ZVEI: Die Elektroindustrie

ZVEI | EXPLANATORY LEAFLET

33015:2017-12

Guideline

Retention of Conformity Following Modifications of Software at the Example of Fire Alarm Equipment – Industry Requirements

Safety and Security Division

We particularly wish to thank the following authors

Martin Bemba	Novar GmbH
Michael Brotz	Siemens AG
Gunnar Bellingen	VdS Schadenverhütung GmbH
Claus Caspari	Bosch Sicherheitssysteme GmbH
Roland Caßebohm	D+H Mechatronic AG
Florence Daniault	Wagner Group GmbH
Günther Grundmann	VdS Schadenverhütung GmbH
Markus Ibba	Bosch Sicherheitssysteme GmbH
Peter Joost	Novar GmbH
Axel Kunze	Siemens AG
Christian Lais	Siemens AG
Armin Riemer	Novar GmbH
Petra Riesterer	Hekatron Vertriebs GmbH
Michael Scharnowsky	Hekatron Technik GmbH
Marcel Schmidt	VdS Schadenverhütung GmbH
Robert Tomic	Novar GmbH
Thomas Urban	VdS Schadenverhütung GmbH

Thanks are also due to all participating experts from the member companies.

ZVEI: Die Elektroindustrie

Imprint

Guideline
Retention of Conformity Following Modifications of Software at the Example of Fire Alarm Equipment – Industry Requirements

Publisher:
ZVEI - German Electrical and Electronic Manufacturers' Association
Safety and Security Division
Lyoner Strasse 9
60528 Frankfurt am Main
Germany

Responsible for this document:
Peter Krapp

Phone: +49 69 6302-250
Fax: +49 69 6302-288
E-mail: sicherheit@zvei.org
www.sicherheit.org

December 2017

Contents

Introduction

The elements of which fire alarm control systems are comprised are designated in European Commission Mandate M/109 as construction products. Where harmonized European standards have been published under this European Commission mandate, these elements fall within the scope of the European Construction Products Regulation (CPR). The principles and requirements for application of the CE mark can be found in Articles 8 and 9 of the CPR.

Article 46 of the CPR governs the use of facilities outside the testing laboratory of the notified body. On request of the manufacturer and where justified by technical, economic or logistic reasons, notified bodies may decide to carry out the tests referred to in Annex V of the CPR, for certain systems of assessment and verification of constancy of performance or have such tests carried out under their supervision, either in the manufacturing plants using the test equipments of the internal laboratory of the manufacturer or, with the prior consent of the manufacturer, in an external laboratory. The requirements of the test method must be satisfied and the quality of the test results ensured. Availability and control of the test equipment must be governed by agreement between the test body and the manufacturer in accordance with DAkkS resolution 71 SD 0 019.

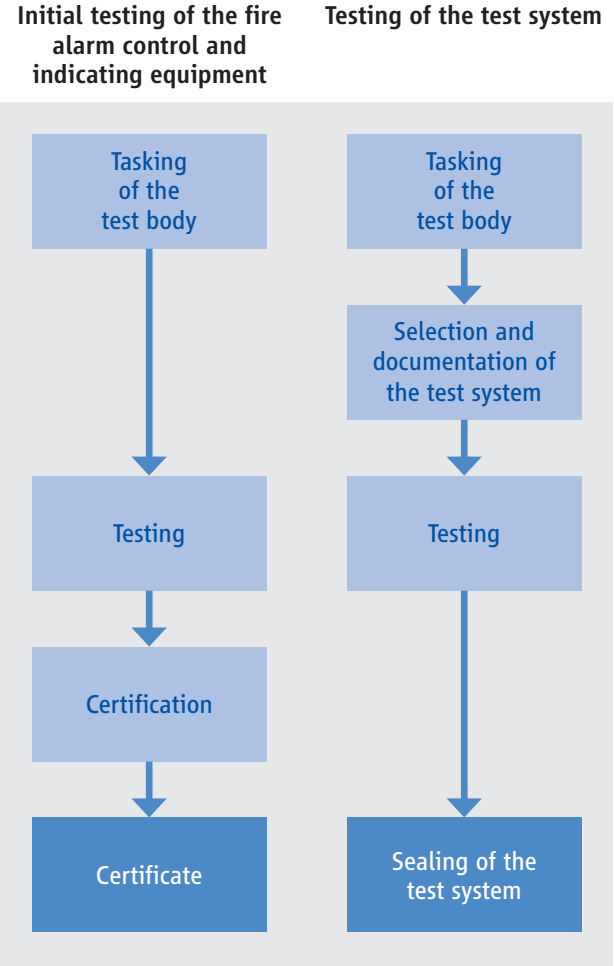
In accordance with the Construction Products Regulation, the elements of fire alarm systems must be tested and certified against the harmonized European standards, such as the EN 54 series. This is confirmed by a declaration of performance to be produced by the manufacturer and indicated on the product by a CE mark with the identification number of the notified product certification body. This includes a defined software version status.

