

12 Safety Engineering

Objectives

The objective of this chapter is to explain techniques that are used to ensure safety when developing critical systems. When you have read this chapter, you will:

- understand what is meant by a safety-critical system and why safety has to be considered separately from reliability in critical systems engineering;
- understand how an analysis of hazards can be used to derive safety requirements;
- know about processes and tools that are used for software safety assurance;
- understand the notion of a safety case that is used to justify the safety of a system to regulators, and how formal arguments may be used in safety cases;

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In Section 11.2, I briefly described an air accident at Warsaw airport where an Airbus crashed on landing. Two people were killed and 54 were injured. The subsequent enquiry showed that a major contributory cause of the accident was a failure of the control software that reduced the efficiency of the aircraft's braking system. This is one of the, thankfully rare, examples of where the behaviour of a software system has led to death or injury. It illustrates that software is now a central component in many systems that are critical to preserving and maintaining life. These are safety-critical software systems and a range of specialized methods and techniques have been developed for safety-critical software engineering.

As I discussed in Chapter 10, safety is one of the principal dependability properties. A system can be considered to be safe if it operates without catastrophic failure, that is, failure that causes or may cause death or injury to people. Systems whose failure may lead to environmental damage may also be safety-critical as environmental damage (such as a leak of chemicals) can lead to subsequent human injury or death.

Software in safety-critical systems has a dual role to play in safety achievement:

1. The system may be software-controlled so that the decisions made by the software and subsequent actions are safety-critical. Therefore, the software behaviour is directly related to the overall safety of the system.
2. Software is extensively used for checking and monitoring other safety-critical components in a system. For example, all aircraft engine components are monitored by software looking for early indications of component failure. This software is safety-critical because, if it fails, other components may fail and cause an accident.

Safety in software systems is achieved by developing an understanding of the situations that might lead to safety-related failures. The software is engineered so that such failures do not occur. You might therefore think that if a safety-critical system is reliable and behaves as specified, it will therefore be safe. Unfortunately, it isn't quite as simple as this. System reliability is necessary for safety achievement but it isn't enough. Reliable systems can be unsafe and vice versa. The Warsaw airport accident was an example of such a situation, which I'll discuss in more detail in Section 12.2.

There are four reasons why software systems that are reliable may not be safe:

1. We can never be 100% certain that a software system is fault-free and fault-tolerant. Undetected faults can be dormant for a long time and software failures can occur after many years of reliable operation.
2. The specification may be incomplete in that it does not describe the required behaviour of the system in some critical situations. A high percentage of system malfunctions are the result of specification rather than design errors. In a study of errors in embedded systems, Lutz (Lutz 1993) concludes:

“...difficulties with requirements are the key root cause of the safety-related software errors, which have persisted until integration and system testing.”

More recent work by Veras *et al.* (Veras et al. 2010) in space systems confirms that requirements errors are still a major problem for embedded systems.

3. Hardware malfunctions may cause sensors and actuators to behave in an unpredictable way. When components are close to physical failure, they may behave erratically and generate signals that are outside the ranges that can be handled by the software. The software may then either fail or wrongly interpret these signals.
4. The system operators may generate inputs that are not individually incorrect but which, in some situations, can lead to a system malfunction. An anecdotal example of this occurred when an aircraft undercarriage collapsed whilst the aircraft was on the ground. Apparently, a technician pressed a button that instructed the utility management software to raise the undercarriage. The software carried out the mechanic's instruction perfectly. However, the system should have disallowed the command unless the plane was in the air.

Safety, therefore, has to be considered as well as reliability when developing safety-critical systems. The reliability engineering techniques that I introduced in Chapter 11 are obviously applicable for safety-critical systems engineering. I therefore do not discuss system architectures and dependable programming here but focus on techniques for improving and assuring system safety.

12.1 Safety-critical systems

Safety-critical systems are systems where it is essential that system operation is always safe. That is, the system should never damage people or the system's environment, irrespective of whether or not the system conforms to its specification. Examples of safety-critical systems include control and monitoring systems in aircraft, process control systems in chemical and pharmaceutical plants and automobile control systems.

Safety-critical software falls into two classes:

1. *Primary safety-critical software* This is software that is embedded as a controller in a system. Malfunctioning of such software can cause a hardware malfunction, which results in human injury or environmental damage. The insulin pump software that I introduced in Chapter 1 is an example of a primary safety-critical system. System failure may lead to user injury.

The insulin pump system is a simple system but software control is also used in very complex safety-critical systems. Software rather than hardware control is essential because of the need to manage large numbers of sensors and actuators, which have complex control laws. For example, advanced, aerodynamically unstable, military aircraft require continual software-controlled adjustment of their flight surfaces to ensure that they do not crash.

2. *Secondary safety-critical software* This is software that can indirectly result in an injury. An example of such software is a computer-aided engineering design system whose malfunctioning might result in a design fault in the object being designed. This fault may cause injury to people if the designed system malfunctions. Another example of a secondary safety-critical system is the Mentcare system for mental health patient management. Failure of this system, whereby an unstable patient may not be treated properly, could lead to that patient injuring themselves or others.

Some control systems, such as those controlling critical national infrastructure (electricity supply, telecommunications, sewage treatment, etc.) are secondary safety-critical systems. Failure of these systems is unlikely to have immediate human consequences. However, if there is a prolonged outage of the controlled systems, this could lead to injury and death. For example, failure of a sewage treatment system could lead to a higher level of infectious disease as raw sewage is released into the environment.

I explained in Chapter 11 how software and system availability and reliability is achieved through fault avoidance, fault detection and removal and fault tolerance. Safety-critical systems development uses these approaches and augments them with hazard-driven techniques that consider the potential system accidents that may occur:

1. *Hazard avoidance* The system is designed so that hazards are avoided. For example, a paper cutting system that requires an operator to use two hands to press separate buttons simultaneously avoids the hazard of the operator's hands being in the blade pathway.
2. *Hazard detection and removal* The system is designed so that hazards are detected and removed before they result in an accident. For example, a chemical plant system may detect excessive pressure and open a relief valve to reduce pressure before an explosion occurs.
3. *Damage limitation* The system may include protection features that minimize the damage that may result from an accident. For example, an aircraft engine normally includes automatic fire extinguishers. If there is an engine fire, it can often be controlled before it poses a threat to the aircraft.

A hazard is a system state that could lead to an accident. Using the above example of the paper cutting system, a hazard arises when the operator's hand is in a position where the cutting blade could injure it. Hazards are not accidents – we

Term	Definition
Accident (or mishap)	An unplanned event or sequence of events that results in human death or injury, damage to property or to the environment. An overdose of insulin is an example of an accident.
Damage	A measure of the loss resulting from a mishap. Damage can range from many people being killed as a result of an accident to minor injury or property damage. Damage resulting from an overdose of insulin could be serious injury or the death of the user of the insulin pump.
Hazard	A condition with the potential for causing or contributing to an accident. A failure of the sensor that measures blood glucose is an example of a hazard.
Hazard probability	The probability of the events occurring which create a hazard. Probability values tend to be arbitrary but range from 'probable' (say 1/100 chance of a hazard occurring) to 'implausible' (no conceivable situations are likely in which the hazard could occur). The probability of a sensor failure in the insulin pump that over-estimates the user's blood sugar level is low.
Hazard severity	An assessment of the worst possible damage that could result from a particular hazard. Hazard severity can range from catastrophic, where many people are killed, to minor, where only minor damage results. When an individual death is a possibility, a reasonable assessment of hazard severity is 'very high'.
Risk	This is a measure of the probability that the system will cause an accident. The risk is assessed by considering the hazard probability, the hazard severity and the probability that the hazard will lead to an accident. The risk of an insulin overdose is medium to low.

Figure 12.1
Safety
terminology

often get into hazardous situations and get out of them without any problems. However, accidents are always preceded by hazards so reducing hazards reduces accidents.

A hazard is one example of the specialized vocabulary that is used in safety-critical systems engineering. I explain other terminology used in safety-critical systems in Figure 12.1.

We are now actually pretty good at building systems that can cope with one thing going wrong. We can design mechanisms into the system that can detect and recover from single problems. However, when several things go wrong at the same time, accidents are more likely. As systems become more and more complex, we don't understand the relationships between the different parts of the system.

Risk-based requirements specification

Risk-based specification is an approach that has been widely used by safety and security-critical systems developers. It focuses on those events that could cause the most damage or that are likely to occur frequently. Events that have only minor consequences or that are extremely rare may be ignored. The risk-based specification process involves understanding the risks faced by the system, discovering their root causes and generating requirements to manage these risks.

<http://software-engineering-book.com/web/risk-based-specification/>

Consequently, we cannot predict the consequences of a combination of unexpected system events or failures.

