8 Cleaning and Disinfection in the Bottled Water Industry

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8.1 INTRODUCTION

With the increase in terrorist attacks in the past years, the importance of protecting the food supply against further terrorist threats became a top priority for governments across the world. The result in many markets has been a strong emphasis on security programs and procedures by companies to continually improve and enhance the strength and effectiveness of their food security programs. Those involved with sanitation must be knowledgeable about food contaminants, including allergens, physical, microbiological, and chemical hazards. In addition, companies must increasingly be aware of the threats to food safety through contamination of product, tampering during processing and preparation, and the potential for extortion. Increased food safety and environmental stewardship has created additional challenges for the bottled water industry. In addition, with the increased financial pressures of a new world economy, cleaning and disinfection become even more important. With ever tightening profit margins, the bottled water industry cannot overlook the importance of maximum utilization of assets and hence faster cleaning and disinfection, but without compromising quality.

As before, this chapter deals with the science and technology of cleaning and disinfection methods used within the bottled water industry. The choice of methods, combinations, and frequencies will depend on equipment design, process layout, factory location, and the quality of the incoming water. It will also be influenced by the normal operating pattern of the factory, whether it is running 24 hours a day, 7 days a week, or on an intermittent basis. No bottling plant can operate continuously without a well-considered and correctly implemented cleaning and disinfection regime. It will require the allocation of time to maintain product safety and quality standards. The amount of time required will also depend on the nature of the facility and the technology available; for example, a dedicated water bottling line will require a significantly different program from a soft drink factory with lines that also produce bottled waters. In deciding the amount of time required, methods and frequency of cleaning and disinfection, advice should be sought from the manufacturers of cleaning products and equipment suppliers.

The role of cleaning and disinfection in the bottled water industry is more than that of only cleaning the filler and filling room. In considering an effective program for a water bottling facility, it is important to take into account the whole operation, from the parking lot to the point of dispatch. The principal concern in this chapter however, is to discuss the methods for sanitation of the primary product contact areas – pipework, storage vessels, and filling equipment.

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Firstly, some definitions: depending on which dictionary or other reference source is used, the terminology associated with sanitation can be ambiguous in its definitions. Though cleaning and disinfection (in some countries referred to as cleaning and sanitizing) are two separate procedures, potential for confusion exists because in different parts of the world the words used to describe the various products employed are also different. For example, in the United States, a sanitizer (see definition below) has only biocidal properties and is not recommended for the purpose of cleaning:

- Cleaning is the process that removes soil and prevents accumulation of residues, which may decompose to support the growth of disease or nuisance causing organisms. It must be accomplished with water, mechanical action, and detergents.
- A cleaner (detergent) is a substance that breaks the bond between the soil and the surface being cleaned. Not only must it remove the soil, it must also hold it in suspension and allow it to be flushed away. It does not kill bacteria.
- Disinfection is the killing or inactivation of micro-organisms, except for some spore forms. The efficacy of disinfection is affected by a number of factors, including the type and level of microbial contamination, the activity of the sanitizer, and the contact time. Organic material and soil can block sanitizer contact and may inhibit activity. Therefore, cleaning must precede all disinfection processes. There are three different levels of disinfection:
    - (i) High level disinfection refers to sterilization activities in which all microbial life, including spores and viruses, are destroyed. High level disinfection is reserved for special applications, such as disinfection of surgical equipment and medical devices.
    - (ii) Medium level disinfection usually refers to elimination of micro-organisms as well as the destruction of the more resistant types of viruses.
    - (iii) Low level disinfection refers to the destruction of bacteria and is not effective against spores and viruses.
- A disinfectant is a chemical agent that is capable of destroying disease causing bacteria or pathogens, but not spores and not all viruses. In a technical and legal sense, a disinfectant must be capable of reducing the level of pathogenic bacteria by 99.999 % during a time frame of more than 5 but less than 10 minutes, as tested by the Association of Analytical Communities (AOAC) method.

The main difference between a sanitizer and a disinfectant is that at a specified use dilution, the disinfectant must have a higher kill capability for pathogenic bacteria than that of a sanitizer:

- To sanitize means to reduce the number of micro-organisms to a safe level.
- A sanitizer, according to the AOAC test method, should be capable of killing 99.999 % (5 log reduction) of a specific bacterial test population, (*staphylococcus aureus* and *Escherichia coli*) within 30 seconds at 25°C (77°F). A sanitizer may or may not necessarily destroy pathogenic or disease-causing bacteria, as is a criterion for a disinfectant.
- Sanitation is the term used to describe the complete plant cleaning and disinfection program to ensure public health.

Although this chapter deals with cleaning and disinfection, as used here, the word "disinfection" refers to low level disinfection, and this is in practice achieved without the use of disinfectants as defined above, but rather through the use of cleaners and sanitizers.

Today, with larger processing facilities and worldwide distribution, the importance of sanitation is greater than ever before, and a well-managed sanitation program must encompass the employee, the customer, and the environment. An effective sanitation program is important for many reasons:

- to protect the company's reputation;
- to reduce the potential for financial losses;
- to remove and prevent bacterial buildup;
- to reduce the chance of off flavors developing;
- to maximize the shelf life of the product;
- to ensure compliance with Government regulations.

However, the main reason that the bottled water industry needs well-managed sanitation programs is to ensure customer satisfaction and safety standards. A complete bottled water food safety program should include both cleaning and disinfection and the use of methods of microbiological testing as a means of monitoring the performance of the sanitation program.

8.1.1 Why clean?

In order to control cleanliness and minimize the spread of bacteria, it is important to know proper sanitation procedures, to determine application frequencies, and to be vigilant in following the procedures. It is also useful to be able to understand and distinguish between micro-organisms such as pathogens (disease causing organisms, such as *Escherichia coli* – Fig. 8.1b), and spoilage organisms. There are thousands of different kinds of bacteria, yeasts, molds, and viruses, which are categorized by their shapes and the way in which they grow. Bacterial cells exist in many different shapes, but there are three basic forms: round or cocci, rod shaped, and spiral (see Fig. 8.1a).

Identification of different types of bacteria can provide some insight into their source and control. The major causes of food contamination are pathogenic micro-organisms that live in soil, water, air, and organic matter and on the bodies of animals and humans. Put simply, they are to be found everywhere.

Most bacteria do not have the ability to travel on their own, at least not very far. Those that can move independently – motile bacteria – use appendages called flagella. All bacteria have the ability to travel widely by "hitching rides" on air, water, bottles, caps, people, and anything else that goes from place to place.

Not only are bacteria plentiful and easily spread from surface to surface, they can also reproduce quickly. One bacterium becomes two, two become four, four become eight, and so on and on by a process of cell division called binary fission, which can occur as frequently as every 20 to 30 minutes.

In a short time, one bacterium can produce millions of bacteria. This build-up of bacteria on surfaces is often referred to as biofilm (see Fig. 8.2).

Under ideal conditions, bacteria will grow in phases and in a short time can get out of control. The first phase, called the lag phase, typically lasts 3–4 hours, and during this time, binary fission occurs relatively slowly as bacteria adapt to their surroundings. After that however, they reproduce faster and faster – this is called the logarithmic phase – and contamination becomes much more difficult to control. Eventually they will reach a stationary

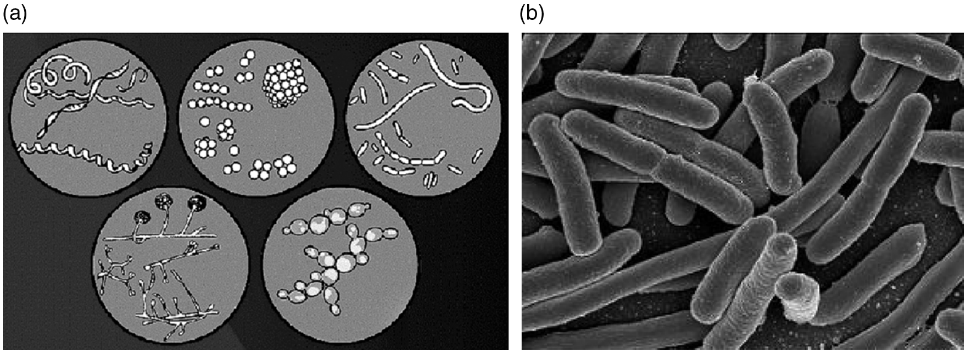

Fig. 8.1 (a) Top row (from left to right): Spiral bacteria, cocci, and rod-shaped bacteria; (b) *Escherichia coli* bacteria.

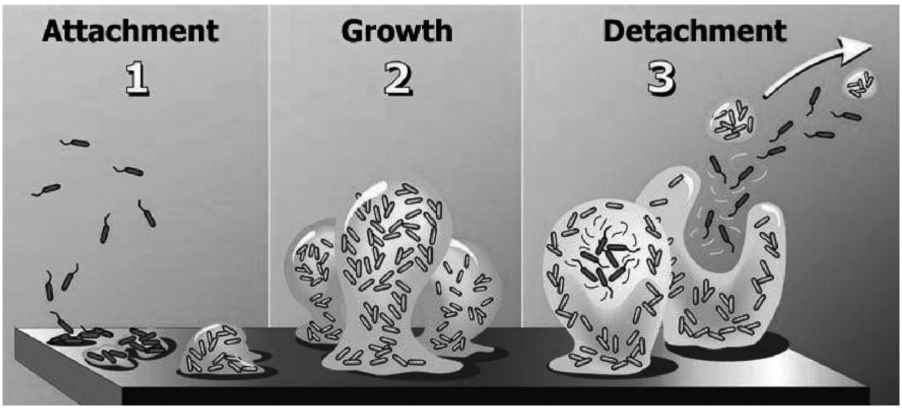

Fig. 8.2 The biofilm life-cycle: individual cells populate the surface, attachment becomes irreversible as biofilm develops and matures and finally single cells are released from the biofilm.

phase where they can maintain a very high population, and finally, in the death phase, they begin to die off due to lack of food, water, and other nutrients.

