

ISO 9001 7.x

by Helen Davidson

Applying generic “quality” standards to testing can appear complicated, perhaps because it is itself concerned with quality. But understanding what those standards mean to testing might lead to valuable improvement



Helen Davidson
explores ISO 9001 in
the context of testing

IDBS, which produces software for research and development organizations, is an ISO 9001 certified company. As a test team lead there I have experienced several certification audits and many customer audits. During all of them, when talking to me, the auditors referred to clause 7.3.6 *Conduct design and development validations*. But I think more of 9001 than this applies to software testing: if testing is a service, the whole of section 7 *Product realization* becomes relevant to it.

Is software testing a service?

The many consultancies currently selling

it as such clearly think so. So does Ashfaque Ahmed, author of the book *Software Testing as a Service* (ISBN-13: 978-1420099560). Ivan Ericsson of SQS advocated centralizing testing within an organization in the March 2010 issue of *Professional Tester*.

I asked various software people who expressed quite strong but differing views. I'd like to be able to say that the testers among them agreed with one another, but they did not. I believe their opinion related to their organization's view and treatment of testing: testers who felt the test function within which they worked was able to act independently found it easier to view it as a service. Perhaps then making testing more independent makes it resemble a service more, or perhaps treating it as a service can help to make it more independent. Many sources, for example testing syllabuses such as ISTQB Certified Tester Foundation Level, identify test independence as desirable. And outsourced testing *is* a service by definition.

I am lucky that independent testing is valued in my current project and that I am in direct ownership of the approach and activities. I definitely feel that the test teams are independent and provide a service. So, would applying section 7 help us to define or improve our test process and the deliverables required for

ISO 9001 – TickIT quality plan	Test strategy
Customer specified and implied quality requirements	Test objectives
Quality requirement for the project	
Key features of the product and/or service that are likely to impact upon quality	Lists of project and product risks or a reference to the risk register and the prioritisation of requirements, objectives or work items
Specific risks	Lists of project and product risks or a reference to the risk register
References to quality system procedures to be used	References to test (or other) procedures to be used, eg test case review
Methods, tools etc	List of test tools (eg test management tool) and/or test methodologies (eg test design techniques)
Relevant statutory and regulatory requirements	For example US Food and Drug Administration guideline 21 CFR Part 11 (varies with sector)
Verification and validation strategy	Test specification and test case review
Exit criteria for procedures	Entry and exit criteria for phases of software testing
Deviations and in new initiatives to standard processes	Processes that are not being followed and details of why; details of initiatives being trialled

Table 1: Quality planning elements in a test strategy

it? Or would it just generate unnecessary paperwork? To try and find out, I studied the section in depth, attended two relevant training courses, then set about comparing our process with section 7 looking for gaps. Where I found them, I considered what we would need to do to achieve compliance.

Clause 7.1 Planning of product realization

TickIT, a guide to interpreting the requirements of 9001 for the software industry (see <http://tickit.org>), addresses this with its “quality plan”, a description of how the product or service provided is to be developed focusing on project-specific decisions: methods, tools and techniques. When the service is software testing, this is what most testers call the test strategy. Table 1 compares the quality plan with the test strategy standard we use at IDBS.

7.2 Customer-related processes

To move toward compliance first the customer must be identified. The test function can be considered as providing a service to developers, business analysts, product owners or the software buyer depending upon the current objective of testing, so the customer varies with sector, organization, context, testing phase and testing activity.

Perhaps the best approach is to consider the information produced by testing. Whoever receives and uses that, whether to correct defects or inform decision making, is the customer. For compliance, the test service must identify and review the customer’s requirements and communicate with the customer. For a test service that is achieved by reporting, so the reporting objectives must be defined, in either or both of the project test strategy

or organizational test policy. The reporting frequency and mechanism must be defined in the 9001 “Quality Management System”. Our test team collaborates with its customers on the test strategy using Microsoft SharePoint: this makes providing evidence of communication to auditors easy.

7.3 Design and development

It’s important to keep sight of the fact that in the current context this is about planning, designing and developing the *testing*, not the software being produced. 7.3 requires that inputs are defined and outputs provided in a form that enables them to be verified against the design. Any test process that documents its strategy and plans effectively should achieve this.

