

CO304 Software Quality Assurance

Assignment 2

0210286 T.L. Atherden

Assignment 2

Question

Using Case Study 2 (see Appendix I)

How could the Systems staff at Dyalasist Medical have prevented the malfunctioning of the dialysis machine through the better use of product and process metrics, as well as better integrity assurance techniques such as testing, validation and verification? Critically evaluate the case and identify which metrics would have been best suited to the prevention of the malfunction. In addition, highlight any other issues which you feel should have been addressed.

Use appropriate literature and examples from other cases to support your argument. Essays without adequate research and references will not receive high marks. I have been advised to analyze three of the issues in the 2,000 words required.

Metrics

Kidney dialysis provides an artificial replacement for lost kidney functions due to renal failure, but does not necessarily improve the kidney. It is extremely useful for life support. Kidney dialysis machines provide calculable tubing to pass blood and remove waste when the kidney itself is not capable. This *haemodialysis* should be quite metrically and integrally practical in both product and process from a computers integration. The metrics best suited for conducting kidney dialysis machines, according to Adams and Thompson (2002), are not single-metrics, which Denaro, Lavazza and Pezzè (2003) evaluated as fault-prone in most codes except Java's 00 metrics. Quality assurance or outside testing of the software used in kidney dialysis machines is rare but seldom uses Java. Prototype testing was performed, but the software has been updated often and Buckley states that the latest software testing tools are used. That may not recognise internally updated errors. It may also not environmental affects, from temperature to culture, into account. While the programmers under Buckley are strong, they cannot necessarily understand either medical staff induced metrics or global environmental input. Page 10-11's two Medical Devices Incident Reports state that the software upgrades are prevented on all machines and downgraded to the previous software release. So will the safer SPARK Ada be recognised in testing? Or is the testing only performed on the C and C++ against the requirements for mark III?

The 'people metrics' of Lanchester Royal Infirmary's medical staff and the computing staff of Dyalasist Medical supervised by Abel and Simmons, are veritably and widely experienced. It should be noted that the testing team at Dyalasist are not listed by experience; a similar case for the project manager Simon Buckley. These two latters give some weakness to the 'people metrics' of the Case Study. The Cambridge Dictionary notes the selective removal of substances in kidney or renal dialysis. Surely this selectivity is a biologically perceived illness, rather than advanced computer metrics. 'People metrics' are clearly more important than code. Semi-permeability can possibly be recognised and realistic by SPARK Ada, as concluded by Chapman, Burns and Wellings (1994) depending on input-data, the

‘people metric’, or system modes. Worst-case analysis timing for hard real-time and safety-critical systems is complimentary to the Case, but does not support it fully under a constantly changing system or environment. In contrast the original Greek *haemodialysis* is quite effectively mitigated by most computing metrics despite its biological solubility.

While the development of mark III may aid analysis, the software quality of Dyalasist’s kidney dialysis machines, as well as its medical staffs’ usability, this constant change means Abel has to employ professional software engineers as well as his regular staff. He will also find the requirement due to that staffs’ lack of experience with SPARK Ada and mark III’s necessities. Buckley’s lack of knowledge on SPARK Ada testing methodology will constantly test him. Legal proceedings, as in Frank Burdett’s case, will follow the software development, causing personal injury and further court cases against Dialysist Medical. Dyalasist Medical’s staff are noted as hardware rather than software engineers, despite being encouraged to upgrade to a safer language from C and C++ to SPARK Ada. If they have to burden themselves with new software, it would be better if they were originally more software resilient. Hardware is intrinsically important in dialysis machinery according to de Palma (1999), although its use is not regularly monitored except by Buckley, who also has software maintenance duties, in the Case Study. The human observation of a patient’s condition is more important than computer coded regulation. But more programming experience would be more protective to the company, the patients and the software used by medical staff. Of the three software team Thomas’s experience is limited, although Vale has more. The latter’s actual software knowledge is not listed, despite her senior programmer signification. The team leader Cook has limited code practice outside of Cobol and Visual Basic for a financial company. With mark III Murphy is only improving the display with no effect on the functionality of the device. The temperature alarm that resulted in Burdett’s heart attack may have been display fault written by Murphy. If that is the problem, it is possible mark III could reiterate the heart attack or cause other problems. Do single metrics, 00’s, in SPARK Ada? Or does Thomas’s improved display code increase the benefit of human defined metrics more than Object-Oriented code would? Java’s Object-Oriented Polymorphism can allow quadrilateral performance on rectangles observe Deitel and Deitel (2003). There is no Java experience noted in the Dyalasist Medical’s programming staff, although their members outside of Thomas have reasonable knowledge of available software. Fortunately Deitel, Deitel and Nieto (1999:768) had noted that ‘integrity can be maintained’ in database management systems of Visual Basic 6, a code previously used widely in Dyalasist’s software.

