Mastering Systems Integration; Terminology

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Abstract

This presentation defines terms, which are used in relation to systems integration, such as validation, verification, qualification, evidence, approval process, certification, and acceptance.
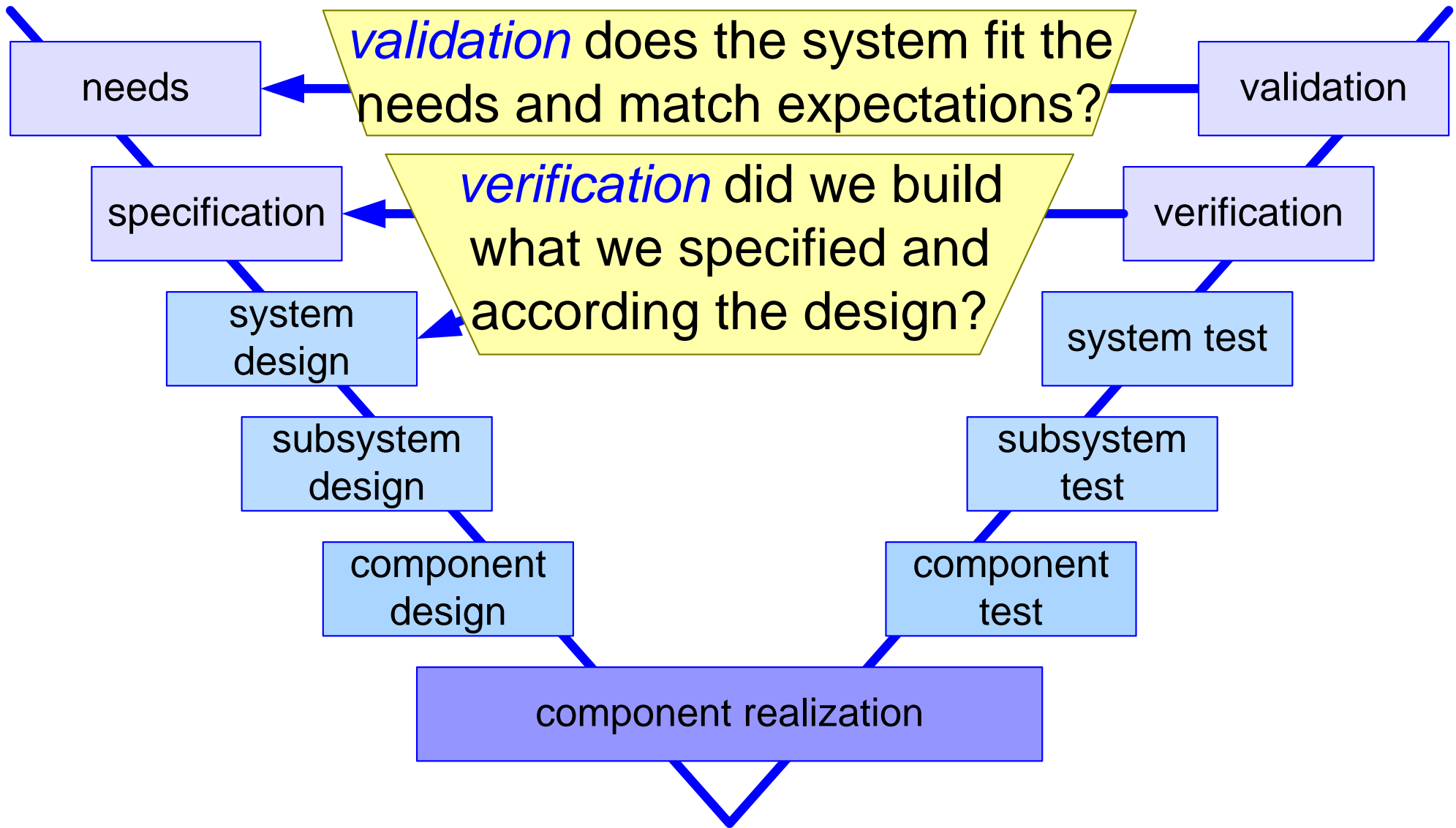
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Validation and Verification in the V-model

needs

validation *validation* does the system fit the needs and match expectations?

