Expert Review of Taxonomy based Testing: A Testing Framework for Medical Device Software

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Keywords: The US FDA, Taxonomy, SW91, ISO/IEC/IEEE 29119, IEC 62304, Framework, Expert Review, Software Testing, Recalls.

Abstract: This paper details the expert review of a framework developed to implement a novel testing approach called taxonomy-based testing (TBT) for the medical device software domain. This framework proposes three approaches to implement TBT and has been validated by experts from the software testing industry and the medical device software domain. This paper details the results from the expert review. The expert review focused on validating the three approaches to TBT, the benefits of TBT to medical device software development, the accuracy of mappings of testing techniques from ISTQB and ISO/IEC/IEEE 29119-4:2015 to defects from a defect taxonomy, the integration of TBT into the standard test processes, ISTQB and ISO/IEC/IEEE 29119-2:2013 and the structure of the framework. The contribution of this paper is to reveal that (i) the framework is implementable in medical device software organisations that follow the IEC 62304:2006+A1:2015 software development process or that use standard test processes, (ii) using a defect taxonomy could standardise the application of experience-based approaches to software testing and (iii) considering potential defects before writing test cases could identify additional defects for test cases.

1 INTRODUCTION

This research proposed a testing approach called taxonomy-based testing (TBT) to improve medical device software (MDS) quality and to reduce adverse events caused by MDS defects (Alemzadeh et al. 2013; Rajaram et al. 2020; Felderer and Beer 2013). This research uses a defect taxonomy called SW91, Classification of Defects in Health Software. SW91 is a standard for health software which has been developed by the Association for the Advancement of Medical Instrumentation (AAMI) in collaboration with the US FDA (AAMI 2018). SW91 includes a total of 186 defects from the planning phase to the maintenance phase of a system. In TBT, the requirements will be mapped into potential SW91 defects, and test cases will be written based on the requirements and the mapped defects. Test cases will be executed to verify whether the software complies with the relevant requirements and does not contain the mapped defects. By applying TBT, an organisation can achieve benefits such as root cause analysis, risk minimisation and early detection of defects (Rajaram et al. 2020).

This research identified the need for a framework detailing the TBT implementation process and the alpha TBT (α – TBT) framework was developed to meet this need (Rajaram(&) et al. 2019). The main purpose of this framework was to implement TBT in any MDS organisation with limited resources and without the researcher's involvement with the organisation's requirement and defect data.

The literature revealed that expert review is important to identify the usefulness and applicability of research. (Offenberger et al. 2019; Sjøberg et al. 2007; Dumas and Sorce 1995; MacMahon et al.

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Rajaram, H., Loane, J., MacMahon, S. and Caffery, F.
Expert Review of Taxonomy based Testing: A Testing Framework for Medical Device Software.
DOI: 10.5220/0010458503310339
In *Proceedings of the 16th International Conference on Evaluation of Novel Approaches to Software Engineering (ENASE 2021)*, pages 331-339
ISBN: 978-989-758-508-1

2014). This research used expert review to validate whether the α – TBT framework was implementable in MDS organisations. This will be followed by implementing the framework in MDS organisations to provide additional validation.

This paper details the expert review of the α – TBT framework. Section 2 explains the α –TBT framework and the validation points considered in the expert review. Section 3 details the process followed during this expert review. Section 4 details reviews of the α – TBT framework. Section 5 details subsequent changes considered in the next version of the framework. Section 6 is future work. It details how this research plans to implement TBT in MDS organisations to complete the validation process. Section 7 details the summary and conclusion of this paper.

2 ALPHA TBT FRAMEWORK

The α–TBT framework details what TBT is and the following three approaches to TBT:
Approach A: TBT using all SW91 defects.
Approach B: TBT using testing technique mappings.
Approach C: TBT at different phases of software development.

The purpose of providing three different approaches is that the organisation can select an appropriate approach in light of their resources and testing practices. Also, the three approaches help to narrow down the selection of SW91 defects from 186 and allow the implementation of TBT at any phase of MDS development. The α – TBT framework details the TBT implementation steps - review SW91 defects, plan-TBT, map requirements to SW91 defects, write test cases, execute tests and analyse results. These steps have been integrated into the two standard test processes: the ISO/IEC/IEEE 29119-2:2013(ISO/IEC/IEEE 2013); and the test process of the International Software Testing Qualifications Board (ISTQB) (ISTQB 2010). These integrations were published in (Rajaram(&) et al. 2019). The rest of this section details the three approaches to TBT and the points considered in the expert review of the α – TBT framework.