Integration Testing

Gallagher, Offut and Cincotta (2006) state that in object-oriented coding, one of the goals of integration testing is to ensure that messages from one class or module are sent and received in accuracy and have the desired effect on the state of the objects that receive the commands. SPARK Ada’s integral testing requires 9000 verification conditions to complete according to King et al’s (2000) abstract. This number of conditions and proof reading will occupy much time from Buckley’s team, especially with all of Dyalasist’s overseas sales development.

Crocker (2004:10), in his annotated development with extended static analysis, recommends SPARK Ada as the most successful approach to behavioural verification. He states that Java and C++, by their Object-Oriented code, allow a variable or parameter of any non-primitive type to have a null value. The complexity metrics are not likely to be calculated accurately. This could have been the affect of Burdett's death in use of a mark II machine. Dyalasist Medical's mark III, which the first Medical Evidence Incident Report on page 9 lists as a high classification, will clearly be an improvement to prevent a recurrence of the event. Murphy's doctoral strength may allow him research a previously unknown code. Buckley's management skills will observe all of his team's software development, as his recognition of mark II's issues shows. Erkkinen (1999) observed during a symposium both governmental bodies and private companies adopting safety-critical software requirement and reliability. He admits SPARK Ada is the way to go for software used in aircraft safety and military equipment. He hints that medical software security using SPARK Ada subsets will improve over Java Byte code and others subsets. Verification of Object-Orientation using unit testing is of primary importance. The medical devices in the Case Study show the design of the software was very unwieldy, with no real integration between the user interface, warning system and control functions. Murphy's impact on mark III may ease the user interface, but not strengthen the warning system or control functions. Hopefully the general programming of SPARK Ada will alleviate these latter two as per Erkkinen's report.

Process Thinking and Process Models - Relativity

Whalen and Heimdahl (1999) in their conference on automated software engineering suggested SPARK Ada can be used to satisfy customer quality, safety regulation and required legality, which will reassure Dyalasist Medical of their management processing. They do note the 9000 verification conditions necessary. Those were the ones already mentioned here by King et al (2000). Unified process models include the speed of verification and testing and are incremental, although the tasking of the software development will be different: it is possible that Murphy's different code experience will be most safety-critical. Jacobson, Booch and Runbaugh (1999:4) explain that the model process is architecture centric and incremental in unified processing. Buckley's software team will be very busy. Perhaps an increase in staff is advisable. They later suggest that roles will change within an organisation and that models will continue to be self-contained, or should be. Legal cases are often brought in kidney dialysis patients' conditions, regardless of computer inoculation of the machines used. Solicitors aim for what may win them their court appeal, including political affiliation and scientific ambivalence, says Delany (1993). The case of Burdett seems not to be unusual.

The survey made by Caseley, Tudor and O'Halloran's (2003) tells us that the subsets of SPARK Ada ease refinement processes and are highly sought for safety-critical software. They warn there is a deficiency in the number of experienced programmers of Ada as well as approve that formal semantics have been written to underpin the language. The Canadian Therac-25 is a good reflection on what might happen in legal cases. To my best ability I have been unable to find any case of SPARK Ada operated machinery being used in a court case, although the original Ada has been used in the U.S. Court of Appeals for the First Circuit in the case of the Dentist's Liability for

HIV Discrimination, available online from U.S. Department of Justice (1997). Augusta Ada King would be proud of her namesake's prowess.

Software upgrades are required often with medical machinery write Shellock et al (1992) in their *roentgenological* examination of sleep apnea. Process thinking must incorporate this. Wood (1996) sees process modules as essential for tool integration allowing the processing of several wafers from the same body simultaneously. This should be attended to by Dyalasist's staff responsible for kidney dialysis machines computerised performance.

