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Introduction

What is decontamination?

First “to do no harm”

Of the Epidemics, Hippocrates (~400 BC)

Health is an important subject to all. It affects us as individuals, our families and the communities in which we live. Our health is improved by promoting well-being and preventing disease or other negative health impacts. A disease may be defined as any effect that impairs/harms the body’s normal function and therefore has an impact on our health (mild, moderate or even severe). Diseases can be infectious or non-infectious (such as cancer, effects of drug abuse, stress, chemicals, etc.). Infectious diseases are a leading cause of sickness and death worldwide. They are caused by living creatures that cannot be seen by the naked eye, known as “microorganisms”, such as viruses and bacteria. It is estimated that infectious diseases affected our breathing, digestive and immune systems are responsible for ~17% of human death worldwide (the next highest cause of death is coronary heart disease at ~12%). These rates are estimated across the whole world, but are even higher in lower income regions. Examples of health efforts to reduce these risks in the general public include improving drinking water quality (chemical and microbiological), immunization (vaccination), and safe handling/disposal of waste. Many of these efforts influence our daily lives, but the risk of infectious disease significantly increases when we are sick or when our bodies are otherwise compromised (e.g. when undergoing a surgical procedure). For these reasons, healthcare institutions (such as hospitals and clinics) have many procedures and practices in place to control the spread of infectious disease within these facilities, and to protect patients, staff and the general

public. It is an important philosophy in medical practice: First “to do no harm” or in Latin “*primum non nocere*”. These are collectively referred to as “safe” or “infection control/prevention” practices that prevent the spread of disease or other negative effects from one patient to another (or to/from staff or visitors within these facilities). These practices include:

- Immunization
 - Isolation of patients with specific diseases
 - Decontamination of equipment and various surfaces
- As “contamination” refers to something being “dirty” or “soiled”, “decontamination” is the means to render it safe for handling, use or disposal. Dirt or soil may include things like dust, patient materials (such as blood, feces, various tissues from surgical procedures, etc.) and associated microorganisms that can cause disease. In this book, the terms “decontamination” and “reprocessing” are used interchangeably. In healthcare facilities a variety of physical and/or chemical products or processes are used for decontamination. These include:
- Cleaning, the removal of soil to make something “clean”
 - Disinfection, the antimicrobial reduction of microorganisms; other widely used terms that refer to disinfection can include antisepsis, pasteurization, sanitization and fumigation
 - Sterilization, the complete eradication of all microorganisms
- These are all methods of decontamination and are explained further in this book. Examples of specific decontamination practices will include:
- Hand and skin hygiene, including routine hand disinfection and preparation of the skin for a surgical procedure
 - Taking surgical or medical instruments that have been used on one patient and decontaminating them in preparation for use on another

- Cleaning and disinfection of linens or other materials (including patient bed sheets, sterile towels and cottons fabrics)
- Disinfection of water for drinking or sterilization of water for injection use
- Cleaning and disinfecting environmental surfaces such as floors and beds
- Sterilization of contaminated waste materials for safe disposal (including incineration)

In some cases decontamination is a one-step process, for example sterilization of contaminated waste materials, but is most often a two-step process to include cleaning (the physical removal of soil) and disinfection or sterilization (as the antimicrobial process to inactivate the various types of microorganisms that we cannot see). For re-usable medical and surgical instruments this will normally include at least cleaning and disinfection, but will often include sterilization, this being the highest level of safety. Decontamination is therefore an integral part of infection prevention and should not be underestimated.

A brief history of decontamination

It is clear from many ancient documents that decontamination practices have been considered to have health benefits. Examples include:

- In approximately 1400–1200 BC (estimated to be at the time of Moses), a sanitary code was outlined in the Leviticus, Numbers and Deuteronomy chapters of the Bible. It was noted even at this time that when dealing with disease that hands should be washed under running water and that there was a value in boiling water to make it safe for drinking or other purposes.
- The Eber's Papyrus, a medical document from about 1500 BC, describes a method of combining animal and vegetable oils with alkaline salts to form a soap-like material used for treating skin diseases, as well as for washing hands.
- The world's oldest known medical text outlines the procedures for wound management practiced by the Sumerians (~2000 BC). The wound was cleansed with beer (which contained alcohol) and then bandaged with a cloth soaked in wine and turpentine. The practice of using alcoholic beverages and turpentine would remain the treatment of choice until the modern era.
- Similar examples of wound, water or air treatments have been described by the ancient Greek and Roman cultures. Aristotle (384–322 BC), a Greek philosopher, even described boiling to treat water. Homer (~850 BC),

in his epic poem the *Odyssey*, described the use of sulfur as an area disinfectant.

- Ancient methods of preserving foods from rotting during storage (which we now know is caused by microorganisms) included drying, heating and use of sugar or vinegar.

From these ancient times to the 19th century, infection was a major cause of mortality and morbidity in humans. It would take many thousands of years for the microbiological origin and transmissibility of infection to be discovered. A recurring theme in history was the belief that epidemic diseases were spread by something in the air. Hippocrates (460–370 BC) was an ancient Greek doctor and is often referred to as the father of medicine, being still referred to today by new doctors taking the Hippocratic oath. He put this belief into practice when attempting to drive the plague (now known to be a bacterial disease) from Athens by lighting fires of aromatic wood in the streets. This belief that diseases were spread by something in the air continued throughout history.

Many ancient physicians well understood that when the skin was broken in any way (by a wound or during attempts at surgery) the risks of “bad” things happening was significantly increased. It was unknown at the time that wound infections were caused by various types of microorganisms, particularly bacteria, with dramatic consequences, including destruction of limbs and death. Infections in such cases of skin damage were the major contributor to death and suffering, which is why surgical procedures were attempted only as a last resort. Through the ages operations were performed with little regard for a “clean” environment. Surgeons’ hands, rarely washed, were placed directly into the patient’s wounds. Frequently, onlookers were encouraged to “take a feel” for educational purposes. Surgical instruments used in such procedures were crudely wiped, placed back into their velvet carriers, and re-used, some having been sharpened on the sole of the surgeon’s boot. The floors of the surgical wards were covered with whatever came from the patient, which could include feces, urine, blood and pus, and hygiene practices in other areas of such facilities (if indeed dedicated facilities where used) at the time were also unknown. Not surprisingly, surgical site infection was the major contributor to morbidity and mortality rates, occurring after practically all operations and taking the lives of almost half of all surgical patients.

Hippocrates was one of the first recorded to hold an opinion on the cause of such problems, stating that the formation of pus (suppuration) was not a natural part of the healing process and should be avoided. His

recommendations for managing wounds were: cleansing with wine, applying a bandage, and then pouring wine on the bandage. Another Greek physician Claudius Galen (~AD 130–200) recommended soap for both medicinal and cleansing purposes. He, however, disagreed with Hippocrates, that the formation of pus was not a normal occurrence; he believed that pus was essential for wound healing. It is often considered that this was originally an Arabic idea. Suppuration was actively encouraged by surgeons in traumatic and painful procedures. This disagreement would continue to be debated for centuries.

One thousand years later, the Italian Theodorico Borgognoni (1205–1298) challenged Galen's view of suppuration. He dedicated his career to finding the ideal conditions for wound healing and became one of the most famous surgeons during the Middle Ages. He argued that a wound should be maintained clean and closed (sutured) to control infection (and preserve life). Because his views were contrary to the established teachings, he was denounced by his colleagues and even by the church. Indeed, the surgeon would often welcome the signs of suppuration, depending on how it looked. Wounds were classified into two categories: those with suppuration and those without. Wounds with "laudable pus" (a creamy yellow ooze) tended to run a chronic course, taking months to heal, but the patients were generally free of other negative signs and did not die! Wounds with a thin, watery discharge were associated with a fatal outcome, with the patient dying of sepsis within days. It is not, therefore, surprising that even the most conscientious surgeons preferred and even encouraged the formation of pus. Galen's doctrine of suppuration would remain the rule for wound management until the late 19th century.