In an analysis of serious accidents, Perrow (Perrow 1984) suggested that almost all of these accidents were due to a combination of failures in different parts of a system. Unanticipated combinations of sub-system failures led to interactions that resulted in overall system failure. For example, failure of an air conditioning system may lead to overheating. Once hardware gets hot, its behaviour becomes unpredictable so overheating may lead to the system hardware generating incorrect signals. These may then cause the software to react incorrectly.

Perrow made the point that, in complex systems, it is impossible to anticipate all possible combinations of failures. He therefore coined the phrase 'normal accidents', with the implication that accidents have to be considered as inevitable when we build complex safety-critical systems.

To reduce complexity, we could use simple hardware controllers rather than software control. However, software-controlled systems can monitor a wider range of conditions than simpler electro-mechanical systems. They can be adapted relatively easily. They use computer hardware, which has high inherent reliability and which is physically small and lightweight.

Software-controlled systems can provide sophisticated safety interlocks. They can support control strategies that reduce the amount of time people need to spend in hazardous environments. Although software control may introduce more ways in which a system can go wrong, it also allows better monitoring and protection. Therefore, software control can contribute to improvements in system safety.

It is important to maintain a sense of proportion about safety-critical systems. Critical software systems operate without problems most of the time. Relatively few people worldwide have been killed or injured because of faulty software. Perrow is right in saying that there will always be the possibility of accidents. It is impossible to make a system 100% safe and society has to decide whether or not the consequences of an occasional accident are worth the benefits that come from the use of advanced technologies.

12.2 Safety requirements

In the introduction to this chapter, I described an air accident at Warsaw airport where the braking system on an Airbus failed. The enquiry into this accident showed that the braking system software had operated according to its specification. There were no errors in the program. However, the software specification was incomplete and had not taken into account a rare situation, which arose in this case. The software worked but the system failed.

This illustrates that system safety does not just depend on good engineering. It requires attention to detail when the system requirements are derived and the inclusion of special software requirements that are geared to ensuring the safety of a system. Safety requirements are functional requirements, which define checking and recovery facilities that should be included in the system and features that provide protection against system failures and external attacks.

The starting point for generating functional safety requirements is usually domain knowledge, safety standards and regulations. These lead to high-level requirements that are perhaps best described as ‘shall not’ requirements. By contrast with normal functional requirements that define what the system shall do, ‘shall not’ requirements define system behavior that is unacceptable. Examples of ‘shall not’ requirements are:

“The system shall not allow reverse thrust mode to be selected when the aircraft is in flight.”

“The system shall not allow the simultaneous activation of more than three alarm signals.”

“The navigation system shall not allow users to set the required destination when the car is moving.”

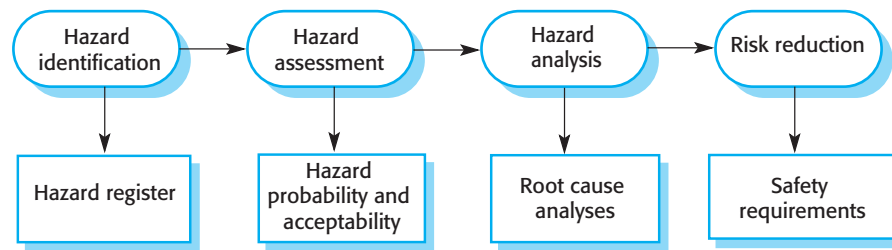
These ‘shall not’ requirements cannot be implemented directly but have to be decomposed into more specific software functional requirements. Alternatively, they may be implemented through system design decisions such as a decision to use particular types of equipment in the system.

Safety requirements are primarily protection requirements and are not concerned with normal system operation. They may specify that the system should be shut down so that safety is maintained. In deriving safety requirements, you therefore need to find an acceptable balance between safety and functionality and avoid over-protection. There is no point in building a very safe system if it does not operate in a cost-effective way.

Risk-based requirements specification is a general approach used in critical systems engineering where risks faced by the system are identified and requirements to avoid or mitigate these risks are identified. It may be used for all types of dependability requirements. For safety-critical systems, it translates into a process driven by identified hazards. As I discussed in the previous section, a hazard is something that could (but need not) result in death or injury to a person.

There are four activities in a hazard-driven safety specification process:

Figure 12.2
Hazard-driven
requirements
specification



1. *Hazard identification* The hazard identification process identifies hazards that may threaten the system. These hazards may be recorded in a hazard register. This is a formal document that records the safety analyses and assessments and which may be submitted to a regulator as part of a safety case.
2. *Hazard assessment* The hazard assessment process decides which hazards are the most dangerous and/or the most likely to occur. These should be prioritized when deriving safety requirements.
3. *Hazard analysis* This is a process of root-cause analysis that identifies the events that can lead to the occurrence of a hazard.
4. *Risk reduction* This process is based on the outcome of hazard analysis and leads to identification of safety requirements. These may be concerned with ensuring that a hazard does not arise or lead to an accident or that if an accident does occur, the associated damage is minimized.

Figure 12.2 illustrates this hazard-driven safety requirements specification process.

12.2.1 Hazard identification

In safety-critical systems, hazard identification starts by identifying different classes of hazard, such as physical hazards, electrical hazards, biological hazards, radiation hazards, service failure hazards and so on. Each of these classes can then be analyzed to discover specific hazards that could occur. Possible combinations of hazards that are potentially dangerous must also be identified.

Experienced engineers, working with domain experts and professional safety advisers, identify hazards from previous experience and from an analysis of the application domain. Group working techniques such as brainstorming may be used, where a group meets to exchange ideas. For the insulin pump system, people who may be involved include doctors, medical physicists and engineers and software designers.

The insulin pump system that I introduced in Chapter 1 is a safety-critical system, because failure can cause injury or even death to the system user. Accidents that may occur when using this machine include the user suffering from long-term consequences of poor blood sugar control (eye, heart and kidney

problems), cognitive dysfunction as a result of low blood sugar levels or the occurrence of some other medical conditions, such as an allergic reaction.

Some of the hazards that may arise in the insulin pump system are:

- insulin overdose computation (service failure);
- insulin underdose computation (service failure);
- failure of the hardware monitoring system (service failure);
- power failure due to exhausted battery (electrical);
- electrical interference with other medical equipment such as a heart pacemaker (electrical);
- poor sensor and actuator contact caused by incorrect fitting (physical);
- parts of machine breaking off in patient's body (physical);
- infection caused by introduction of machine (biological);
- allergic reaction to the materials or insulin used in the machine (biological).

Software-related hazards are normally concerned with failure to deliver a system service, or with the failure of monitoring and protection systems. Monitoring and protection systems may be included in a device to detect conditions, such as a low battery level, which could lead to device failure.

A hazard register may be used to record the identified hazards with an explanation why the hazard has been included. The hazard register is an important legal document as it records all safety-related decisions about each hazard. It can be used to show that the requirements engineers have paid due care and attention in considering all foreseeable hazards and that these hazards have been analyzed. In the event of an accident, the hazard register may be used in a subsequent inquiry or legal proceedings to show that the system developers have not been negligent in their system safety analysis.

12.2.2 Hazard assessment

The hazard assessment process focuses on understanding the factors that lead to the occurrence of a hazard and the consequences if an accident or incident associated with that hazard should occur. You need to carry out this analysis to understand whether a hazard is a serious threat to the system or environment. The analysis also provides a basis for deciding on how to manage the risk associated with the hazard.

For each hazard, the outcome of the analysis and classification process is a statement of acceptability. This is expressed in terms of risk, where the risk takes into account the likelihood of an accident and its consequences. There are three risk categories that you can use in hazard assessment:

1. Intolerable risks in safety-critical systems are those that threaten human life. The system must be designed so that such hazards either cannot arise or, that

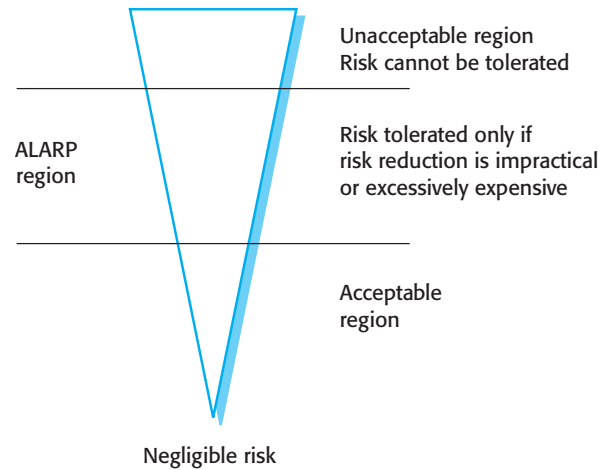


Figure 12.3 The risk triangle

if they do, features in the system will ensure that they are detected before they cause an accident. In the case of the insulin pump, an intolerable risk is that an overdose of insulin should be delivered.