We were asked to reference Herman, and some of her work would lead to the practicality of Murphy's programming and Dyalasist's ongoing use of SPARK Ada. Herman et al (2003) note that distributed interactive simulation (DIS) only contains rudimentary logistics protocols. This interactive simulation is amnisiant to Murphy's team membership and Dyalasist's management. DIS will improve their kidney dialysis machines' interaction. The migratory object protocol (MOP) family addresses the transfer of control and will be met by SPARK Ada programming. MOP will process modules better than previous code. Herman's other works are fascinating, but not relevant here. Try to read her work relating to process management: it is aimed at academic processes. Is that management?

Summary

As far as it is possible to examine the evidence of Case Study 2 it appears that Dyalasist Medical have maintained rule observation in their production, maintenance and upgrades to their software. More programming staff could be advisable, as well as constant software training relevant to future mark III and SPARK Ada production. Future production of Dyalasist's machines is recommended, and it's management without fault in Burdett's fatality. Complexity of software testing must be uppermost to Simmons and of note to Abel and the press. The software quality is sufficient. The measurement of Total Quality Management in Dyalasist Medical is debateable, but the stability and incrementation of Cook's team is straight thinking.

Both *haemodialysis* and *peritoneal* kidney dialysis result in approximately 23% mortality failure depending on region of treatment. Burdett's death is no fault of Dyalasist Medical.

Word Count: 1,926 (excluding references and appendix)

References

- Adams, J. and Thompson, M. (2002) Taking account of societal concerns about risk: Framing the problem Norwich: HMSO, Health and Safety Executive
- Chapman, R., Burns, A. and Wellings, A (1994) Integrated program proof and worst-case timing analysis of SPARK Ada Unpublished available from: <URL: <http://www.cs.york.ac.uk/ftplib/reports/YCS-94-246.pdf>>
- Crocker, D. (2004) Safe Object-Oriented Software: The Verified Design-By-Contract Paradigm, Heidelberg, DE: Springer
- Deitel, H., Deitel, P. and Nieto, T. (1999) Visual Basic 6: How to Program Upper Saddle River, NJ: Prentice Hall
- Deitel, H. and Deitel, P. (2003) Java: How to Program Upper Saddle River, NJ: Prentice Hall
- Delany, L. (1993) Health Care Analysis, Vol. 1, No. 2, Dordrecht: Springer Netherlands
- Denaro, G. Lavazza, L. and Pezzè, M (2003) An Empirical Evaluation of Object Oriented Metrics in Industrial Setting, Unpublished discussion in the 5th CaberNet Plenary Workshop available from: <URL: <http://www.lta.disco.unimib.it/homepage/giovanni.denaro/papers/CaberNet03.pdf>>
- de Palma, J. (1999) Daily Hemodialysis: A Very Odd Concept in Sherman, A. (Ed.) (1999) Seminars on Dialysis Vol. 12 Issue 6 Oxford: Blackwell Publishing Ltd.
- Erkkinen, T. (1999) Safety-Critical Software Generation, Unpublished available from <URL: <http://ieeexplore.ieee.org/iel5/6553/17498/00808654.pdf>>
- Gallagher, L. Offut, and Cincotta (2006) Integration testing of object-oriented components using finite state machines Unpublished available online: <URL: <http://www3.interscience.wiley.com/cgi-bin/fulltext/112229641/PDFSTART>>
- Herman, D., Taylor, D., Morrison, J., Katz, W. and Felton, E. (2003) New logistics protocols for distributed interactive simulation, Proceedings of SPIE Vol. 2495 Unpublished abstract available from <URL: <http://spiedl.aip.org/getabs/servlet/GetabsServlet?prog=normal&id=PSISDG002495000001000051000001&idtype=cvips&gifs=yes>>
- Jacobson, I., Booch, G. and Rumbaugh, J. (1999) The Unified Software Development Process Boston, MA: Addison-Wesley Longman Publishing Co. Inc.
- King, S., Hammond, J., Chapman, R. and Pryor, A. (2000) Is Proof More Cost-Effective Than Testing? Unpublished available online: <URL: <http://csdl2.computer.org/persagen/DLabsToc.jsp?resourcePath=/dl/trans/ts/&toc=comp/trans/ts/2000/08/e8toc.xml&DOI=10.1109/32.879807>>

Shellock, F., Schatz, C., Julien, P., Steinberg, F., Foo, T., Hopp, M. and Westbrook, P. (1992) Occlusion and narrowing of the pharyngeal airway in obstructive sleep apnea: evaluation by ultrafast spoiled GRASS MR imaging, Leesburg, VA: American Journal of Roentgenology