Approach A - TBT using all SW91 Defects: In this approach, the organisation has to search and map the potential defects for each requirement to all SW91 defects. In this approach, the participants of TBT must have a good understanding of all SW91 defects and their classification.

Approach B - TBT using Testing Technique Mappings: This approach uses testing techniques from the ISO/IEC/IEEE 29119-4: 2015 and ISTQB (Graham et al. 2006; ISO/IEC/IEEE 2015). These testing techniques have been mapped into their potential SW91 defects, which can be identified when applying these techniques. The purpose of this mapping is to reduce the number of SW91 defects that need to be considered for each requirement.

Approach C - TBT at Different Phases of Software Development: This approach allows an organisation to narrow down the number of SW91 defects to those specific to a particular software development phase. Table 1 shows the number of SW91 defects from each phase of software development that needs to be considered when using TBT approach C.

Table 1: SW91 defects.

Parent level defects	Number of defects
Planning (1)	2
Requirements (2)	15
Architecture and Design (3)	28
Implementation (4)	106
Test (5)	18
Release Defects (6)	4
Maintenance (7)	13

2.1 Validation of the α – TBT Framework

The α – TBT framework involves software testing, MDS development, application of defect taxonomies, and use of the ISO/IEC/IEEE 29119-2:2013 and ISTQB test processes. The goal of this expert review was to validate the following five points of the α – TBT framework:

1. The three approaches to TBT.
2. The three approaches to TBT for MDS development.
3. Testing technique mappings.
4. Standard test processes and TBT.
5. The structure of the α – TBT framework.

After the expert review, the TBT framework will be implemented in a number of MDS organisations to provide further validation. This validation plan is presented in Section 6. The next section details the process followed in this expert review and Section 3.3 details the reviews.

3 EXPERT REVIEW PROCESS AND EXPERT PROFILES

The following steps have been followed in this expert review: (1) Find relevant experts. (2) Develop questionnaires and request permission. (3) Receive and analyse reviews.

3.1 Find Relevant Experts

As detailed in Section 2.1 the α – TBT framework has different parts to validate. It was not possible to find individuals with expertise in all areas of the TBT framework. Therefore, we looked to find one expert for each point that we were looking to validate. There was some overlap in expertise between experts. This accounts for the difference in numbers of experts validating each point. In order to validate the different parts of the α – TBT framework, the following search criteria have been used in expert selection:

- Expertise in software testing
- Expertise in defect taxonomy application
- Expertise in testing techniques application
- Expertise in MDS development
- Expertise in SW91 defects
- Expertise in the standard test processes such as ISO/IEC/IEEE 29119-2:2013 and ISTQB.

Six experts were selected from authors who have conducted taxonomy-supported testing and published several papers, from the software testing industry and from the MDS industry. Table 2 details the experts' expertise considered for the framework validation.

Table 2: Experts.

Experts	**Expertise considered in this research**
Expert 1	More than twenty years of experience in software testing. Trainer for different levels of ISTQB certification for more than fifteen years. Leading active member of testing standard family ISO/IEC/IEEE 29119.
Expert 2	More than fifteen years of experience in the software development industry. Internationally recognised researcher who has conducted several research projects in software industry including defect taxonomy-supported testing by applying the ISTQB test process.
Expert 3	Industrial testing consultant with knowledge in the application of defect taxonomy-supported testing in industrial projects along with testing techniques and the ISTQB test process. Thirty years' experience in test management, test automation and quality assurance.
Expert 4	Testing expertise with agile and the ISTQB test process. Over thirty years' experience in the software development industry.
Expert 5	Medical device regulatory expert who works at U.S. FDA for over ten years. Active and leading member of the standard development, AAMI SW91 "Classification of Defects in Health Software".
Expert 6	Quality assurance manager for over ten years at a leading multi-national software testing organisation.

3.2 Develop Questionnaires and Request Permission

As the framework is complex and had multiple distinct parts to validate, three sets of open-ended questionnaires (questionnaires A, B and C) were developed. All three questionnaires had 80% overlap. Table 3 details the questionnaires and experts who received those questionnaires. Questionnaire B included the same questions as Questionnaire A and it added a set of questions focused on the testing technique mappings. Questionnaire C included questions from Questionnaire A, but it added questions focused on finding the applicability of the framework to the MDS domain and did not focus on validating the point about standard test processes and TBT.