2. As low as reasonably practical (ALARP) risks are those that have less serious consequences or that are serious but have a very low probability of occurrence. The system should be designed so that the probability of an accident arising because of a hazard is minimized, subject to other considerations such as cost and delivery. An ALARP risk for an insulin pump might be the failure of the hardware monitoring system. The consequences of this are, at worst, a short-term insulin underdose. This is a situation that would not lead to a serious accident.
3. Acceptable risks are those where the associated accidents normally result in minor damage. System designers should take all possible steps to reduce 'acceptable' risks, so long as these do not significantly increase costs, delivery time or other non-functional system attributes. An acceptable risk in the case of the insulin pump might be the risk of an allergic reaction arising in the user. This usually causes only minor skin irritation. It would not be worth using special, more expensive materials in the device to reduce this risk.

Figure 12.3 shows these three regions. The width of the triangle reflects the costs of ensuring risks do not result in incidents or accidents. The highest costs are incurred by risks at the top of the diagram, the lowest costs by risks at the apex of the triangle.

The boundaries between the regions in Figure 12.3 are not fixed but depend on how acceptable risks are in the societies where the system will be deployed. This varies from country to country – some societies are more risk averse and litigious than others. Over time, however, all societies have become more risk-

Identified hazard	Hazard probability	Accident severity	Estimated risk	Acceptability
1. Insulin overdose computation	Medium	High	High	Intolerable
2. Insulin underdose computation	Medium	Low	Low	Acceptable
3. Failure of hardware monitoring system	Medium	Medium	Low	ALARP
4. Power failure	High	Low	Low	Acceptable
5. Machine incorrectly fitted	High	High	High	Intolerable
6. Machine breaks in patient	Low	High	Medium	ALARP
7. Machine causes infection	Medium	Medium	Medium	ALARP
8. Electrical interference	Low	High	Medium	ALARP
9. Allergic reaction	Low	Low	Low	Acceptable

Figure 12.4 Risk classification for the insulin pump

averse, so the boundaries have moved downwards. For rare events, the financial costs of accepting risks and paying for any resulting accidents may be less than the costs of accident prevention. However, public opinion may demand that money be spent to reduce the likelihood of a system accident irrespective of cost.

For example, it may be cheaper for a company to clean up pollution on the rare occasion it occurs, rather than to install systems for pollution prevention. However, because the public and the media will not tolerate such accidents, clearing up the damage rather than preventing the accident is no longer acceptable. Events in other systems may also lead to a re-classification of risk. For example, risks that were thought to be improbable (and hence in the ALARP region) may be reclassified as intolerable because of external events, such as terrorist attacks, or natural phenomena, such as tsunamis.

Figure 12.4 shows a risk classification for the hazards identified in the previous section for the insulin delivery system. I have separated the hazards that relate to the incorrect computation of insulin into an insulin overdose and an insulin underdose. An insulin overdose is potentially more serious than an insulin underdose in the short term. Insulin overdose can result in cognitive dysfunction, coma and ultimately death. Insulin underdoses lead to high levels of blood sugar. In the short term, these cause tiredness but are not very serious; in the longer term, however, they can lead to serious heart, kidney and eye problems.

Hazards 4–9 in Figure 12.4 are not software related, but software nevertheless has a role to play in hazard detection. The hardware monitoring software should monitor the system state and warn of potential problems. The warning will often allow the hazard to be detected before it causes an accident. Examples of hazards that might be detected are power failure, which is detected by

monitoring the battery, and incorrect fitting of the machine, which may be detected by monitoring signals from the blood sugar sensor.

The monitoring software in the system is, of course, safety-related. Failure to detect a hazard could result in an accident. If the monitoring system fails but the hardware is working correctly then this is not a serious failure. However, if the monitoring system fails and hardware failure cannot then be detected, then this could have more serious consequences.

Hazard assessment involves estimating the hazard probability and risk severity. This is difficult as hazards and accidents are uncommon so the engineers involved may not have direct experience of previous incidents or accidents. In estimating probabilities and accident severity, it makes sense to use relative terms such as 'probable', 'unlikely', 'rare', 'high', 'medium' and 'low'. Quantifying these terms is practically impossible because there is not enough statistical data available for most types of accident.

12.2.3 Hazard analysis

Hazard analysis is the process of discovering the root causes of hazards in a safety-critical system. Your aim is to find out what events or combination of events could cause a system failure that results in a hazard. To do this, you can use either a top-down or a bottom-up approach. Deductive, top-down techniques, which are easier to use, start with the hazard and work from that to the possible system failure. Inductive, bottom-up techniques start with a proposed system failure and identify what hazards might result from that failure.

Various techniques have been proposed as possible approaches to hazard decomposition or analysis (Storey 1996). One of the most commonly used techniques is fault tree analysis, a top-down technique, which was developed for the analysis of both hardware and software hazards (Leveson, Cha, and Shimeall 1991). This technique is fairly easy to understand without specialist domain knowledge.

To do a fault tree analysis, you start with the hazards that have been identified. For each hazard, you then work backwards to discover the possible causes of that hazard. You put the hazard at the root of the tree and identify the system states that can lead to that hazard. For each of these states, you then identify further system states that can lead to them. You continue this decomposition until you reach the root cause(s) of the risk. Hazards that can only arise from a combination of root causes are usually less likely to lead to an accident than hazards with a single root cause.

Figure 12.5 is a fault tree for the software-related hazards in the insulin delivery system that could lead to an incorrect dose of insulin being delivered. In this case, I have merged insulin underdose and insulin overdose into a single hazard, namely 'incorrect insulin dose administered'. This reduces the number of fault trees that are required. Of course, when you specify how the software should react to this hazard, you have to distinguish between an insulin underdose and an insulin overdose. As I have said, they are not equally serious – in the short-term, an overdose is the more serious hazard.

From Figure 12.5, you can see that:

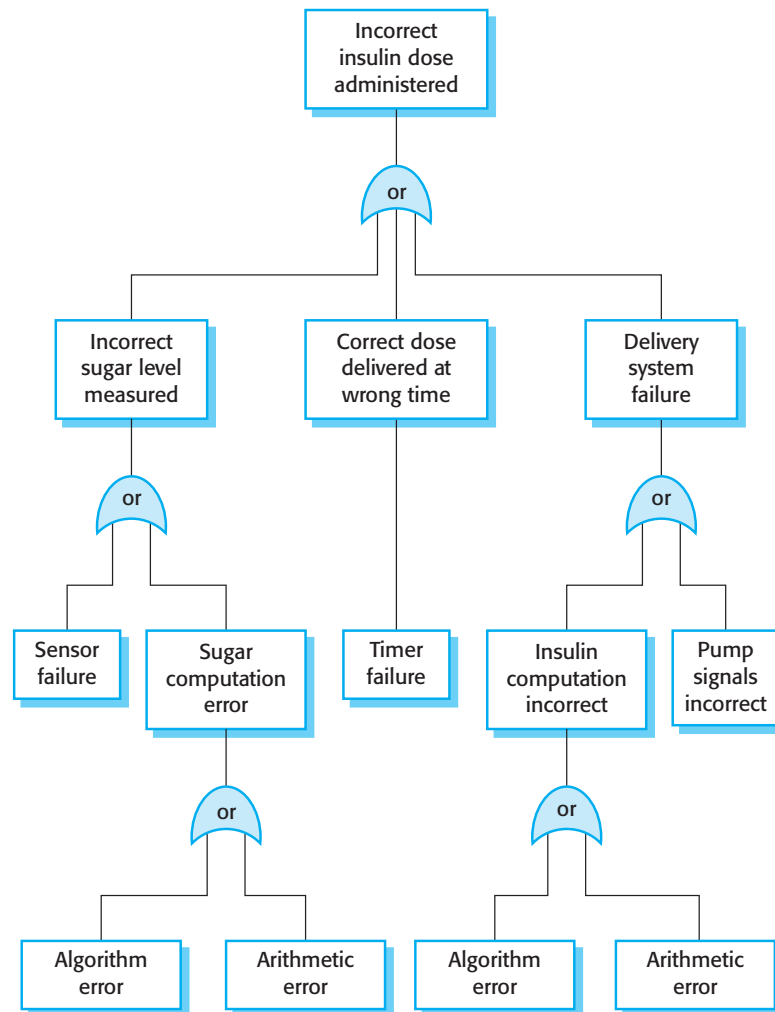


Figure 12.5 An example of a fault tree

1. There are three conditions that could lead to the administration of an incorrect dose of insulin. The level of blood sugar may have been incorrectly measured so the insulin requirement has been computed with an incorrect input. The delivery system may not respond correctly to commands specifying the amount of insulin to be injected. Alternatively, the dose may be correctly computed but it is delivered too early or too late.
2. The left branch of the fault tree, concerned with incorrect measurement of the blood sugar level, identifies how this might happen. This could occur either because the sensor that provides an input to calculate the sugar level has failed or because the calculation of the blood sugar level has been carried out incorrectly. The sugar level is calculated from some measured parameter, such as the conductivity of the skin. Incorrect computation can

result from either an incorrect algorithm or an arithmetic error that results from the use of floating point numbers.