U.S. Department of Justice (1997) Enforcing the ADA, Unpublished available from <URL: <http://www.usdoj.gov/crt/ada/janmar97.htm>>

Whalen, M. and Heimdahl, M. (1999) An approach to automatic code generation for safety-critical systems Unpublished available from: <URL: <http://www.umsec.umn.edu/files/43.65.cg-requirements-hase99.pdf>>

Wood, S (1996) Simple performance models for integrated processing tools Unpublished available from <URL: <http://dx.doi.org/10.1109/66.536105>>

APPENDIX I
CASE STUDY 2
DYALISIST MEDICAL CASE STUDY

Appendix I - Case Study 2

This case study concerns an incident that took place in Lanchester in the northwest of England. A kidney dialysis machine produced by the company Dyalasist Medical malfunctioned causing the death of a 63-year old man undergoing overnight treatment at Lanchester Royal Infirmary (LRI). The deceased was a local Labour councillor who was very active in helping to raise the living standards of the more vulnerable members in his community. The local people have been very upset by the untimely death of a well-known and respected figure. The press has publicised the case and those undergoing kidney dialysis are understandably nervous about continuing their treatment.

The Medical Devices Directorate within the Department of Health is undertaking an inquiry into the cause of the malfunction, led by Dr Steven Hope. Meanwhile, there has been a recall of this particular version of the machine. Legal proceedings may be brought against Dyalasist if they are found to be at fault. Dyalasist is an important local employer and its machines are sold throughout the world. This version had not yet been introduced into the United States as the process to satisfy the Food and Drugs Agency (FDA) can take years longer than gaining the CE mark needed for the European Community market.

Key people involved in the incident are:

Staff nurse **Jean Bury** who has worked on the kidney ward for nine years, with no previous incidents, supervising patients undergoing dialysis treatment. **Dr. Hugh Simmons**, Chief Executive of Dyalasist Medical maintains that his machines have helped to extend and improve the quality of life of thousands of people with no previous problems. The recent software update was routine and would have had no bearing on the incident.

Professor James Abel is head of the medical physics research group at Lanchester University medical school who developed the device and its software in partnership with Dyalasist. He is concerned that the incident will tarnish his department's reputation for state of the art, safe medical devices. The team is composed of **Stan Wright** who has been with the group for fifteen years, **Asif Mamoud** who has worked there for five years and **Kieran Murphy**, the most recent addition to the team, who is just completing his doctorate.

Professor Abel's team develops the software and the software team at Dyalasist performs testing. Their team leader is **Sam Cook** and programmers are **Julie Vale** and **Martin Thomas**.

The Project Manager at Dyalasist, **Simon Buckley**, is responsible for the quality of both the hardware and software of the dialysis machines. He draws up the quality procedures for each project and is responsible for checking that they are adhered to.

There follows transcripts of the newspaper article, interviews and other documents used by the inquiry to decide the cause of the malfunction.

Excerpt from the Lanchester Times (A Local Newspaper)

Lanchester has lost a true citizen and three young children, Jack (12), Ellie (9) and Rosie (6) are mourning the untimely death of their much-loved granddad, Frank Burdett. Frank, who was 63, was well known in Lanchester. He was a Labour councillor for fifteen years, championing the causes of those least able to defend themselves.

Last Sunday night it was Frank who was unable to defend himself. He was undergoing his usual dialysis treatment at Lanchester Royal Infirmary, as he had done three times a week for nearly four years. Tragically, there was a fault in the machine, which caused the temperature of the dialysis fluid to rise to a dangerous level. Frank suffered a massive heart attack and died.

Nurse Jean Bury (aged 36) was on duty at the time. "I got to know Frank well in the years we were treating him. He was a lovely man and I feel so sad for his family. When I checked on him, I could not believe that something had gone wrong. These machines are usually so safe and an alarm goes off if there is any problem. We tried our best to revive him but it was too late."

Millionaire business man and former don, Dr. Hugh Simmons, the Chief Executive of Dyalasist, issued a statement saying "All our products are extensively tested and must satisfy EC regulations before they are marketed. They are very safe."

An inquiry is being held into the incident. The Burdett family was too upset to be interviewed but a family friend said that they are consulting their solicitor.

