1 Introduction

What is device processing?

> As to diseases, make a habit of two things – to help, or at least 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 can have 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, effects of toxic chemicals, etc.). Infectious diseases are a leading cause of sickness and death worldwide. They are caused by living organisms that cannot be seen by the naked eye, known as "microorganisms," such as viruses and bacteria. It is estimated that infectious diseases that affect our breathing, digestive, and immune systems are responsible for ~17% of human deaths worldwide (the next highest cause of death is coronary heart disease at ~12%). These rates are averaged across the whole world, but are even higher in lower-income regions. Examples of advances in health efforts in the last 200 years in particular to reduce these risks in the general public include improving drinking water quality (chemical and microbiological), immunization practices (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, or if we have an existing sickness). 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. The prevention of harm is an important philosophy in medical practice and is the basis of the Hippocratic oath traditionally taken by medical staff stating "first, to do no harm" or in Latin *primum non nocere* (in Greek ὠφελέειν ἡ μὴ βλάπτειν), often attributed first to the Greek physician Hippocrates. Such procedures are collectively referred to as "safe" or "infection control/prevention" practices that prevent the spread of disease or other negative effects to or between patients (or to/from staff or visitors within these facilities). These practices include:

- Immunization.
- Isolation of patients with specific diseases.
- Hand hygiene.
- 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," "reprocessing," and "processing" 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 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 cotton fabrics).

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• Disinfection of water for drinking or sterilization of water and other liquids (such as saline or glucose) for injection or infusion into the body.
• Cleaning and disinfecting environmental surfaces such as table-tops, contact surfaces, floors, and bedrails.
• Sterilization of contaminated waste materials for safe disposal (including incineration or burning).

In some cases decontamination is a one-step process, for example sterilization of contaminated waste materials, but it is most often a two-step process to include cleaning (the physical removal of soil) and disinfection or sterilization (as the antimicrobial processes to inactivate the various types of microorganisms that we cannot see). For reusable 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. This was before a true understanding of the existence of microorganisms such as bacteria and viruses. 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, 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 Ebers 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, also 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 death and suffering (mortality and morbidity) in humans. It would take many thousands of years for the microbiological origin and reasons behind the 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, and as the source of the Hippocratic oath discussed earlier. He put this belief into practice when attempting to drive the plague (now know to be a bacterial disease) out of 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 reused, 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 were used) were also unknown at the time. 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 as holding 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 included 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' view 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. Unfortunately, the generation of pus in a wound (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 Theodoric 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 local 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 often 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. In Europe, following the fall of the Roman Empire in AD 467 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 (caused by a type of bacteria) 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 the Black Death; 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 surfaces (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 contact. In the 1670s Antonie van Leeuwenhoek is often considered one of the first microbiologists to observe individual, live microorganisms by using a simple microscope he designed. 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 (a type of acid). 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 Denis Papin developed the first recognizable steam-generating machine.
- In 1774 Carl Wilhelm 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 sulfate, zinc chloride, and sodium permanganate, acids, alkalis, sulfurs, and alcohols were recognized as disinfectants.

In the late 1840s Dr. Ignaz Semmelweis, while 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 Semmelweis, 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, contributed to this debate.

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 infection prevention 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 a growth liquid (food or 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 1700s–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 that disease. This became known as vaccination and was previously described by the Chinese, Indians, and Turks. Wortley Montagu 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, seasonal flu, and more recently COVID-19. Polio, a virus that can cause a serious disease, 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 (a bacterial disease); 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 antisepsis, 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 started applying phenol to compound fracture wounds; the wounds often 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 (1861–1865), Keen was one of the first physicians in the world to adopt aseptic surgical technique. Infectious disease was the cause of 90% of the deaths on both sides rather than direct death from military trauma. While bayoneting killed fewer 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" in either 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 and competitor of Pasteur, 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 bacterium *Mycobacterium tuberculosis*. Tuberculosis was estimated as 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 in 1881 (*Über Desinfection* or *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, Johannes von Mikulicz-Radecki 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 fewer 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 remain widely used for treating bacterial infections and also for preventing them (known as prophylaxis, such as when given prior to surgery). With increasing rates of antibiotic-resistant bacteria today, there is a refocus on efforts to prevent infection by isolating and eliminating any variable that could pose a risk, including decontamination practices.