In addition to wound infection, general standards of public hygiene and their impacts on public health were not widely appreciated. As an example in Europe, following the eventual fall of Rome in AD 476 many simple hygiene practices were neglected. Examples included a decline in bathing habits, lack of personal cleanliness and unsanitary living conditions (lack of waste disposal, etc.). It is well appreciated that such conditions contributed heavily to the great plagues of the Middle Ages, and especially to the Black Death of the 14th century. At the same time, it was understood that contact with sick individuals could rapidly spread a disease, as highlighted by the fear associated with bacterial diseases such as leprosy and bubonic plague; in fact, infected bodies have been used over the ages as effective weapons in battles and sieges! Equally, infected bodies and materials were often dealt with by burning (incineration).

Hieronymus Fracastorius (1478–1553) suggested that the cause of infectious disease was from invisible living "seeds" (*seminaria contagionum*). He even at this period described three modes of disease spread: direct contact with infected persons, indirect contact with fomites and airborne transmission. Ambroise Paré (1510–1590), considered one of the fathers of modern surgery, believed that infection was introduced from the environment. In 1625 Francis Bacon described some methods to prevent or control wound infections, such as by the use of salt or excluding air. In the 1670s Anton van Leeuwenhoek was the first microbiologist to observe individual, live microorganisms, by using a simple microscope. He called these animalcules or "little animals." He also described the first direct evidence of disinfection in observing the death of animalcules treated with pepper (in water) or vinegar. Similar disinfection studies were described shortly after by Edmund King and John Pringle. It could be argued that this was the start of the modern era of understanding infectious diseases and their control, but even then the "microbial theory" remained debated for the next few centuries.

In the meantime, the benefits of disinfection practices continued to be better understood. Ancient disinfection methods had been previously recognized, such as the benefits of storing water and other liquids in copper or silver vessels (as a preservative method from the release of copper or silver into the water), burning with fire (as a method of incineration) and boiling water. In the modern era further advances were made such as:

- In 1680 Dennis Papin developed the first recognizable steam generating machine.
- In 1774 Scheele discovered chlorine and its antimicrobial effects.
- In the 1830s William Henry published studies on the "disinfection power of increased temperatures".
- In the mid-1800s copper sulphate, zinc chloride and sodium permanganate, acids, alkalis, sulfurs and alcohols were recognized as disinfectants.

In the late 1840s, Dr Ignaz Semmelweis, whilst working in the maternity wards of a Vienna hospital, observed that the mortality rate in a delivery room staffed by medical students was up to three times higher than in a second delivery room staffed by midwives. Expectant mothers were terrified of the room staffed by the medical students! Semmelweis observed that the students were coming straight from their lessons in the autopsy room to the delivery room. He believed that they were carrying infectious agents from the lab to their patients. When he implemented a hand washing protocol at the hospital the

mortality rate dropped to less than 1%. Today, he is recognized as the father of hand hygiene, one of the most important measures to be taken by healthcare practitioners to reduce cross-contamination. Due to the lack of indoor plumbing at the time, it was difficult to get water to wash hands, making this an unpopular idea. In order to make the water comfortably warm, it would have to be heated over a fire. Besides, contact with water was associated with diseases such as malaria and typhoid fever. Unknown to him, similar results had been described a few years previously by the American scientist Oliver Wendell Holmes. Both suggestions fell on deaf ears. Semmelweis, for his efforts, was committed to an asylum and died of a blood infection.

Despite the earlier work by others such as van Leeuwenhoek, the prevailing theory at the time was known as “spontaneous generation”. This is often originally attributed to the Greek philosopher Aristotle (384–322 BC) and simply regards the origins of life as being from inanimate matter or non-living substances. Many famous names in the modern history of infection control, such as Pouchet, Nightingale and Virchow subscribed. Louis Pasteur was born in 1822 in France and in 1857 he proposed the “germ theory of disease”, which is regarded as one of the most important discoveries in decontamination history. The theory proposed that most infectious diseases are caused by germs; he also specifically described the existence of bacteria. In the 1860s Pasteur commenced his anti-spontaneous generation experiments and demonstrated that “microorganisms are present in air but not created by air”, thereby disproving the concept of spontaneous generation. This was vigorously debated for many years after, with many leading scientists refusing to accept this idea, but the modern era of microbiology had begun. Pasteur proved that protection from air, by sealing or providing a tortuous path, prevented contamination; if growth media was exposed to air it resulted in contamination by microorganisms. With the development of the germ theory by Pasteur and its subsequent application to surgical practices, surgeons were able to operate with a substantially reduced risk of infection. Pasteur was also able to show that bacteria could be killed by various processes. “Pasteurization” is a heat-based process to control microorganisms that still bears his name and he also designed some simple steam cabinet sterilizers (with Charles Chamberland in 1880).

During the 1700–1800s, various scientists described the phenomenon that by injecting healthy people with fluids (such as blood) from patients suffering from certain

diseases, particularly with milder or similar types of disease, they could be protected from disease. This became known as vaccination and was previously described by the Chinese, Indians and Turks. Worthly-Montague and Jenner used such methods to prevent smallpox, a prevalent infectious disease at the time and now eradicated. Pasteur also developed vaccination methods (e.g. against rabies). Vaccination is now an important part of public health, including the prevention of common diseases such as measles, mumps and seasonal flu. Polio has all but been eradicated due to immunization.

Pasteur’s work accelerated other investigations in microbiology and infection control/prevention. As an example, Agostino Bassi (1773–1856) described the use of a variety of disinfectants in the control of different diseases such as cholera; these included alcohol, acids and chlorine. Joseph Lister (1827–1912), a professor of surgery in Glasgow, Scotland, quickly noticed the connection between Pasteur’s work and the suppuration of wounds. He concluded that microbes in the air were most likely causing the infection and had to be destroyed before they entered the wound. Lister began to clean wounds and dress them using a solution of carbolic acid (phenol). Little did he know that at the same time other European surgeons were already practicing similar methods with other chemicals. In 1867 he published a paper on antiseptic, stating that “all the local inflammatory mischief and general febrile disturbance which follow severe injuries are due to the irritating and poisoning influence of decomposing blood or sloughs”. Lister began applying phenol to compound fracture wounds; wounds healed without infection. The application of germ theory to wound healing changed the practice of surgery. Lister also campaigned for heat or chemical sterilization (and for surgeons to use something other than sawdust swept up from the floors of the mills for surgical dressings!).

During the Franco-Prussian war (1870–1871) antiseptic practices were shown to have an impact on saving soldiers’ lives. German surgeons were beginning to practice antiseptic surgery, using sterilized instruments and materials. In 1876, Lister presented his ideas at the International Medical Congress in Philadelphia. William W. Keen (1837–1932) attended the presentation and became one of the first American surgeons to implement Lister’s ideas. During the American Civil War, Keen was one of the first physicians in the world to adopt aseptic surgical technique. During the American Civil War, 90% of the deaths on both sides were due to infectious disease rather than direct death from military trauma. While

bayoneting killed less outright, minor scratches from other injuries often festered into mortal wounds. Keen recommended and practiced the following surgical set-up in hospitals at the time:

- All carpets and unnecessary furniture were removed from the patient's room.
- Walls and ceilings were carefully cleaned the day before the operation, and the woodwork, floors, and remaining furniture were scrubbed with carbolic solution. This solution was also sprayed in the room on the morning preceding but not during the operation.
- The day before the operation, the patient was shaved, scrubbed with soap and water, and ether, and covered with wet corrosive sublimate dressing until operated on, and then ether and mercuric chloride washings were repeated.
- The surgical instruments were boiled in water for two hours, and sponges for use during the procedures were treated with carbolic acid before use.
- The surgeon's hands were cleaned and disinfected with soap, water and alcohol.