Modifications may be made to software for a wide range of reasons, and their impacts are at times difficult to assess. They extend from minimally invasive changes, through the implementation of purely convenience functions, to completely new setups.

The requirements profile below shows how software modifications are to be handled in the relationship between the manufacturer and the notified product certification body in accordance with the CPR, with reference to the example of fire alarm control and indicating equipment.

This guide applies to products in safety installations such as fire alarm control and indicating equipment, systems for smoke and heat exhaust, etc. which are covered by the Construction Products Regulation (EU) 305/2011.

Procedure for initial tests of fire alarm control and indicating equipment and their test systems



Sealing relates to the documentation of a specific, verifiable scope of performance and functionality by the recording of software and hardware version states (test system) and by means of suitable configuration management.
Testing of the test system may be performed either simultaneously with testing of the product, or at different times.

Requirements imposed on the procedure by industry

New systems must always be subjected to an initial test at a notified product certification body's premises in accordance with the CPR, Annex V[1], with reference to the applicable standards. The result is an initial certified software version. All subsequent software modifications should be verified as described below. This enables the certificates issued to continue to be used for the conformity assessment of new products:

- The manufacturer is able to develop automated tests for functionality compliant with the standards. This test system can be approved by the notified product certification body based upon the initial test.
- The automated function test must include all relevant tests governed by the standards. Additional, more far-reaching functional tests may be included, particularly if certification is performed with reference to further standards or regulations. One or more test cases must be implemented for each normative requirement. The test results must be documented for each test cycle.
- The test system employed for testing of the modification may be set up and operated by the manufacturer and need not necessarily be located at the premises of a notified product certification body. The test system may employ real-case or simulated peripherals. The general functionality and if applicable „calibration" of the test system must be reviewed at the manufacturer's premises by the notified product certification body.
- The test system, including change management, access rights, etc. must be documented. The notified product certification body must be informed of any modifications to the test system.
  Where further test scenarios are added to the test system without the system software being modified, documentation of the modifications is sufficient; the notified body need not be informed in such cases.
- Modified software that has been tested on this test system serves as the basis for the modification test. For this reason, all test results obtained on the automated test system must be documented. The modification test is completed together with the software documentation modification review.
- New software functionality/new software versions can be tested in the test system either manually or automatically (in conjunction with presentation once again of the test system to the notified product certification body), whereby they are incorporated into the automated test system.

Article 46 of the CPR (Use of facilities outside the testing laboratory of the notified body)[2] and Resolution 2 of DAkkS 71 SD 0 019 of 14 September 2016[3] (testing/calibration/examination with the use of facilities/equipment not belonging to the laboratory, „external equipment/facilities") must be observed.

The modification test should result at least in confirmation by the notified product certification body or a comprehensive test report.

[1] Cf. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0005:0043:EN:PDF, Page 38.
[2] Cf. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0005:0043:EN:PDF, Page 22.
[3] Cf. http://www.dakks.de/sites/default/files/dokumente/71_sd_0_019_beschluesse_horizontal_20160914_v1.0.pdf