A good food handling, processing, and sanitation program will take advantage of the lag phase, in which very little growth occurs. A quick, thorough response to control bacteria is therefore a critical factor in sanitation. The sooner bacteria can be destroyed, the greater the chances of eliminating contamination and biofilm build-up, thus reducing the potential for sickness and disease. Equipment that has already been sanitized but that might harbor bacteria surviving beyond the three-to-four hour lag phase should always be sanitized again before use.

8.2 CLEANERS (DETERGENTS)

In the sanitation process, Time, Temperature, Concentration, and Mechanical Action are the four cleaning variables. Choosing the right systems is a necessary part of the process, but they cannot work without the right cleaners and sanitizers. In most parts of the world cleaners and sanitizers are two distinct categories and sometimes governed by different agencies. To choose the right cleaner, consideration should first be given to the water, the surface to be cleaned, and the method used (application method) and the environment.

Selection of cleaning compounds, methods, and frequency of use depends upon the following factors:

- the type and amount of "soiling" on the surface;
- nature of the surface to be cleaned;
- physical nature of the cleaning compound;
- method of cleaning (foaming, CIP, soaking, manual cleaning, etc.);
- quality of water available;
- time available;
- temperature allowance.

Heat breaks up fat and grease and assists in its removal and an increase in temperature by 32.4°C (18°F) will double the activity of the chemical. However, excessive temperature can also cause cleaning problems. For example, temperature above the "denaturization" point will increase the adhesion of protein to the surface.

An effective cleaner must have the following properties:

- rapid penetrating and wetting power;
- ability to control water hardness;
- high detergent power to remove soil;
- suspending power to keep the removed soil from redepositing on the surface;
- easy rinsability;
- non-corrosiveness to surfaces being cleaned and to cleaning equipment.

In practice, these functions are not performed independently, but tend all to occur together. No simple chemical – alkali, acid, wetting agent, etc. can supply all the properties, but by combining selected chemicals, cleaners can be prepared that are effective on given applications. Different cleaning compounds are required for different cleaning tasks; one group of cleaners that works satisfactorily in one plant may not be effective in another, because of differences in composition of the water supply. However, chemicals should never be mixed at the point of use; any combination of chemicals must be performed by the manufacturers.

8.2.1 Chemistry of cleaning

Bacteria are living organisms that have the same basic needs as man to sustain life and to multiply. That is, they need food, moisture, sometimes oxygen or air, a place to live, and time; cleaning chemistry will remove one of those basics, namely food, and by scheduling cleaning, the time required for multiplication of organisms is addressed.

There are no magic wands in the area of cleaning chemistry; but the selection of cleaning chemicals can either make the job a lot easier or turn it into a nightmare. Even a properly designed cleaning product, if handled incorrectly, can become a dangerous liability.

One tool used in selecting the proper cleaning chemistry is the pH scale, which gives some general information on how alkaline or acidic is the type of cleaning product being used. Different organic challenges require different pH levels in cleaning chemicals.

In general, fats, oils, greases, proteins, and carbohydrates require a cleaner with a pH of above 12, which is highly alkaline. Low pH products are commonly used for removing mineral deposits such as calcium carbonate, which is sometimes known as "stone". The most efficient method for removing this build-up is by using a phosphoric acid or a blend of acids such as phosphoric, nitric, sulfuric, etc.

Cleaners act in two ways: they either interact with soils on a physical basis by changing their solubility characteristics or they interact with soils chemically to form a modified substance with desirable solubility characteristics in water. Cleaner components are generally classified in the following manner:

(i) *Surface active agents (surfactants)*: are organic materials generally composed of two parts, one part that is water loving (hydrophilic) and one part that is water hating (hydrophobic), or oil loving (lipophilic). Consequently they have one part of their structure that wants to dissolve in water and one part that is insoluble in water; they provide three types of action: wetting/penetration, emulsification, and suspension.

(ii) *Builders*: a category that includes:
alkaline builders;
acid builders;
enzymes;
water conditioners; and
oxidizing agents:

- Alkaline builders are generally used to provide a source of alkali-negative ions in cleaners. Alkaline builders are a rich source or donor of electrons, or negative ions. These electrons congregate at the surfaces of many soils and in much the same way as emulsification by surfactants; they disrupt the structure, swell the soil, and break it free. The highly negatively charged particles are repulsed from each other and dispersed in the cleaning solution. Strong alkalis such as sodium hydroxide are used in heavy-duty alkaline cleaners for bottle washing or various CIP applications. Highly alkaline materials at high temperatures react with fats and oil to form soaps which are soluble in water.
- Acid builders include phosphoric acid, nitric acid, and sulfuric acid. In the food and water industries, phosphoric acid is commonly used to remove and help prevent mineral stone on processing equipment.
- Enzymes are specialized protein catalysts or molecules, which speed up a chemical reaction. An enzyme reacts with a specific organic substance, a protein, a fat, or carbohydrate. Enzymes are very specific in their action; they will only interact with the particular substance they are designed to work on. This generally is not used in the bottled water industry, as protein is not found in our normal process.
- Water conditioners can be an important component in treating impurities in the water source. Minerals such as calcium and magnesium salts in the water may react with ingredients in the cleaning compound to form insoluble salts. These salts then form a film that builds up on equipment. To prevent this, materials are added to alkaline cleaners to interact with the calcium and magnesium.
- Oxidizing agents are used as a cleaning booster in many alkaline detergents. Sodium hypochlorite is sometimes used as an aid in protein removal at concentrations in the

range of 50–100 ppm as available chlorine. Sodium hypochlorite is also often used as an effective sanitizer. However, when it is used in a high pH environment, it loses its sanitizer properties but remains very effective in solubilizing and removing protein soils or protein films from equipment surfaces.

There is a great deal of flexibility in the selection of cleaners to match specific cleaning requirements and conditions. To make the right choice, it is necessary to select the detergent system that adequately conditions the water and neutralizes its effects on the cleaning system, provides wetting or contact with the soil, dissolves the soil, and holds it in suspension so that it can be flushed away.

8.2.2 The five factors

Before finally selecting a cleaner, the interaction of five key factors needs to be understood:

(i) *The nature of the soil*: an understanding of the soil to be cleaned is essential in determining the right choice for cleaning. This is further complicated by other factors; the solubility varies depending on the soil's condition, the quantity of heat and how long it was applied, and the age and moisture content of the deposit. Here are some examples of soils and methods of cleaning them:
- *Light soil*: in this case, an oxidizing agent such as sodium hypochlorite in the presence of an alkaline cleaner will be effective. This will hydrolyse, meaning that it attacks the large molecule and breaks it up into smaller, more easily dissolved particles. Typical chlorine concentrations should be somewhere between 50 and 100 parts per million in the alkaline cleaner solution.
- *Mineral salt*: calcium and magnesium in their insoluble form are responsible for most mineral salt deposits. However, iron and manganese are also objectionable because of their intense color. These deposits not only create sanitation problems, but if they are allowed to accumulate, they may contribute to corrosion and poor heat transfer. Acid is the most economical material for removing mineral deposits; Inorganic acids such as phosphoric acid are preferred because of their effectiveness, low cost, and generally non-corrosive nature to stainless steel food processing equipment. Organic acids, such as citric acid, may have special applications but are not widely used because of their cost.
- *Grease and oil*, including those approved for use in the bottled water industry, are not solubilized by either acids or alkali. Surfactants allow the detergent solution to wet these soils so that they can be suspended in water or so they can be flushed from the surface to be cleaned.

(ii) *The role of water*: more than 99% of the cleaning solution is water and it is necessary to know about the specific attributes and impurities in the water being used, including the following:
- *Water hardness*: the most important chemical property of water because it has a direct effect on cleaning and disinfection. It is responsible for excessive detergent consumption; it also encourages scale deposits, so that undesirable films and precipitates can be left on equipment following improper cleaning procedures. Hardness forms scale or leaves film. When calcium and magnesium are present in

water as bicarbonates, it is referred to as "temporary" hardness. Both of these salts are quite soluble in water, and consequently, they can both exist in water at very high concentrations. However, when water containing these salts is heated, they convert to calcium and magnesium carbonates, which are insoluble in water, and will precipitate in the form of scale. "Permanent" water hardness (which cannot be forcibly precipitated by heating) exists when calcium, magnesium, or both are present as chloride or sulfate salts.

- *Micro-organisms*: water can harbor significant numbers of micro-organisms, which can exist in water for extended periods, even if nutrient levels are low. Groundwater may contain significant amounts of organic matter that can provide the nutrient source, either in dissolved or dispersed form.
- The pH of water also varies considerably. The normal range is from 6.5–8.5, (with a pH of 7 being neutral) and a pH outside these limits is considered unusually alkaline or acid. It may be necessary to treat water in these extreme ranges in order to achieve effective results. Acid and alkaline cleaners are generally not affected by water pH; their acidity or alkalinity far outweighs the effect of the water itself. In sanitizer solutions however, the pH of the water supply and the resulting pH of the sanitizer solution can greatly affect its effectiveness as an antimicrobial agent.