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 processing 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 referred to by a variety of names, such as decontamination service (DS), central sterile services department (CSSD), sterile services department (SSD), sterile processing center (SPC), and theater 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 prevention and control nurses 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 infection prevention and control specialists 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 processing demands for traditional and advanced instrumentation. Safety requirements can include consideration of risks to the patient, those applying the technology (e.g. facility staff), devices or surfaces being treated, and the environment. But it is also important to note that disinfectants and sterilants kill different forms of life and can, when not controlled correctly, have negative impacts on human health.

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), acquired immune deficiency syndrome (AIDs)/human immunodeficiency virus (HIV), flu (influenza), hepatitis (e.g. hepatitis A and B viruses), 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 expand.

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. with the use of more invasive surgical procedures, types of drugs, etc.), there is a much greater emphasis than ever before on the prevention of infection. Decontamination and process practices play a central role in infection prevention strategies and ensuring patient safety.

Goals of decontamination and the Spaulding classification

Decontamination is the removal of contaminants to specified levels, and 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 endpoints of decontamination should include:

- 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 (e.g. toxins).
- To ensure that the decontamination process does not damage the device or surface 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 over time and during use. Even cosmetic changes in the device can sometimes impact its practical use (e.g. loss of color-coding marks or labeling).
- A final concern is the impact of decontamination on the environment. On the positive side, decontamination reduces the risks to the general public from exposure to contamination. But equally it requires the use of energy (e.g. generation of steam or use of an automated washing disinfection process), large quantities of water, and many different types of chemicals/materials. The negative effects of chemicals and materials 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 opportunities in healthcare facilities, various methods are considered acceptable under different situations to ensure safety. First, inanimate objects are treated separately to animate (or living) ones. 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 (or 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. The emphasis was on microbiological and infection risk. But it was clearly stated that the first step was to ensure that the contact surfaces were visually clean; this was to safeguard the effectiveness of any antimicrobial process/product, as the presence of soil or dirt can interfere with its 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, including the effectiveness against certain types of viruses (especially enveloped viruses such as influenza and HIV), most bacteria, and some fungi. Cleaning and disinfection may sometimes be performed in a one-step process, but are 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 reusable thermometers. In these cases, meticulous cleaning and disinfection are recommended, but at a higher level of disinfection to ensure the inactivation of a wider range of microorganisms. This would include certain types of microbes that are considered more difficult to kill, such as non-enveloped viruses (e.g. polio- or noroviruses), fungi, and mycobacteria. As before, 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. Cleaning followed by 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 greater 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 purpose. 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. with 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 antisepsis), and sterilization products/processes, which vary from country to country and region to region. 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 with international standards (see the section "Where to start"), demonstrating effectiveness using standardized test methods (for antimicrobial efficacy and toxicity), routine or periodic tests, and compliance with local registration requirements. As these can vary considerably, those purchasing or using decontamination products should take care to ensure that they do provide the required level of effectiveness and safety.

The decontamination process

A summary of the various processing steps for patient-used devices, instruments, and materials is given as a guide in Figure 1.1. The central cycle is typical for all devices, where non-critical or semi-critical devices can include disinfection steps, and semi-critical or critical devices can include sterilization (often but not always utilizing packaging to allow for sterile presentation immediately prior to use).

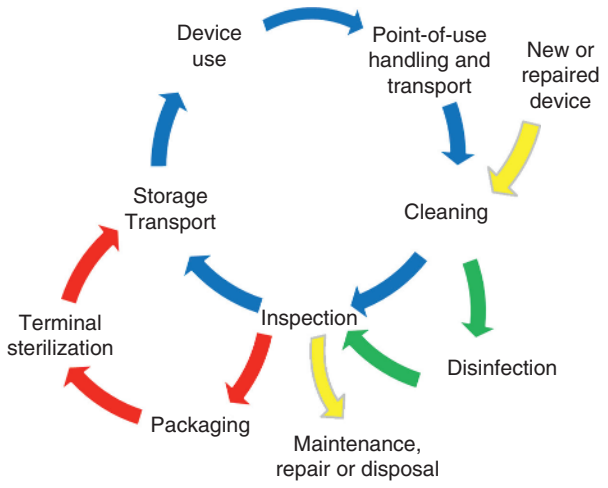

Figure 1.1 Processing cycle.