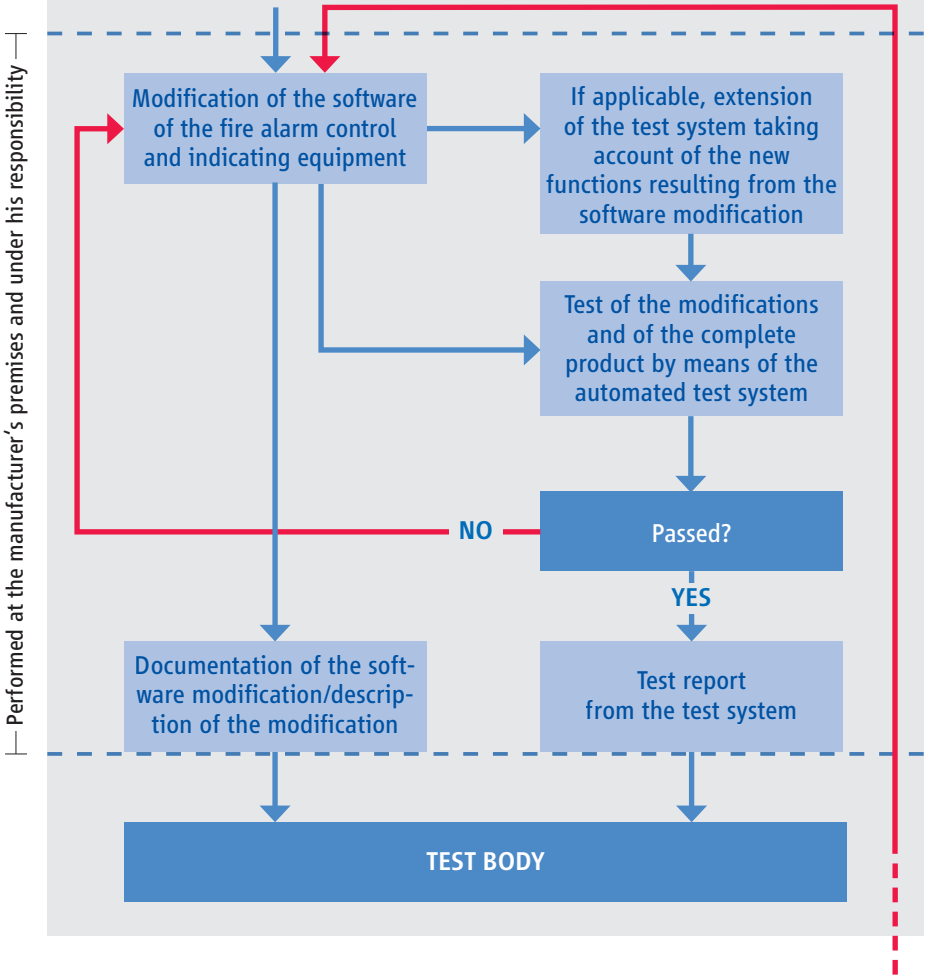
Procedure flow chart

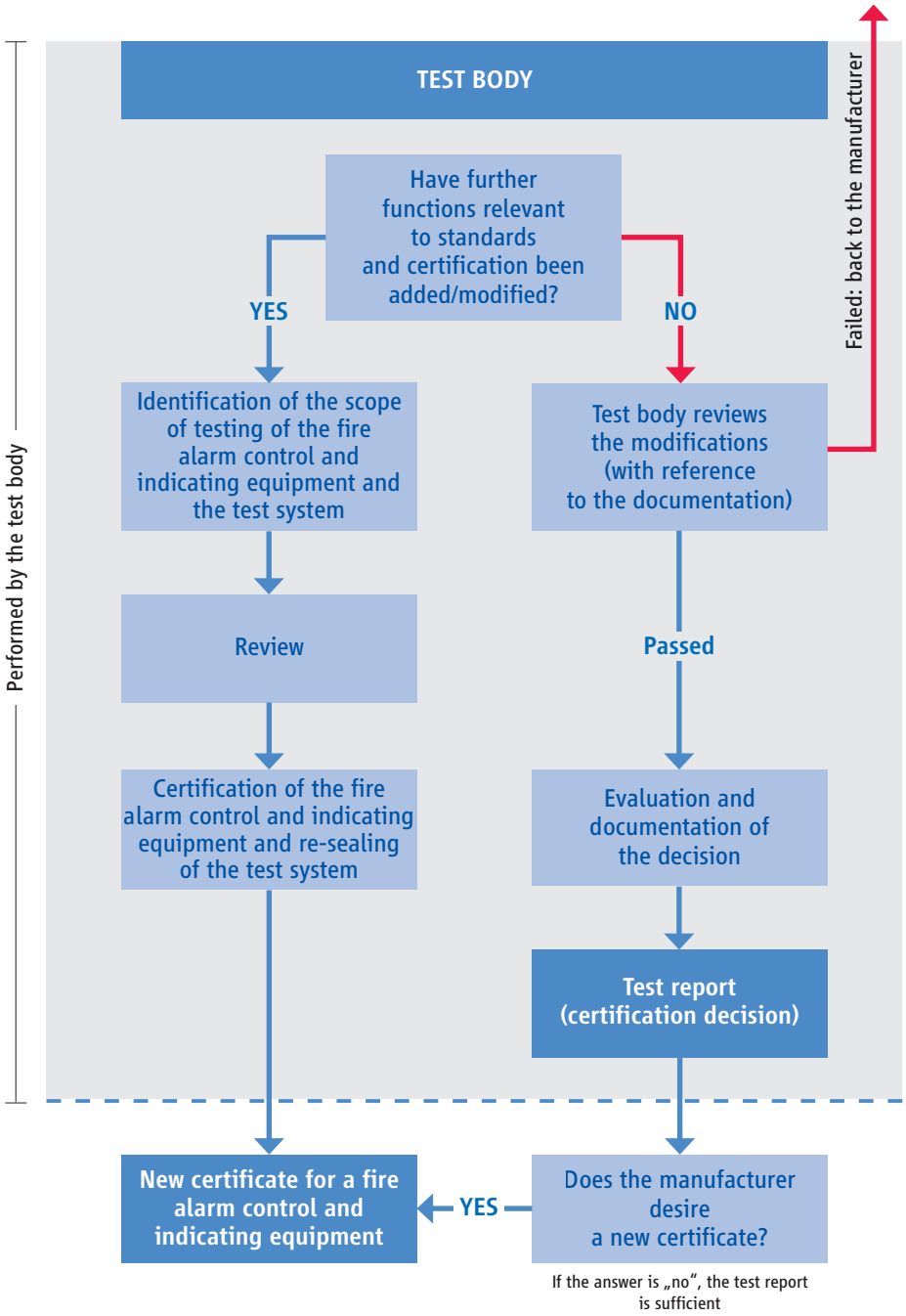
Flow chart for testing and certification of software modifications, with reference to the example of fire alarm control and indicating equipment