(iii) *The surface or material to be cleaned*: it is essential to consider the composition of the surface being cleaned whether it is stainless steel, aluminum, brass, copper, iron, tile, or plastic. Different materials interact with soil and with the cleaner in different ways. In the bottled water industry, stainless steel is the best material for product contact surfaces, and 304 or 316 stainless is often preferred, because it presents a smooth, cleanable surface, as well as protecting the organoleptic integrity of the water. Rough, cracked, pitted surfaces are much harder to clean because of the difficulty of removing the soil from crevices or holes.

(iv) *The method of application*: there is a number of different ways to apply cleaners to the area being cleaned and each presents a different level of exposure to the employee:

- *Hand or manual cleaning*: because the employee has the greatest potential for physical contact, with manual or hand cleaning the pH of the solution must remain between 4 and 10.5.
- *Spray or high-pressure cleaning*: because of misting and atomization there is likely to be some exposure of the employee to cleaning products. Products should not be used that are highly alkaline or acid, unless employees are provided with suitable personal protective equipment.
- *Cleaners applied as foam or gel*: have less potential for employee contact.
- Where mechanical cleaning or CIP is used, no direct employee contact would be expected. This provides the least risk to the employee, since the solution is contained within a vessel or lines.

(v) *Environmental concerns*: all cleaning solutions and soils eventually become part of the waste stream and need to be properly treated prior to disposal or discharge. This effluent may be treated at a public or privately owned treatment plant; in either case, there are certain restrictions on the quality or characteristics of that waste stream. Major considerations are pH, phosphorus, biological oxygen demand (BOD), fats, oils and greases, the volume of water discharged, dissolved solids, conductivity, and the presence of heavy metals.

8.2.3 Types of cleaner (detergents)

There are four basic categories of cleaning chemistry: alkaline, acid, neutral pH, and solvents. Prior to using any cleaner, it is first necessary to consider the organic challenge and the technology of the equipment and surfaces being cleaned:

(i) *Alkaline cleaners*: these cleaners have a pH of 11–13.5:
- *Heavy-duty alkaline cleaners*: usually caustic cleaners such as sodium or potassium hydroxide. Chelators have been added to tie up minerals and wetting agents added to allow free rinsing. Because of their caustic nature, they should not be used on soft metals and should have very little or no human contact.
- *Medium alkaline cleaners*: in most cases these are excellent products to remove fats, oils, and greases and are commonly applied by using foam.
- *Chlorinated alkaline cleaners*: may be either heavy or medium alkaline. Hypochlorite is added to the alkali to peptize the proteins for easier removal. Excellent on fats, oils, grease, proteins, and carbohydrates, they are also used for CIP cleaning of pipes, tanks, etc.

(ii) *Acid cleaners*: are at the other end of the pH spectrum; these include:
- *Phosphoric acid*: effective on most light mineral salts and relatively safe for hand scrubbing. It is often used at a concentration between 2 and 3% for cleaning.
- *Sulfamic acid*: excellent for use in enclosed vessels because it is lower in pH than phosphoric acid. Concentration used at 1–3% for cleaning.
- *Acid blends*: there are various products that combine acids such as phosphoric, nitric, sulfuric, and sulfamic. These products are very effective on mineral build-up.

(iii) *Neutral pH cleaners*: these are designed specifically for use where an acid or alkaline cleaner can do damage to a specialized piece of material or equipment, such as packaging systems, scales, or other sensitive equipment.

(iv) *Solvents*: water based solvents are used where light oil, light grease, and other soft organics are deposited. These products can contain a foaming agent to aid in the application and cleaning. Unlike high alkaline cleaners that digest the organics, solvents break down the organics.

In general, Table 8.1 should assist in choosing cleaning chemicals.

8.3 SANITIZERS

Cleaning removes soils, but after the cleaning operations, equipment surfaces and the environment can still be contaminated with micro-organisms. If these micro-organisms are not destroyed, the bottled water being produced may be contaminated. Disinfection is therefore the most critical step in a sanitation program. To ensure a high degree of sanitizer efficacy:

- Analyze and determine the best sanitizer for the application. The supplier should have a high degree of expertise in this area.
- Ensure that all cleaning chemical residues have been rinsed thoroughly before disinfection.

Table 8.1 Properties of detergents.

Acid detergents	**Ingredients**	**Mineral/Scale removal**	**Emulsification**	**Penetration**	**Suspension**	**Rinseability**	**Foam**	**Noncorrosive stainless steel**	**Noncorrosive soft metals**	**Nonirritating**	**Passivation**
		Comparative ability									
Mineral acids	Muriatic hydrochloric	A	C	B	C	C	D	D	C	D	DD
	Sulfuric	B	B	C	C	B	D	D	C	B	D
	Sulfamic	C	C	C	C	C	D	C	C	C	C
	Nitric	C	B	C	C	C	C	C	C	C	D
	Phosphoric	C	B	C	C	B	A	A	C	A	A
Organic acids	Citric	C	A	C	C	A	AA	A	C	A	A
	Hydroxyacetic	C	A	C	C	A	AAA	A	C	A	A
	Gluconic	C	C	C	C	C	B	C	C	A	A
	Wetting agents	C	C	C	C	C	AA	C	C	A	A

Alkaline detergents	**Ingredients**	**Saponification**	**Emulsification**	**Protein control**	**Penetration**	**Suspension**	**Water conditioning**	**Rinseability**	**Foam**	**Noncorrosive**	**Nonirritating**
		Comparative ability									
Basic alkalis	Caustic	A	C	B	C	C	D	D	C	D	DD
	Silicates	B	B	C	C	B	D	D	C	B	D
	Carbonates	C	C	C	C	C	D	C	C	C	C
	Trisodium phosphate	C	B	C	C	C	C	C	C	C	D
Complex phosphates	Tetrasodium pyrophosphate	C	B	C	C	B	A	A	C	A	A
	Sodium tripoly phosphate	C	A	C	C	A	AA	A	C	A	A
	Sodium polyphosphate	C	A	C	C	A	AAA	A	C	A	A
	Gluconates	C	C	C	C	C	B	C	C	A	A
Organic materials	EDTA	C	C	C	C	C	AA	C	C	A	A
	Phosphonates	C	C	C	C	C	AA	A	C	A	A
	Ploymers	C	B	C	C	A	A	B	C	A	A
	Wetting agents	C	AA	C	AA	A	C	AA	A	A	A
	Chlorine source	C	C	A	C	C	C	C	C	B	B

A, excellent; B, good; C, no ability; D, negative performance.

- Dilute all sanitizers according to label directions, and follow all labels and instructions to the letter.
- Confirm approval by regulatory/environmental authorities.
- Ensure that the sanitizer application methods provide coverage for all food contact surfaces.
- Train staff in proper use and handling of sanitizers, and also in using them to best advantage given the particular plant conditions and circumstances.
- Use automatic dilution systems to ensure the correct dilution rate.

Sanitizers can be sprayed on or circulated through equipment. They can also be foamed on a surface or fogged (under very extreme and exceptional circumstances) into the air to help reduce airborne contamination. The key to effectiveness of any application method is intimate contact of the proper sanitizer concentration with the microbial cell. The sanitizer needs to thoroughly cover the surface for the proper recommended contact time.

Ideally, disinfection on equipment should be performed just prior to start up. However, there are times when equipment is left idle before production re-starts. In this case, it is recommended that the sanitizer be applied to the equipment immediately after cleaning in order to leave the surface with minimal microbial contamination. This will minimize any regrowth that could occur during downtime. Following extended downtime, sanitizer should be applied again, and the equipment finally rinsed with product or treated water at start up.

8.3.1 Regulatory considerations

The sanitizer used must always comply with the regulations applicable in the geographical location. For example, sanitizers in the USA are regulated by the Environmental Protection Agency (EPA) and are of two types: no-rinse food contact surface sanitizers and non-food contact surface sanitizers. The second are generally referred to as environmental sanitizers. The Food and Drug Administration (FDA) is charged with approving anything used on food contact surfaces that could potentially contact food items. Ingredients used in sanitizers must comply with FDA requirements as safe and effective. The active ingredients for approved no-rinse food contact sanitizer formulations and their usage concentrations are listed in *the US Code of Federal Regulations*, 21 CFR 178.1010.

In the USA, the official challenge test demands that they must reduce microbial activity of two standard test organisms (*staphylococcus aureus* and *Escherichia coli*) from a designated microbial load by as much as 99.999% or 5 logs in 30 seconds at 25°C (77°F).

Regulations for usage instructions are very specific for each product and label instruction must be followed precisely. In fact, the EPA requires a warning statement on the label that says, "It is a violation of federal law to use this product in a manner inconsistent with its labeling." Sanitizers are treated differently worldwide and it is important to consult local regulations to ensure that they are used accordingly.

Sanitizer solutions can only be prepared using potable water and concentrations must be accurate. If the concentration is below the recommended level, the result may be inadequate microbial control. A concentration that is too high is also undesirable. "No-rinse" food contact sanitizers are considered indirect food additives, so concentrations above recommended levels are not allowed. However, in the bottled water industry, the use of no-rinse sanitizers without a final rinse is ill-advised, as it can potentially leave residues, which affect product quality and jeopardize its inherent properties, thus altering the nature of the product.

8.3.2 Types of sanitizers and their uses (Table 8.2)

(i) *Chlorine products*: these are the most commonly used. Typical chlorine sanitizers include various forms; of which the most popular is sodium hypochlorite.