3. The central branch of the tree is concerned with timing problems and concludes that these can only result from system timer failure.
4. The right branch of the tree, concerned with delivery system failure, examines possible causes of this failure. These could result from an incorrect computation of the insulin requirement, or from a failure to send the correct signals to the pump that delivers the insulin. Again, an incorrect computation can result from algorithm failure or arithmetic errors.

Fault trees are also used to identify potential hardware problems. Hardware fault trees may provide insights into requirements for software to detect and, perhaps, correct these problems. For example, insulin doses are not administered at a very high frequency, no more than five or six times per hour and sometimes less often than this. Therefore, processor capacity is available to run diagnostic and self-checking programs. Hardware errors such as sensor, pump or timer errors can be discovered and warnings issued before they have a serious effect on the patient.

12.2.4 Risk reduction

Once potential risks and their root causes have been identified, you are then able to derive safety requirements that manage the risks and ensure that incidents or accidents do not occur. There are three possible strategies that you can use:

1. *Hazard avoidance* where a system is designed so that the hazard cannot occur.
2. *Hazard detection and removal* where a system is designed so that hazards are detected and neutralized before they result in an accident.
3. *Damage limitation* where a system is designed so that the consequences of an accident are minimized.

Normally, designers of critical systems use a combination of these approaches. In a safety-critical system, intolerable hazards may be handled by minimizing their probability and adding a protection system (see Chapter 11) that provides a safety backup. For example, in a chemical plant control system, the system will attempt to detect and avoid excess pressure in the reactor. However, there may also be an independent protection system that monitors the pressure and opens a relief valve if high pressure is detected.

In the insulin delivery system, a 'safe state' is a shutdown state where no insulin is injected. Over a short period this is not a threat to the diabetic's health. For the software failures that could lead to an incorrect dose of insulin are considered, the following 'solutions' might be developed:

1. *Arithmetic error* This may occur when an arithmetic computation causes a representation failure. The specification should identify all possible arithmetic errors that may occur and state that an exception handler must be

Figure 12.6
Examples of safety
requirements

- SR1:** The system shall not deliver a single dose of insulin that is greater than a specified maximum dose for a system user.
- SR2:** The system shall not deliver a daily cumulative dose of insulin that is greater than a specified maximum daily dose for a system user.
- SR3:** The system shall include a hardware diagnostic facility that shall be executed at least four times per hour.
- SR4:** The system shall include an exception handler for all of the exceptions that are identified in Table 3.
- SR5:** The audible alarm shall be sounded when any hardware or software anomaly is discovered and a diagnostic message as defined in Table 4 shall be displayed.
- SR6:** In the event of an alarm, insulin delivery shall be suspended until the user has reset the system and cleared the alarm.

included for each possible error. The specification should set out the action to be taken for each of these errors. The default safe action is to shut down the delivery system and activate a warning alarm.

2. *Algorithmic error* This is a more difficult situation as there is no clear program exception that must be handled. This type of error could be detected by comparing the required insulin dose computed with the previously delivered dose. If it is much higher, this may mean that the amount has been computed incorrectly. The system may also keep track of the dose sequence. After a number of above-average doses have been delivered, a warning may be issued and further dosage limited.

Some of the resulting safety requirements for the insulin pump software are shown in Figure 12.6. Tables 3 and 4 relate to tables that are included in the requirements document – they are not shown here. These are user requirements and, naturally, they would be expressed in more detail in a more detailed system requirements specification.

12.3 Safety engineering processes

The software processes that are used for the development of safety-critical software are based on the processes used in software reliability engineering. In general, a great deal of care is taken in developing a complete, and often very detailed, system specification. The design and implementation of the system usual follows a plan-based, waterfall model, with reviews and checks at each stage in the process. Fault avoidance and fault detection are the drivers of the process. For some types of system, such as aircraft systems, fault tolerant architectures, as I discussed in Chapter 11, may be used.

Reliability is a pre-requisite for safety-critical systems. Because of the very high costs and potentially tragic consequences of system failure, additional verification activities may be used in safety-critical systems development. These activities may include developing formal models of a system and analysing these to discover errors and inconsistencies and using static analysis software tools that parse the software source code to discover potential faults.

Safe systems have to be reliable, but, as I have discussed, reliability is not enough. Requirements and verification errors and omissions may mean that reliable systems are unsafe. Therefore, safety-critical systems development processes should include safety reviews, where engineers and system stakeholders examine the work done and explicitly look for potential issues that could affect the safety of the system.

Some types of safety-critical systems are regulated, as I explained in Chapter 10. National and international regulators require detailed evidence that the system is safe. This evidence might include:

1. The specification of the system that has been developed and records of the checks made on that specification.
2. Evidence of the verification and validation processes that have been carried out and the results of the system verification and validation.
3. Evidence that the organizations developing the system have defined and dependable software processes that include safety assurance reviews. There must also be records that show that these processes have been properly enacted.

Not all safety-critical systems are regulated – for example, there is no regulator for automobiles although these now have many embedded computer systems. The safety of car-based systems is the responsibility of the car manufacturer. However, because of the possibility of legal action in the event of an accident, developers of unregulated systems have to maintain the same detailed safety information. If a case is brought against them, they have to be able to show that they have not been negligent in the development of the software in the car.

The need for this extensive process and product documentation is another reason why agile processes cannot be used, without significant change, for safety-critical systems development. Agile processes focus on the software itself and (rightly) argue that a great deal of process documentation is never actually used after it has been produced. However, where you have to keep records for legal or regulatory reasons, you must maintain documentation about both the processes used and the system itself.

Safety-critical systems, like other types of system that have high dependability requirements, need to be based on dependable processes (see Chapter 10). A dependable process will normally include activities such as requirements management, change management and configuration control, system modeling, reviews and inspections, test planning and test coverage analysis. When a system is safety-critical, there may be additional safety assurance and verification and analyses processes.

12.3.1 Safety assurance processes

Safety assurance is a set of activities that check that a system will operate safely. Specific safety assurance activities should be included at all stages in the software development process. These safety assurance activities record the safety analyses that have been carried out and the person or people responsible for these analyses. Safety assurance activities have to be thoroughly documented. This documentation may be part of the evidence that is used to convince a regulator or system owner that a system will operate safely.

Examples of safety assurance activities are:

1. Hazard analysis and monitoring, where hazards are traced from preliminary hazard analysis through to testing and system validation.
2. Safety reviews, which are used throughout the development process.
3. Safety certification, where the safety of critical components is formally certified. This involves a group external to the system development team examining the available evidence and deciding whether or not a system or component should be considered to be safe before it is made available for use.

To support these safety assurance processes, project safety engineers should be appointed who have explicit responsibility for the safety aspects of a system. This means that these individuals will be held responsible if a safety-related system failure occurs. They must be able to demonstrate that the safety assurance activities have been properly carried out.

Safety engineers work with quality managers to ensure that a detailed configuration management system is used to track all safety-related documentation and keep it in step with the associated technical documentation. There is little point in having stringent validation procedures if a failure of configuration management means that the wrong system is delivered to the customer. Quality and configuration management are covered in Chapters 24 and 25.

Hazard analysis is an essential part of safety-critical systems development. Hazard analysis involves identifying hazards, their probability of occurrence and the probability of a hazard leading to an accident. If there is program code that checks for and handles each hazard, then you can argue that these hazards will not result in accidents. Where external certification is required before a system is used (e.g. in an aircraft), it is usually a condition of certification that this traceability can be demonstrated.

The central safety document that should be produced is the hazard register. This document provides evidence of how identified hazards have been taken into account during software development. This hazard register is used at each stage of the software development process to document how that development stage has taken the hazards into account.

Hazard Register. Page 4: Printed 20.02.2012						
System: Insulin Pump System		File: InsulinPump/Safety/HazardLog				
Safety Engineer: James Brown		Log version: 1/3				
Identified Hazard		Insulin overdose delivered to patient				
Identified by		Jane Williams				
Criticality class		1				
Identified risk		High				
Fault tree identified		YES	Date	24.01.11	Location	Hazard register, Page 5
Fault tree creators		Jane Williams and Bill Smith				
Fault tree checked		YES	Date	28.01.11	Checker	James Brown
System safety design requirements						
<div>1. The system shall include self-testing software that will test the sensor system, the clock and the insulin delivery system.</div> <div>2. The self-checking software shall be executed once per minute.</div> <div>3. In the event of the self-checking software discovering a fault in any of the system components, an audible warning shall be issued and the pump display shall indicate the name of the component where the fault has been discovered. The delivery of insulin shall be suspended.</div> <div>4. The system shall incorporate an override system that allows the system user to modify the computed dose of insulin that is to be delivered by the system.</div> <div>5. The amount of override shall be no greater than a pre-set value (maxOverride), which is set when the system is configured by medical staff.</div>						

Figure 12.7 A simplified hazard register entry

A simplified example of a hazard register entry for the insulin delivery system is shown in Figure 12.7. This documents the process of hazard analysis and shows design requirements that have been generated during this process. These design requirements are intended to ensure that the control system can never deliver an insulin overdose to a user of the insulin pump.