Healthcare devices can be classified in a variety of ways, such as their 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). Another classification is when the device is labeled for single use (on a single patient) or reuse (may be used with many patients). A single-use device can be defined as a device that has been provided by a manufacturer to be used on a single patient. These are usually discarded following use on that patient, although in some cases they may be used a number of times with the same patient. They can include implantable devices (devices that are inserted and maintained within the body that can be for a short time or in many cases for years). They can be provided immediately ready for use (e.g. already clean and sterile) or require processing prior to use.

A reusable device has been designed to be used on a patient, decontaminated (or processed), and then used again. Depending on the manufacturer's instructions, the number of reuse cycles can be defined and this can include a maximum number of times (e.g. 2, 5, or 10) or where the device is no longer needed, damaged, unsafe to use, or otherwise needs to be replaced. The emphasis is therefore placed on ensuring that the device is safely handled, decontaminated, and fit for purpose between patients. The decontamination cycle describes this process used in healthcare facilities. Devices can enter the cycle either as new from the manufacturer or as already used for their intended use. The various steps in the process are briefly discussed here and in more detail in the subsequent chapters of this book. They include:

- Point-of-use (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 include not being damaged or lost and not posing any safety risks to staff, visitors, and subsequent patients. This can include sorting (e.g. disposable from non-disposable items following surgical use) and then safely containing and transporting them to an area designated for decontamination. There may be specific pre-cleaning or safe handling instructions to be performed at this point. These steps are typically recommended to be done within the same area where they are used ("point of use"), but may be conducted in a separate, adjacent room/area or at another location.
- 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 can include the removal of 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). This is because soil can interfere with the effectiveness of these processes and can cause other patient risks. In some cases, such as with non-critical devices/surfaces, cleaning can be combined with disinfection.
- 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. Microorganisms can be very different in their structures, with some easier to kill than others. They also are different in their abilities to be able to cause problems to human health (e.g. their ability to cause disease). This will be considered in further detail. Different levels of antimicrobial activity (disinfection or sterilization) may be required, depending on the risk associated with the device/surface. In some cases only disinfection is used to render the device safe for use. In others disinfection is an interim step, being applied first (to reduce the risk of handling devices) and followed by packaging and sterilization. Sterilization may also be applied to the device without disinfection. If this is conducted without sterile packaging, the device is only safe for immediate use with or on a patient, as it can become recontaminated on storage or further handling. Many devices can leave the decontamination cycle at the disinfection stage for patient use (following some inspection to ensure they are safe for use and, where appropriate, interim storage).
- Inspection and, where appropriate, packaging (Chapter 10). Prior to direct patient use or further decontamination, devices or materials are checked for cleanliness, functionality, dryness, and so on. Devices may be identified at this point for repair or even disposal (although this may occur at any stage during the decontamination cycle, right up to the point of patient use). They may then be safely transported to a site of patient use or for further assembly/packaging in preparation for sterilization. Specifically, sterile 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. At this stage, surgical devices can often be assembled in dedicated trays designed for specific types of surgical procedures (Chapter 3). Note that there may be other practices where devices are covered or stored in various ways prior to use on a patient to prevent cross-contamination, but care should be taken to ensure that such practices are safe and effective.
- Sterilization (Chapter 11) is a process used to render a surface or product free from viable organisms, including those that are particularly hard to kill such as bacterial spores. Following sterilization, devices may be transported for direct patient use or, when correctly packaged, stored until required for the patient procedure.
- Storage and distribution (Chapter 12). The correct storage (if applicable) and distribution of reusable devices to the next point of use are essential to complete the decontamination cycle.

In addition to these steps in the decontamination cycle, the acquisition of devices and other materials used during the decontamination process is discussed, as well as the safe handling of wastes. Consideration is also given in specific chapters to basic principles that are important to decontamination practices, such as:

- Human anatomy and physiology (Chapter 2).
- 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 and quality principles (Chapter 14).

