification listing must minimally include indication of the following information:

- The specific product or type of product certified
- The qualification standard that the product is judged to meet

What is an Accreditation Body?

The International Accreditation Forum (IAF) has a listing of all recognized Accreditation Bodies whose accreditations to the ISO 17065 standard are deemed equivalent.

"IAF" is encouraging more of its members to join the MLA as soon as they have passed a rigorous evaluation process to ensure that their accreditation programs are of world standard. The consequence of joining the IAF MLA is that conformity assessment certificates issued, within the scope of the IAF MLA, by conformity assessment bodies accredited by any one of the members of the IAF MLA will be recognised in the world wide IAF program."

Most countries only have a single Accreditation Body representing their economy in the IAF MLA. The two exceptions are the United States with American National Standards Institute (ANSI), American National Standards Institute - American Society for Quality National Accreditation Board (ANAB, a subdivision of ANSI), American Association for Laboratory Accreditation (A2LA), and International Accreditation Service (IAS) as signatory members, Europe with the TUV Technischer Überwachungs-Verein, English: Technical Inspection Association, and Korea which is represented by Korea Accreditation Board (KAB) and Korean Accreditation System (KAS). These listings are current as of March 2012, but will likely change in the future as more Accreditation Bodies undergo the required peer evaluations in order to become signatory members of the MLA. The United Kingdom Accreditation Body is UKAS and The Netherlands is RvA.

Each Accreditation Body is required to keep a listing of those organisations it accredits, as well as a Scope of Accreditation which details the activities that the organizations can perform, whether that is testing, inspection, or product certification.

Accreditation Bodies routinely audit the Product Certifiers whom they have accredited in order to determine if the performance or actions of the organisation have changed and do not meet the requirements of the Accreditation Body and the International Standards they are to conform to.

Accreditation Bodies issues acceptance of both Product Certifiers under ISO 17065 and Test and Calibration laboratories under ISO/IEC 17025.

What is ISO/IEC 17065?

Most product certification bodies (or product certifiers) are accredited to ISO/IEC 17065, an international standard for ensuring competence in those organizations performing product certifications. The organisations which perform this accreditation are called Accreditation Bodies, and they themselves are assessed by international peers against the ISO 17011 standard. Accreditation bodies which participate in the International Accreditation Forum (IAF) Multilateral Agreement (MLA) also ensure that these accredited Product Certification

What is an ISO 17025 Laboratory?

The ISO/IEC 17025 "General requirement for the competence of testing and calibration laboratories" is the main ISO standard used by testing and calibration laboratories.
In most major countries, ISO/IEC 17025 is the standard for which most labs must hold accreditation in order to be deemed technically competent. In many cases, suppliers and regulatory authorities will not accept test or calibration results from a laboratory that is not accredited to ISO/IEC 17025.

Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the International Organization for Standardization in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 is more specific in requirements for competence. And it applies directly to those organizations that produce testing and calibration results. Since its initial release, a second release

was made in 2005 after it was agreed that it needed to have its quality system words more closely aligned with the 2000 version of ISO 9001.

Laboratories use ISO/IEC 17025 to implement a quality system aimed at improving their ability to consistently produce valid results. It is also the basis for accreditation from an accreditation body. Since the standard is about competence, accreditation is simply formal recognition of a demonstration of that competence. A prerequisite for a laboratory to become accredited is to have a documented quality management system. The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard.

What is a Quality Management System (ISO 9001)?

A **quality management system** (QMS) is a collection of business processes focused on achieving your quality policy and quality objectives — i.e. what your customer wants and needs.[1] It is expressed as the organisational structure, policies, procedures, processes and resources needed to implement quality management. Early systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. Of all QMS regimes, the ISO 9000 family of standards is probably the most widely implemented worldwide - the ISO 19011 audit regime applies to both, and deals with quality and sustainability and their integration.