- Advantages:
  - Chlorine is effective against a wide variety of bacteria, fungi, and viruses, including bacteriophage. All chlorine products, regardless of their type (elemental chlorine, hypochlorites, or organochlorines) form hypochlorous acid (HOCl) in solution. HOCl is the most germicidal species of chlorine. The amount of HOCl is dependent on the pH of the solution. As the pH is lowered, more HOCl is formed. However, as the pH is decreased below 4.0, increasing amounts of toxic and corrosive chlorine gas (Cl_2) are formed. Chlorine is much more stable at higher pH, but is less effective. Hard water salts do not affect chlorine unless they cause an upward drift in the pH of the use solution. Chlorine is effective at fairly low temperatures and is not as temperature sensitive as other common sanitizers. It has the advantage of being relatively inexpensive and is often preferred because it does not foam.
- Disadvantages:
  - Residual chlorine at low levels imparts a taste and odor to the water and obviously alters its nature.
  - The potential for toxic gas formation: care must be taken, as deadly chlorine gas (Cl_2) will be formed if the pH drops below 4. Chlorine is also corrosive to many metals; inorganic forms are more corrosive than organic forms and may adversely affect plastics and rubber. A concern for those who work with chlorine is that it is irritating to the skin and mucous membranes.
  - Chlorine is unstable and dissipates rapidly from solution. It loses activity rapidly in the presence of organic materials, light, air, and metals. Liquid chlorine deteriorates during storage and stability decreases with increasing temperature. Because chlorine products degrade with age, solutions need to be prepared more frequently than some other sanitizers with concentration level tested and adjusted to obtain the required level of available chlorine.
  - There is also controversy over its environmental impact, because of the formation of potentially toxic organochlorine by-products. This concern is based on findings that chlorine reacts with naturally occurring organic materials, primary humic acid, naturally present in some waters, which results in the formation of suspected carcinogenic trihalomethane (THM) compounds.

(ii) *Iodophors*: these are compounds that contain iodine dissolved in a surfactant carrier and an acid. The surfactant carrier provides a soluble, stable medium for the iodine and in the diluted form controls the release of iodine. On a parts per million basis, iodophors are one of the most effective sanitizers available, and are especially effective against most yeasts and molds.

- Advantages:
  - Iodophors provide a weak acid rinse for mineral control, and are less irritating to the skin than chlorine. They offer less toxicity, and have a broader effective pH range than chlorine. Generally more effective at pH 2–5, iodophors offer acceptable disinfection efficacy at slightly alkaline pH, depending on the formulation and conditions.

  - They are less corrosive than chlorine when used below 48.9°C (120°F), and the activity is not lost as rapidly as chlorine in the presence of organic matter. This is especially true at low pH. Concentrated iodophors also have a long shelf-life – another advantage over chlorine. Working with iodophors offers a number of other advantages: the concentration is easily determined by common field methods, and the amber color is an obvious visual indicator of the presence of active iodine, which makes this type of sanitizer good for hand disinfection.
- Disadvantages:
  - Iodophors can cause staining problems and discolor equipment. Depending on the formulation, iodophors may be more adversely affected by water hardness than chlorine and they have poor activity against bacteriophage.
  - The efficacy of iodophors is adversely affected by low temperatures; this effect can be overcome by using higher concentrations or longer contact times. In addition, they cannot be used at temperatures above 48.9°C (120°F) or on hot equipment. At that temperature, iodine begins to vaporize and the vapor is very corrosive to equipment, including stainless steel. In addition, some people find the odor of iodophors offensive. Iodophors are more expensive than hypochlorite.

(iii) *Quaternary ammonium compounds*: these are sometimes referred to as Quat sanitizers, or QACs. They are often the right choice when the situation calls for an effective environmental sanitizer. The maximum concentration allowed by FDA for use in a no-rinse food contact sanitizer is 200 ppm of the active QAC.

- Advantages:
  - QACs at normal use concentrations are non-toxic, relatively odorless, colorless, and non-corrosive. They are stable to heat and relatively stable in the presence of organic matter. Most QAC sanitizers have a neutral pH, but are effective over a fairly broad pH range. In most cases, the maximum efficacy is exhibited in the alkaline pH range. However, research has indicated that the effect of pH may vary with bacterial species, with gram negatives being more susceptible to Quats in the acid pH range, pH 7 and below, and gram positives in the alkaline pH range, pH 7 and above.
  - These compounds possess some detergency because of their surfactant activity. They are active against a wide variety of micro-organisms, including yeasts and molds.
- Disadvantages:
  - QACs are generally considered less effective against gram-negative bacteria than against gram-positive bacteria. This drawback can be overcome by using higher concentrations, or by providing longer contact time.
  - QACs are less effective against bacteriophage and because they are cationic molecules, they are incompatible with soaps and anionic detergents (most general cleaners are anionic). Therefore, surfaces must be rinsed thoroughly between the cleaning and disinfection steps to prevent inactivation of the sanitizer. They also have low hard water tolerance, although it can be improved by the addition of chelating agents such as Ethylenediaminetetra-acetic acid (EDTA). QACs are not as effective at low temperature as the oxidizing sanitizers such as chlorine and peroxyacetic acid. When used in mechanical operations they can cause a foaming problem, which is why they are not recommended for use as CIP sanitizers.

Table 8.2 Advantages and disadvantages of sanitizer types.

Chemical	Advantages	Disadvantages
Chlorine	• Broad spectrum of activity • Hard water tolerant • Low temperature. Efficacy • Relatively inexpensive • No residual activity • Non film forming	• Potential for toxic gas formation • Corrosive • Irritation • Unstable, short shelf-life • Potential for toxic by-products
Chlorine dioxide	• Strong oxidizing chemical • More tolerant of organic matter than chlorine • Less corrosive to stainless steel • Less pH sensitive	• Safety • Toxicity • Sensitive to light & temperature • Cost
Iodophors	• Broad spectrum of activity • Less irritating than chlorine • Low toxicity • Effective pH range • Broader than chlorine • Less corrosive than chlorine • Stable, long shelf-life • Color of use solution provides visual control	• Staining porous and plastic materials • Poor activity against bacteriophage • Poor low temperature efficacy • Corrosive at high temperatures. • DO NOT USE ABOVE 120°F (48.9°C) • May produce excessive foam on CIP application • More expensive than chlorine • Odor may be offensive
Quaternary ammonium	• Non toxic, odorless, colorless • Non-corrosive • Temperature stable • Relative stability in presence of organic soil • Broad spectrum of activity • Residual antimicrobial film • Some detergency and soil penetrating ability • Stable, long shelf-life • Mold and odor control	• Incompatible with anionic wetting agents • Low hard water tolerance • Limited low temperature activity • Excessive foaming in mechanical applications • Antimicrobial activity may vary depending on formulation
Acid anionic sanitizers – older technology for CIP application	• Stable – long shelf-life • Generally non-corrosive • Non-staining • Low odor	• Incompatible with anionic wetting agents • Low hard water tolerance • Limited low temperature activity • Excessive foaming in mechanical applications

	• Not affected by hard water • Removes and controls mineral films • Good bacteriophage activity	• Antimicrobial activity may vary depending on formulations
Carboxylic acid sanitizer	• Low foaming CIP application • Broad spectrum of bacterial activity • Stable, good shelf life • Not affected by hard water salts • Remove and control mineral films • Non-staining	• Limited and varied activity against fungi • pH sensitivity – optimum activity pH < 3.5 • Inactivated by cationic surfactants • Temperature sensitivity, use at > 55°F (12.7°C) • Corrosion potential & equipment compatibility issues
Peroxy acid compounds – newer formulations combine carboxylic acid for better mold and fungi control	• Low foam • Broad temperature range of activity • Combine disinfection and acid rinse • No residue • Generally non-corrosive to stainless steel • Relative tolerance to organic soil • Phosphate free • Environmentally responsible • Broad spectrum of bactericidal activity • Active over broad pH range up to pH 7.5	• Metal ion sensitivity • Corrosive to soft metals • Odor of concentrate • Varied activity against fungi
Hot water - Min. of 185°F for 15 minutes	• Inexpensive • Easily available • Broad spectrum efficacy • Non-corrosive • Penetration	• Slow • Film formation • Equipment damage • Condensation formation • Safety • Cost
Ozone	• Powerful oxidizing gas • Broad spectrum germicidal activity	• Unstable • pH sensitive • Temperature sensitive • Safety issues • Toxicity • Cost

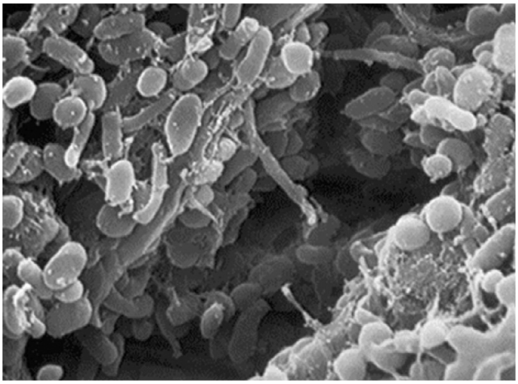

Fig. 8.3 Biofilm (see also Fig. 8.2).

(iv) *Acid anionic sanitizers*: these are fast-acting compounds.