It is interesting to note that many of these practices are still in use today (such as washing or the use of alcohol on the hands), while others are not (such as the use of mercury). As the knowledge on the use of various chemicals improved, it was realized that while many of these practices could kill or prevent the growth of microorganisms, many could also do harm to human health (or were "toxic" either in the short or long term).

As scientific knowledge expanded during the late 19th century so did the advancement of infection prevention. Another important milestone was when Robert Koch (1843–1910), a German physician, was able to demonstrate the cause-and-effect relationship between a specific bacterium (*Bacillus anthracis*) and the disease anthrax. He used a sequence of experimental steps to directly relate a specific microbe to a specific disease; these steps of disease association, isolation, inoculation, and re-isolation became known as Koch's Postulates. These still form the basis of defining an infectious agent today. In 1882 Koch also discovered the causative agent of tuberculosis, the bacteria *Mycobacterium tuberculosis*. Tuberculosis was the cause of one in seven deaths in the mid-19th century; interestingly, in the 21st century tuberculosis is once again a major problem due to the development of drug (antibiotic) resistant forms of the bacterium. Koch also published a book (*On Disinfection*) that described various types of disinfectants and the differences in their abilities to kill various types of microorganisms (with *Mycobacterium tuberculosis* and

Bacillus anthracis being particularly difficult to inactivate, the latter due to its ability to form heat/chemical resistant spores). Other advances before the end of the 19th century included:

- In 1883, Gustav Neuber introduced the use of sterile gowns and caps during surgery.
- In 1890, William Stewart Halsted introduced surgical gloves after he commissioned the Goodyear rubber company to fashion gloves for his nurse to protect her hands from the mercuric chloride solutions used to disinfect the instruments. Rubber gloves were routinely used after 1890.
- In 1891 Ernst von Bergmann introduced routine heat sterilization of instruments, which proved superior to chemical methods used at the time.
- In 1897, Mikulicz introduced the use of surgical masks. During the early part of the 20th century a variety of other chemicals began to be used for infection prevention purposes, including hydrogen peroxide, various types of phenols, dyes and quaternary ammonium compounds. During the 1920s, Sir Alexander Fleming (1881–1955), working in London, made the accidental discovery of penicillin, one of the first and most widely used antibiotics. Antibiotics are drugs used to treat or prevent bacterial infections. It was not until the Second World War (in the 1940s) that penicillin was widely introduced, as an extract from the fungus (another type of microorganism) known as *Penicillium*. This led to a revolution in the development and manufacturing of various types of antibiotics (such as tetracycline and methicillin). It seemed that bacterial infections might be something of the past, but quickly it was shown that bacteria could develop resistance to antibiotics and in the present day there are less antibiotics available to treat a greater variety of antibiotic-resistant bacteria (such as methicillin-resistant *Staphylococcus aureus*, MRSA and multi-drug resistant *Mycobacterium tuberculosis*, MDR-TB). Despite this, antibiotics became and still remain widely used for treating bacterial infections and also in preventing them (known as prophylaxis, such as when given prior to surgery). With increasing rates of antibiotic-resistant bacteria today, there is a re-focus on efforts to prevent infection by isolating and eliminating any variable that could pose a risk, including decontamination.

Up until the 1940s, medical/surgical supplies were mainly decontaminated (or "reprocessed") and maintained in the surgery or patient care area in which they were to be used. Under this system, there was duplication of both time and equipment at various locations within larger healthcare facilities, and it was difficult to maintain consistently high standards. As the number and variety of

surgical procedures grew and the types of medical/surgical devices, equipment and supplies increased, it became apparent that centralized reprocessing areas were needed for efficiency, economy and patient safety. The work of scientists such as W.B. Underwood and J.J. Perkins was instrumental in encouraging healthcare facilities to establish separate and distinct areas/departments with specialized expertise and direct responsibility for providing clean and sterile medical/surgical supplies and equipment to patient care areas. These areas are often referred to by a variety of names, such as decontamination service (DS), central sterile services department (CSSD), sterile services department (SSD), sterile processing centre (SPD) and theatre sterile services unit (TSSU) to mention but a few. It was also in the 1940s that various organizations (such as the British Medical Research Council) advocated that in order to reduce surgical sepsis and other associated infections in healthcare facilities, “fulltime special officers” should be appointed to supervise the control of infection. These officers became experts in infection control and prevention practices within facilities, such as infection control nurses (ICN) and doctors. Further recommendations included the establishment of an infection control committee with multidisciplinary representatives, including doctors, nurses and administrators. It is now normal practice worldwide to employ ICNs and to have established infection control committees with a mandate to monitor and prevent hospital or healthcare-acquired infections (HAIs).

Advances in various sterilization methods including those based on steam, dry heat and even low temperature chemical methods, such as those based on ethylene oxide, became standard practices in the preparation of surgical devices. Focus was also placed on the variety of devices and instruments that were being developed and used on patients, both medically and surgically. Examples included flexible endoscopes that allowed internal structures of the body to be examined by entering through natural openings (such as through the mouth). During the 1950s a classification system was proposed by Dr E. Spaulding that suggested devices could be considered as critical (entering the “sterile” areas of the body, including blood contact), semi-critical (contacting non-intact skin or mucous membranes) and non-critical (intact skin contact). While sterilization was recommended for critical devices, various levels of disinfection (ranging from low to high level) could be safely used for the other device classification. New types of high-level disinfectants (sometimes even referred to as “sterilants”), such as those based on glutaraldehyde, became widely

used as effective and more rapid alternatives to heat and chemical sterilization methods. Medical/surgical devices continue to show new innovations, including replacement parts of the body (e.g. hips and knees), as well as allowing for robotic surgery. In parallel, newer and even safer disinfectants and sterilization processes have been developed to meet the decontamination demands for traditional and advanced instrumentation.

Our knowledge of the various different types of microorganisms that cause infections has continued to develop. Examples include the ever increasing types of bacteria, fungi and protozoa that are implicated as causing various diseases. At the end of the 19th century, a further group of infectious agents were first described that appeared to be much more basic in nature than previously considered: viruses. It was not until the 1930s, with the invention of powerful electron microscopes that their nature was truly understood. Viruses are now well known as the causative agents in many diseases such as measles (the measles virus), AIDs (HIV), flu (influenza), hepatitis (e.g. Hep A and B) and some forms of cancer (e.g. papillomavirus). During the 1970–1980s further groups known as “prions”, were identified as causative agents in diseases such as “mad cow disease” in animals and humans. Indeed, the range of microorganisms that are implicated in disease continues to grow.

In the modern era, with increasing microbial resistance to drugs (not only in bacteria but in other microorganisms) and greater risks of infections (e.g. more invasive surgical procedures, etc.) there is a much greater emphasis than ever before on the prevention of infection. Decontamination practices play a central role in infection prevention strategies and ensuring patient safety.

Goals of decontamination and the Spaulding classification

Decontamination practices are designed to render devices, instruments and materials “safe” for handling, use and/or disposal. It has already been highlighted that the primary goal is to reduce or even completely remove microbial contamination, but in fact it is more than that. Overall, it is to ensure safety: safety for the patient, staff, the devices and even the environment. The goals of decontamination are:

- To reduce or completely remove microbial contamination to a level that is safe for use by medical staff and with/in a patient.