The design of a decontamination area

Decontamination (or processing) areas may be at or adjacent to the patient procedure area (e.g. a TSSU or decontamination room/area), at a remote location within the hospital (e.g. a CSSD or decontamination service departments), or at a completely different facility (e.g. a regional or contract sterilization facility). Despite the location, the primary purpose of the area, department, or facility is to ensure the safe processing of devices. It should be dedicated and appropriate for that purpose. The area should be designed to:

- Allow for the safe processing 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 reusable devices. This will include costs (budget), available space, equipment, and staffing requirements.
- Reduce the risk of accidental mixing of "dirty," "clean," or disinfected/sterilized devices or cross-contamination. This will include workflow design.

An important factor in managing an effective decontamination service is good area design and workflow. Workflow must allow for the logical flow of devices from being dirty to clean to disinfected/sterile. Such workflow systems are designed to prevent the accidental mixing of dirty and clean (or decontaminated) devices/materials. Such areas may be part of a room, a dedicated room, or a whole, purposely built decontamination department or facility. Examples of area layouts that highlight such workflows are shown in Figure 1.2.

Maintaining good workflow implies proper functioning and coordination between distinct decontamination areas. These include:

- "Dirty" area: here devices/materials are received, disassembled, and decontaminated. For non-critical equipment this can include cleaning and disinfection. For washing the area can include a manual cleaning area alone, but consideration should also be given to include automated washers or washer-disinfectors. For manual cleaning of semi-critical or critical devices, a double (two) or even triple (three) sink arrangement is optimal, one or two for cleaning and one for rinsing. Automated washers or washer-disinfectors are often preferred in these areas and can be provided as single- or double-door designs. Double-door designs allow for the physical separation of the dirty and clean areas of the decontamination area, where dirty devices enter on one side and exit on the opposite side, most commonly into a separate room.
- "Clean" area: cleaned, and most often disinfected, devices/materials are inspected in this area and reassembled or prepared for use. For semi-critical or critical devices this area is also used for packaging and subsequent sterilization (when applicable). There may be provisions made for specific transfer methods (e.g. transfer hatches) between physically separated department designs (for example for the return of devices that have been inspected and found not to be clean; 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 the layout of decontamination areas is found to be inadequate.

The area should be designated for device decontamination purposes only (e.g. not mixed with recreation or 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, standard procedures, and staff training are essential to prevent cross-contamination. These risks are particularly minimized in larger, physically separated area designs (Figure 1.3). It is important to remember that in addition to the receiving, decontamination, and storage/dispatch of reusable 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 reusable), labels, indicators, and so on. Equally, the area can have many items (contaminated or non-contaminated) that will be designated for waste disposal and will need to be considered. Areas will also be required to allow for staff to prepare themselves to enter/exit the different areas (e.g. gowning, washing hands, etc.). 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 present minimum disruption to the decontamination