- Advantages:
  - Acid anionic sanitizers work well on yeasts and viruses. Bacteria do not survive well in an acid environment and an acid sanitizer can work best when the pH range is below 3. Antimicrobial activity is drastically reduced or stops when pH levels climb to neutral. Acid anionic sanitizers not only rapidly kill bacteria but they also provide a method to acid rinse equipment, which leaves stainless steel bright and shiny. They have very good wetting properties and are usually non-corrosive, which means they can be left on equipment overnight, and do not stain. Hard water and organic challenge do not have a major effect on the ability of acid anionic sanitizers to kill micro-organisms, and they can be applied by CIP or spray, or can be foamed on if a foam additive is used.
- Disadvantages:
  - Acid sanitizers can lose all their effectiveness in the presence of any alkaline residuals or cationic surfactants. It is important to thoroughly rinse all cleaning agents from surfaces before application of the sanitizers.

(v) *Peroxy acid compounds*: hydrogen peroxide products represent the newest class of sanitizers, although they have been used extensively in Europe since the 1970s. Peroxyacetic acid is a strong, fast acting sanitizer that (like chlorine-based sanitizers) works on the basis of oxidation. FDA regulation allows peroxyacetic acid to be used as a no-rinse food contact surface sanitizer at the dilution specified on the label, but it is advised that within the bottled water industry, it is thoroughly rinsed from all production equipment prior to production.

Peroxyacetic acid is one of the most effective sanitizers against biofilms, which are composed of a collection of bacteria that have attached to surfaces and have excreted an extracellular polysaccharide, or slime layer (Fig. 8.3). This slime layer protects the cells from adverse environmental conditions. In fact, research shows that bacteria within a biofilm are up to 1000 times more resistant to some sanitizers than those cells freely-dispersed in solution.

- Advantages:
  - The low foam characteristics of these compounds, like chlorine, make them suitable for CIP applications. They offer a broad range of temperature activity, even down to 4.4°C (40°F). As acid-type sanitizers, they combine the

sanitizer and acid rinse in one step. They leave no residues and they are generally non-corrosive to stainless steel and aluminum in normal surface application. They are relatively tolerant of organic soil, which probably accounts for their superior activity against bacteria harbored in biofilms.

  - o Peroxyacetic acid sanitizers are generally formulated with phosphate-free compounds, which are environmentally friendly. They are readily biodegradable and break down into water, oxygen, and acetic acid, and this lack of environmental impact is a major positive benefit. They provide a broad spectrum of bactericidal activity, and they can be used in a broader pH range than other acid–type sanitizers, with activity up to pH 7.5.
- Disadvantages:
  - o Peroxyacetic acid sanitizers lose their effectiveness in the presence of some metals and organic materials, for example, when make-up water contains more than 0.2 ppm iron. They are corrosive to some metals, such as brass, copper, mild steel, and galvanized steel. This corrosiveness is accelerated by the presence of high chlorides in the water (>75 ppm). High temperatures will also accelerate the corrosion rate. Although "use" solutions are virtually odorless, full strength peroxyacetic acid sanitizers have a strong, pungent smell. As with all chemicals, proper, safe-handling techniques must be followed.

(vi) *Hot water*: another disinfection method providing a viable alternative to chemical sanitizer is also one of the oldest and simplest: heat. It is critical that a proper time and temperature combination is used, i.e. 85°C (185°F) for 15 minutes.

- Advantages:
  - o Hot water has the advantages of being relatively inexpensive, easily available, and effective on a broad spectrum of micro-organisms. It is non-corrosive, and provides excellent heat penetration into "difficult to reach" areas such as behind gaskets, and in threads, pores, and cracks.
- Disadvantages:
  - o It is comparatively slow compared to chemical sanitation, requiring a lengthy process involving heat, hold, and cool down. It can lead to film formation or "heat fixing" of any remaining soils, making future clean-up much more difficult. Hot water can shorten equipment life. Thermal expansion and contraction stresses equipment and can lead to premature failure. Equipment, including gasket materials, must be specially designed to withstand temperatures in excess of 82.2°C (180°F). Hot water in the system also creates potential condensation problems within the plant production environment.
  - o Water heated in excess of 76.6°C (170°F) is hot enough to cause serious burns; as with chemical sanitizers, proper safe handling procedures must be followed. Energy costs can be high to sustain high temperatures and there are others costs, including that of the water, heating equipment, and maintenance. In addition, water conditions are important, as high temperatures will increase the formation of hard water film and scale.

(vii) *Ozone*: an allotrope of oxygen, ozone is a powerful and naturally unstable oxidizing gas. It is a more powerful oxidizer than chlorine with an excellent broad spectrum of germicidal activity. Because of its instability, it cannot be stored, but must be produced on site at the location where it is to be used. Like chlorine, ozone is affected by pH, temperature, organics, and inorganics. It is most effective at a pH of 6–8.5. As the temperature increases, the half-life of ozone is reduced. It is not tolerant of organic soil. There are safety issues with the use of ozone, as it is a powerful irritant to the respiratory tract. There is also a high capital cost associated with the use of ozone.

Disinfection is the most critical step in a sanitation program. To ensure a high degree of sanitizer efficacy:

- It is necessary to determine the best sanitizer for the application. The supplier should have a high degree of expertise in this area.
- Ensure that all cleaning-chemical residues have been rinsed thoroughly before disinfection.
- Cleaning agent surfactants need to be compatible with sanitizer surfactants.
- All sanitizers must be diluted according to label directions.
- Staff must be educated not only on the proper use and handling of sanitizers, but in how to use them to best advantage given the particular plant conditions and circumstances.

Generally in selecting a sanitizer, it is important to consider the method of application, and spray, circulate, and foam are the normal choices. A sanitizer can only reduce the number of bacteria; it must therefore be applied to as clean a surface as possible. Corrosion is one of the largest concerns, as it damages lines and filling equipment and acts as a harborage for microbes. All sanitizers should be used at the proper temperature within the recommended concentration guidelines.

8.3.3 Maximizing effectiveness

Whichever sanitizer is chosen, a number of additional factors contribute to the effectiveness of disinfection:

- *Cleanliness of the surface*: soil can chemically inactivate the sanitizer as well as physically protect the microbial cell from direct contact with the sanitizer. The surface must be cleaned and thoroughly rinsed, so that it is free of soil and residual detergent that can chemically inactivate the sanitizer.
- *Intimate contact*: in order for a sanitizer to be effective, it must come into contact with the cell wall of the organism. Harborages, such as pits, crevices, and cracks, as well as soil residue can prevent this intimate contact from occurring.
- *Suitable product temperature and concentration*: chemical reactions are accelerated by a rise in temperature, so the efficacy increases as temperature and concentration is increased. An exception to the rule is in the case of iodophors, which vaporize at temperatures above 49 °C (120°F), so their use is somewhat limited.
- *Contact time*: the longer the contact time, the greater the kill.
- *Proper pH is crucial*: this is especially true with acid sanitizers and with chlorine, since chlorine has greater activity as the pH is lowered.
- *Composition of the water*: this can make the sanitizer chemically inactive, or buffer the pH and diminish the sanitizer's effectiveness.
- *Types of micro-organism*: not all sanitizers are equally effective against all micro-organisms, or the various forms of the micro-organisms. For example, cells in the spore state or in a biofilm are much more resistant than cells in the vegetative and freely suspended state.
- *Numbers of organisms present*: a sanitizer is only capable of reducing the number of bacteria, which means the higher the initial number present, the higher the number of possible survivors. High numbers can overwhelm the sanitizer.

All of these factors are interrelated and can normally be compensated for by adjusting another. If the sanitizer can only be prepared in cold water, it may be necessary to increase the contact time or the concentration to obtain the effectiveness comparable to that at a higher temperature with a shorter contact time or lower concentration. Also, to ensure maximum effectiveness, sanitizer solutions should be prepared fresh for each use.

In the past it was standard practice to spray or flood disinfectants on the surface of the filler. Today suppliers are offering sanitizers built on the latest chemistry that are self foaming and approved for no rinse applications when used in accordance with label directions. They offer the advantage of visual monitoring and longer cling time to vertical surfaces. Acid-based foaming sanitizers are available to aid in controlling mineral deposits on stainless steel surfaces. For walls, floors, and conveyors made of plastic polymers, self foaming quaternary ammonium based sanitizers using long chain technology have also been developed. In order to save time, and to increase efficacy, these new products are worth a practical test in the bottling facility.

8.3.4 New chemical technology for water and energy saving

Just as in every other part of the food industry (and perhaps more so), the bottled waters industry is responding to the increased emphasis on environmental stewardship, coupled with growing food safety concerns, and this is a key driving force affecting the choice of chemicals used for cleaning in the modern bottled water plant. Whether imposed by choice or by regulation, this has led to the development of cleaners that are effective at lower temperatures, which clean faster, and also save water.

Low temperature, one-step CIP cleaners are more commonly used in Europe, where they are often classified or recognized as germicidal cleaners, but are expected increasingly to come into use elsewhere. One such cleaner, tested for cleaning efficiency and efficacy, is a two-part product:

(i) Part A – Heavily wetted caustic solution.
(ii) Part B – PAA (Peroxyacetic acid).

The caustic solution and wetting agent penetrate the attached micro-organisms and/or soils. When the PAA combines with caustic, it releases free oxygen radicals that further break the attachment, freeing the soil and/or micro-organisms from the surface.

The example below illustrates how this new formulation compares favorably with more conventional methods.