Individuals who have safety responsibilities should be explicitly identified in the hazard register. There are two reasons why personal identification is important:

1. When people are identified, they can be held accountable for their actions. This means that they are likely to take more care because any problems can be traced back to their work.
2. In the event of an accident, there may be legal proceedings or an enquiry. It is important to be able to identify who was responsible for safety assurance so that they can defend their actions as part of the legal process.

Safety reviews are reviews of the software specification, design and source code whose aim is to discover potentially hazardous conditions. These are not automated processes but involve people carefully checking for errors that have been made and for assumptions or omissions that may affect the safety of a system. For example, in the aircraft accident that I introduced at the beginning of this chapter, a safety review might have questioned the assumption that an aircraft is on the ground when there is weight on both wheels and the wheels are rotating.

Licensing of software engineers

In some areas of engineering, safety engineers must be licensed engineers. Inexperienced, poorly qualified engineers are not allowed to take responsibility for safety. In 30 states of the USA, there is some form of licensing for software engineers involved in safety-related systems development. These states require that engineering involved in safety-critical software development should be licensed engineers, with a defined minimum level of qualifications and experience. This is a controversial issue and licensing is not required in many other countries.

<http://software-engineering-book.com/safety-licensing/>

Safety reviews should be driven by the hazard register. For each of the identified hazards, a review team examines the system and judges whether or not it would cope with that hazard in a safe way. If there are doubts raised, these are flagged in the review team's report and have to be addressed by the system development team. I discuss reviews of different types in more detail in Chapter 24, which covers software quality assurance.

Software safety certification is used when external components are incorporated into a safety-critical system. When all parts of a system have been locally developed, complete information about the development processes used can be maintained. However, it is not cost-effective to develop components that are readily available from other vendors. The problem for safety-critical systems development is that these external components may have been developed to different standards than locally developed components. Their safety is unknown.

Consequently, it may be a requirement that all external components that are used may have to be certified before they can be integrated with a system. The safety certification team, which is separate from the development team, carries out extensive verification and validation of the components. If appropriate, they liaise with the component developers to check the developers have used dependable processes to create these components and to examine the component source code. Once they are satisfied that a component meets its specification and does not have 'hidden' functionality, they may issue a certificate allowing that component to be used in safety-critical systems.

12.3.2 Formal verification

Formal methods of software development, as I discussed in Chapter 10, rely on a formal model of the system that serves as a system specification. These formal methods are mainly concerned with a mathematical analysis of the specification; with transforming the specification to a more detailed, semantically equivalent representation; or with formally verifying that one representation of the system is semantically equivalent to another representation.

The need for assurance in safety critical systems has been one of the principal drivers in the development of formal methods. Comprehensive system testing is extremely expensive and cannot be guaranteed to uncover all of the faults

in a system. This is particularly true of systems that are distributed, so that system components are running concurrently. Several safety-critical railway systems were developed using formal methods in the 1990s (Dehbonei and Mejia 1995; Behm et al. 1999). Companies such as Airbus routinely use formal methods in their software development for critical systems (Souyris et al. 2009).

Formal methods may be used at different stages in the V & V process:

1. A formal specification of the system may be developed and mathematically analyzed for inconsistency. This technique is effective in discovering specification errors and omissions. Model checking, discussed in the next section, is a particularly effective approach to specification analysis.
2. You can formally verify, using mathematical arguments, that the code of a software system is consistent with its specification. This requires a formal specification. It is effective in discovering programming and some design errors.

Because of the wide semantic gap between a formal system specification and program code, it is difficult and expensive to prove that a separately developed program is consistent with its specification. Work on program verification is now mostly based on transformational development. In a transformational development process, a formal specification is systematically transformed through a series of representations to program code. Software tools support the development of the transformations and help verify that corresponding representations of the system are consistent. The B method is probably the most widely used formal transformational method (Abrial 2010). It has been used for the development of train control systems and avionics software.

Advocates of formal methods claim that the use of these methods leads to more reliable and safer systems. Formal verification demonstrates that the developed program meets its specification and that implementation errors will not compromise the dependability of the system. If you develop a formal model of concurrent systems using a specification written in a language such as CSP (Schneider 1999), you can discover conditions that might result in deadlock in the final program, and be able to address these. This is very difficult to do by testing alone.

However, formal specification and proof do not guarantee that the software will be safe in practical use:

1. The specification may not reflect the real requirements of system users. As I discussed in Chapter 10, system users rarely understand formal notations so they cannot directly read the formal specification to find errors and omissions. This means that there it is likely that the formal specification is not an accurate representation of the system requirements.
2. The proof may contain errors. Program proofs are large and complex, so, like large and complex programs, they usually contain errors.

3. The proof may make incorrect assumptions about the way that the system is used. If the system is not used as anticipated, then the system's behavior lies outside the scope of the proof.

Verifying a non-trivial software system takes a great deal of time. It requires mathematical expertise and specialized software tools, such as theorem provers. It is an expensive process and, as the system size increases, the costs of formal verification increase disproportionately.

Many software engineers therefore think that formal verification is not cost-effective. They believe that the same level of confidence in the system can be achieved more cheaply by using other validation techniques, such as inspections and system testing. However, companies such as Airbus that make use of formal verification claim that unit testing of components is not required and this leads to significant cost savings (Moy et al. 2013).

I am convinced that that formal methods and formal verification have an important role to play in the development of critical software systems. Formal specifications are very effective in discovering some types of specification problem that that may lead to system failure. Although formal verification remains impractical for large systems, it can be used to verify critical safety and security critical core components.

12.3.3 Model checking

Formally verifying programs using a deductive approach is difficult and expensive but alternative approaches to formal analysis have been developed that are based on a more restricted notion of correctness. The most successful of these approaches is called model checking (Jhala and Majumdar 2009). Model checking involves creating a formal state model of a system and checking the correctness of that model using specialized software tools. The stages involved in model checking are shown in Figure 12.8.

Model checking has been widely used to check hardware systems designs. It is increasingly being used in critical software systems such as the control software in NASA's Mars exploration vehicles (Regan and Hamilton 2004; Holzmann 2014) and by Airbus in avionics software development (Bochot et al. 2009).

Many different model-checking tools have been developed. SPIN was an early example of a software model checker (Holzmann, 2003). More recent systems include SLAM from Microsoft (Ball, Levin, and Rajamani 2011) and PRISM (Kwiatkowska, Norman, and Parker 2011)

The models used by model-checking systems are extended finite state models of the software. Models are expressed in the language of whatever model-checking system is used – for example, the SPIN model checker uses a language called Promela. A set of desirable system properties are identified and written in a formal notation, usually based on temporal logic. For example, in the wilderness weather system, a property to be checked might be that the system will always reach the 'transmitting' state from the 'recording' state.

The model checker then explores all paths through the model (i.e. all possible state transitions), checking that the property holds for each path. If it does,

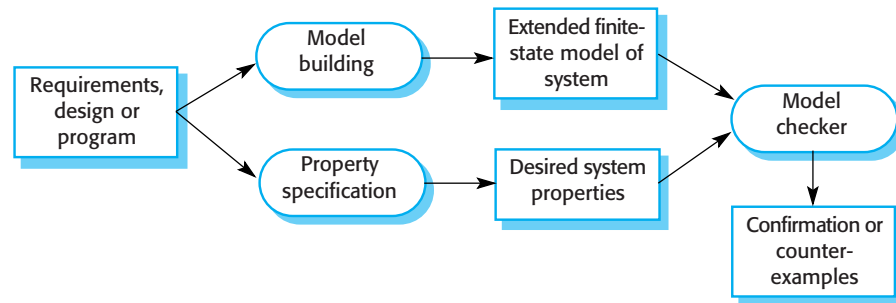


Figure 12.8 Model checking

then the model checker confirms that the model is correct with respect to that property. If it does not hold for a particular path, the model checker outputs a counter-example illustrating where the property is not true. Model checking is particularly useful in the validation of concurrent systems, which are notoriously difficult to test because of their sensitivity to time. The checker can explore interleaved, concurrent transitions and discover potential problems.

A key issue in model checking is the creation of the system model. If the model has to be created manually (from a requirements or design document), it is an expensive process as model creation takes a great deal of time. In addition, there is the possibility that the model created will not be an accurate model of the requirements or design. It is therefore best if the model can be created automatically from the program source code. Model checkers are available that work directly from programs in Java, C, C++ and Ada.

Model checking is computationally very expensive because it uses an exhaustive approach to check all paths through the system model. As the size of a system increases, so too does the number of states, with a consequent increase in the number of paths to be checked. This means that, for large systems, model checking may be impractical, due to the computer time required to run the checks. However, better algorithms under development to identify parts of the state that do not have explored to check a particular property. As these are incorporated into model checkers, it will be increasingly possible to use model-checking routinely in critical systems development.