However, the basis of a QMS does not mean that the product that is manufactured or even the materials used in manufacturing under ISO 9000 will comply with any product standard or regulatory requirements form any country.

What is a Product Standard?

A published standard that establishes methods of testing, grading, and marking of a relevant product. The objective of product standards is to define requirements for specific products in accordance with the principal demands of the trade. Product standards are published by private organisations, manufacturers, distributors, approval bodies and users.

What is a National Standard?

A published national standard of a country is a standard that establishes methods of testing, grading, and marking the product. The objective of product standards is to define requirements for specific products in accordance with the principal demands of the trade. National standards are published by the national organisation of the Government of the country in question e.g.

BS = British Standard
NEN = Dutch Standard
DIN = German Standard.

What is an EN Standard?

A European standard is a standard that establishes methods of testing, grading, and marking the product. The objective of product standards is to define requirements for specific products in accordance with the principal demands of the trade. EN standards are produced by CEN where all the countries within the European Union have inputs into the development of EN standards. These EN Standards are then published by CEN and are adopted by each State within the European Union and are then called e.g.

BS EN = EN Standard adapted by UK
NEN EN = EN Standard adapted by Holland
EN DIN = EN Standard adopted by Germany.

What is an ISO Standard?

An ISO standard is a standard that establishes methods of testing, grading, and marking the product. The objective of product standards is to define requirements for specific products in accordance with the principal demands of the trade. ISO standards are produced by ISO where all the countries around the world can take part in their developments if they wish.

What is a TMV (Thermostatic Mixing valve)?

A thermostatic mixing valve (TMV) is a valve that blends hot water with cold water to ensure constant, comfortable shower and bath outlet temperatures, preventing scalding.
The storage of water at high temperature removes one possible breeding ground for Legionella; the use of a thermostat, rather than a static mixing valve, provides increased safety against scalding, and increased user comfort, because the hot-water temperature remains constant.

Many TMV's use a wax thermostat for regulation. They also shut off rapidly in the event of a hot or cold supply failure to prevent scalding or thermal shock.

It is increasingly common practice around the world to regulate the storage water temperature to above 60°C, and to circulate or distribute water at a temperature at 55°C. Water at these temperatures can cause scald injuries. Many countries, states, or municipalities now require that the temperature of all bath water in newly built and extensively refurbished domestic premises to a maximum of 46 to 48°C. Installing thermostatic mixing valves can ensure that water is delivered at the required temperature, thereby reducing the risk of scalding accidents; it also reduces hot water consumption from a supply that is maintained at a higher temperature.

TMVs are intended to deliver water that can be used directly for oblutionary purposes. Tempering valves also blend hot and cold water, uasually for the delivery at temperature not suitable for oblutionary purposes.

What is a Type 2 TMV?

This is a thermostatic mixing valve defined by UK Building Regulations as complying with BS EN 1111 or BS EN 1287 for use within commercial or domestic premises.

What is a Type 3 TMV?

This is a thermostatic mixing valve defined by NHS Regulations as complying with D O8 for use within any building which falls under the NHS Regulations including hospital and any health care premises.

What is a Tempering valve?

A tempering valve is a thermostatic valve used with water heaters to cool hot water by mixing in some cold water. This lowers the temperature enough to make the water safe to use but not suitable for use by oblutionary purposes.

WHAT does KUK mean?

KUK is the certification mark used by Kiwa Watertec (A Division of Kiwa UK), to show the product is accepted by Kiwa Watertec ISO 17065 certification scheme.

What is the Kiwa UK Expert Group?

This Group is made up of Experts form the Industry which oversees the Certification Scheme under UKAS and the Regulations deemed acceptable under ISO 17065 Accreditation.

What is a CE Marking?

Companies who place products on the market within the European market have a statutory obligation to provide their products with a CE Mark. Manufacturers have to test their products in accordance with European Technical Directives and in some cases these are defined within EN Standards.