Medical Devices Incident Report

To certifying authority:	Medical Devices Directorate Department of Health
Reporting Firm Name:	Dyalasist Medical Ltd.
Medical Device Commercial name:	Dyalasist Dialysis mark II machine
Model or catalogue number:	034124d
Software version:	5.1a running on Windows98
Risk classification:	III (high)
Similar incidents having impact on the current report?	None known
If yes - list:	
Incident date:	21/11/2004
Incident description:	At 3.45am, in the haematology ward of Lanchester Royal Infirmary, nurse Jean Bury discovered that a dialysis machine had malfunctioned. The dialysis fluid had been heated to a dangerous level (41° Celsius). The temperature alarm had not been activated. The dialysis patient

	suffered a massive heart attack and died despite attempt at resuscitation. It has not been proven that the two incidents are related.
Outcome:	Death
Manufacturer's preliminary comments:	This medical device had recently been upgraded with new software whose purpose was to improve the display of information but had no effect on the functionality of the machine. Full quality processes have been followed and documentation demonstrating this is available.
Corrective action (if any):	The software upgrade has been recalled on all machines and they have reverted to the previous software release.

Note: Submission of this report does not, in itself, represent a conclusion by the manufacturer that the content of this report is complete or accurate, that the device(s) listed failed in any manner and/or that the device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Medical Devices Incident Investigation

Investigator:	Dr. Steven Hope
Investigation reference number:	Hdm2004/06
Interview with Lanchester University medical physicists research group:	Professor James Abel, head of research group.

Professor Abel explained that there was a long relationship between his research group and Dyalasist Medical. This particular dialysis machine, the mark II, had been in manufacture for about six years and sold very well throughout the world.

He explained that there had been various advances in medical technology over this time so there had been several modifications to the machine, both hardware and software. It was a very competitive area and they were constantly striving to keep one step ahead of their competitors.

The latest software update was very minor. It was aimed at improving the display to make it easier to read. As it was such a minor change, in an area that was not safety critical, Kieran Murphy, the new team member worked on this change.

Professor Abel and Asif Mamoud were very busy working on mark III. This will incorporate the latest research into kidney function and is a revolutionary design that will reduce the time of dialysis considerably. They are really interested in the hardware and are not software engineers by training. They program in C and C++ but the team members at Dyalasist Medical were constantly asking them to upgrade to a safer language such as SPARK Ada. Their plan was to switch to SPARK Ada for the development of the mark III. However, the design of the mark II had become so involved and convoluted over the years with all the software upgrades that they did not want to play around with it too much. Professor Abel said that they had plans to employ a couple of professional software engineers to help with the mark III as software was playing an increasingly important part in medical devices.

Closer questioning revealed that Professor Abel and his team did follow software processes laid out by the Dyalasist Project Manager, Simon Buckley. They increasingly resented the amount of documentation they had to write, feeling that they spent too much time on documentation and not enough time on real productive work. Professor Abel had made the documentation available to the investigation. As he claimed, it was complete and followed the processes laid down. However, the design of the software was very unwieldy, with no real separation between the user interface, warning system and control functions.

Medical Devices Incident Investigation

Investigator:	Dr. Steven Hope
Investigation reference number:	Hdm2004/06
Interview with Lanchester University medical physicists research group:	Asif Mamoud, researcher Kieran Murphy, researcher

Dr Asif Mamoud had worked on the mark II machine but said he had not been deeply involved in the latest upgrade. "We are far too interested in the mark III machine," he said. "We let Kieran Murphy write the software. It was a trivial change to improve the display and our hazard analysis showed it should not have had any effect on the functionality of the device. Kieran has only just started with us, so it was good experience for him to get into the software. He will have to maintain the code when we move to the development of the mark III." Dr Mamoud said he did not envy Kieran that job, as the software is rather unstructured, as it has gone through so many revisions and updates.

Of course, he remarked, he had looked at the code as part of the static code inspection and review process. It had seemed fine to him at the time, though the design was rather convoluted. It was all properly documented according to our standards. He said he had looked at the code again since the accident and had noticed a slight error with the pointer arithmetic so that it overwrote a byte of memory. It could not have affected anything else or the testing would have picked it up, he said confidently.

Kieran Murphy was very upset to think he might have caused someone's death. "I haven't been working here very long", he said. "They have thrown me in at the deep end a bit. Life is very difficult for me at the moment. I'm trying to finish my PhD thesis and keep up with this new job." He had performed the software changes asked of him, saying it should have been quite a trivial change but the software was so badly designed that he had to alter several parts of the program. He made the code available to the investigation, highlighting his changes. He had used pointer arithmetic to update several areas of the screen display and was quite proud of that, not being very experienced with pointers. He described how it had taken a bit of fiddling to get it to work. His research work is related to the effect of dialysis on the digestive system.