12.3.4 Static program analysis

Automated static analyzers are software tools that scan the source text of a program and detect possible faults and anomalies. They parse the program text and thus recognize the different types of statements in a program. They then detect whether or not statements are well-formed, make inferences about the control flow in the program and, in many cases, compute the set of all possible values for program data. They complement the error detection facilities provided by the language compiler, and can be used as part of the inspection process or as a separate V & V process activity.

Automated static analysis is faster and cheaper than detailed code reviews and is very effective in discovering some types of program faults.. However, it

Fault class	Static analysis check
Data faults	Variables used before initialization Variables declared but never used Variables assigned twice but never used between assignments Possible array bound violations Undeclared variables
Control faults	Unreachable code Unconditional branches into loops
Input/output faults	Variables output twice with no intervening assignment
Interface faults	Parameter type mismatches Parameter number mismatches Non-usage of the results of functions Uncalled functions and procedures
Storage management faults	Unassigned pointers Pointer arithmetic Memory leaks

Figure 12.9
Automated static
analysis checks

cannot discover some classes of errors that could be identified in program inspection meetings.

Static analysis tools (Lopes, Vicente, and Silva 2009) work on the source code of a system and, for some types of analysis at least, no further inputs are required. This means that programmers do not need to learn specialized notations to write program specifications so the benefits, of analysis can be immediately clear. This makes automated static analysis easier to introduce into a development process than formal verification or model checking.

The intention of automatic static analysis is to draw a code reader's attention to anomalies in the program, such as variables that are used without initialization, variables that are unused, or data whose values could go out of range. Examples of the problems that can be detected by static analysis are shown in Figure 12.9.

Of course, the specific checks made by the static analyzer are programming-language specific and depend on what is and isn't allowed in the language. Anomalies are often a result of programming errors or omissions, so they highlight things that could go wrong when the program is executed. However, these anomalies are not necessarily program faults; they may be deliberate constructs introduced by the programmer, or the anomaly may have no adverse consequences.

There are three levels of checking that may be implemented in static analyzers:

1. *Characteristic error checking* At this level, the static analyzer knows about common errors that are made by programmers in languages such as Java or C. The tool analyzes the code looking for patterns that are characteristic of

that problem and highlights these to the programmer. Although relatively simple, analysis based on common errors can be very cost-effective. Zheng and his collaborators (Zheng et al. 2006) analyzed a large code base in C and C++. They discovered that 90% of the errors in the programs resulted from 10 types of characteristic error.

2. *User-defined error checking* In this approach, the users of the static analyzer define error patterns to be detected. These may relate to the application domain or be based on knowledge of the specific system that is being developed. An example of an error pattern is ‘maintain ordering’ e.g. method A must always be called before method B. Over time, an organization can collect information about common bugs that occur in their programs and extend the static analysis tools with error patterns to highlight these errors.
3. *Assertion checking* This is the most general and most powerful approach to static analysis. Developers include formal assertions (often written as stylized comments) in their program that state relationships that must hold at that point in a program. For example, an assertion might be included that states that the value of some variable must lie in the range $x..y$. The analyzer symbolically executes the code and highlights statements where the assertion may not hold.

Static analysis is effective in finding errors in programs but commonly, generates a large number of ‘false positives’. These are code sections where there are no errors but where the static analyzer’s rules have detected a potential for error. The number of false positives can be reduced by adding more information to the program in the form of assertions but this requires additional work by the developer of the code. Work has to be done in screening out these false positives before the code itself can be checked for errors.

Static analysis is routinely used by many organizations in their software development processes. Microsoft introduced static analysis in the development of device drivers where program failures can have a serious effect. They extended the approach across a much wider range of their software to look for security problems as well as errors that affect program reliability (Ball, Levin, and Rajamani 2011). Checking for well-known problems, such as buffer overflow, is effective for improving security as attackers often base their attacks on those common vulnerabilities. Attacks may target little used code sections that may not have been thoroughly tested. Static analysis is a cost-effective way of finding these types of vulnerability.

12.4 Safety cases

As I have discussed, many safety-critical, software-intensive systems are regulated. An external authority has significant influence on their development and deployment. Regulators are government bodies whose job is to ensure that

commercial companies do not deploy systems that pose threats to public and environmental safety or the national economy. The owners of safety-critical systems must convince regulators that they have made the best possible efforts to ensure that their systems are safe. The regulator assesses the safety case for the system, which presents evidence and arguments that normal operation of the system will not cause harm to a user.

This evidence is collected during the systems development process. It may include information about hazard analysis and mitigation, test results, static analyses, information about the development processes used, records of review meetings, etc. It is assembled and organized into a safety case, a detailed presentation of why the system owners and developers believe that a system is safe.

A safety case is a set of documents that includes a description of the system to be certified, information about the processes used to develop the system and, critically, logical arguments that demonstrate that the system is likely to be safe. More succinctly, Bishop and Bloomfield (Bishop and Bloomfield 1998) define a safety case as:

A documented body of evidence that provides a convincing and valid argument that a system is adequately safe for a given application in a given environment.

The organization and contents of a safety case depends on the type of system that is to be certified and its context of operation. Figure 12.10 shows one possible structure for a safety case but there are no universal industrial standards in this area. Safety cases structures vary, depending on the industry and the maturity of the domain. For example, nuclear safety cases have been required for many years. They are very comprehensive and presented in a way that is familiar to nuclear engineers. However, safety cases for medical devices have been introduced more recently. The case structure is more flexible and the cases themselves are less detailed than nuclear cases.

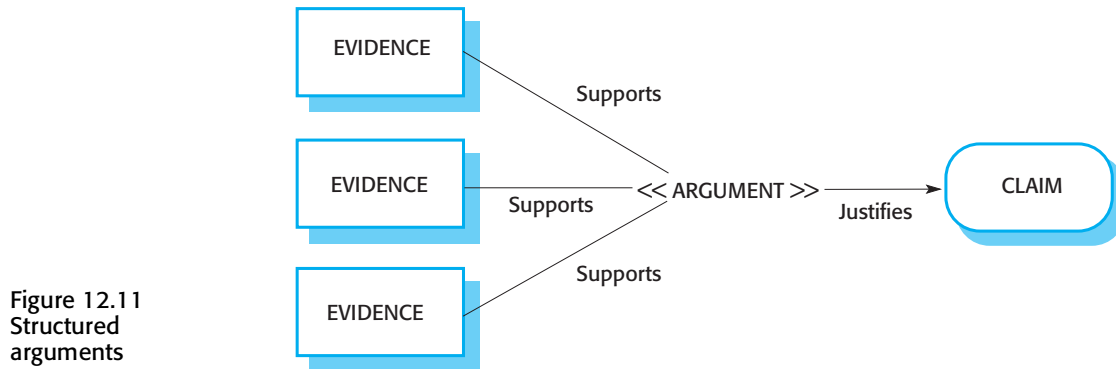
A safety case refers to a system as a whole and, as part of that case, there may be a subsidiary software safety case. When constructing a software safety case, you have to relate software failures to wider system failures and demonstrate either that these software failures will not occur or that they will not be propagated in such a way that dangerous system failures may occur.

Safety cases are large and complex documents and so they are very expensive to produce and maintain. Because of these high costs, safety-critical system developers have to take the requirements of the safety case into account in the development process:

Chapter	Description
System description	An overview of the system and a description of its critical components.
Safety requirements	The safety requirements taken from the system requirements specification. Details of other relevant system requirements may also be included.
Hazard and risk analysis	Documents describing the hazards and risks that have been identified and the measures taken to reduce risk. Hazard analyses and hazard logs.
Design analysis	A set of structured arguments (see section 12.4.1) that justify why the design is safe.
Verification and validation	A description of the V & V procedures used and, where appropriate, the test plans for the system. Summaries of the test results showing defects that have been detected and corrected. If formal methods have been used, a formal system specification and any analyses of that specification. Records of static analyses of the source code.
Review reports	Records of all design and safety reviews.
Team competences	Evidence of the competence of all of the team involved in safety-related systems development and validation.
Process QA	Records of the quality assurance processes (see Chapter 24) carried out during system development.
Change management processes	Records of all changes proposed, actions taken and, where appropriate, justification of the safety of these changes. Information about configuration management procedures and configuration management logs.
Associated safety cases	References to other safety cases that may impact on the safety case.

Figure 12.10
Possible
contents of a
software safety

1. Graydon *et al.* (Graydon, Knight, and Strunk 2007) argue that the development of a safety case should be tightly integrated with system design and implementation. This means that system design decisions may be influenced by the requirements of the safety case. Design choices that may add significantly to the difficulties and costs of case development can then be avoided.
2. Regulators have their own views on what is acceptable and unacceptable in a safety case. It therefore makes sense for a development team to work with them from early in the development to establish what the regulator expects from the system safety case.