In order to develop questionnaires, the question design process detailed by Dawson was followed in this study (Dawson 2009). Questions were developed to validate different points of the α – TBT framework detailed in Section 2.1. After developing questions, a draft of the questions was reviewed by another researcher to determine how well the questions

Table 3: Questionnaires, validation points and experts.

Questionnaires	Validation points	Experts
Questionnaire A	Three approaches to TBT.	Expert 1 Expert 2 Expert 4
	Standard test processes and TBT.	
	The structure of the α – TBT framework.	
Questionnaire B	Three approaches to TBT.	Expert 3 Expert 6
	Testing technique mappings.	
	Standard test processes and TBT.	
	The structure of the α – TBT framework.	
Questionnaire C	Three approaches to TBT for MDS development.	Expert 5
	The structure of the α – TBT framework.	

fulfilled their purpose and to ensure that they did not contain any ambiguity.

Since expertise between experts was overlapped, different numbers of experts were considered for validating each point of α – TBT framework. Due to this, an imbalance of experts to validate each point was observed. As this research will further validate the framework with MDS organisations, the imbalance of experts for each point was not considered as a major validity issue to this research.

Expert 5 was involved in the development of SW91. This is considered a strength rather than a limitation of this expert review. Their in-depth knowledge of SW91 along with their medical device software regulatory expertise means that they were an ideal candidate to validate the framework.

After identifying the experts and developing the questionnaires, emails were sent to the experts requesting that they review the α – TBT framework. The experts were also asked to participate in a focus group interview to discuss the findings from their reviews.

3.3 Receive and Analysis of Reviews

All experts agreed to provide written feedback and to join a focus group interview or individual interview after their initial reviews were analysed. Experts 1 and 3 participated in the focus group interview. The other experts were unable to join at the requested time. Additional interviews were held with Experts 5 and 6. Expert 4 was also contacted for further clarification and he has provided this clarification via email. The researcher analysed the reviews collected from questionnaires, focus group interviews and individual interviews. The next section presents the analysis of the reviews.

4 EXPERT REVIEW OF THE ALPHA TBT FRAMEWORK

The remainder of this section details the reviews on the five points of α – TBT framework listed in Section 2.1.

4.1 Three Approaches to TBT

This part was validated by experts 2, 3, 4 and 6. This part of the expert review focused on validating the benefits of the three approaches to TBT in practice and implementation of the three TBT approaches.

Expert 2 and 3 did not point out any difficulties with the three approaches to TBT. This is significant, as these two experts have experience in the application of defect taxonomy-supported testing. They prefer approach B, which uses testing techniques. They said that this approach facilitates an efficient design of test cases and it will be a good testing strategy to consider when planning the testing for projects which use testing techniques.

Expert 2 said that by adopting any of the approaches, the implementation phase of a project would have enhanced traceability by checking code against requirements and mapped defects.

Expert 3 said that since TBT uses a defect taxonomy from the MDS industry, it should include defects which are familiar and that TBT could be easily implemented into a MDS organisation.

Expert 4 said that the three TBT approaches could be beneficial. He suspects only a minority of MDS organisations will use it. Unless the adherence to standards is made mandatory by regulatory bodies, the overhead of application is too great for most companies. He also said that TBT could be hard to sell to an organisation due to the cost of the third step of TBT, mapping requirements to SW91 defects.

Expert 6 said that defect taxonomies are often used informally as an experienced-based technique during test case generation. The TBT framework could be seen as standardising, something that was previously based primarily on experience. TBT can be used as an additional review before or after the creation of the initial test specification. During this review using the lens of the mapped defect taxonomy, the test cases could be reviewed for coverage. However, he also suspected that TBT would be hard to sell unless defect taxonomy analysis was part of the existing test creation phase.

Experts 2 and 3 have provided positive feedback. Experts 4 and 6 suspect that TBT is hard to sell to organisations. Since both experts 4 and 6 have provided feedback based on their expertise in non - MDS, their feedback was discussed with a MDS expert, expert 5. Expert 5 strongly disagreed with their comments and said that while the "the overhead of application is too great for most companies might be legitimate", there is still no proper evidence to show the cost or time of the mappings from TBT implementation. Expert 5 said the benefits of TBT such as early detection of defects, root cause analysis have to be prioritised first and that the time needed to conduct the mappings has to be identified through industrial validation of this framework. The time taken to conduct the mapping between requirements and SW91 defects will be identified through validation with MDS organisations. This is detailed in Section 6.

