



DETERMINATION OF INPUT DATA FOR THE PROCESS OF VALIDATION OF OWN CALCULATION SOFTWARE FOR BASIC MATERIAL DATA IN STATIC STRENGTH TESTS

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Abstract

The paper deals with the idea of validation of own application software related to data analysis in conditions of an accredited laboratory. Defined conditions require suitable approach to the chosen problem. While the accreditation process is directly connected with ISO/IEC 17025:2005 which refers to ISO 9001:2000 standards the quality management approach has been proposed in order to perform suitable requirements. Tensile testing method sets an example for the discussed topic as well as the application software supporting the method. Among various input data authors do mention i.e. environmental and organizational conditions, personnel qualifications or measurement equipment.

Keywords: *laboratory, accreditation, data analysis software, software validation, tensile testing*

1. Introduction

A testing laboratory fulfills requirements of customers from the point of view of reliability of test results. Actually this is not always an issue from legal point of view but in general each customer of the laboratory needs as reliable results as possible. To support both practical and legal requirements of clients ISO/IEC 17025:2005 standard [2] has been elaborated. The standard [2] specifies the general requirements for the competence to carry out tests. It covers testing performed using standard methods, non-standard methods, and laboratory-developed methods. The standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing activities. As it is stated in the document it is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. The term 'management system' used in the standard means the quality, administrative and technical systems that govern the operations of a laboratory. Moreover if testing laboratories comply with the requirements of the standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001 [2].

Authors' professional and scientific experience is connected with testings performed in conditions of an accredited laboratory. Especially having in mind requirements of customers mentioned in the first indention the usage of ISO/IEC 17025 is an essential advantage in testing

services.

As technology develops more and more IT tools are used in testing processes. They support various tests on different stages i.e. data analysis. In such a case one can discuss commercial software that requires payment before it can be used or own software developed by the laboratory itself. In the second case the developed applications needs to be validated. Validation can be discussed from the point of view of information technology as well as ISO 17025:2005 requirements.

The aim of the paper is to discuss the process of determination of input data for validation of own software application in an accredited testing laboratory on the example of the calculation software for basic material data in strength static tests.

2. Software validation as a requirement of software engineering as well as quality management

In software engineering validation for software, in its simplest terms, is the demonstration that the software implements each of the software requirements correctly and completely. In other words, the right software product was built. In the United States since the mid-1980s, for example, the Food and Drug Association (FDA) has enforced validation of software and computer systems in pharmaceutical manufacturing for consumers' safety. In response to this important industry need, the industry has created special task forces with the primary mission of developing guidelines for computer and software validation - known as the Computer System Validation Committee of the Pharmaceutical Research and Manufacturing Association (PhRMA) [9].

Discussing benefits of the validation process the document [6] states that software validation is a critical tool used to assure the quality of device software and software automated operations. Software validation can increase the usability and reliability of the device, resulting in decreased failure rates, fewer recalls and corrective actions, less risk to patients and users, and reduced liability to device manufacturers. Software validation can also reduce long term costs by making it easier and less costly to reliably modify software and revalidate software changes. Software maintenance can represent a very large percentage of the total cost of software over its entire life cycle. An established comprehensive software validation process helps to reduce the long-term cost of software by reducing the cost of validation for each subsequent release of the software.

Sometimes it is hard to find the difference in terms validation and verification. The terms are frequently used in the software testing world but the meaning of those terms are mostly vague and debatable. One encounter all kinds of usage and interpretations of those terms, and it is our humble attempt here to distinguish between them as clearly as possible [10]. Table 1 presents basic differences.