Medical Devices Incident Investigation

Investigator:	Dr. Steven Hope
Investigation reference number:	Hdm2004/06
Interview with Dyalasist Medical staff:	a) Dr. Hugh Simmons, Chief Executive b) Simon Buckley, Project Manager

Dr. Hugh Simmons explained that he had originally worked at the university medical department and then formed a company to market the dialysis machines. He had made a lot of money but the market was becoming increasingly competitive and they all had to work harder and smarter to maintain their competitive edge. In the early days, there was not such an emphasis on following standards and satisfying regulatory authorities. Today we have to jump through hoops he claimed, especially for the FDA. My staff spend more time documenting than producing. However, he recognised the need for an emphasis on safety and valued his project manager's emphasis on quality and use of metrics. He hoped that the mystery of why the alarm had not warned of a hardware malfunction would soon be solved and had every confidence in his staff. This particular software update was very minor so the full certification process was not gone through.

Simon Buckley described the quality processes he had set in place. We have ISO9001 and ISO9000-3 accreditation and follow the latest Institute of Physics and Engineering in Medicine (IPEM) guidelines for safety of medical devices, he claimed. Buckley described the strict testing regime that he had created for testing all the software with repeatable test harnesses, using the latest software testing tools. He took his job very seriously and pointed to the row of standards manuals he had created for his company and the university medical team. When questioned more closely, it emerged that the university team was not as enthusiastic as he was about following standards and it was hard to keep track of them as they were on a different site. Their boss,

Professor Abel, was quite dismissive about the whole business and was only interested in his research, he grumbled.

Medical Devices Incident Investigation

Investigator:	Dr. Steven Hope
Investigation reference number:	Hdm2004/06
Interview with Dyalasist Medical staff ctd.:	c) Sam Cook, team leader d) Julie Vale, programmer e) Martin Thomas, programmer

Sam Cook had joined the team from a commercial software house dealing mainly in financial systems. He was not familiar with the technical content of the programs and had mainly programmed in Cobol and Visual Basic. However, he was very familiar with the quality assurance techniques needed to keep the project on track and got on well with Project Manager, Simon Buckley. They had developed very extensive test plans for the mark II machine and had performed extensive black box testing. Sam Cook expressed dismay and sadness at the possibility that someone could have been killed by a machine that he had tested. He clearly took great pride in his job. He expressed frustration with dealing with the university medical physicists. They are not programmers and do not understand the importance of design, he complained. They think of testing as an afterthought, no matter how many times I tell them, he said.

Julie Vale is the more senior programmer and had not been involved with the testing of the latest software release. She said that she and Sam Cook had been busy planning for the mark III machine and had left the testing to Martin Thomas, the new programmer.

Martin Thomas was very nervous at the interview. He described how he had run the whole test suite on his own. "This is the first time I was allowed to do that as I have just finished my training", he said. He made the test results available to the investigation. To his relief, they were all in order, passing the module tests and the integration tests. The test plans showed that the alarm for the temperature sensor had been tested and worked satisfactorily. The dialysis machine ran on a standard Windows operating system. Over the years, new versions had been introduced. He had tested the software on Windows 2000, Windows NT and Windows XP.

Medical Devices Incident Investigation

Investigator:	Dr. Steven Hope
Investigation reference number:	Hdm2004/06
Interview at Lanchester Royal Infirmary:	Nurse Jean Bury, haematology ward.

Nurse Bury was understandably upset about the death of her patient. She showed the investigation a printout of the treatment that evening. All appeared to be in order - the self-test had run perfectly and there was a clear record of the correct entry and matching of the patient's parameters by two separate nurses.

Jean Bury explained that the machine had always been extremely reliable. It was one of the very earliest models because the local hospital was used to pilot the new machines before putting them on the general market. They had never had any real trouble before, just the odd hardware fault that was soon fixed. This time, the machine had been taken away for investigation and it was discovered, as suspected, that there was a fault with the heater so it had not shut off when it reached the desired temperature. Jean Bury remembered that this had happened a couple of years earlier but the system had automatically shut down to a fail-safe state and an alarm had gone off to warn them. She explained that the machine has a lot of safety features so if anything goes wrong, such as air bubbles in the system or out of range concentrates in the dialysis solution, the system is automatically shut down and an alarm sounds. She could not understand why the system had not gone into a fail-safe state this time.