MDS expert 5 did not agree with expert 4's comment that the regulatory bodies should make adherence to standards mandatory. Expert 5 said that regulations aim to ensure safe and reliable software development and to assist the MDS organisations in developing software in the right way. MDS organisations should not be governed by regulatory bodies. They should understand the purpose and benefits of regulations.

4.2 Review of the Three Approaches to TBT for MDS Development

This part of the expert review has focused on finding out the benefits of the three approaches to TBT for MDS development. This part was validated by expert 5.

Expert 5 provided a review of the three approaches to TBT and their implementation to different situations in a MDS organisation. Expert 5 said that approach C seems a good starting point that will bring benefits to MDS development. The selection of an approach has to be based on the software development methodology. Existing development methodologies at a MDS organisation could determine which approach can be selected. For example, test-driven development can use approach B. Approach C is implementable in agile development. However, approach A may also work with an agile methodology where the focus is on all the defects that match the current sprint. Expert 5 suggested detailing how TBT can be implemented at a company that uses agile.

Expert 5 said that since IEC 62304:2006+A1:2015 is a process standard that does not include test criteria, it is hard to tell whether or not the three approaches comply with the processes of IEC 62304:2006+A1:2015. As there were no test criteria in IEC 62304:2006+A1:2015 (Bujok et al. 2017), expert 5 suggested that the TBT framework should include the following three direct links between IEC 62304:2006+A1:2015 and SW91 defects:

Link 1: The defect category Security (3.8) from SW91 was developed with IEC 62304:2006+A1:2015 in mind. MDS organisations can use this category and its definition to refer to defects related to security.

Link 2: Segregation necessary for risk control (3.2) is one defect category from SW91. This category aligns with Section 5.3.5 of IEC 62304:2006+A1:2015 (IEC 2015).

Link 3: The framework suggests considering potential defects of SW91 in each phase before that phase. This can be linked with Section 5.1.12 from IEC 62304:2006+A1:2015. Section 5.1.12 details the identification and avoidance of common software defects.

The researcher extended the study on the link between IEC 62304:2006+A1:2015 and SW91 defects and found the following fourth link:

Link 4: Section 5.1.6 of IEC 62304:2006+A1:2015 details that each life cycle activity has to include verification. This can be linked with the TBT framework, approach C which details how SW91 defects can be used in the verification at different phases of MDS development.

The links above between SW91 and IEC 62304:2006+A1:2015 show that the application of the α – TBT framework could help MDS organisations to achieve regulatory compliance.

4.3 Review of Testing Technique Mappings

Testing techniques from the ISTQB and the ISO/IEC/IEEE 29119-4:2015 were mapped into potential SW91 defects. These mappings are used in TBT approach B. These mappings were validated by expert 3 and expert 6.

This part of the validation focused on establishing the accuracy of the mappings. Expert 3 said that the "mappings in the excel sheets are understandable and plausible". Expert 3 said that this mapping could help testers to design test cases effectively and that it would also significantly improve the design of test cases.

Expert 6 said that these mappings are good and comprehensively cover the testing techniques in the software testing industry. Expert 6 said that the granularity of defects in the mappings is much finer than what his organisation currently works with. For example, the mapping of equivalence partitioning testing technique includes defects such as Data definition (4.1), Scalar data type (4.1.1) and Scalar Data Operations (4.1.1.1). Expert 6 said that testers would not log this granularity of defects to a root cause in their defect management/software life cycle application.

Since expert 6 is from non-MDS testing, this comment was discussed with expert 5 to know about the granularity of defects in MDS development. Expert 5 said MDS organisations should consider root causes and contributing factors to ensure quality via mitigation of root causes.

4.4 Standard Test Processes and TBT

The six steps of the TBT implementation process are integrated into the two standard test processes, ISO/IEC/IEEE 29119-2:2013 and ISTQB. These integrations were detailed and published in (Rajaram(&) et al. 2019). This part of the validation focused on finding out:

- Whether or not the two standard test processes are aligned correctly.
- Whether the six steps of TBT are correctly integrated into the standard test processes.
- Whether TBT is implementable in an organisation which follows a standard test process.