- To ensure that no toxic substances remain on the surface that could cause other negative patient reactions. This can include patient soil (even in some cases at low concentrations), water or decontamination chemistry (e.g. cleaning and disinfection chemicals) residues and even parts of microorganisms that have been killed.
- To ensure that the decontamination process does not damage the device and that the process is therefore “compatible” with the device. Negative effects can include visual and undetected damage that may lead to device failure or breakage during use. Even cosmetic changes in the device can sometimes impact its use (e.g. loss of color-coding marks).
- A growing concern is the impact of decontamination on the environment. On the positive side, decontamination reduces the risks of general public exposure to contamination. But equally it requires the use of energy (e.g. generation of steam or use of an automated washing-disinfection process), water and many different types of chemicals. The negative effects of these chemicals need to be minimized, particularly in the use and disposal of chemicals that have a minimum impact on the environment. There are other issues that may need to be considered, such as costs, but these are secondary to the primary aim of patient and staff safety.

Given the range of potential decontamination issues in healthcare facilities, various methods may be considered acceptable to ensure safety. First, inanimate objects are treated separately to animate (or living). Consider, for example, the various types of physical and chemical antimicrobial methods that can be used on medical and surgical devices; these will include various heat and/or chemical methods, but many of these could not be safely used on the skin. Disinfection of skin (“antisepsis”) can include the washing of hands and the preparation of the skin for an injection or surgical incision. Only a limited number of antimicrobial methods may be used, due to the sensitive nature of the skin. Therefore, the decontamination of the skin (and mucous membranes) is considered separate to various “hard” surfaces such as tables, benches and surgical devices. Second, different classification systems can be used that define the level of decontamination that is applicable depending on the use of the surface, device or instrument. The most widely used classification for medical/surgical devices is known as the Spaulding classification (as introduced briefly in the previous section). During the 1950s, Dr Earl Spaulding defined the minimum levels of disinfection/sterilization to be employed according to the infection risk associated with a device/surface when used with a patient. It was

assumed that the first step was to ensure that the surface was visually clean; this was to ensure the effectiveness of any antimicrobial process/product in reducing the level of soil or dirt that could interfere with their activity. The required use of the device then dictates the recommended antimicrobial process:

- Non-critical devices or surfaces are considered to have the lowest risk to patients, being any surface that only contacts intact skin. Examples could include table tops, bedrails and chairs, as well as some medical devices such as stethoscopes and blood-pressure monitoring cuffs. For such non-critical devices, cleaning alone may be sufficient (to physically remove microorganisms and visual signs of soiling). In other cases, disinfection (to a low level) may be recommended, encompassing certain types of viruses (especially enveloped viruses such as influenza and HIV), most bacteria and some fungi. Cleaning and disinfection may sometimes be achieved in a one-step process, but is most often achieved using a two-step process of cleaning followed by disinfection. Remember, disinfection only reduces the level of microorganisms present and is not expected to completely remove all microorganisms.
 - Semi-critical devices pose a higher risk as they may come into contact with mucous membranes or non-intact (broken) skin. These devices may include a variety of endoscopes, probes or even re-usable thermometers. In these cases disinfection is recommended as a minimum, but to a higher level to ensure the inactivation of a wider range of microorganisms. This would include certain types of microorganisms that are considered much more difficult to inactivate. To ensure efficacy, cleaning is a necessary first step, followed by disinfection.
 - Critical devices pose the highest risk as they enter or have contact with a normally “sterile” (or microorganism-free) area of the body, such as the blood or tissue. Sterilization is recommended for these devices. Sterilization is a process used to render a surface or product free from viable microorganisms, including bacterial spores. Sterilization therefore includes disinfection, but provides a great level of safety.
- Note that in this system a device can change its classification depending on how it is used with a patient. For example, the same device may be critical when used for a surgical procedure or semi-critical if used for a non-invasive diagnostic purposes. Although other classification systems may be used (e.g. class 1, 2a, 2b and 3), the Spaulding classification is a practical and widely used system worldwide. Examples of other systems include the classification of antiseptics as being used with water (e.g.

soap-based hand washes) or without water (“waterless”, such as alcohol hand rubs) or for use for routine hand hygiene, higher risk applications (such as in preparation for surgery by surgeons, using surgical scrubs or on patients using a pre-operative skin preparation antiseptic) and even therapeutic applications (such as treatment of skin acne or fungal infections).

These exact requirements ensure the safety and effectiveness of cleaning, disinfection (including antiseptics) and sterilization products/processes, which vary from country to country and region to region. Various different guidelines, standards and regulations can be consulted or are even required to be followed to ensure such products/processes are effective. These will include compliance to international standards (section 1.6), standardized test methods (for antimicrobial efficacy and toxicity), routine or periodic tests and compliance to local registration requirements. As these can vary considerably, particular care should be taken by those purchasing or using decontamination products to ensure that they do provide the required level of safety.

The decontamination process

A summary of the decontamination process for patient-used devices, instruments and materials is given in Figure 1.1.

Healthcare devices can be classified in a variety of ways, such as purpose of use, materials of construction and the risk of contamination/infection transmission to a patient (as defined by the Spaulding classification, in the previous section). A further classification is if the device is for single use (on a single patient) or re-use (with many patient). A single-use device can be simply defined as a device that has been designed and provided by a manufacturer to be used on a single patient. These are usually discarded following use on that patient, although in some cases this may be used once or a limited number of times but with the same patient. A re-usable device has been designed to be used on a patient, decontaminated and then used again.

This can be repeated many times with the use of the device until it is no longer needed, damaged, unsafe to use or otherwise replaced. The emphasis is therefore placed on ensuring that the device is safely handled and decontaminated between patients. The decontamination cycle describes this process as used in healthcare facilities today. Devices enter the cycle as either new devices

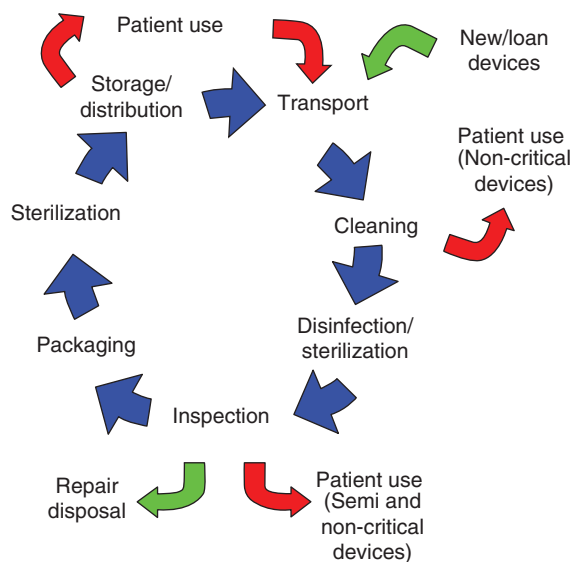


Figure 1.1 The decontamination cycle.

provided by a manufacturer (that need to be prepared for use for the first time) or following clinical use. The various steps in the process are briefly discussed here and in more detail in the subsequent chapters of this book. They include:

- Post-procedure handling and transport (Chapter 7). Medical or surgical procedures using devices and materials can be performed in various locations within a healthcare facility. Post-procedure it is important that these are handled correctly to ensure that they are not damaged or lost and do not pose any safety risks to staff, visitors and subsequent patients. They should be sorted (e.g. disposable from non-disposable items) and then safely contained and transported to an area designated for decontamination. This can be within the same room, a separate room/area or even at another facility.
- Cleaning (Chapter 8) is the removal of contamination (or “soil”) from an item to the extent necessary for its further processing and its intended subsequent use. This may include the removal of various materials such as patient materials (blood, tissues, etc.), microorganisms and even different chemicals used during a procedure (e.g. cements, gels, etc.). Cleaning may be the only decontamination step required (e.g. for some non-critical devices/surfaces), but is always a required step before any further decontamination steps in the cycle (such as disinfection and/or sterilization).
- Disinfection (Chapter 9) is the antimicrobial reduction of microorganisms from a surface to a level determined

to be appropriate for its intended further handling or use. Various different levels of disinfection may be required, depending on the risk associated with the device/surface. In some cases, sterilization may be directly applied at this stage as an alternative to disinfection and for immediate use with/or a patient. Again, many devices may leave the decontamination cycle at this stage, for patient use (following some inspection to ensure they are safe for use). Disinfection may also be conducted at this stage to allow for staff to safely handle devices in preparation for sterilization.