Wash comparison example:

Conventional wash	**Low temp wash**
1. Pre-rinse/establish circulation	1. Pre-rinse/establish circulation
2. Caustic wash 71°C (160°F) 20 min at 3900 ppm	2. Low temp wash 105°F 15 min a. 1.5% active caustic
3. Post-rinse	b. POAA 8 min injection during final portion of caustic wash 1% to 1.5% must have active residual in return line.
4. Acid wash 60°C (140°F) 20 min at 4000 to 10000 ppm	3. Treated water rinse to release.
5. Post-rinse	
6. Hot water sanitize 85°C (185°F) 15 min)	
7. Treated water rinse to release.	
Total time 311 min.	Total time 116 min.

Savings: Temperature = Energy
Total Water = Incoming + sewer
Time = Opportunity time for production, less down time

The advantages can easily be illustrated by putting financial values to the numbers. The following example is in USD:

Energy cost per million BTU (British thermal unit)
– $ 14.80 Water – plant source cost to pump only
Sewer – city municipality $6.00/1000 gal
Line Speed 1100 BPM
Efficiency 85%
Opportunity time value $1000 per hour

	Energy	Chemical	Time	Water	Total
Current	$18.03	$13.88	$10,366.67	$192.60	$10,591.18
Low temp	$6.10	$28.80	$1,933.33	$73.80	$2,042.04
Savings	$11.93	($14.92)	$8,433.33	$118.80	$8,549.14

With only a small investment in chemistry, thousands of dollars worth of added time can be realized for production. This is accomplished without any compromise in disinfection efficacy.

8.4 TYPES OF CLEANING AND BASICS

Depending on the facility and the situation, there are several types of cleaning that make up a well-managed sanitation program, including dry cleaning, wet cleaning, manual and automatic, Clean in Place (CIP), Clean out of Place (COP), and Hi-Pressure.

In order for these to be effective, there are basic rules that employees and management must follow, generally referred to as the "6 × 4" process, comprising 6 steps necessary for cleaning and the 4 variables that we control in the process. The 6 steps are preparation, pre-rinse, washing, post-rinse, inspection, and disinfection. The 4 variables are time, temperature, concentration, and mechanical action.

Many sanitation articles refer to the "4 × 4" process, often without reference to the 2 steps of preparation and inspection. However, good preparation prevents cross-contamination during cleaning and ensures that the employee has necessary training and equipment to do the job. Inspection ensures that the cleaning process is done properly, with no short cuts. In modern line CIP applications, inspection may be facilitated by observing swing elbows or hook-up stations. Emphasizing inspection as part of the process will gain valuable data that will ensure control of the process and consequently clean lines and vessels.

8.4.1 Cleaning dynamics

Installing the proper sanitation equipment will accomplish two basic things. First, it will increase labor efficiency by reducing costs; second, it will provide a consistently effective sanitation program. Whether manual or mechanical soil removal is selected, the four variables, sometimes referred to, in automated cleaning, as the 4 Ts – Time, Temperature, Titration, and Turbulence, apply to every cleaning operation. All four are equally important, and effective sanitation cannot take place without the use of all variables in one degree or another. There are two basic ways to remove soils: manually or by mechanical methods. Each is effective in particular situations and for particular types of equipment.

8.4.1.1 *Manual method*

There is no doubt that the best-known and oldest method of cleaning is using just a bucket and brush. Hand cleaning is good for small areas or small pieces of equipment that must be disassembled and manually scrubbed. With manual methods, one is restricted to small areas and mild detergents, and if the person cleaning does not expend enough manual energy, poor cleaning will result. The detergent must be mild enough so that splashing will not cause skin burns. The contact time will vary with the size of the equipment but must be sufficient to ensure soil removal. Chemical usage can be high if an automatic dispensing system is not used, and manual cleaning is time-consuming with higher labor costs. In addition, cleaning aids, such as sponges or rags, should never be used in a bottled water plant; they entrap soils, providing breeding conditions for microbes, are hard to clean, and can contaminate surfaces. Color coded equipment for different areas or tasks are recommended and all equipment should be maintained in clean condition, fit for the purpose.

8.4.1.2 *Mechanical methods*

These offer advantages in controlling the temperature and concentration; however, it takes more engineering design to achieve proper mechanical action.

Depending on the concentration, temperature, and mechanical action, it is possible to adjust the contact time to maximize the cleaning cycle. One can increase one or the other of these variables, but they must all be in balance. However, the law of diminishing returns comes into play; just because good cleaning is achieved with a 0.5% solution at 71°C (160°F) for 30 minutes contact time, it does not necessarily mean that a change to 5% solution at 71°C (160°F) for 3 minutes will achieve the same results. In most situations, minimal contact time at a given temperature and proper mechanical action is needed to get consistent results. In addition, it would take extra rinsing to remove the 5% solution. When optimizing cleaning, it is necessary to establish base-line data and monitor the results of the changes. Changes in cleaning parameters should be made only with the assistance of the chemical supplier and plant management. The effects on the effluent system, water, and sewer cost also come into play when determining the best cleaning parameters.

Production time may be the most costly part of the sanitation process. Generally, cleaning and disinfection takes place at the expense of operations, and often it is viewed as a necessary evil. This is not a suitable or sustainable approach, as cleaning and disinfection is an essential function of the process. It is up to the plant management to learn how to optimize cleaning time and performance. The ultimate cost, in addition to lost product and product recalls, may well be "your brand", and in optimizing mechanical cleaning, investment must be weighed against the return. Several methods of cleaning need to be analyzed against the expense of time and utilities, energy, water, and sewer cost.

Some examples of mechanical systems are:

- *Foam systems*: foam application systems are widely used and are very effective for a range of applications. Foam cleaners can be applied directly to the surface of the soiled equipment, where the foam remains for three to five minutes, providing extended contact time. A brush is then used to scrub down all surfaces and properly rinse equipment with clean soft water to remove the cleaner and loosened soil. Foam in itself does not contribute to cleaning other than helping the chemistry to work more effectively. Care must be taken when using any high foaming product and it is important to be sure that the product in question has a specified content of cleaning product, so that the factory is not just buying "suds". It is also important to read the Material Safety Data Sheet and to review the chemical breakdown of the cleaning product by comparing cleaning compound content and dilution rates. Both foam and thin film will allow the employee to clean more surface area faster than bucket and brush; however; they are only ways to dispense the cleaning chemical. The real-time savings come by combining them with a properly designed rinse system.
- *Foam tank*: this is a 5, 15, or 30 gallon tank, which must meet regulatory requirements as a pressure vessel. Water and an appropriate amount of cleaner are added to the tank, the lid is secured; with an air hose attached, the pressure is brought from 40 to 60 psi to provide thick foam.
- *Wall mounted foamer*: this unit works off a central system in which the chemical is brought up into the foamer from the one-gallon container. Air and water are supplied to the unit and the chemical is automatically diluted. A wall-mounted unit can be configured to include cleaner and sanitizer dispensing systems with a rinse feature, enabling foam, rinse, and sanitizer from a single unit.
- *Central system*: in this application, the chemicals and the pumping system are located in a central room. One pump brings prediluted cleaning product to foam or sanitation stations throughout the plant. Sanitizer is also pumped out to these stations through a separate line. Pump and line size are important, and the type of pump is also critical; it should be made of sanitary plastic tubing or stainless steel, so it will have the highest resistance to chemical corrosion. This is an excellent method of cleaning and allows total control.
- *High pressure spray*: this is not best suited for use inside a processing environment because a spray unit creates aerosols, meaning that pathogens can be carried on the airborne spray to other areas throughout the plant. The spray can also have the disadvantage that instead of ridding the processing area of organics, it may only be blowing them from one side to another. One other concern with high pressure is possible damage to process equipment by blowing the grease out of bearings or forcing water into crevices and electrical outlets. Care and instruction need to be provided to personnel, as high pressure air can be dangerous.

A good sanitation program may also use COP (Clean out of Place) and CIP (Clean in Place) systems, both of which allow the employee efficient use of time. COP washer tanks (Fig. 8.4) are designed for parts that are otherwise manually washed, the parts being placed in baskets that are loaded into the COP tank. Each COP System uses a variety of different high velocity water jets to clean the parts as they are submerged in a cleaning solution. This allows parts to be cleaned while the operator does additional tasks; higher temperature and concentrations are also possible than with manual methods. Ultrasonic baths can also be used for cleaning intricate small parts.

Fig. 8.4 A COP tank.

The above methods can save time and increase sanitation efficiency; again, the only factors controlled are time, temperature, concentration, and mechanical action. Nevertheless, a well-trained, well-motivated employee is the most important part of good sanitation. However, as bottling plants grow, high volume production equipment and lines require stand-alone CIP equipment, and this is covered in Section 8.5.

8.4.2 Brush Program – guidelines on the proper use of brushes in bottling plants

Brushes used in different parts of the plant and for different purposes should be segregated. Brushes should be maintained in good repair, properly stored when not in use, and sanitized in between uses. Brushes and the maintenance of brushes are important parts of a complete sanitation program:

(i) Why should you color-code?
- Help prevent cross-contamination between food contact areas and non-food contact areas.
- Easy reference on proper use of color-coded tools.
- Reduce cleaning tools migrating from one dept to another.
- Better credibility with current and potential customers, a well-designed color-coding system is an important part of GMPs, HACCP plan and overall food safety programs.
- Ship safer product.

(ii) Color-coding in practice:
- The first step is planning. Involve both employees and management. Management should explain the reasons for color-coding to all employees. The best ideas for color-coding often come from production, sanitation, and/or maintenance workers. Also, employees are more likely to be enthusiastic about color-coding if they have been involved in the planning stages.