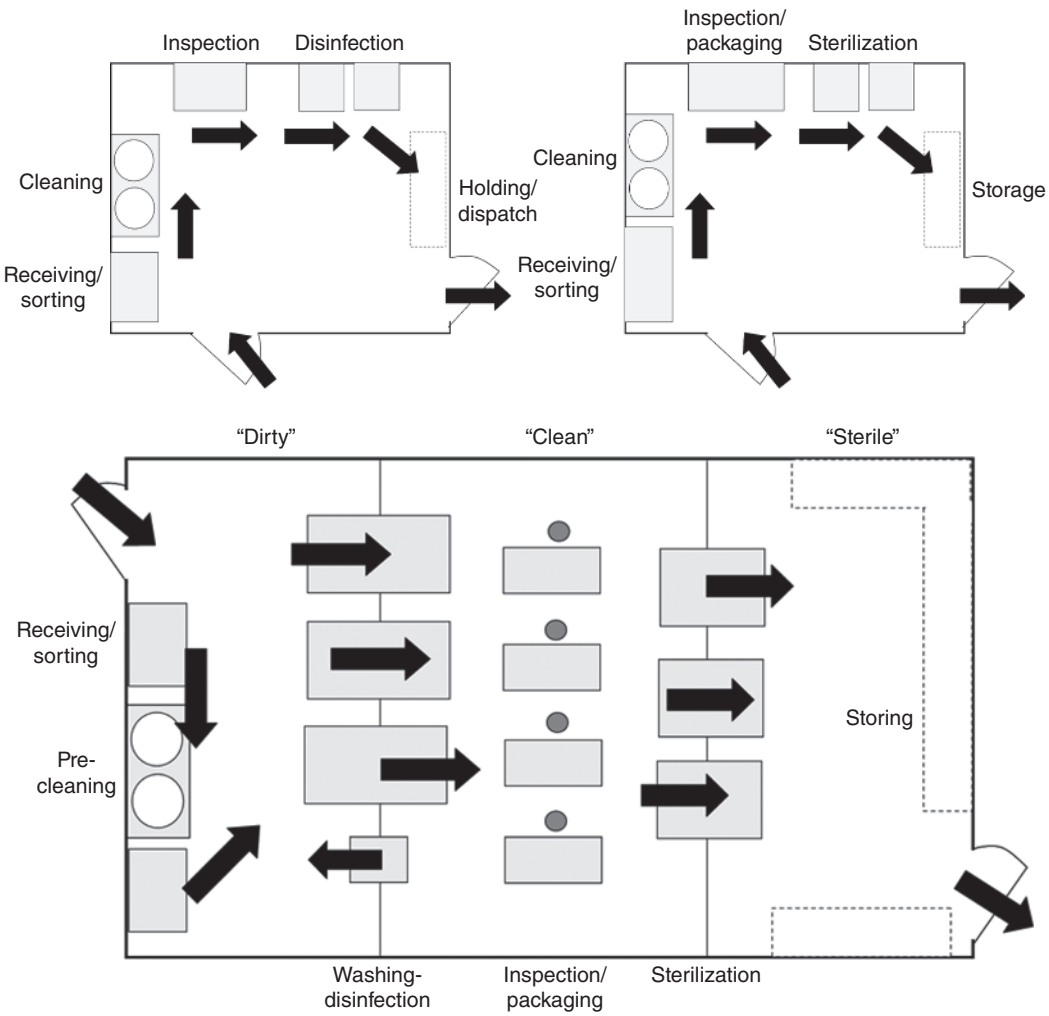

Figure 1.2 Examples of decontamination area/facility workflow plans. On the upper panel are examples of single rooms for cleaning–disinfection (left) and cleaning–sterilization (right). In the disinfection example, devices are received in one area, passed through the process, and held in a separate area waiting for release for the new patient procedure. The sterilization example is identical, but in this case the devices/sets are packaged, sterilized, and adequately 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 (which 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 areas, to allow for devices that have not been adequately cleaned to pass back to the dirty area for additional cleaning.

needs of the facility. It goes without saying that these utilities should be of the correct capacity and quality to meet the decontamination needs of the facility.

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

- 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 used. Consideration should also be given to ensure there is adequate lighting (particularly for inspection areas) and noise control.
- Ventilation: the cleaning area, in particular for manual cleaning, can pose a safety risk to staff and visitors (from microorganisms, patient tissues, and various chemicals used

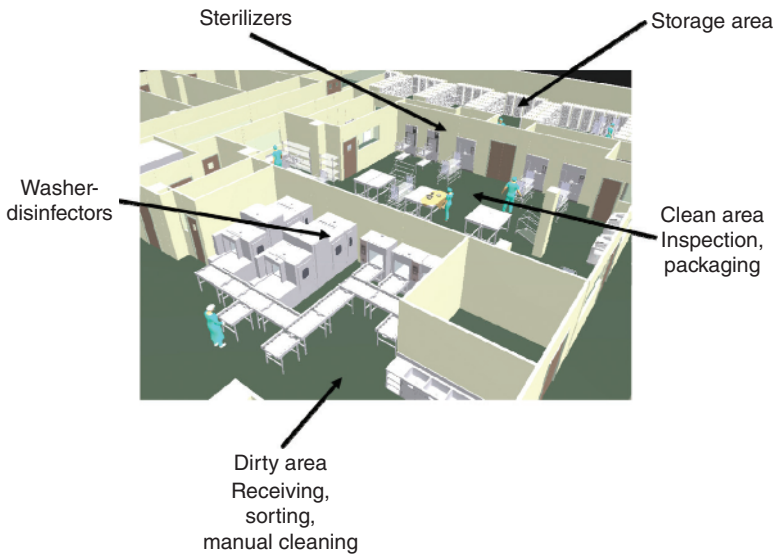

Figure 1.3 The layout of a modern decontamination facility, designed to have physical separation between dirty, clean, and sterile storage/dispatch areas.

in the cleaning process). These areas should be adequately ventilated, typically providing ~10–20 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 (~10–20 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 cleaning or, particularly in dirty areas, 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. Sterile packaged items may be compromised by exposure to extremes of temperature and humidity.
- 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 resting or 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 established procedures are in place, deviations to them 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. In many, if not most, countries these areas of healthcare facilities are considered regulated and therefore it is mandatory that specific controls and procedures are in place.