The development of safety cases is expensive because of the costs of the record keeping required as well as the costs of comprehensive system validation and safety assurance processes. System changes and rework also add to the costs of a safety case. When software or hardware changes are made to a system, a large part of the safety case may have to be rewritten to demonstrate that the system safety has not been affected by the change.

12.4.1 Structured arguments

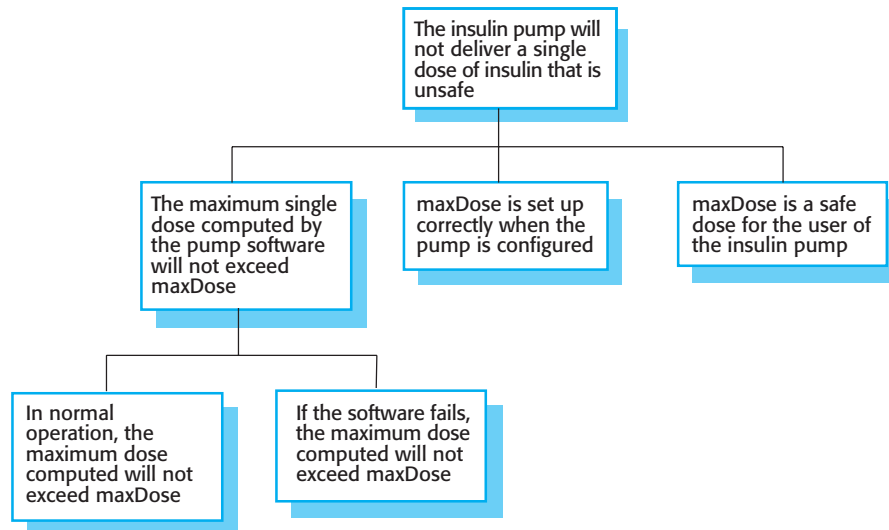
The decision on whether or not a system is operationally safe should be based on logical arguments. These should demonstrate that the evidence presented supports the claims about a system's security and dependability. These claims may be absolute (event X will or will not happen) or probabilistic (the probability of occurrence of event Y is 0.n). An argument links the evidence and the claim. As shown in Figure 12.11, an argument is a relationship between what is thought to be the case (the claim) and a body of evidence that has been collected. The argument, essentially, explains why the claim, which is an assertion about system security or dependability, can be inferred from the available evidence.

Arguments in a safety case are usually presented as 'claim based' arguments. Some claim about system safety is made and, on the basis of available evidence, an argument is made why that claim holds. For example, the following argument might be used to justify a claim that computations carried out by the control software in an insulin pump will not lead to an overdose of insulin being delivered. Of course, this is a very simplified presentation of the argument. In a real safety case more detailed references to the evidence would be presented.

Claim: The maximum single dose computed by the insulin pump will not exceed **maxDose**, where **maxDose** has been assessed as a safe single dose for a particular patient.

Evidence: Safety argument for insulin pump software control program (covered later in this section).

Figure 12.12 A safety claim hierarchy for the insulin pump



Evidence: Test data sets for the insulin pump. In 400 tests, which provided complete code coverage, the value of the dose of insulin to be delivered, `currentDose`, never exceeded `maxDose`.

Evidence: A static analysis report for the insulin pump control program. The static analysis of the control software revealed no anomalies that affected the value of `currentDose`, the program variable that holds the dose of insulin to be delivered.

Argument: The evidence presented demonstrates that the maximum dose of insulin that can be computed is equal to `maxDose`.

It is therefore reasonable to assume, with a high level of confidence, that the evidence justifies the claim that the insulin pump will not compute a dose of insulin to be delivered that exceeds the maximum single safe dose.

The evidence presented is both redundant and diverse. The software is checked using several different mechanisms with significant overlap between them. As I discussed in Chapter 10, using redundant and diverse processes increases confidence. If there are omissions and mistakes that are not detected by one validation process, there is a good chance that these will be found by one of the other processes.

There will normally be many claims about the safety of a system, with the validity of one claim often depending on whether or not other claims are valid. Therefore, claims may be organized in a hierarchy. Figure 12.12 shows part of this claim hierarchy for the insulin pump. To demonstrate that a high-level claim is valid, you first have to work through the arguments for lower-level claims. If you can show that each of these lower-level claims is justified, then you may be able to infer that the higher-level claims are justified.

12.4.2 Software safety arguments

A general assumption that underlies work in system safety is that the number of system faults that can lead to safety hazards is significantly less than the total number of faults that may exist in the system. Safety assurance can therefore concentrate on these faults, which have hazard potential. If it can be demonstrated that these faults cannot occur or, if they occur, the associated hazard will not result in an accident, then the system is safe. This is the basis of software safety arguments.

Software safety arguments are a type of structured argument, which demonstrate that a program meets its safety obligations. In a safety argument, it is not necessary to prove that the program works as intended. It is only necessary to show that program execution cannot result in it reaching a potentially unsafe state. This means that safety arguments are cheaper to make than correctness arguments. You don't have to consider all program states – you can simply concentrate on states that could lead to a hazard.

Safety arguments demonstrate that, assuming normal execution conditions, a program should be safe. They are usually based on contradiction, where you assume that the system is unsafe then show that this is impossible. The steps involved in creating a safety argument are:

1. You start by assuming that an unsafe state, which has been identified by the system hazard analysis, can be reached by executing the program.
2. You write a predicate (a logical expression) that defines this unsafe state.
3. You then systematically analyze a system model or the program and show that, for all program paths leading to that state, the terminating condition of these paths, also defined as a predicate, contradicts the unsafe state predicate. If this is the case, you may then claim that the initial assumption of an unsafe state is incorrect.
4. When you have repeated this analysis for all identified hazards then you have strong evidence that the system is safe.

Safety arguments can be applied at different levels, from requirements through design models to code. At the requirements level, you are trying to demonstrate that there are no missing safety requirements and that the requirements do not make invalid assumptions about the system. At the design level, you might analyze a state model of the system to find unsafe states. At the code level, you consider all of the paths through the safety-critical code to show that the execution of all paths leads to a contradiction.

```

-- The insulin dose to be delivered is a function of
-- blood sugar level, the previous dose delivered and
-- the time of delivery of the previous dose

currentDose = computeInsulin () ;

// Safety check—adjust currentDose if necessary.

// if statement 1

if (previousDose == 0)
{
    if (currentDose > maxDose/2)
        currentDose = maxDose/2 ;
}
else
    if (currentDose > (previousDose * 2) )
        currentDose = previousDose * 2 ;

// if statement 2

if ( currentDose < minimumDose )
    currentDose = 0 ;
else if ( currentDose > maxDose )
    currentDose = maxDose ;

administerInsulin (currentDose) ;

```

Figure 12.13
Insulin dose
computation
with safety
checks

As an example, consider the code outlined in Figure 12.13, which is a simplified description of part of the implementation of the insulin delivery system. The code computes the dose of insulin to be delivered then applies some safety checks that this is not an overdose for that patient. Developing a safety argument for this code involves demonstrating that the dose of insulin administered is never greater than the maximum safe level for a single dose. This is established for each individual diabetic user in discussions with their medical advisors.

To demonstrate safety, you do not have to prove that the system delivers the ‘correct’ dose, merely that it never delivers an overdose to the patient. You work on the assumption that **maxDose** is the safe level for that system user.

To construct the safety argument, you identify the predicate that defines the unsafe state, which is that **currentDose > maxDose**. You then demonstrate that all program paths lead to a contradiction of this unsafe assertion. If this is the case, the unsafe condition cannot be true. If you can do this, you can be confident that the program will not compute an unsafe dose of insulin. You can structure and present the safety arguments graphically as shown in Figure 12.14.