This part was validated by experts 1, 2, 3 and 4. Experts 1 and 3 said that both standard test processes have different scopes and that the researcher had not explained this during the alignment of both standard test processes. The ISO/IEC/IEEE 29119-2:2013 test process has three sub processes, from the organisation level to the project level. The scope of the ISTQB test process is project-level testing only. It cannot be aligned with the organisational test process from ISO/IEC/IEEE 29119-2:2013. The experts suggested detailing the difference in scope in the framework.

Regarding the integration of TBT into the test processes ISO/IEC/IEEE 29119-2:2013 and ISTQB, all the experts provided positive comments on the integration. They suggested that TBT is currently integrated into the older version of the ISTQB test process and should be integrated into the newer version of the ISTQB test process.

Regarding the six steps of TBT, the experts suggested that Step 1: Review SW91 defects, should not be considered in the test processes. This step should be considered as knowledge sharing and conducted at the requirement engineering phase, which is outside of the test process. If this step is considered at the requirement engineering phase, this will provide an opportunity to consider all potential defects from all phases of software development. The experts also suggested minor changes related to terminologies and their explanations in both test processes. The experts said that both test processes, the ISTQB and the ISO/IEC/IEEE 29119-2:2013 process allow the selection of appropriate testing techniques for a project. TBT is a new testing technique and could be considered when a testing team selects testing techniques for a project in an organisation. TBT is implementable in an organisation using either standard test process, the ISTQB or the ISO/IEC/IEEE 29119-2:2013.

4.5 Review of the Structure of the Framework

This part was validated by experts 1, 2, 3, 4 and MDS expert 5. The purpose of this part of the validation is to find out whether the framework is coherent. It also aimed to assess if the framework was implementable in MDS organisations.

Expert 1 and expert 3 said that the framework is readable, understandable and well structured. The six steps are explained very well. If the researcher includes examples throughout the framework, it will be clearer to the reader. Expert 2 and expert 4 said that the α – TBT framework is clearly structured, although they pointed out the challenges on the implementation of TBT due to the time it will take to conduct the mappings between requirements and SW91 defects. Expert 5 said that by including identified pros and cons for each approach, it would make the decision-making easier for MDS organisations by showing that possible failure points have been taken into consideration.

In order to make the implementation of TBT easier, they said that the researcher should perform training on conducting mappings using sample requirements and SW91 defects at the organisation which agreed to implement it. The experts suggested that by implementing TBT in an organisation, efficiency can be measured and that this detail should be included in the framework. They suggested giving thought to automating this framework.

5 CHANGES RESULTING FROM EXPERT REVIEW

The experts provided their reviews on the α–TBT framework. This section summarises the changes resulting from the expert review that will be built into the next version of the framework, the β – TBT framework.

The first part of the α–TBT framework validation focused on the three approaches to TBT. No changes to the α–TBT framework were suggested apart from finding the time needed to conduct the mappings between requirements and SW91 defects. This will be identified through the validation of TBT approach B in a MDS organisation and it will be included in the β - TBT framework. This has been detailed in future work, Section 6.

The second part of the α–TBT framework validation focused on the three approaches to TBT for MDS development. This was validated by expert 5, who suggested detailing the direct links between IEC 62304:2006+A1:2015 and SW91. This suggestion has been adopted and these links have been included in the β - TBT framework. Expert 5 also suggested including details on how TBT can be used with an agile methodology. A document will be developed detailing how to implement TBT when using an agile methodology. This document will be added to the β - TBT framework.

The third part of the α–TBT framework validation focused on testing technique mappings. Testing techniques from the ISTQB and the ISO/IEC/IEEE 29119-4:2015 were mapped into the potential SW91 defects and used in approach B of TBT. This part was validated by experts 3 and 6, who provided positive comments about the accuracy of the mappings. Expert 6 said that the mappings contain much finer defect details than they typically work with. Testers would not log the finer detail of defects in their defect management/software life cycle. This review was discussed with expert 5, who said that MDS organisations should consider finer detail of defects to find root causes. Taking into account the statement made by Expert 5 on finer defect details, the use of finer defect details will be investigated through the TBT approach B implementation with MDS organisations. This has been detailed in future work, Section 6.

The fourth part of the α–TBT framework validation focused on standard test processes and TBT. The experts said that TBT is implementable in an organisation which follows the standard test process, either ISO/IEC/IEEE 29119-2:2013 or ISTQB. However, the experts suggested the following changes, which have been adopted into the β - TBT framework:

- Do not integrate the first step of TBT into both standard test processes, ISTQB and ISO/IEC/IEEE 29119-2:2013. Consider it at the requirement gathering phase.
- Detail the scope of both test processes ISTQB, ISO/IEC/IEEE 29119-2:2013 and where TBT can fit.
- Integrate TBT into the new version of the ISTQB test process and provide additional detail to the phases of both test processes ISTQB and ISO/IEC/IEEE 29119-2:2013.