For effective decontamination, other considerations 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 safe decontamination of devices and patient safety.
- Sufficient draining or liquid waste disposal, 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 periodically 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 expected, 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/face shields 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 and standards regarding decontamination should be considered.

A correctly designed decontamination area is the first step to ensuring patient safety, but is closely followed by the second, staff training. Designated and qualified 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, and so on. Periodic retraining 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 local requirements for decontamination practices, including quality control, the design of decontamination facilities, minimal steps for device/materials processing, waste disposal, use of chemicals, selection of equipment and their use, and so on.

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 provision or use of medical/surgical equipment, as well as various products and processes used for decontamination. Examples, at the time of writing, include:

- European Union (EU). The CE mark (CE) stands for Conformité Européenne or "European conformity," which when attached to a device (or device labeling) 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:
  - The EU Medical Device Regulation (EU 2017/745, which replaced Directive 93/42/EEC on medical devices and Directive 90/385/EEC on implantable medical devices). This regulation 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, etc. Medical devices are further sub-classified based on their use and risk to patients. Examples of their use include duration of use (transient or <60 minutes, short term at 60 minutes to 30 days, and long term at >30 days) or being non-invasive, invasive, or implantable. Risk to patient classifications are rated from classes 1 to 3, with class 1 being lower risk and class 3 being higher risk. Similar (but often different) classifications are used in many other parts of the world. For the EU, class 1 devices are low risk, and either do not touch a patient or if they do only touch intact skin (similar to non-critical devices described earlier under the Spaulding classification system). Examples include beds, wheelchairs, and many types of reusable surgical instruments. Class II devices are separated into two subtypes and include many devices that contact injured skin or mucous membranes or invasive devices. Class IIa are considered low–medium risk, such as hearing aids and many types of surgically invasive devices intended for short-term use, and class IIb are medium–high risk, such as many surgical devices used to administer a medicinal product using a delivery system, or implantable devices. Class III are the highest risk and include many types of implantable devices such as those in direct contact with the heart, joint or spinal disc replacements, or many devices controlling or monitoring implantable devices. It is important to note that the classification of devices under the regulation is the responsibility of the manufacturer in collaboration with the local regulatory bodies, and the information given here is only a guide. Equipment and products used in the processing of devices (disinfectants, sterilizers, etc.) are also considered "medical devices" under this regulation (typically classes IIa and IIb). The manufacturer, with reference to the "essential" requirements of the regulation as well as other standards (international and/or European) that are specific to the type 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 separate regulations may be in place for specific types of medical devices, such as *in vitro* diagnostic medical devices under EU regulation 2017/746.
  - 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

on general surfaces, but excludes their specific use on medical devices (since when used as such they are required to meet the requirements of the Medical Devices Directive). In addition to these essential requirements, a series of specific test methods have been under development in Europe that should be used to confirm any disinfectant efficacy claims (e.g. kills bacteria or viruses). These methods are discussed in further detail in Chapter 9.