Development and delivery of a new product and its software

Creation of an automated test system for testing of the software of the new product: this test system must be capable of verifying all function tests of the product standards and regulations against which testing is performed.

Initial test of the product and of the test system by the test body
(in accordance with the flow chart, Page 6)




TEST BODY
Have further functions relevant to standards and certification been added/modified?
YES
NO
Failed: back to the manufacturer
Identification of the scope of testing of the fire alarm control and indicating equipment and the test system
Test body reviews the modifications (with reference to the documentation)
Review
Passed
Certification of the fire alarm control and indicating equipment and re-sealing of the test system
Evaluation and documentation of the decision
Test report (certification decision)
Performed by the test body
New certificate for a fire alarm control and indicating equipment
YES
Does the manufacturer desire a new certificate?
If the answer is „no“, the test report is sufficient

Checklist for the description of changes

The documentation must be sufficiently detailed to permit review of compliance with the requirements of the relevant regulation/standard.

A predefined form of the documentation (for example in standards) does not exist at this point in time; preference is however given to an electronic format. Electronic documents should be provided in a form that is comprehensible for the test body. Attention should be paid to the following:

- Supply in the form of files on data media or by e-mail (encrypted if appropriate).
- Provision of a cohesive document in electronic form (e.g. PDF, HTML, XML, etc.) – ideally with a table of contents – together with the source code.
- It must be possible to determine all functions and properties required by the relevant regulation or standard with reference to the documentation.
- The documentation of the modifications must be comprehensible to the certification body.

Information on the modifications (Where multiple version steps are involved, multiple tables should be created if appropriate in order to facilitate comprehension)	
New software version number:	
Date/software version:	
Nature of the modification: • Supplementary or convenience functions (changes to operation or display texts, where not governed by the standards, etc.) • Bug fixes (elimination of software errors) • Bringing into line with standards (e.g. EN 54-X, etc.) • Other changes, where not already stated	
Reason for the modification:	
Changes to hardware: (controllers, memory modules, etc.)	
Affected files/modules/functions:	
The software is approved and is being used for the following device/product/assembly: (where existing software has been modified)	
Further aspects to be considered where applicable:	
Comments:	

ZVEI - German Electrical and Electronic
Manufacturers' Association
Lyoner Strasse 9
60528 Frankfurt am Main
Germany

Phone: +49 69 6302-0
Fax: +49 69 6302-317
E-mail: zvei@zvei.org
www.zvei.org