specification

verification *verification* did we build what we specified and according the design?

system design

system test

subsystem design

subsystem test

component design

component test

component realization

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Functional Model of Verification
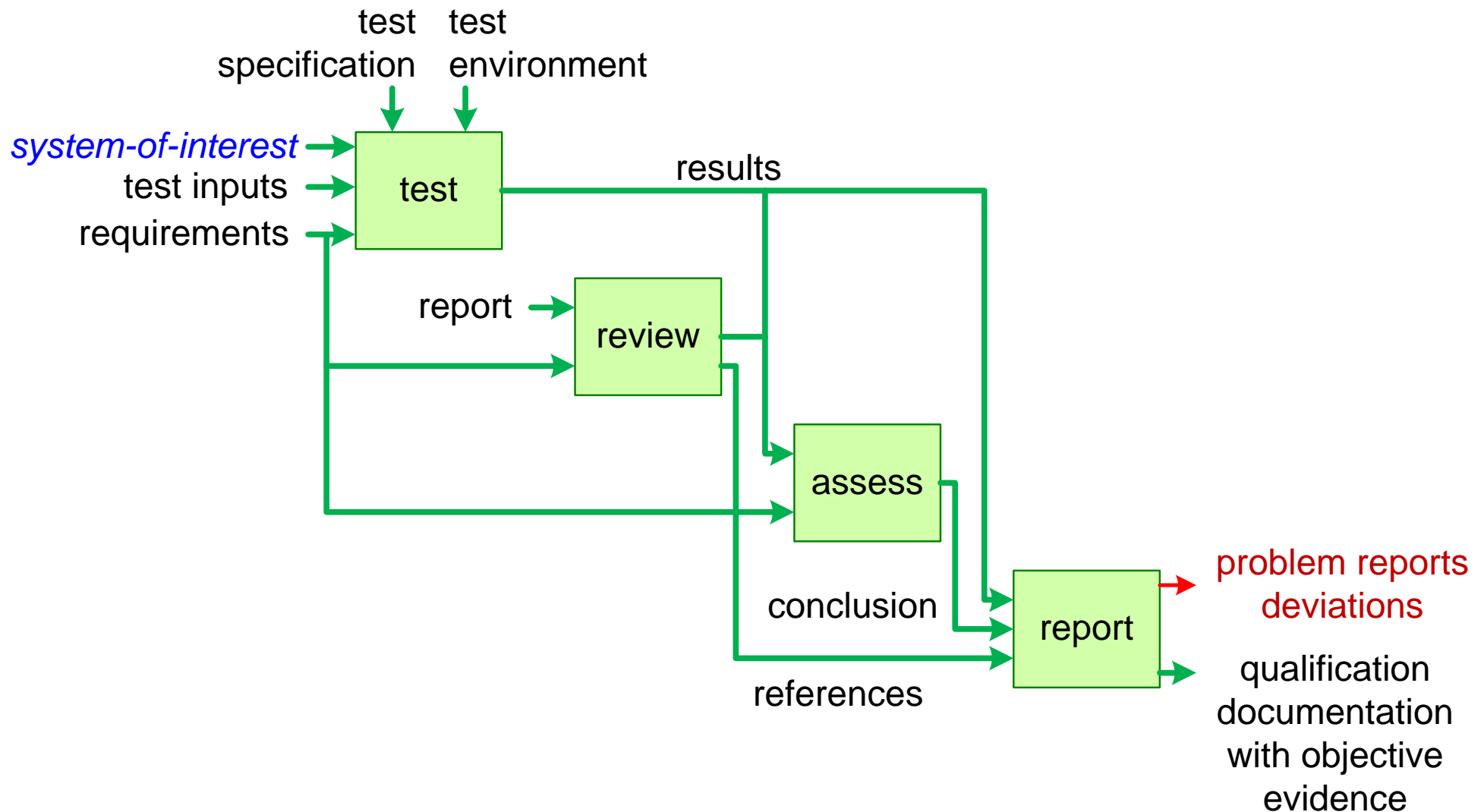
Certification