- Inspection and packaging (Chapter 10). Prior to direct patient use or further decontamination, instruments or materials are checked for cleanliness and functionality. Devices may be identified at this point for repair or even disposal (although this may occur at any stage during the decontamination cycle). They may then be safely transported to a site of patient use or for further assembly/packaging in preparation for sterilization. Packaging is designed to protect a single device or set of assembled devices during sterilization, storage and transport, for future use with or on a patient. Surgical devices are generally assembled into dedicated trays designed for specific types of surgical procedures (Chapter 3).
- Sterilization (Chapter 11) is a process used to render a surface or product free from viable organisms, including bacterial spores. Following sterilization, devices may be transported for direct patient use or stored until required for a specific procedure.
- Storage and distribution (Chapter 12). The correct storage (if applicable) and distribution of re-usable devices is an essential step to complete the decontamination cycle.

Other considerations in this cycle will include the acquisition of devices and raw materials, and the handling of wastes. In addition to these specific decontamination steps and sections, further consideration is given in this book to various background subjects that are important, such as:

- Human anatomy and physiology (Chapter 2)
- Various different types of medical and surgical procedures (Chapter 3)
- The variety of medical and surgical devices used (Chapter 4)
- Principles of microbiology and infection prevention/control (Chapter 5)
- Basic understanding of chemistry and physics (Chapter 6)
- Safety considerations (Chapter 13)
- Management principles (Chapter 14)

The design of a decontamination area

Decontamination (or reprocessing) areas may be at or adjacent to the procedure area (e.g. a theatre sterile services unit, TSSU, or decontamination room/area), at a remote location within the hospital (e.g. a central sterile services department, CSSD, or decontamination service departments) or even at a completely different facility (e.g. a “super-center” or contract sterilization facility). Despite the location, the primary purpose of the area, department or facility is to ensure the safe reprocessing of devices. It should be dedicated and appropriate for that purpose. The area should be designed to:

- Allow for the safe reprocessing of devices and/or materials, should they require cleaning alone; cleaning and disinfection; or cleaning, disinfection and sterilization, as examples. Safety considerations should include patient as well as staff and visitor risks.
- Ensure it can meet the workload demands to maintain a supply of re-usable devices. This will include budget, available space, equipment and staffing requirements.
- Reduce the risk of accidental mixing of “dirty”, “clean” or disinfected/sterilized devices or cross-contamination. This can be achieved by workflow design.

An important factor in running an effective decontamination service is good area design and workflow. Workflow must always be from dirty to clean to disinfected/sterile. Such workflow systems are designed to prevent the accidental mixing of dirty and decontaminated devices/materials. They may be part of a room, a dedicated room or a whole, purposely build decontamination department. Examples of area layouts that highlight such workflows are shown in Figure 1.2.

To maintain good workflow implies proper functioning and coordination between the various distinct decontamination areas. These include:

- “Dirty” area: here devices/materials are received, disassembled and washed. For washing the area will include at least a manual cleaning area, but consideration should also be given to include automated washer or washer-disinfectors. For manual cleaning, a double (two) sink arrangement is optimal, one for cleaning and one for rinsing. Automated washers or washer-disinfectors are often preferred and can be provided as single or double-door designs (the latter to allow for physical separation of the dirty and clean areas of the decontamination area).
- “Clean” area: cleaned, and often disinfected, devices/materials are inspected and reassembled for use and

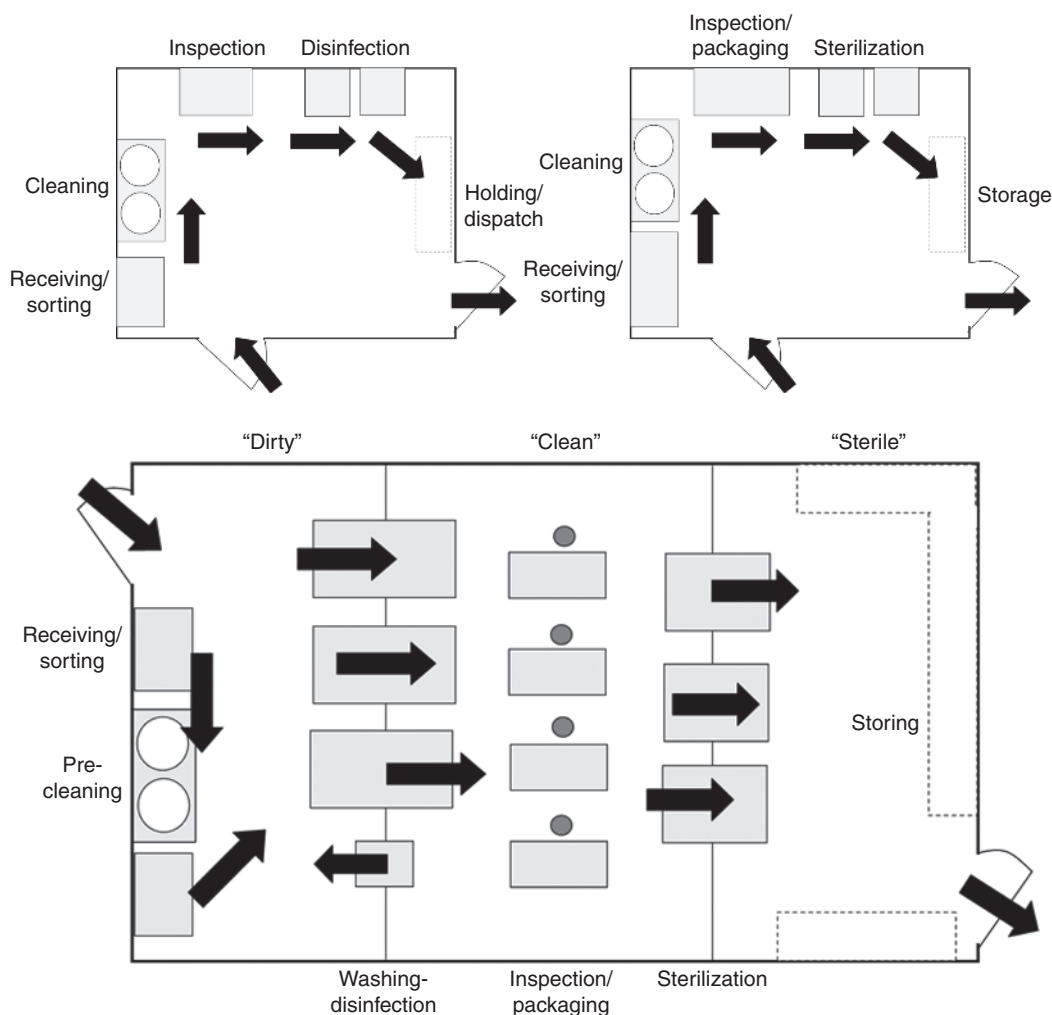


Figure 1.2 Examples of decontamination area/facility workflow plans. On the upper panel are examples of single rooms for cleaning-disinfection (left) and cleaning-sterilization (right). In the disinfection example, devices are received in one area, passed through the process and held in a separate area waiting for release for the new patient procedure. The sterilization example is identical, but in this case the devices/sets are packaged, sterilized and stored ready for patient use. The lower panel shows a typical physically separated area design,