◦ REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals); Regulation (EC) 1907/2006. This regulation concerns 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 earlier) 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:
  ◦ The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for regulating those who manufacture, repackage, relabel, 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 are reviewed and formally approved prior to selling in the United States. The FDA also provides guidance documents to manufacturers regarding device/process-specific requirements, such as for sterilizers or high-level disinfectants/sterilants, and device processing validation requirements and instructions.
  ◦ The Environmental Protection Agency (EPA) regulates the use of general/environmental surface disinfectants under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Note that any disinfectants used on medical devices are registered for use in the United States by the FDA, while those for environmental surface disinfection should be registered by the EPA. It refers 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 for any human and ecological risks from exposure. The EPA also provides guidance documents on various aspects of disinfectant use and 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 Aged Care, is the regulatory authority for therapeutic goods, including medical devices and their processing methods. Medical devices are registered under the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002. All products are required to be listed in the Australian Register of Therapeutic Goods (ARTG), unless specifically exempt, before they can be supplied in Australia. The Office of Devices Authorisation (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 I) to high (class III or active implantable devices separately). Device disinfectants, for example, are considered class IIb devices. Liquid chemical disinfectants are considered under the Therapeutic Goods (Standard for Disinfectants and Sanitary Products) Order 2019, known as TGO 104. But this excludes antiseptics (disinfectants used on the skin), sterilants, and disinfectants specifically used for water treatment. The TGA also provides various guidance documents such as infection control guidelines for the prevention of transmission of infectious diseases and reducing public health risks associated with reusable medical devices.
- Canada:
  ◦ Medical devices regulations are under the authority of the Food and Drugs Act. Health Canada (under the Medical Devices Directorate) monitors and evaluates all medical devices to assess their safety, effectiveness, and quality before they are 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 processing instructions for use and reporting problems with medical devices.

As can be seen from this brief but not exhaustive review, specific country/region 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 in their content, but they can also be associated with more detailed requirements included in various standards and guidelines. Examples of different 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

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

Title	Notes
International Organization for Standardization (ISO)	A non-governmental, international body based in Geneva, Switzerland Develops draft standards through technical committees (e.g. ISO/TC 198 *Sterilization of healthcare products*) 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/European Committee for Standardization (CEN)	A not-for-profit European organization based in Brussels, Belgium Develops draft standards through technical committees (e.g. CEN/TC 204 *Sterilization of medical devices* and CEN/TC 216 *Disinfectants and antiseptics*) that are then approved by European country (national) member bodies[3] CEN collaborates closely with CENELEC (Comité européen de normalisation en électronique et en électrotechnique/European Committee for Electrotechnical Standardization) on matters of electrotechnical standardization and with ISO on the development of harmonized international standards[2]
British Standards Institution (BSI)	National standards body in the United Kingdom BSI also uses the "Kitemark" to indicate that a product has been independently tested to conform with a relevant British Standard
Deutsches Institut für Normung (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 United States
Association for the Advancement of Medical Instrumentation (AAMI)	AAMI develops 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 in various applications or the design, testing, and labeling of reusable devices)
ASTM International (previously known as the American Society for Testing and Materials)	Standards body based in the United States, focused on the development of test method (e.g. chemical and microbiological) standards
AOAC International (previously known as the Association of Analytical Communities)	Standards body based in the United States, focused on 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 can be prefixed with "GB/T"
Standards Australia and/or New Zealand	Standards 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 (2014) on processing of reusable devices in health service organizations (replaced in Australia by a new AS5369 standard on processing for health- and non-health-related facilities)

[1] Examples of national standard bodies include BSI (UK), AFNOR (France), DIN (Germany), and AAMI (United States), see the table.
[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 processing 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 standards body.
[3] CEN members are the national standards bodies of different European countries. Members should comply with the CEN/CENELEC regulations that stipulate that a European Standard should be given the status of a national standard without any alteration.

standards organization (e.g. International Organization for Standardization, ISO, and Comité européen de normalisation (CEN), the European Commission for Standardization). Most countries will have some legal requirements, directly or indirectly, regarding decontamination of reusable devices/materials; these are typically included in different standards or guidance within a given country/region. International standards (such as those developed by ISO) are continually under development for 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 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 their writing and can be frequently updated. During the course of this book, different standards and guidelines are referenced for each phase of the decontamination cycle.