In the safety argument shown in Figure 12.14, there are three possible program paths that lead to the call to the **administerInsulin** method. You have to show that the amount of insulin delivered never exceeds **maxDose**. All possible program paths to **administerInsulin** are considered:

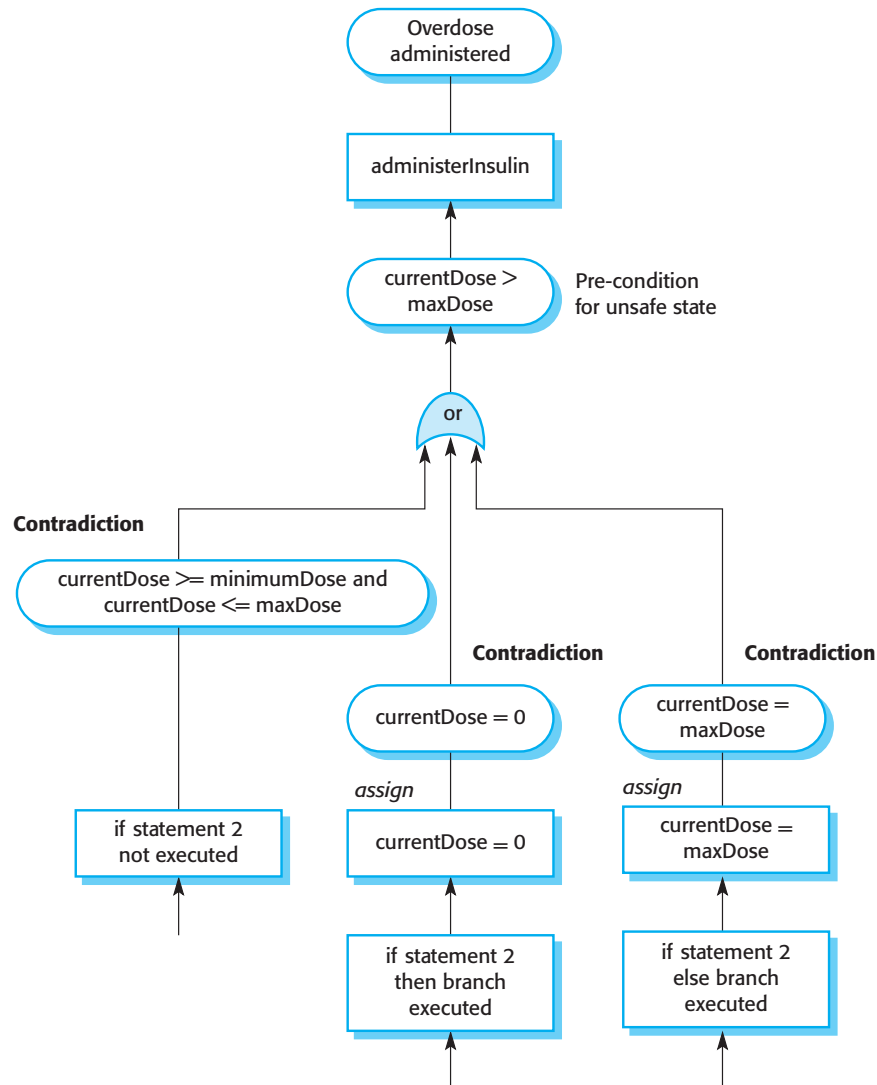


Figure 12.14
Informal safety
argument based on
demonstrating
contradictions

1. Neither branch of if-statement 2 is executed. This can only happen if **currentDose** is outside of the range **minimumDose..maxDose**. The post-condition predicate is therefore:

$$\text{currentDose} \geq \text{minimumDose} \text{ and } \text{currentDose} \leq \text{maxDose}$$
2. The then-branch of if-statement 2 is executed. In this case, the assignment setting **currentDose** to zero is executed. Therefore, its post-condition predicate is **currentDose = 0**.

3. The else-if-branch of if-statement 2 is executed. In this case, the assignment setting `currentDose` to `maxDose` is executed. Therefore, after this statement has been executed, we know that the post-condition is `currentDose = maxDose`.

In all three cases, the post-condition predicates contradict the unsafe pre-condition that `currentDose > maxDose`. As both cannot be true, we can claim that our initial assumption was incorrect and so the computation is safe.

To construct a structured argument that a program does not make an unsafe computation, you first identify all possible paths through the code that could lead to a potentially unsafe assignment. You work backwards from the unsafe state and consider the last assignment to all of the state variables on each path leading to this unsafe state. If you can show that none of the values of these variables is unsafe, then you have shown that your initial assumption (that the computation is unsafe) is incorrect.

Working backwards is important because it means you can ignore all intermediate states apart from the final states that lead to the exit condition for the code. The previous values don't matter to the safety of the system. In this example, all you need be concerned with is the set of possible values of `currentDose` immediately before the `administerInsulin` method is executed. You can ignore computations, such as if-statement 1 in Figure 12.13, in the safety argument because their results are over-written in later program statements.

KEY POINTS

Safety-critical systems are systems whose failure can lead to human injury or death.

A hazard-driven approach may be used to understand the safety requirements for safety-critical systems. You identify potential hazards and decompose these (using methods such as fault tree analysis) to discover their root causes. You then specify requirements to avoid or recover from these problems.

It is important to have a well-defined, certified process for safety-critical systems development. The process should include the identification and monitoring of potential hazards.

Static analysis is an approach to V & V that examines the source code (or other representation) of a system, looking for errors and anomalies. It allows all parts of a program to be checked, not just those parts that are exercised by system tests.

Model checking is a formal approach to static analysis that exhaustively checks all states in a system for potential errors.

Safety and dependability cases collect all of the evidence that demonstrates a system is safe and dependable. Safety cases are required when an external regulator must certify the system before it is used.

FURTHER READING

Safeware: System Safety and Computers. Although now 20 years old, this book is still offers the best and most thorough coverage of safety-critical systems. It is particularly strong in its description of hazard analysis and the derivation of requirements from this. (N. Leveson, Addison Wesley, 1995)

‘Safety-critical software’. A special edition of *IEEE Software* magazine that focuses on safety-critical systems. It includes papers on model-based development of safety-critical systems, model checking and formal methods. (*IEEE Software*, 30 (3), May/June 2013)

‘Constructing safety assurance cases for medical devices’. This short paper gives a practical example of how a safety case can be created for an analgesic pump. (A. Ray and R. Cleaveland, Proc. Workshop on Assurance Cases for Software-Intensive Systems, San Francisco, 2013)
<http://dx.doi.org/10.1109/ASSURE.2013.6614270>

WEBSITE

PowerPoint slides for this chapter:

<http://software-engineering-book.com/slides/chap12/>

Links to supporting videos:

<http://software-engineering-book.com/videos/reliability-and-safety/>

EXERCISES

12. 1 Identify six consumer products that are likely to be controlled by safety-critical software systems.

12.2 Explain why the boundaries in the risk triangle shown in Figure 12.3 are liable to change with time and changing social attitudes.

12.3 In the insulin pump system, the user has to change the needle and insulin supply at regular intervals and may also change the maximum single dose and the maximum daily dose that may be administered. Suggest three user errors that might occur and propose safety requirements that would avoid these errors resulting in an accident.

12.4 A safety-critical software system for treating cancer patients has two main components:

A radiation therapy machine that delivers controlled doses of radiation to tumor sites. This machine is controlled by an embedded software system.

A treatment database that includes details of the treatment given to each patient. Treatment requirements are entered in this database and are automatically downloaded to the radiation therapy machine.

Identify three hazards that may arise in this system. For each hazard, suggest a defensive requirement that will reduce the probability that these hazards will result in an accident. Explain why your suggested defense is likely to reduce the risk associated with the hazard.

12.5 A train protection system automatically applies the brakes of a train if the speed limit for a segment of track is exceeded, or if the train enters a track segment that is currently signaled with a red light (i.e. the segment should not be entered). There are two critical safety requirements for this train protection system:

The train shall not enter a segment of track that is signaled with a red light.

The train shall not exceed the specified speed limit for a section of track.

Assuming that the signal status and the speed limit for the track segment are transmitted to on-board software on the train before it enters the track segment, propose five possible functional system requirements for the onboard software that may be generated from the system safety requirements.

12.6 Explain when it may be cost-effective to use formal specification and verification in the development of safety-critical software systems. Why do you think that some critical systems engineers are against the use of formal methods?

12.7 Explain why using model checking is sometimes a more cost-effective approach to verification than verifying a program's correctness against a formal specification.

12.8 List four types of systems that may require software safety cases, explaining why safety cases are required.

12.9 The door lock control mechanism in a nuclear waste storage facility is designed for safe operation. It ensures that entry to the storeroom is only permitted when radiation shields are in place or when the radiation level in the room falls below some given value (`dangerLevel`). So:

- (i) If remotely controlled radiation shields are in place within a room, an authorized operator may open the door.
- (ii) If the radiation level in a room is below a specified value, an authorized operator may open the door.
- (iii) An authorized operator is identified by the input of an authorized door entry code.

The code shown in Figure 12.15 (see below) controls the door-locking mechanism. Note that the safe state is that entry should not be permitted. Using the approach discussed in this chapter, develop a safety argument for this code. Use the line numbers to refer to specific statements. If you find that the code is unsafe, suggest how it should be modified to make it safe.

```
1  entryCode = lock.getEntryCode () ;
2  if (entryCode == lock.authorizedCode)
3  {
4      shieldStatus = Shield.getStatus () ;
5      radiationLevel = RadSensor.get () ;
6      if (radiationLevel < dangerLevel)
7          state = safe;
8      else
9          state = unsafe;
10     if (shieldStatus == Shield.inPlace() )
11         state = safe;
12     if (state == safe)
13     {
14         Door.locked = false ;
15         Door.unlock () ;
16     }
17     else
18     {
19         Door.lock () ;
20         Door.locked := true ;
21     }
22 }
```

Figure 12.15 Door entry code

12.10 Should software engineers working on the specification and development of safety-related systems be professionally certified or licensed in some way? Explain your reasoning.

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