The subclauses go on to require that systematic reviews, verification and validation of the design and development are performed. It may be argued that for a testing service the reviews can be of its outputs, eg test documentation. If so, this activity can also achieve verification of these against the input requirements. If the customer as identified for clause 7.2 takes part, these reviews might be able to achieve validation of the testing too.

Finally, 7.3 requires that changes to design and development are recorded, reviewed, verified and validated. It might be addressed using configuration management of the inputs and outputs,

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but a better interpretation is probably that it indicates the use of a defined mechanism for test process improvement.

7.4 Purchasing

This is a hard one. It requires evidence of a formal selection, evaluation and verification process used to choose the test tools being used. If that took place some time ago, or in fact the process used was not sufficiently systematic, the only solution might be to re-specify, re-evaluate and re-verify the tools, plus alternatives, to justify (or change) past choices.

The clause could apply also to the purchase of consultancy and outsourced testing services.

7.5 Production and service provision

To meet the requirements of this it is necessary to provide evidence that the test service is provided under controlled conditions. The definition of these in 7.5 seems to align well with the test policies, strategies and plans, monitoring and measurement of test effectiveness, and configuration management mechanisms typically used by a test organization. In that case, the required verification of these can be achieved by internal audit. The requirement to exercise care with customer property is probably met by prevailing data protection and other governance standards.

It also requires that the processes are verified and in most organizations monitoring of this adherence is done through internal audits that demonstrate

compliance with the described processes and allow correction of any deviations.

7.6 Control of monitoring and measuring devices

This seems to refer to the methods used for the monitoring and measurement of testing required by 7.5. Calibrating these and safeguarding them from incorrect adjustments, damage or deterioration, or even defining what that means, would be a challenge: but it may not be necessary for compliance because the clause states that it need be done only "where necessary to ensure valid results". A periodical examination of the reporting mechanisms, perhaps including test runs with invented input data, might be considered sufficient.

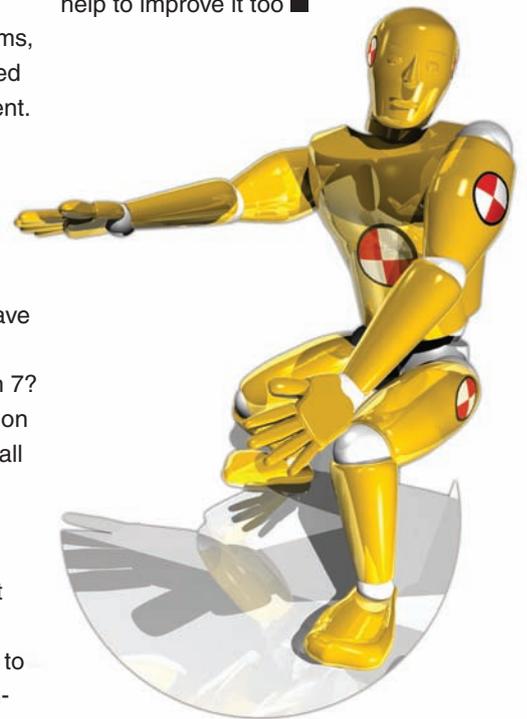
Can test organizations achieve compliance with 9001 and is it worthwhile?

It is possible: the many certified outsourced testing service providers have proved that. So do their auditors follow similar reasoning to mine about section 7? Could they audit an internal test provision in the same way? It may be as well for all organizations that test software to be ready in case they do.

But compliance does not mean the test process is effective or the software products are good. I think the best way to derive benefit from 9001 and other non-

testing standards is to consider what they are trying to achieve and how it applies to what we as testers understand to be good testing practice: to help us understand why our process is as it is, buy into it fully, and improve it continually.

As I have tried to show in this article, a sequential test process seems to align reasonably well with both the letter and spirit of 9001 section 7. What about testing as it is done to support an "agile" development approach? Perhaps considering that in the same way would help to improve it too ■



Helen Davidson is test team lead at IDBS (<http://idbs.com>) which provides advanced software solutions to research and development organizations, including those working in pharmaceuticals, agrochemicals, animal health, cosmetics, petrochemicals, forensics, manufacturing, academic research and government, worldwide.

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