The last part of the α–TBT framework validation focused on the structure of the framework. All the experts provided positive comments on the structure of the α–TBT framework. However, the experts suggested performing training on how to conduct mappings between requirements and SW91 defects at the organisation which agreed to implement TBT. The experts suggested including the efficiency, pros and cons of TBT approaches in the framework to make the selection easier for the organisation.

This research will validate TBT approach B in an MDS organisation. From this validation, the efficiency, pros and cons of TBT approach B will be investigated and includes in the β - TBT framework. This has been detailed in future work, Section 6. Table 4 summarises the changes suggested from the expert review. Changes in bold have already been adopted into the β – TBT framework. The rest of the changes will be addressed through future work.

Table 4: Changes for building β – TBT framework.

Validation points	Suggested changes
Three approaches to TBT.	Investigate the time taken to conduct the mappings.
Three approaches to TBT and MDS development.	Develop an approach for implementing TBT in Agile development.
	Examine the direct links between SW91 and IEC 62304:2006+A1:2015.
Testing technique mappings.	Include the benefits of finer defects to MDS development.
TBT and standard test process.	**Consider the first step of TBT at the requirement gathering phase.**
	Provide the scope of both test processes ISTQB and ISO/IEC/IEEE 29119-2:2013 and TBT.
	Integrate TBT into the newer version of ISTQB.
The structure of the α – TBT framework.	Detail the pros and cons of three approaches to TBT.
	Provide examples through the framework.

6 FUTURE WORK

As detailed in Section 1, the expert review on the α – TBT framework is one part of the validation. This validation suggested including the following points in the next version of the framework:

- Pros and cons of the three approaches to TBT.
- Time taken to conduct mappings between requirements and SW91 defects.
- The efficiency of three approaches to TBT.
- Benefits of finer defects to MDS development.

In order to validate the points raised in the expert reviews, a research collaboration was established with an MDS organisation, Company B in the U.K. The researcher presented the three approaches to TBT. By considering resources and project time at Company B, they agreed to implement TBT approach B. During this implementation, five requirements from a past release at Company B will be used to map into SW91 defects using the testing technique mappings. Based on the mappings, the researcher will interview the test engineer at Company B to investigate the points raised in the expert review.

7 CONCLUSION

This paper has detailed a part of the validation, expert review of the α–TBT framework. Six experts from the software testing industry and the MDS industry have reviewed the α–TBT framework. The expert review of α–TBT framework focused on validating approaches to TBT, the benefits of TBT to MDS development, the accuracy of mappings of testing techniques from ISTQB and ISO/IEC/IEEE 29119-4:2015 to defects from SW91, the integration of TBT into the standard test processes such as ISTQB , ISO/IEC/IEEE 29119-2:2013 and the structure of the framework.

Experts provided positive feedback on the three approaches to TBT. The review identified that the three approaches to TBT could be implemented in different situations at MDS organisations. Approaches A and C can fit into agile development. Approach B can fit into test-driven development and it enables the standardisation of the experience-based application of defect taxonomies in software testing. Since the α–TBT framework includes mappings of testing techniques to SW91 defects, it will be beneficial to consider potential defects before writing test cases.

The experts said that the framework is readable and well structured. It is implementable in MDS organisations which use the IEC62304:2006+A1:2015 process. It enables the implementation of TBT into existing standard test processes such as ISTQB and ISO/IEC/IEEE 29119-2:2013. Experts said that the testing technique mappings comprehensively cover the testing techniques in the software testing industry and the mappings are correct. These mappings would significantly improve the design of test cases.

Experts suggested including additional details in the next version of the framework such as (i) pros, cons and efficiency of the three approaches to TBT, (ii) time taken to conduct mappings between requirements and SW91 defects and (iii) benefits of reporting fine grained defects to MDS development. These points will be investigated through validation with MDS organisations. This will be included in the next version of the framework.

ACKNOWLEDGEMENT

This work was supported with the financial support of the Science Foundation Ireland grant 13/R.C./2094 and co-funded under the European Regional Development Fund through the Southern & Eastern Regional Operational Programme to Lero - the Irish Software Research Centre (www.lero.ie).

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