Certification: an independent agency (e.g. DNV-GL) certifies the quality of the system-of-interest, technology, or process

Self-certification: the company has been accredited by the agency to do the certification themselves.
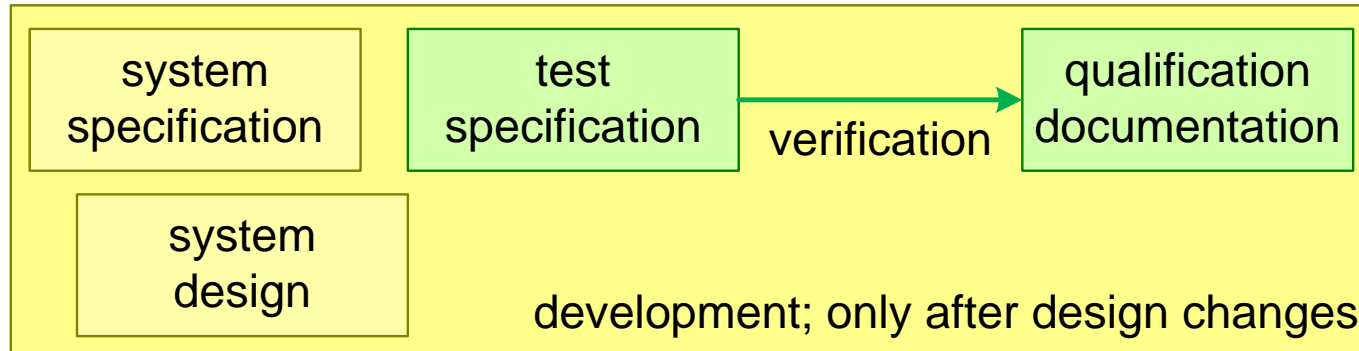
check
qualification data

check process
and organization

optional audit

certify

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Development and (repeated) Production

system specification

system design

test specification → verification → qualification documentation

development; only after design changes

acceptance test procedure — FAT → *factory* FAT report

— SAT → *site* SAT report

production and delivery once per system

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Objective Evidence

From a business perspective: Objective evidence is "information based on facts that can be proved through analysis, measurement, observation, and other such means of research."

From a legal perspective: Objective evidence is "real evidence, also known as demonstrative or objective evidence; this is naturally the most direct evidence."

From a scientific perspective: "To be termed scientific, a method of inquiry must be based on gathering observable, empirical, and measurable evidence subject to specific principles of reasoning. A scientific method consists of the collection of data through observation and experimentation, and the formulation and testing of hypotheses."

From a list of Plain English definitions related to the ISO 9000, 9001 and 9004: Objective evidence is "data that show or prove that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or by using any other suitable method."

from: Understanding Objective Evidence: (What It Is and What It Definitely Is Not), by Denise Dion http://www.eduquest.net/Advisories/EduQuest%20Advisory_ObjectiveEvidence.pdf

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FDA Requirements for Objective Evidence

FDA is a science-based law enforcement agency and, therefore, requires answers that are scientifically and legally supported. FDA expects your objective data to answer the following questions:

- **Scientific** – Can the data be *evaluated by independent observers* to reach the same conclusions?

- **Scientific** – Are the data documented in a manner that *allows re-creation of the data* or the events described?

- **Scientific** – Does the documented evidence provide *sufficient data* to prove what happened, when, by whom, how, and why?

- **Legal** – Was the documentation *completed concurrently* with the tasks?

- **Legal** – Is the documentation *attributable* (directly traceable to a person)?

- **Legal** – Have the data and associated documentation been maintained in a manner that *provides traceable evidence* of changes, deletions, additions, substitutions, or alterations?

- **Legal** – Are the data and associated documentation maintained in a manner that *protects and secures* them from changes, deletions, additions, substitutions, or alterations?

from: Understanding Objective Evidence: (What It Is and What It Definitely Is Not), by Denise Dion http://www.eduquest.net/Advisories/EduQuest%20Advisory_ObjectiveEvidence.pdf

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Regulatory Approval Process