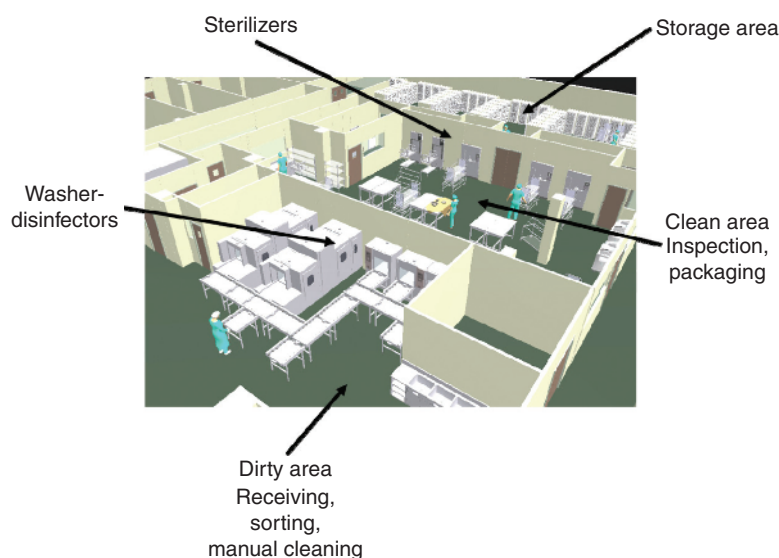
designated areas for receiving/pre-cleaning, cleaning-disinfection, inspection-packaging, sterilization and storage. Physical separation in this case is enabled by using two-door designs of washer-disinfector machines and sterilizers (that open on one end for loading and on the other for unloading); note that an additional pass-through hatch is shown between the clean and dirty area, to allow for devices that have not been adequately cleaned to pass back to the dirty area for additional cleaning.

subsequently packaged for sterilization (if applicable). There may be provisions made for specific transfer methods (e.g. transfer hatches) between physically separated department designs (Figure 1.2).

- Sterilization area (if applicable), where devices/materials are subjected to a sterilization process.

- Processed goods storage and distribution: this may be at the same area or in a separate, designated area of the facility (e.g. with other sterile stores). Serious consideration should always be given to the correct layout of a decontamination area/facility. Too often decontamination areas are found to be inadequate.

Figure 1.3 The layout of a modern decontamination facility, designed to have physical separation between dirty, clean and sterile storage/dispatch areas.



The area should be designated for decontamination purposes only (e.g. not mixed with food or drink preparation areas) and of ample size for the required procedures/workload. These can include single or multiple room/area designs (Figure 1.2). In single room set-ups, correct layout and staff training is essential to prevent cross-contamination. These risks are minimized in larger, physically separated area designs (Figure 1.3). It is important to remember that in addition to the receiving, decontaminating and storage/dispatch of re-usable devices/materials, provision should also be made for the handling of supplies or raw materials for the decontamination process. This will include chemicals, packaging materials (single use or re-usable), labels, indicators, etc. Equally, the area can have many items (contaminated or non-contaminated) that will be designated for waste disposal and will need to be considered. Finally, any equipment within the area (and their associated utilities such as electricity, water/steam supply, drainage, etc.) will require periodic maintenance and testing; therefore access to such equipment should be considered and with minimum disruption to the decontamination needs of the facility.

There are many other environmental concerns to be considered in the design of a decontamination area. These include:

- Access to the area should be limited and controlled. This should prevent any unauthorized person from entering the area without permission.
- Comfort of staff: temperature and humidity control (air conditioning), in particular in areas where heat-associated

equipment (such as steam sterilizers and thermal washer-disinfectors are used), is preferred. Consideration may also be given to ensure there is adequate lighting (preferably natural) and noise control.

- Ventilation: the cleaning area, in particular with manual cleaning, can pose a safety risk to staff and visitors (from microorganisms, patient tissues and various chemicals used in the cleaning process). These areas should be adequately ventilated, so as to provide ~20 air changes/hour. It is also recommended that these areas should have dedicated air handling systems and be maintained at ambient pressure or even at a slight negative pressure (e.g. -5 to -10 Pa) that acts to keep contamination within the area. Equally, the clean or sterile packaging area should also be similarly ventilated (~20 air changes/hour), reducing any risks of airborne contamination and under a slightly positive pressure (e.g. +10 Pa) to keep contamination out.
- The area should be designed to allow for periodic ease of routine cleaning or, particularly in dirty areas, for handling of accidental spillages.
- Sterile or otherwise decontaminated items should be stored in a suitable area designed to reduce any potential for cross-contamination such as from the air, water, damage, etc.
- Staff/visitors should have access to hand washing facilities, separate to those used for cleaning devices, before entering or leaving the areas.
- For larger facilities/departments, provisions may need to be made for management offices, general staff areas (for eating and drinking) and storage that are separated from the decontamination area.

An effective management system should be in place to control the entire decontamination system, from patient use to the next patient use. This may require a coordinated effort from all staff involved, particularly in larger facilities that will include operating room, transport, decontamination and inventory control staff, as examples. For the decontamination process, written procedures should be in place and staff trained on these procedures to ensure that the various decontamination steps are conducted correctly. Once in place, deviations to established procedures should not be tolerated. If deviations are demanded by medical/surgical staff due to patient needs it is recommended that written authorization is obtained from management that accepts any associated patient risk.

For an effective decontamination, other considerations to be considered will include:

- Adequate water supply: this will include cold and hot tap (potable) water, and may also include the provision of a higher water quality for rinsing and other purposes (e.g. for generation of steam). Water, and the various types of chemicals and other materials that can be present in it, can play an important role in the decontamination of devices and patient safety.
- Sufficient draining, with consideration of any local or regional requirements regarding disposal of chemicals or other materials into drains.
- Automated decontamination processes (for cleaning, disinfection and sterilization) are preferred over manual methods. Any equipment provided should be installed correctly and verified to be fit for purpose; for example any equipment that requires temperature control should be routinely checked to ensure it is working at the correct, set temperatures, and only authorized staff should be able to change cycle parameters. Equipment will require periodic maintenance and testing.
- Staff and visitor safety is important: safety equipment (personal protective equipment (PPE)), such as safety glass and proper gloves (e.g. heavy duty for cleaning) should be provided and used. Specific safety equipment will depend on the various procedures or equipment being used within the area.
- International, regional and local guidelines regarding decontamination should be considered.

A correctly designed decontamination area is the first step to ensuring patient safety, but is closely followed by staff training. Designated staff should be trained on the correct procedures (including equipment used) for decontamination within the area and have sufficient allocated time to ensure a quality process. It is important that

training should be conducted when any changes in these procedures are made, such as the introduction of new equipment, chemicals, devices, etc. Periodic re-training should also be considered to ensure that standards are maintained.

Where to start

This book provides a practical guide to decontamination principles and practices from an international perspective. As introduced in the previous section, this includes many background concepts to the subject, such as an introduction to anatomy, chemistry and microbiology, as well as detailed consideration of the various steps of the decontamination process. This book should be used in conjunction with available international, regional and local regulations, standards and guidelines. These will include various aspects of decontamination, including quality control, the design of decontamination facilities, minimal steps for device/materials reprocessing, waste disposal, use of chemicals, selection of equipment and their use, etc.