Table 1. Differences between validation and verification [10]

Criteria	Verification	Validation
Definition	The process of evaluating work-products (not the actual final product) of a development phase to determine whether they meet the specified requirements for that phase.	The process of evaluating software during or at the end of the development process to determine whether it satisfies specified business requirements.
Objective	To ensure that the product is being built according to the requirements and design specifications. In other words, to ensure that work products meet their specified	To ensure that the product actually meets the user's needs, and that the specifications were correct in the first place. In other words, to demonstrate that

	requirements.	the product fulfills its intended use when placed in its intended environment.
Question	Are we building the product right?	Are we building the right product?
Evaluation items	Plans, Requirement Specs, Design Specs, Code, Test Cases	The actual product/software.
Activities	Reviews, Walkthroughs, Inspections	Testing

It is entirely possible that a product passes when verified but fails when validated. This can happen when, say, a product is built as per the specifications but the specifications themselves fail to address the user's needs [10] .

The basic principles behind software validation are as follows[9]:

- a) specify the intended use of the software and user requirements;
- b) verify that the software meets the requirements through proper design, implementation, and testing;
- c) and maintain proper use of the software through an ongoing performance program.

It has to be noticed that the document [6] bases on quality system issues and refers to various quality management standards i.e. AS 3563.1-1991 "Software Quality Management System, Part 1: Requirements" published by Standards Australia [1] or to ISO 9000-3:1997 "Quality management and quality assurance standards - Part 3: Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software" [4] published by International Organization for Standardization.

Discussing the point of view of quality management systems the base standard ISO 9000:2005 [3] defines validation as a confirmation with the use of objective evidence that the requirements for an intended use or application have been fulfilled. In the standard [2] the definition states that validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Considering the IT difference in terms between verification and validation it has to be stated that such a diversification can be also seen in quality standards. Standard [3] defines verification as a confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

From the point of view of the standard [2] according to authors [7] the parallels with validation are obvious as verification is also confirmation, also based on objective evidence and also tested against specified requirements but apparently without a specific use in mind that is part of the definition of validation. In practice the difference lies in the fact that validation is cited in connection with test methods, while verification is used in connection with the confirmation of data.

Although various definitions may be confusing it is obvious that own application software has to fulfill requirements of laboratory personnel to provide reliable data analysis results. Therefore objective evidence has to be provided so that the software validation process has to be designed in details.

On the base of such an assumption, with knowledge on IT and quality management systems from the range of validation, the plan for the validation process can be set.

As the first stage in the process there should be defined input data.

3. Input data in reference to designed software

Considering the assumption made before it seems the the obvious step to take would be to

define the validation process in accordance with ISO 9000:2005 model of the process approach (fig. 1).

One of key roles in the model is played by input data. Discussing static tensile tests and computer application software that supports the analysis of data it is essential to answer the question what would be the content of the input data. Basing on the scientific and professional experience authors of this work decided to define the content as following elements:

- a) testing method,
- b) environmental and organizational test conditions,
- c) measurement equipment,
- d) test piece material,
- e) personnel qualifications,
- f) software for machine.

