



Assessed Coursework

Course Name	Safety Critical Systems M		
Coursework Number	1		
Deadline	Time:	4:30pm	Date: 6 th March 2015
% Contribution to final course mark	20	This should take this many hours:	
Solo or Group ✓	Solo ✓	Group	
Submission Instructions	Submit into the secure box provided outside the Teaching Office, Room F161, Lilybank Gardens		
Who Will Mark This? ✓	Lecturer ✓	Tutor	Other
Feedback Type? ✓	Written	Oral	Both ✓
Individual or Generic? ✓	Generic	Individual	Both
Other Feedback Notes			
Discussion in Class? ✓	Yes	No	
Please Note: This Coursework cannot be Re-Done			

Code of Assessment Rules for Coursework Submission

Deadlines for the submission of coursework which is to be formally assessed will be published in course documentation, and work which is submitted later than the deadline will be subject to penalty as set out below. The primary grade and secondary band awarded for coursework which is submitted after the published deadline will be calculated as follows:

- (i) in respect of work submitted not more than five working days after the deadline
 - a. the work will be assessed in the usual way;
 - b. the primary grade and secondary band so determined will then be reduced by two secondary bands for each working day (or part of a working day) the work was submitted late.
- (ii) work submitted more than five working days after the deadline will be awarded Grade H.

Penalties for late submission of coursework will not be imposed if good cause is established for the late submission. You should submit documents supporting good cause via MyCampus.

Penalty for non-adherence to Submission Instructions is 2 bands

You must complete an "Own Work" form via

<http://www.dcs.gla.ac.uk/socs-online> for all coursework

UNLESS submitted via Moodle

Software Safety in Healthcare (Level M)

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1 Introduction

There are many different issues that arise during the integration of software in healthcare systems – at a superficial level decision support systems can help clinicians to identify and treat a range of illnesses, in other words software applications can save lives. Equally, poorly designed software might offer incorrect advice and delay appropriate interventions. Ethical and technical concerns over the validation of safety-related software have led many manufacturers to argue that their products can only be used to support clinicians; who carry the ultimate responsibility if they follow incorrect advice. In other contexts, software may improve overall survival rates if it ensures that more patients receive the correct treatment even if some mistakes are made – the overall morbidity would be less than if the software had not been developed. This exercise will help you consider these interactions between technical, ethical and commercial aspects of safety-critical software in healthcare applications.

2 Tool Development

Your task in the open assessment is to develop a technique that will help identify the safety-related hazards that arise from the introduction of software into a healthcare setting. The aim is to enable senior or middle management to assess and mitigate the safety related risks. The design of the technique is entirely open. You may choose to use one of the risk assessment techniques that are introduced during this course, such as Fault Trees or Failure Modes, Effects and Criticality Analysis. Alternatively, you may choose to develop an entirely new approach. However, if you use an existing approach you must show how it can be used with specific examples of major changes to existing infrastructures.

The key aim is to help organizations assess the likelihood and consequence of hazards that can arise in the introduction of software related systems into clinical settings. There have been numerous studies on these issues – some look at software for particular devices such as programmable infusion pumps – others look at wider issues raised by failures – most notable the Therac-25 case study. It is VITAL that your answer should contain a detailed case study based on existing research.

You may choose to develop electronic tools that support the application of your technique using any programming methodology. The implementation of the tool could rely on simple web pages generated using HTML, PHP or any other associated technology. Your design may be realized using conventional programming languages or you could simply rely on paper-based support. However, the marking scheme will take into account both the strengths of the design for the risk assessment technique and the effectiveness of an implementation in terms of the support that they offer to the potential end users.

3 Evaluation

It is important that you evaluate your technique/tool for assessing the risks from clinical software. One means of doing this would be to ask a number of different users to try it out, exploiting an appropriate evaluation methodology. For example, you could ask one group to use your technique and another to use an alternate approach developed by someone else in the course. If you do this you **MUST** consider the relevant plagiarism guidance on the School Learning and Teaching Committee web site and state the name of the person you worked with on your submission. You must develop your reports independent of each other. You also need to consider the level of existing expertise that test participants will have in clinical software development.

If you split your users into two groups for each tool then this raises important methodological concerns. Firstly, how would you ensure that both groups have the same level of expertise and background knowledge so that any comparisons are fair? Secondly, how would you go about assessing the accuracy of any risk assessments that are produced? Please consult with me before conducting your evaluation so that I can provide advice in answering some of these questions. You should also consult the course handbook and associated web pages that cover the ethical guidelines for user testing.

4 Transferable Skills

This exercise will provide a first-hand introduction to the challenges that face many large organizations as they develop clinical software – including both decision support tools and embedded code. Alternatively you could look at the growing market in health related app and personal monitoring tools. There is little common agreement on the best approaches to adopt and hence you will be working in an area of active research, which is also a focus for public, government and commercial interest.

5 Assessment Criteria and Submission Details

This exercise is degree assessed. It contributes 20% to the total marks associated with this course; please read the associated warning on the course Moodle page. The body of the report should not exceed fifteen A4 pages. The report must be printed out and must be submitted in a secure binder. It must include: A title page containing your contact details (email etc); a table of contents and appropriate page numbers; a section on the tool that you developed; a section on the evaluation method that you used; a results sections and some conclusions.

In addition to the fifteen pages in the body of the report, you may also include appendices. These should contain the listing of any code used during the study together (this can be included on a CD) with suitable acknowledgements for the source of code that has been borrowed from other programmers. The report should be handed in by 4.30pm, 6th March 2015 using the submission box outside the teaching office in Lilybank Gardens. Please make sure that you keep back-up copies of all of your work and submit a plagiarism statement using the standard on-line form. The following marking scheme will be applied: 30 for the method; 20 for the results; 30 for the conclusion; 20 for the technical documentation. All solutions must be the work of the individual submitting the exercise and the usual lateness penalties will apply unless I am given good reason in advance of the deadline. *You must state the title of this question on the front of your submission so I know you are answering the level M open exercise.*

6 Hints

You will need to do considerable reading first so please do not delay starting this assessment.