Mastering Systems Integration; Terminology

by *Gerrit Muller* TNO-ESI, University College of South East Norway
e-mail: gaudisite@gmail.com
www.gaudisite.nl

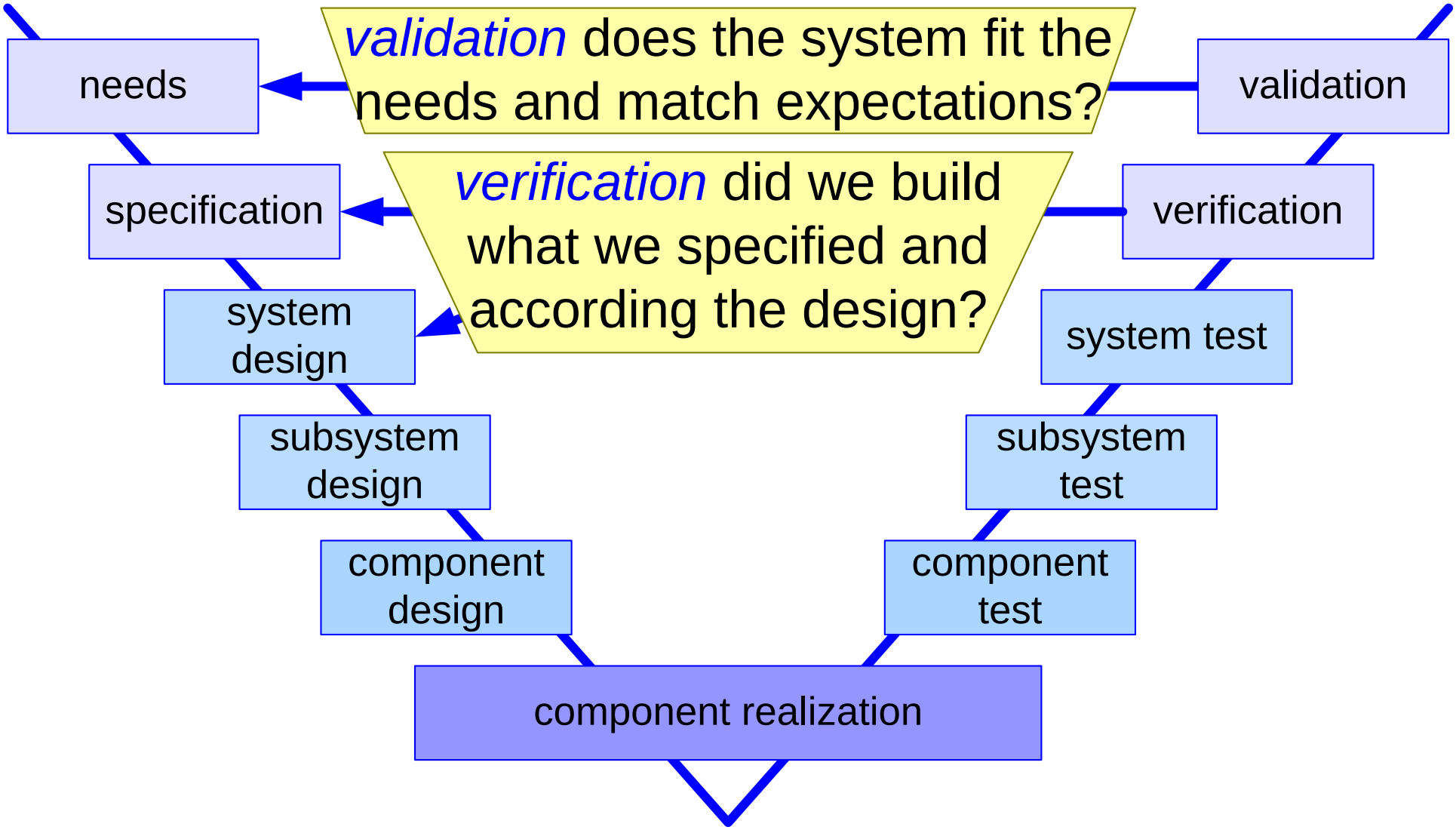
Abstract

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

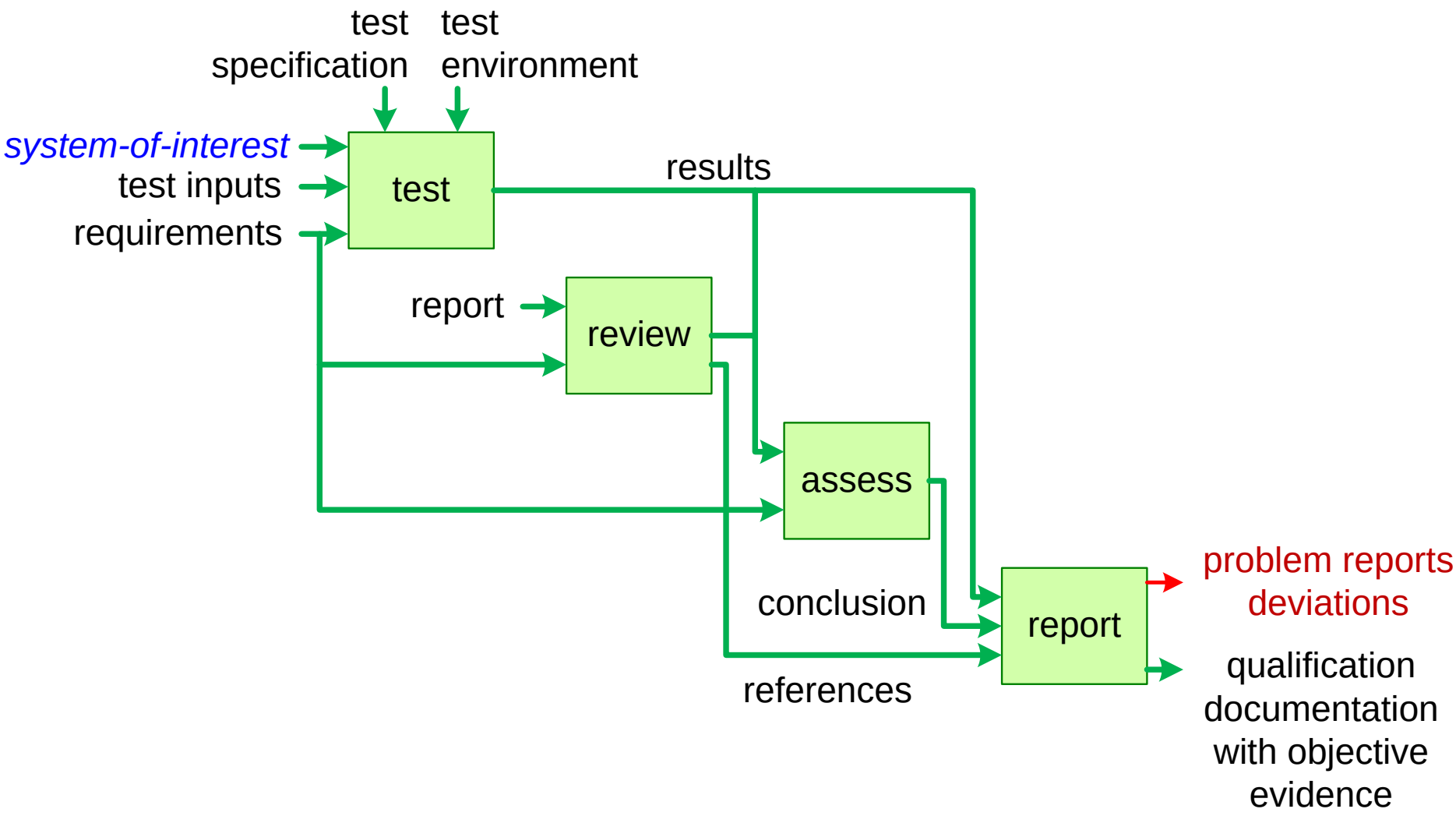
September 7, 2017
status: planned
version: 0

logo
TBD

Validation and Verification in the V-model