- Walk through the plant and try to divide areas into zones with different hygiene requirements. Assign a different color to each zone. This process can take some time, with several modifications along the way. Make sure everyone agrees to the scheme before implementation. Keep in mind there are no standardized plans. Choose the colors that work best for your plant.
- The plan should be visual, and as simple as possible. Overly complicated plans will be difficult for employees to understand and for supervisors to implement.
- Cleaning tools with the same color should be cleaned and stored separately. Once cleaned, they should not come in contact with other brushes.
- All key areas should be marked with signs or posters, in multiple languages if necessary.
- Training is crucial. Behind every successful color-coding plan is a company management that has provided training and motivation to improve hygiene.
- Material of construction – brushes need to be of a synthetic composition (no wood or natural bristle). Polypropylene bristles should be used with acids.
- Wash, rinse, and sanitize food contact brushes between every use. Hang similar color brushes together when not in use. Check condition of brushes regularly. Replace worn and matted brushes as needed.
- Color coding – brushes should be identified and utilized only in specific production areas.
- The following color usage profiles are suggested:

WHITE	Food contact surfaces
BLUE	Non-food contact surfaces
RED	Sanitation
ORANGE	Allergen line
YELLOW	Restrooms
GREEN	Maintenance
GREY	Waste or trash
BLACK	Floor drains

8.4.3 Master sanitation schedule

For effective cleaning and sanitation, it is necessary to define a plan, known as a “master sanitation schedule” or, as some call it, a “task manager”. The master sanitation schedule can range from a simple form to a computer driven database linked to scheduling, man-hour projections, and Sanitation Standard Operating Procedures (SSOPs). In any case, it must cover the whole plant, from parking lot to roof maintenance, to filling room.

This tool ensures that the whole plant is cleaned and sanitized on a regular basis. To acquire information, data will be needed from many sources to determine the frequencies for cleaning and disinfection. Equipment manufacturers will provide general guidelines; laboratory data such as microbiological swabs will also give guidance on appropriate frequencies. Employee feedback, sanitation inspections, and audits will also be a useful source of monitoring to provide information. The key is that this is a living document, and by keeping the schedule updated it is possible to have a cleaner and better running plant, reliably producing safe and wholesome product.

8.4.4 Sanitation Standard Operating Procedures (SSOPs)

Sanitation Standard Operating Procedures (SSOPs) should be in place for every task that is on the Master Sanitation Schedule and should contain the following information:

- *Equipment*: name or reference.
- *Revision date*: everyone needs to know it is current.
- *Supplies needed*: chemical, brushes, wrenches. etc.
- *Safety equipment*: Personal Protective Equipment (PPE) needed for the job – Lock out/ Tag out instructions if needed.
- *Cleaning procedure*: this can be as detailed as needed on complex equipment and pictures can be attached. Abstracts from the equipment manuals may be helpful.
- The employee should be involved in describing the job and cleaning.
- This document should be at the job site and updated if changes in procedures are made.
- Sign off and audit by management and employee.

An inspection and equipment release form should accompany the SSOP, enabling all parties to know that the job has been completed properly. The inspection should have an objective non-biased test if possible to ensure satisfactory results have been achieved. Many inspections include quick testing methods to give employee feedback.

The employee is the key to any sanitation program; he or she must be well trained on Good Sanitation Practices (GSP) and follow them and SSOPs zealously. GSPs involve employee hygiene, equipment, and cleaning aids maintenance.

8.5 CLEANING IN PLACE (CIP)

CIP is the process of bringing the cleaning solution to the equipment and piping. It can be manual or automated, and as bottling plants grow, high volume production equipment and lines require stand-alone CIP equipment. CIP for the Bottled Water Industry is an integral part of the sanitation process. The same basic rules apply, meaning that time, temperature, concentration, and mechanical action must be controlled. In addition, to ensure quality and repeatability, proper data acquisition and monitoring are necessary. The effectiveness of CIP is more than just pushing the buttons; it takes plant management involvement, and it must be properly maintained and monitored. CIP has to be on the same level as the plant's processing equipment. If all the proper components are not in place along with trained employees motivated to do their jobs, CIP will become "Circulate in Place", not "Clean in Place".

CIP systems use fixed pipes, spray devices, valves, tanks, sensors, and controls, to provide closed circuit cleaning and improve the efficiency and repeatability of the cleaning and disinfection process. CIP systems offer significant advantages over other cleaning methods, including reduced labor, energy, and water costs, while providing better results due to the ability to use higher temperatures and concentrations. The automatic programming feature of most CIP systems provides a degree of repeatable performance not found in other methods. In addition, since the processing equipment does not need to be taken apart and reassembled, the risk of re-contamination is greatly reduced.

An effective CIP system delivers some significant advantages:

- reduced labor;
- energy control;
- water control;
- consistent results (repeatable with automated controls);
- higher concentrations when needed;
- higher temperatures;
- safety – employees do not have to touch hot surfaces or come into contact with chemicals.

To achieve desired results, several choices must be made, to include location and type of system, hydraulics, spray devices, and programming. CIP systems must be integrated into the process design.

In the 1920s, two trade associations and one professional society joined together to formulate uniform standards for dairy equipment. These standards became known as "3A standards". Today, equipment fabricators, equipment users (food processor), and regulatory officials work together to develop and set sanitary standards for food processing equipment of all types. Equipment that meets the design criteria is permitted to use the "3A" symbol. In the global market, "3A" works with the International Organization for Standardization (IOS), Technical Committee 199, and the International Dairy Federation (IDF)) Group of Experts B3 for Sanitary Standards.

Once it is known that the equipment and affiliated piping are designed correctly, it is necessary to determine which type of CIP system is right for the operation, and the hydraulics and spray devices required.

Most regulatory agencies require a minimum velocity of 1.5 m (5 ft) per second through all parts of the CIP system. This velocity through a pipe creates turbulent (rather than laminar or straight line) flow. In piping, if the diameter is smaller than 7.5 cm (3 in), 1.5 m (5 ft) per second is acceptable for turbulent flow, and for 7.5 cm (3 in) and larger, 2.4 m (8 ft) per second is required. This provides the necessary scrubbing action inside the piping (see Fig. 8.5 and Table 8.3).

In vessels, spray devices achieve complete coverage and provide the hydraulics. The flow required depends upon the vessel shape and the means by which this is calculated is shown in Appendix 1.

If performed correctly, these calculations will give the flows required to clean both lines and storage vessels. However, CIP is more than just a matter of putting water in; in order to achieve good hydraulics, proper solution return is needed to complete the loop. To obtain balance, the return should be slightly faster than the supply, otherwise water building up

Fig. 8.5 Laminar and turbulent flow.

Table 8.3 Typical cleaning flow.

Typical cleaning flow				
Pipe size		**Velocity ft/sec.**	**Flow GPM**	**Time to fill 10 gal. can**
O.D.	**I.D.**			
1.5	1.40	5 fps	24 gpm	25 sec.
2	1.87	5 fps	43 gpm	14 sec.
25	237	5 fps	69 gpm	9 sec.
3	287	8 fps	163 gpm	4 sec.
4	383	8 fps	288 gpm	2 sec.

Table 8.4 Tank outlet valve flow.

		TOV flow
Pipe size		**Gravity flow through TOV**
O.D.	**L.D.**	
1.5	1.40	40 gpm
2	1.87	75–80 gpm
2.5	2.37	115–120 gpm
3	2.87	190–200 gpm
4	3.83	250–275 gpm

will cause "puddling", inhibiting the cleaning process. Other factors to consider when CIP cleaning vessels are shown in Table 8.4:

- *Tank outlet valves*: suitable size.
- *Return pumps*: 12–18 inches (0.3048–0.4572 m) below tank outlet.
- *Tanks pitched*: 3/4 inch per ft (19 mm/0.3048 m).

The selection of spray devices is also critical, as it is important to have complete coverage and flow rate compatible with the vessel. The spray device should be self-draining, self-cleaning, and made of sanitary materials (304/316 stainless steel). Fixed and rotating spray devices are both commonly used; the fixed types have no moving parts and are the most widespread in use today. They come in a variety of sizes and shapes (Fig. 8.6).

Spray devices must provide proper coverage at designed flow rates to make it possible to use large tanks and vessels that could not otherwise be cleaned manually. Effective and repeatable CIP cleaning depends upon the proper selection of the spray device, based on the size and configuration of each tank and vessel. If the correct spray device is installed, cleaning will take less time, which saves water and chemicals and minimizes effluent charges. Fixed devices have advantages over rotating ones, in that they have no moving parts to break. All spray devices can clog with foreign materials such as gasket pieces, etc., even if a strainer is in line. Checking for clogging should be a regular part of CIP preparation.

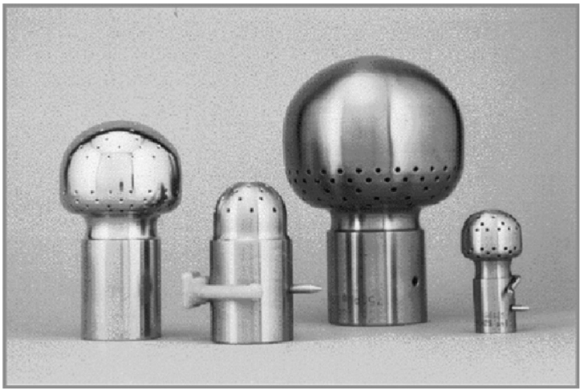

Fig. 8.6 Selection of fixed spray devices.