Regulations are rules or orders issued by a region, country, community or administrative agency, under legal authority, and have the force of law. Depending on the region or country you live in, there may be various laws or directives concerning the safe use of medical/surgical equipment, as well as various products and processes used for their decontamination. Examples, at the time of writing, include:

- European Union (note that **CE** mark stands for *Conformité Européenne* or “European conformity”, which when attached to a device is a manufacturer’s claim that it meets all the requirements of applicable European legislation). This can vary depending on the type of product, with examples including:
 - Medical Device Directive (the most recent version being 2007/47/EC). This directive covers the essential requirements for any medical device, defined as any instrument or other article (used alone or in combination) intended to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease. Medical devices are further sub-classified based on their risk to patients, ranging from class 1 (low risk, such as beds and wheel-chairs), class 2a (low-medium risk, such as hearing aids), class 2b (medium-high risk, such as many surgical devices and equipment used to reprocess them like sterilizers and washer-disinfectors) and class 3

(e.g. implants like heart valves). Equipment and products used in the reprocessing of devices (disinfectants, sterilizers, etc.) are also considered “medical devices” under this directive. The manufacturer, with reference to the “essential” requirements of the directive as well as other standards (international and/or European) that are specific to the types of device/equipment, ensures compliance and should provide a certificate (or “declaration”) of conformance. In most cases this is reviewed and approved by an independent organization known as a Notified Body. Note that a separate directive may be in place for specific types of medical devices, such as the Active Implantable Medical Devices (including pacemakers) under Directive 90/385/EEC.

- Machinery Directive (2006/42/EC), defining essential health and safety requirements for machinery. “Machinery” is any assembly using moving parts and therefore would apply to equipment like washers and sterilizers. Compliance is similar to that described for the medical devices directive.

- Biocidal Products Directive (98/8/EC). “Biocides” are defined active substances/preparations supplied to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any harmful organism. Interestingly, this includes the use of chemical disinfectants/sterilants using on general surfaces, but excludes their specific use on medical devices (as when used as such they are required to meet the requirements of the medical devices directive). In addition to these essential requirements, at the time of writing a series of specific test methods are under development in Europe that should be used to confirm any efficacy claims (e.g. kills bacteria or viruses) used with disinfectants (these are discussed in further detail in Chapter 9).

- REACH (Registration, Evaluation and Authorization of Chemicals; Regulation (EC) 1907/2006). Regulation on the production and use of any chemical, with an emphasis on human and environmental health. This would include a wide range of chemicals used, for example in cleaning chemistries or chemical disinfectants. Other directives/regulations apply to specific types of chemicals such as biocides (98/8/EC, as discussed above) and detergents (regulation (EC) 648/2004).

These directives are applicable for all EU countries and compliance allows for the devices to be legally sold in all countries; however, in some cases additional requirements can be put in place in individual countries.

- United States of America (USA):

- The Federal Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH) is responsible for regulating those who manufacture, repackage, re-label, and/or import medical devices sold in the United States. Medical devices are classified based on their risk, to include class 1, 2 and 3 (from low to high risk). These include surgical devices and decontamination processes such as washer-disinfectors, sterilizers and device disinfection chemistries. Class 2 (such as sterilizers and device disinfectants) and class 3 devices, specifically, require a formal approval by the FDA known as a Premarket Notification 510(k) or Premarket Approval (PMA). In either case, the safety and efficacy of a product/process is reviewed and formally approved prior to selling in the USA. The FDA also provides guidance documents to manufacturers regarding device/process specific requirements, such as for sterilizers, high-level disinfectants/sterilants and reprocessing instructions.

- The Environmental Protection Agency (EPA) regulates the use of general/environmental surface disinfectants under Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Note: any disinfectants used on medical devices are registered for use in the USA by the FDA, while those for environmental surface disinfection should be registered by the EPA. They refer to biocides or antimicrobial chemistries as “antimicrobial pesticides”. The EPA requires that special tests (such as those described by AOAC International) are used to ensure disinfectant efficacy, as well as or any human and ecological risks from exposure. The EPA also provides guidance documents on various aspects of disinfectant registration, such as testing for specific antimicrobial claims and dental issues.

- Australia:

- The Therapeutic Goods Administration (TGA), a division of the Department of Health and Ageing, is the regulatory authority for therapeutic goods, including medical devices and their reprocessing methods. Medical devices are registered under the Therapeutic Goods (Medical Devices) Regulations (2002). All products are required to be listed in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. The Office of Devices Authorization (ODA) is responsible for initial registration of medical devices, while the Office of Product Review (OPR) is responsible for any post-registration issues. Devices are also classified based on risk ranging from low (class 1) to high (class 3 or active implantable devices

separately). Device disinfectants, for example, are considered class 2b devices. Liquid chemical disinfectants and sterilants, for example, are regulated under Therapeutic Goods Order No. 54 (1996), but this excludes antiseptics (disinfectants used on the skin) and water treatment. The TGA also provide various guidance documents such as infection control guidelines for the prevention of transmission of infectious diseases and reducing public health risks associated with re-usable medical devices.

- Canada:
 - Medical Devices Regulations are under the authority of the Food and Drugs Act. Health Canada reviews all medical devices to assess their safety, effectiveness and quality before being authorized for sale in Canada. Medical devices are classified based on risk, ranging from class 1 to class 4. For example, equipment/products used for disinfecting or sterilizing a medical device are classified as class 2. Health Canada also provides guidelines such as for reporting problems with medical devices.

As can be seen from this brief but not exhaustive review, the specific requirements can be complicated and are regularly updated or changed. These laws/directives generally control the legal marketing and use of medical/surgical devices, as well as requirements for decontamination, within those specific areas. It is the responsibility of the healthcare facility to understand these requirements and ensure that they are correctly applied. Many of these regulations are general and include specific requirements in further standards and guidelines. Examples of various standard/guideline organizations are shown in Table 1.1.

Standards are documents that specify the minimum acceptable characteristics of a product or material, issued by a standards organization (e.g. ISO, International Organization for Standardization and CEN, European Commission for Standardization). Most countries will have some legal requirements, directly or indirectly, regarding decontamination of re-usable devices/materials; these may or may not include such standards within a given country/region. International standards (such as those developed by ISO) are continually under development for various different aspects of decontamination procedures and practices. A summary of some of these standards is provided in Table 1.2. Other regional (e.g. CEN within Europe) and local standards and best practice guideline documents are also important to consider, and are often mandated in certain countries (Chapter 14). Guidelines are documents used to

communicate regional recommended procedures, processes or usage of particular practices; they are often considered best practice at the time of writing. During the course of this book, various different standards and guidelines are referenced for each phase of the decontamination cycle.

A particularly important standard that should be considered in decontamination is ISO 17664 (2004) *Sterilization of medical devices – information to be provided by the manufacturer for the processing of re-sterilizable medical devices*. Although it is the responsibility of a healthcare facility to safely decontaminate re-usable items, it is the responsibility of the suppliers of these items to provide detailed instructions on how they should be safely reprocessed. These instructions should be verified as being effective by the manufacturer. The title of this standard does specifically apply to “resterilizable medical devices”, but it is a useful and practical reference for all re-usable devices/materials (e.g. for cleaning alone or cleaning/disinfection). Instructions provided should include:

- The device manufacturer and their contact information.
- Device(s), by model number and device description or generic type.
- Any appropriate warnings or limitations, such as care on handling (e.g. sharp edges), restrictions on reprocessing conditions (e.g. “cannot be immersed in water” or “electrical hazard”).
- Instructions on handling the device at its point of use and for transport to a decontamination area. Examples include inspections, pre-cleaning, care in handling, etc.
- Instructions on preparation for decontamination, including disassembly. The use of specific tools and procedures may need to be described, depending on the device design.
- Cleaning instructions, manual and automated. This will include the cleaning chemistries and procedures to be used. At a minimum, a manual cleaning method should be described in detail. A further automated cleaning should be described, although this is sometimes not possible due to the device design.
- Disinfection (if applicable). Manual and automated procedures should be described, unless automated processes cannot be employed. This should include applicable thermal and/or chemical disinfection methods, equipment required and requirements for rinsing (in particular with chemical disinfection to ensure the device is safe for patient use or further reprocessing).
- Drying (if applicable). Instructions for the drying of the device should be provided.