**Public statement about Medical Devices Incident investigation
Hdm2004/06**

Based on a number of interviews and careful examination of the relevant documentation, independent investigator, Dr Steven Hope, came to a number of conclusions. These are as yet confidential and will not be released to the public until after the pending lawsuit.

All characters and organisations in this case are fictitious apart from the Department of Health. Any similarities to real events are entirely coincidental.

Appendix 4. ICT Fields Assessment Grid

Mark %	Comment	Grade & Characteristics	Theory & Academic Approach	Practice & Deliverables
0		Fail	plagiarism, collusion, non-pres., name only	as theory
1-9		Fail	no understanding, very short, inadequate	no effective deliverables
10-19		Fail	factual but little interpretation, lacks coherence, short, errors, misconceptions	requirements not met; not recoverable
20-29		Reassess: <i>weak; recoverable with considerable effort</i>	basic task understood but very limited: partial, imbalanced, unclear, omissions, errors, consisting mainly of quotations	some required outcomes delivered but very limited, needs considerable work to recover

30-39		Reassess: <i>inadequate but recoverable with limited effort</i>	coherent but mechanical notes, basic task OK but limited - partial - rudimentary answer, limited interpretation, lack of knowledge of topic, weak English but some appropriate use of language of topic	deliverables partially complete, not all requirements met, limited response to brief.
40-49		3rd, D Pass: Sufficient for award of credit <i>adequate mainly descriptive approach, fair, limited conceptual or theoretical ability</i>	adequate response, demonstration of basic knowledge, relevant content, clear intention communicated, evidence of reading, acceptable minimum level of English for business presentation but may lack precision, some limited analysis / application of knowledge / theory / weighting of evidence, inconsistent	deliverables meet basic requirement correctly but limited, just adequate but not innovative, interesting or exciting, for higher marks, 45+ just exceeds minimum specification, might be good in some areas but not consistent
50-59		2ii, C Edexcel Merit - 53-59 Edexcel Pass - 50-52 Satisfactory <i>Satisfactory with some conceptual ability but lacks good evaluation or synthesis of ideas</i>	good response to task, collates info, <i>satisfactory</i> analysis & judgement, constructs generalisations based on evidence & opinion, argues clearly, logically & constructs a case, some limited ability to state a personal position, correct English with few imprecise statements	good deliverables, some evidence of good design or execution, coherent and organised product, some limited evidence of self criticism concerning deliverable, some independence, initiative, autonomy, appropriate techniques, integration of knowledge for task
60-69		2i, B Edexcel Merit -60-65 Edexcel Distinction -66-69 Good. <i>Good analysis, evaluation, synthesis, integration & argument.</i>	evaluates info. & synthesises generalisations, good ability to state & defend personal position, good analysis & judgement, applies knowledge to new situations, sound on theory, critical, understands limitations of methods, selective coherent & logical approach, well written with clear, correct and precise English	all criteria met to good standard, evidence of good design or execution, good integration of academic & practical issues, solid evidence of self critique/evaluation of deliverables, products well organised - documented - coherent. Evidence of independence, initiative, autonomy, creativity, adaptability, resourcefulness. Integration of knowledge,
70-79		First class, A, Excellent. Edexcel Distinction <i>as above but also stronger evidence of excellent, original, innovative, articulate work</i>	very strong ability to state & defend position, uses criteria & weighting in judgements, wide knowledge and theoretical ability, full understanding of possibilities and limitations of methods & theories, 75+ more original, innovative approach, command of critical positions, lively articulate writing, excellent grasp of material - synthesis of ideas	most criteria met to high standard, strong evidence of evaluation of deliverables, 75+: deliverables excellent - all criteria met in clear and definite manner, evidence of excellent design or execution, elegance, innovation, very good evaluation of deliverables,
80-89		Outstanding. Edexcel Distinction <i>as above but also authoritative, superlative, creative</i>	as above but also :- seen all possibilities in task, gone beyond accepted conceptual/critical positions, evidence of creative, intelligent, innovative approach consistently & forcefully expressed	as above but also :- all aspects of deliverables superlative beyond 80% emphasis on theory rather than practice/deliverables
90-100		Faultless Edexcel Distinction	as for 80-89 but also :- all work superlative & without fault	as for 80-89

© UoGBS ICT Fields: Sep 05