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.

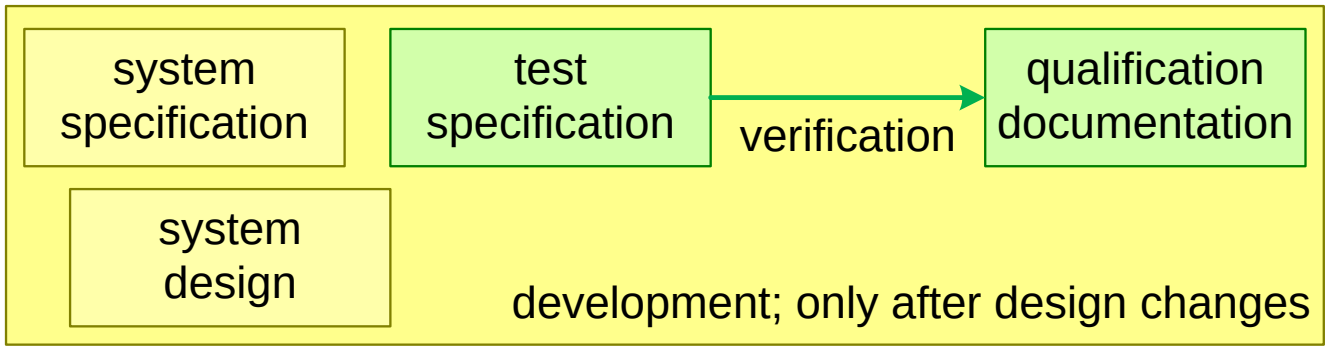
check qualification data

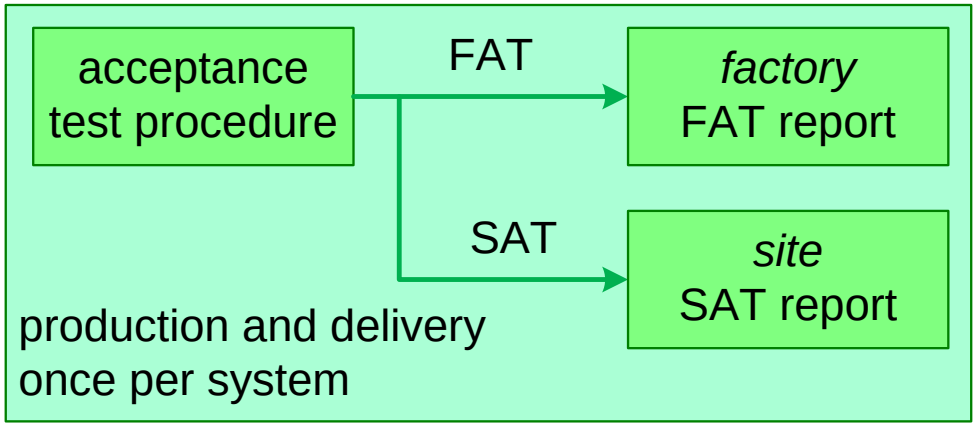
check process and organization

optional audit

certify

Development and (repeated) Production





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

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

Regulatory Approval Process