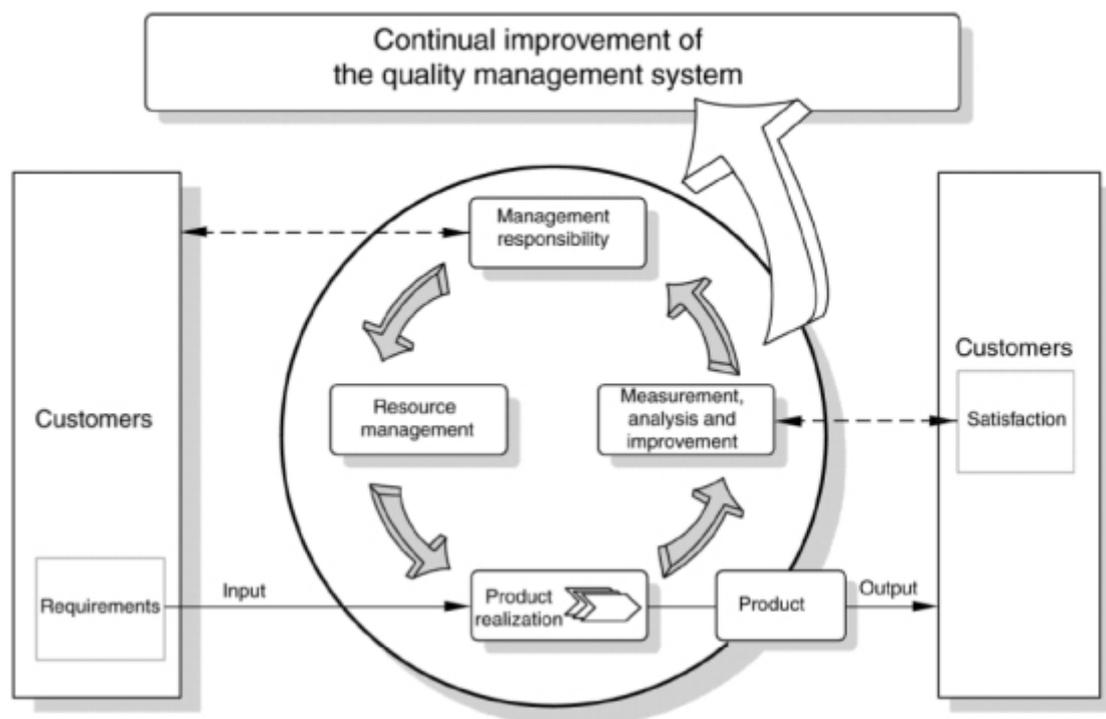


Fig. 1. Model of the process approach in accordance with [3]

At first the test method is an issue. The question is whether it is based on an international standard. Obviously it is easier to perform test on the base of standard or other specifications from the organizational point of view. There is no need to perform extra documentation as well as the method does need to be validated. In such a situation the first impression is that taking into consideration standard tests is more efficient form the financial point of view. However, considering both technical and organizational issues, the problem seems to be more complicated. For example standard test are limited to special environmental conditions or defined test pieces. It requires purchasing of i.e. new equipment. On the other hand sometimes customer needs non-standard materials or elements to be tested.

From the point of view of validation of own software the second option is much more sophisticated. While standard testing methods give limits and requirements strictly defined the non-standard methods that use own application software require cooperation with an author of the

method and laboratory personnel that uses it. The more unique testing method the less chance to find the reliable comparison tool. The easiest way to deliver objective evidence is to compare test results obtained with different (2 or more) data analysis software. For instance the commercial one and the new elaborated tool of the laboratory. Objective evidence is easy to get while previously the laboratory used commercial software that underwent verification as an element of the testing method during the accreditation process.

In static tensile tests authors assume that designing software for data analysis makes sense while a machine provides data in digital form. What is more any machine (type, producer etc.) able to cooperate with own software should provide the same data.

While for tensile tests there are needed various physical quantities such as temperature or length it is essential to define precisely requirements for measurement instruments. Cooperation of measurement instruments and own application software surely affect measurement uncertainty.

Test pieces usually depend on customer's needs. It is more comfortable for the laboratory while specimens are based on the standard as it is presented in fig. 2 (main types of test pieces according to [5]. B – A refer to annexes published with the standard). However it needs to be discussed if our software limits to such situations or also reflects non-standard requirements of the customer.

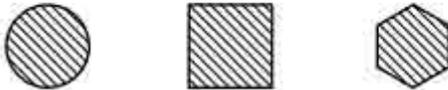
Type of product		Corresponding Annex
Sheets — Plates — Flats  Thickness a	Wire — Bars — Sections  Diameter or side	
$0,1 \leq a < 3$	—	B
—	< 4	C
$a \geq 3$	≥ 4	D
Tubes		E

Fig. 2. Main types of test piece according to product type [5]

There is also the problem of personnel qualifications. It can be discussed from different points of view as well: technical in the range of testing method (how experienced and efficient he/ she is in his/ her everyday work related directly to specific tests), technical in the range of usage of IT tools (gaining quickly new knowledge and skills from the area) or organizational (new methods of work vs. old habits and complaints on changes).