Particularly important standards that should be considered in decontamination are the ISO 17664 series on information to be provided by the medical device manufacturer for the processing of medical devices, be they critical, semi-critical, or non-critical (Table 1.2). Although it is the responsibility of the healthcare facility to safely decontaminate reusable items, it is the responsibility of the suppliers of these items to provide detailed instructions on how they should be safely processed. These instructions should be validated as effective by the manufacturer. These standards have been recently updated to apply to the wider range of medical device types, as well as to provide greater and more consistent processing instructions. Instructions provided should include:

- The device manufacturer and its 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) or restrictions on processing conditions (e.g. "cannot be immersed in water" or "electrical hazard").
- Service life of a device, based on a specific number of processing cycles or some other type of end-of-life indication.
- 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. These will include recommendations for the types or restrictions (e.g. due to damage risks) of cleaning chemistries, conditions, equipment, and procedures to be used. Preference is given to providing at least one automated cleaning method (which may include some manual steps), but full manual cleaning methods are to be specified if automated cleaning is not possible and/or desired to meet specific needs. Methods used for inspection of cleanliness, in particular for areas of the device known to be difficult to clean, will also be important.
- Disinfection (if applicable). As for cleaning, automated disinfection (typically using moist heat methods) is preferred, but manual procedures can be described where automated processes cannot be employed. Methods 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 processing). As for other parts of the decontamination process, the quality of water used will also be an important consideration.
- Drying (if applicable). Instructions for the drying of the device should be provided. This may or may not include the consideration for using chemicals that aid in the drying process (e.g. alcohols or rinse aids).
- Maintenance, inspection, and testing. This will include instructions for periodic testing, lubrication, inspections, reassembly, etc. to ensure that the device can be safely used on the next patient. Inspection is a particularly important variable here and can sometimes require diligent and specific requirements (such as inspection of moving parts, internal lumens, etc.).
- 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, should not be 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.
- Transportation. When applicable, instructions may be required to reduce the risk of device damage or compromising cleaning, disinfection, or sterilization during transport to the place of use.

Processing instructions are essential in order to ensure patient safety. They require close cooperation between medical/surgical device manufacturers, processing staff, those using the devices with patients, and the suppliers of cleaning, disinfection, and sterilization products/processes. Although it is often impractical for manufacturers to provide detailed instructions to meet individual requirements for each country (due to historical requirements in these countries or specific and changing guidelines), it is important that they consider local decontamination standards and guidelines. In the absence of adequate instructions, it may 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 while it discusses the

Table 1.2 Examples of international standards that consider various decontamination aspects. These may or may not apply to a given region or country and the associated dates can change over time depending on periodic updates to the standard requirements.

Standard Number[1]	Title	Description
ISO 13485 (2016)	*Medical devices – quality management systems – requirements for regulatory purposes*	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 17664-1 (2021)	ISO 17664-1:2021 *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices*	Instructions to be provided by the device manufacturer to ensure safe processing of critical or semi-critical medical devices
ISO 17664-2 (2021)	ISO 17664-2:2021 *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices. Part 2: Non-critical medical devices*	Instructions to be provided by the device manufacturer to ensure safe processing of non-critical medical devices not intended to be sterilized
ISO 15883 series	*Washer-disinfectors. General requirements, definitions and tests*	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, Part 5 specifies updated performance requirements and test method criteria for demonstrating cleaning efficacy, and other parts provide more details on specific types of machines (e.g. surgical instruments and flexible endoscopes)
ISO 9398 series	*Specifications for industrial laundry machines*	Series of standards on laundry machines, including definitions, testing of capacity, and consumption characteristics
ISO 14937 (2009)	*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*	Development, validation, and routine control of any sterilization process used for healthcare devices and other materials
ISO 17665-1 (2006)	*Sterilization of healthcare products – moist heat. Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices*	Development, validation, and routine control of moist heat (steam) sterilization processes for devices
ISO 20857 (2010)	*Sterilization of healthcare products – dry heat – requirements for the development, validation and routine control of a sterilization process for medical devices*	Development, validation, and routine control of a dry heat sterilization process for devices
ISO 11135 (2014)	*Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*	Development, validation, and routine control of an ethylene oxide sterilization process for medical devices

[1] International standards, as published by ISO, are designated by a specific number but also the date of 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 (designates a harmonized standard for the United Kingdom, European Union, and international) or AMMI ISO xxxx (designates a US-AAMI version of an international standard); note that 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.

basic principles of decontamination and related guidelines, it should not be used as a replacement for local legislative or guidance documents issued in particular 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 that include as a basic minimum adequate cleaning, inspection, and disinfection and/or sterilization in order to render a reusable item safe for further use on patients and for handling by staff. Decontamination and processing of reusable devices and materials is essential in minimizing the risk of transmission of infectious agents and other patient risks.