What are the Construction Products Directive (CPD)/Construction Products Regulations (CPR)?

From July 2013 the CPD has replaced the CPR. The most significant implication for manufacturers is that CE marking will become mandatory in the European Union for products covered by harmonised European Standards (hEN) or European Technical Assessment (ETA).

What is Factory Production Control (FPC)?

The FPC is a management system focusing mainly on the production process. It aims to ensure that product quality is consistently maintained to the required specifications.
Implementation of the FPC ensures that equipment is properly tested and calibrated, product conformity is continually assessed and any non-conforming product can be managed accordingly.

The FPC is largely akin to a quality management system and the requirements are covered in the applicable product standard. If your company already holds an ISO 9001:2008 registration these requirements may be fulfilled by that system.

What is Attestation and Verification of Constancy of Performance?

The system for the Attestation Verification of Constancy of Performance (AVCP) in the CPR, is set by the European Commission for product families and can if applicable be found in Annex ZA of the applicable EN Standard. There are five systems (levels) for all systems of AVCP. The manufacturer must have a Factory Production Control (FPC) system, the type and extent of which is determined by the relevant product standard, and initial type testing (ITT) shall be conducted.

The level of the AVCP depends on the level of safety a product is required to meet. An example of this is:
Structural products within a building would require Level 1, paint used within the building would be Level 3 and materials in contact with drinking water would be Level 1+.

Attestation Level 1+ is the highest level for which an indepenent Notified Body is to be used, where Level 3 is a less onerous level where the manufacturer is able to show compliance without an inspection of their FPC or their ITT done by a third party.

System Type	Responsibility	Type of notified body	Tasks
System 1+	Notified body	Production certification body	Initial Inspection of the FPC System. Continuous Surveillance of the FPC system. Determination of the product type Audit testing
	Manufacturer		Factory Production Control (FPC) and further testing of samples
System 1	Notified body	Production certification body	Initial Inspection of the FPC System. Continuous Surveillance of the FPC system. Determination of the product type.
	Manufacturer		Factory Production Control (FPC) and further testing of samples
System 2+	Notified body	Factory production control certification body	Initial Inspection of the FPC System. Continuous Surveillance of the FPC system.
	Manufacturer		Determination of product type
System 3	Notified body	Test laboratory	Determination of product type
	Manufacturer		Factory Production Control (FPC)
System 4	Manufacturer	No independent involvement	Factory Production Control. Determination of product type

What is an IQC Scheme?

IQC scheme: An Internal Quality Control Scheme, which is defined by the pre-inspection by Kiwa Watertec of the manufacturing process which describes the manufacturing process and quality inspections carried out by the supplier as part of their quality system.

What is a surveillance inspection?

This is the inspection/audit of the manufacturer's production process to ensure that their FPC is being maintained and includes the audit of the materials of construction stated in the manufacturer's application forms.

3 Titles of standards

Number	Title
BS EN 1111:1998	Sanitary tapware – Thermostatic mixing valves (PN 10) – General technical specifications.
BS EN 1287:1999	Sanitary tapware – Low Pressure Thermostatic mixing valves – General technical specifications.
BS EN 15092: 2008	Building valves. Inline hot water supply tempering valves. Tests and requirements
NHS D 08	National Health Service Model Engineering Specification D08 Thermostatic mixing valves (Healthcare premises) Issue 4 September 2011.
BS EN ISO/IEC 17011	BS EN ISO/IEC 17011:2004 Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies
BS EN ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
BS EN ISO/IEC 17065:2012	Conformity assessment. Requirements for bodies certifying products, processes and services
BS EN ISO 19011:2011	Guidelines for auditing management systems
BS EN ISO 9000:2005	Quality management systems. Fundamentals and vocabulary
BS EN ISO 9001:2008	Quality management systems. Requirements
ISO/IEC Guide 25:1990	General requirements for the competence of calibration and testing laboratories