Finally the own application software has to cooperate, as it was noticed before, with the testing machine. The machine has to provide data in digital form but it is impossible to require more from machine producers. That is why the software has to be as efficient as possible in data processing on the way machine – user – software.

4. Summary

Reliable test results depend on many organizational and technical issues. It is very hard to design and build such a unique organization as a testing laboratory. Quality management standards, especially the ones dedicated strictly to special types of organizations, can be useful in organizational and technical development. ISO/IEC 17025:2005 standard directly refers to testing

laboratories. Therefore it can be applied in material testing units as well.

Different tests methods should undergo the process of validation. While the method is based on the standard the laboratory does not need to perform the process. If the method is elaborated as a unique one for the laboratory validation is necessary. In both cases laboratories nowadays use more and more IT tools to develop testing processes. If the software supporting the process is new it has to be validated as well.

Authors proposed the quality management approach which corresponds also to software engineering basics. In such a case it is essential to define input data. In the paper input data were defined in the form of different elements such as: testing method, environmental and organizational test conditions, measurement equipment, test piece material, personnel qualifications, software for machine. The content of input data bases on scientific and organizational experience in the range of material strength tests.

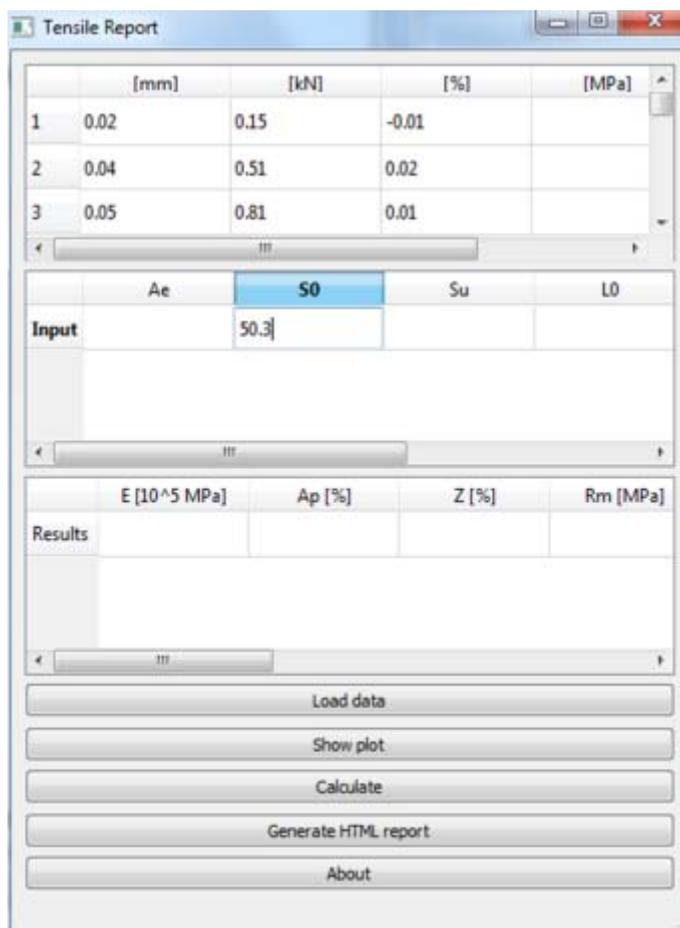


Fig. 3. "Tensile report". Main window [8]

On the base of the defined content authors are planning to perform validation of own software application "Tensile report". The software was developed as a result of cooperation between an academic teacher (one of the authors of this paper) and a student and finally became a base for a graduation project [8]. Results of the validation process in accordance with the proposed approach will be presented in further publications.

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