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**Studying Documentation Requirements for
Quality Assurance in Healthcare Software
Development Environments following Scrum
Practices**

A Thesis Submitted for Examination for the Degree of
MPhil in Engineering at Massey University New Zealand

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ABSTRACT

Over the past decade software development has expanded into almost every sector of business and technology. Currently, Agile software development methods are much preferred over traditional software development methods which rely on heavy documentation. Agile methodologies such as Scrum (the focus of the study) rely on minimal documentation. However, software development organizations who seek accreditation against an internationally recognized quality management system (QMS) standard such as ISO 9001:2008 need to maintain a certain level of documentation to meet the requirements stipulated in the QMS standard. This study was undertaken to answer the following overall research question, in relation to healthcare software development: *what would be the minimum level of documentation that would be acceptable for a Health-IT organization pursuing Scrum, if they are to maintain an internationally recognized QMS standard such as ISO 9001:2008?* This overarching research question was first investigated through in-depth literature synthesis and subsequently discussed with a panel of experts. An iterative research design utilizing Delphi-like problem solving method was used to gather insights from Scrum practitioners. The study identified 23 documents to have varying levels of usefulness and importance to three categories of Scrum users, specifically Scrum Master, Product Owner, and Development Team. The study further identified the level of conciseness required in each document (to suit each category of Scrum users) and the stage in which each document should be prepared to add maximum value in using documentation. The study identified seven negative experiences Scrum practitioners come across: documents being difficult to understand by nontechnical customers; purpose of documents not being explicit; no follow-up with client's feedback; excessive re-work on documents; deficiencies in document validation; lack of risk analysis reports and disruptions in software development. The study also identified seven problems practitioners face in creating important documents: lack of skilled document writers; last minute/hasty document preparation; misunderstanding the purpose/intent of Agile; lack of a common documentation standard; perceiving document creation as a burden; poor tooling for documentation and lack of right staff. It is expected that the study would benefit both the academia and the practitioner in gaining greater insights on the issue of documentation in Scrum.

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