Table 1.1 Examples of various standard and guideline publishing organizations internationally. This list is by no means exhaustive.

Title	Notes
International Standards Organization (ISO)	A non-governmental, international body based in Geneva, Switzerland. Develops draft standards through technical committees (e.g. ISO/TC 198 <i>Sterilization of healthcare products</i>) that are then approved by a majority of country (national) member bodies ¹ . ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization and with CEN on harmonized international standards ² .
Comité Européen De Normalisation (CEN). European Committee for Standardization	A not-for-profit European organization based in Brussels, Belgium. Develops draft standards through technical committees (e.g. CEN/TC 204 <i>Sterilization of medical devices</i> and CEN/TC 216 <i>Disinfectants and antiseptics</i>) that are then approved by European country (national) member bodies ³ . CEN collaborates closely with CENELEC (Comité Européen de Normalisation Électrotechnique; European Committee for Electrotechnical Standardization) on matters of electrotechnical standardization and with ISO on the development of harmonized international standards ² . 
British Standards Institute (BSI)	National standards body in the UK. BSI also use the “kite mark” to indicate that a product has been independently tested to conform with a relevant British Standard.
(DIN)	National standards body in Germany.
Association Française de Normalisation (AFNOR)	National standards body in France.
American National Standards Institute (ANSI)	National standard and guideline bodies in the USA. AAMI develop standards and recommended practices, with many being approved by (ANSI) as American National Standards. For example, a TIR (Technical Information Report) provides guidance on a particular aspect (e.g. use of disinfectants/sterilants or water quality).
Association for the Advancement of Medical Instrumentation (AAMI)	
ASTM International (previously known as the American Society for Testing and Materials, ASTM)	Standards body in the USA, particularly in the development of test method (e.g. chemical and microbiological) standards.
AOAC International (previously known as the Association of Analytical Communities (AOAC))	Standards body in the USA, particularly in the development of test method (chemical and microbiological) standards.
Standardization Administration of China (SAC)	Standards body in China. Mandatory standards are prefixed with “GB”, while recommended standards are prefixed “GB/T”
Standards Australia	Standard bodies in Australia and New Zealand. Joint Australian (AS) and New Zealand (NZS) Standards and Guidelines are often developed (known as AS/NZS). An example is AS/NZS 4187 (2003) on cleaning, disinfection and sterilization of re-usable devices in healthcare facilities.

¹ Examples of national standard bodies include BSI (UK), AFNOR (France), DIN (Germany) and AAMI (United States), see above.

² The Vienna Agreement (1991) is an agreement on technical cooperation between ISO and CEN in the development of standards. As an example, ISO/TC 198 *Sterilization of healthcare products* and CEN/TC 204 *Sterilization of medical devices* cooperate to develop harmonized standards in the reprocessing or sterilization of devices. An example of a harmonized standard is EN ISO 14937 *Sterilization of healthcare products – general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*. Despite these efforts, sometimes the standard is not adopted in all countries or modifications of the standard are made/published by the national standard body.

³ CEN members are the national standards bodies of different European countries. Members should comply with the CEN/ CENELEC regulations that stipulate a European Standard should be given the status of a national standard without any alteration.

Table 1.2 Examples of international standards that consider various decontamination aspects. These may or may not apply to a given region or country.

Standard Number ¹	Title	Description
ISO 13485 (2003)	<i>Medical devices – quality management systems – requirements for regulatory purposes.</i>	The requirements for the development, implementation and monitoring of a quality management system for the manufacturer of medical devices. Generally for device manufacturers, but can also apply to healthcare facilities decontaminating devices.
ISO 17664 (2004)	<i>Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices.</i>	Instructions to be provided by the device manufacturer to ensure safe reprocessing/decontamination of the device of re-use.
ISO 15883-1 (2005)	<i>Washer-disinfectors. General requirements, definitions and tests.</i>	Design, performance and testing of washer-disinfectors, including cleaning and disinfection requirements. Provided in a series, part 1 describes the requirements for all washer-disinfectors and subsequent parts provide more details on specific types of machines (e.g. surgical instruments and flexible endoscopes).
ISO TS 15883-5 (2005)	<i>Washer-disinfectors. Part 5: test soils and methods for demonstrating cleaning efficacy of washer-disinfectors.</i>	Technical specification that provides information about various methods used around the world to test cleaning efficacy.
ISO 9398 series	<i>Specifications for industrial laundry machines.</i>	Series of standards on laundry machines, including definitions, testing of capacity and consumption characteristics.
ISO 14937 (2009)	<i>Sterilization of healthcare products – general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.</i>	Development, validation and routine control of any sterilization process used for healthcare devices and other materials.
ISO 17665-1 (2006)	<i>Sterilization of healthcare products – moist heat. Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices</i>	Development, validation and routine control of moist heat (steam) sterilization processes for devices.
ISO 20857 (2010)	<i>Sterilization of healthcare products – dry heat – requirements for the development, validation and routine control of a sterilization process for medical devices</i>	Development, validation and routine control of a dry heat sterilization process for devices.
ISO 11135-1 (2007)	<i>Sterilization of healthcare products. Ethylene oxide. Part 1: requirements for development, validation and routine control of a sterilization process for medical devices.</i>	Development, validation and routine control of an ethylene oxide sterilization process for medical devices.

¹International standards, as published by ISO, are designated by a specific number, but also the date or issue (as they are periodically updated). When (and if) the standard is accepted regionally or within a specific country it may be designated, for example BS EN ISO xxxx (designated a harmonized standard for the United Kingdom, European Union and International) or AMMI ISO xxxx (designates a USA-AAMI version of an international standard); note, in such cases modifications, specific to that region or country, may be included before publication in these areas. All attempts are made internationally to harmonize such standards, but at the time of writing this is not always possible.

- Maintenance, inspection and testing. This will include instructions for periodic testing, lubrication, inspections, etc., to ensure that the device can be safely used on the next patient.
- Packaging (if applicable), in preparation for storage and/or terminal sterilization.
- Sterilization (if applicable). At least one method of sterilization should be provided, but the instructions may also include restrictions on what should or should not be applied, such as “should not be immersed”, not subjected to low pressure levels or should not exceed certain temperatures.
- Storage. Any recommendations for the time or conditions of storage prior to use, if required.

Reprocessing instructions are essential in order to ensure patient safety. They require close cooperation between medical/surgical device manufacturers, those using the devices and the suppliers of cleaning, disinfection and sterilization products/processes. Although it is often difficult for manufacturers to provide detailed instruc-

tions to meet individual requirements for each country, it is important that they consider local decontamination standards and guidelines. In the absence of adequate instructions, it will not be possible to ensure patient safety and the healthcare facility may decide not to use such devices/materials.

In conclusion, this book has been written for a wide interdisciplinary, international audience, and whilst it discusses the basic principles of decontamination and related guidelines, it should not be used as a replacement for local legislative or guidance documents issued in respective countries or regions. However, regardless of your location, the same basic principles should be applied to decontamination practices throughout the world, using a combination of processes which include as a basic minimum adequate cleaning and disinfection or sterilization in order to render a re-usable item safe for further use on patients and for handling by staff. Decontamination of re-usable devices and materials is essential in minimizing the risk of transmission of infectious agents.