Having addressed the minimal CIP flow requirements, it is necessary to choose between manual Vs mechanical (automatic) systems. Manual CIP can only be relied upon for the simplest of circuits, generally referred to as pot-and-pump applications. Even then, there is likely to be little or no documentation to ensure proper cleaning. With the many regulations covering the bottled water industry, it is essential to know that the proper time, temperature, concentration, and mechanical action are achieved each and every time. This can only be done successfully with modern CIP systems designed for the plant's cleaning needs and that will be capable of repeatable cleaning performance. Automation is the only way to meet these standards, and the choice will be in determining the right kind of system and controls that best fit the plant.

It is crucial that all processing equipment, including storage tanks, piping, filter housings, UV units, contact tanks, fillers, and tanker trucks be properly cleaned and sanitized to maintain high product quality and shelf-life, and to prevent the spread of microorganisms.

Filling machinery in most cases will be integrated into the CIP system. Most fillers will require a pressure ring or CIP cup attachment for cleaning. It is important that filling equipment be designed for the CIP process with parts that are compatible with the temperature and chemical concentrations needed in CIP programs. Gaskets should also be the subject of a selection and maintenance program and be compatible with the water to be bottled, cleaning chemicals, and methods used. When integrating fillers and other specialty equipment into the CIP system, it is important to consult the equipment manufacturer for recommended cleaning protocols, programming, and flow requirements, The plant Quality Assurance department and chemical suppliers both needs to be part of the CIP process to ensure chemical capability and efficacy.

8.5.1 Automated CIP

Consistent CIP results were made possible in the early 1950s, largely with the advent of the automated valve, which in the bottled water industry are usually air operated, sanitary valves. They are used to control the direction of the flow in the circuit or to block or shut off flow (Fig. 8.7).

The simplest is the 2-way (shut-off or blocking) valve, in which the actuator opens and closes to stop flow. This is used for simple tasks, and a typical application would be for a

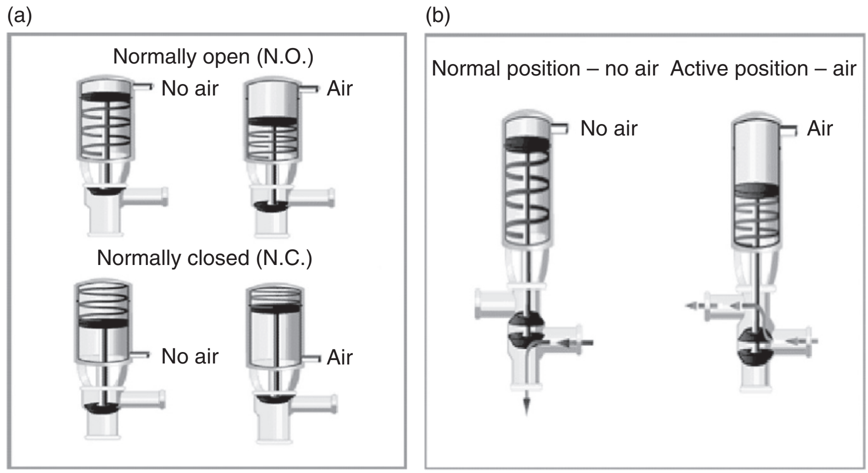

Fig. 8.7 Automated valves: (a) shut-off or blocking valve; (b) three-way valve.

tank outlet valve. The 3-way valve is used for directional flow control, but without stoppage of flow; this valve is commonly used and referred to as a divert valve. The flexibility provided by using these valves in various configurations gives the ability to move water and other liquids to any filler from any storage vessel in the plant.

Valve matrices that have been put in modern facilities require special programming and valve routing during cleaning. Each valve must be cleaned and sanitized on both sides, the valve seats, stems, o-rings, and seals being cycled so that each valve is cleaned on all surfaces.

The plant also has the responsibility to prevent cross-contamination and deadlegs that could allow product to sit idle for hours at a time, jeopardizing both safety and quality. Several methods have been designed to prevent this, and some allow idle lines to be cleaned or purged while the rest of the plant is operating. The most common method is the block and bleed configuration. In this case, flow is stopped and then diverted to drain or the CIP return. Double block and bleed allows an atmospheric air break to ensure that product and unlike fluids (e.g. product in one circuit and CIP chemicals in another) cannot be mixed. To eliminate the extra valves needed, new sanitary valves have been designed for mix-proof operation. These allow two different products to flow through one valve, allowing cleaning on one side and product on the other. The valve consists of two bodies, which are welded together. The seats for the upper and lower plugs are located between the bodies, two independent plug seals forming a leakage chamber between them. Any leaking product from one side or the other flows into the leakage chamber and is discharged through the leakage outlet. The cost is much greater but this valve allows more flexibility in cleaning and production.

8.5.2 Types of CIP systems

CIPs systems are of four common types: single use, re-use, solution recovery, and multi-use. There are advantages and disadvantages to each, so it is important to know the process, equipment, and environment in deciding which to use.

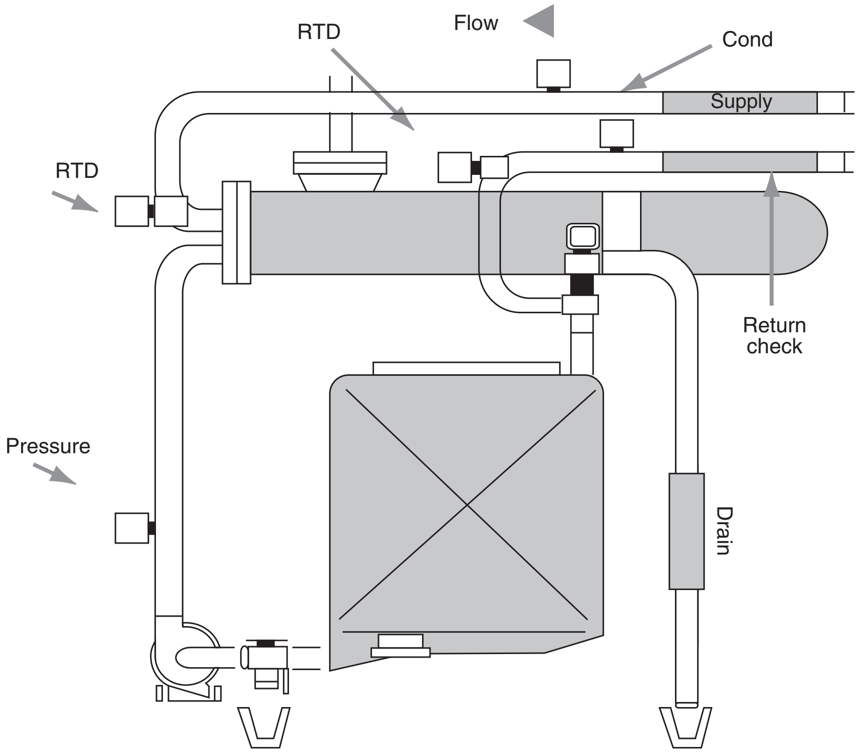

Fig. 8.8 Flow diagram for single use CIP system.

(i) *Single use system*: a fresh cleaning or sanitizer solution is prepared for each cleaning cycle and then discharged to the drain (Fig. 8.8).

Advantages	**Disadvantages**
• Versatile	• High water use
• Multiple detergents/concentrations	• High detergent use – Line circuits
• Fresh wash solutions	• Longer delay to temperature
• Low volume wash water	
• Multiple temperatures	
• Less thermal shock	

(ii) *Three tank re-use CIP system*: separate tanks are used for fresh water and for each cleaning solution needed. They continually use the same wash solution from CIP circuit to CIP circuit. The wash solution must be boosted for each use to maintain the specified concentration. The tank must be drained regularly to remove the accumulated soil, and refilled with fresh water and fresh detergents. A fresh sanitizer solution is prepared for each cleaning cycle and discharged to drain (Fig. 8.9).

Fig. 8.9 Three tank re-use CIP system.

Advantages	Disadvantages
• Easy to use	• Single detergent/concentration
• Effective	• Limited wash temperatures
• Low detergent use	• High sanitizer costs
• Short delay to temperature	• Heat shock

(iii) *Solution recovery*: a recovery tank is used to recover the wash solution and post-rinse, which is then used for the second and third pre-rinses on the next CIP circuit (Fig. 8.10). This type of system can be used in connection with a multi-tank (re-use) or a single use CIP system.

Advantages	Disadvantages
• Versatile	• Detergent use
• Reduced water use	– Higher than re-use
• Some energy savings	
• Better pre-rinse	

(iv) *Multi-use CIP system*: through the use of 3 or 4 tanks and extra valves, CIP systems can be set up to operate either as a re-use or single use, with or without solution

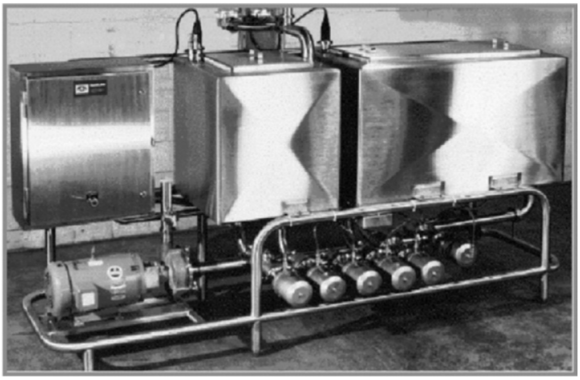

Fig. 8.10 Solution recovery CIP system.

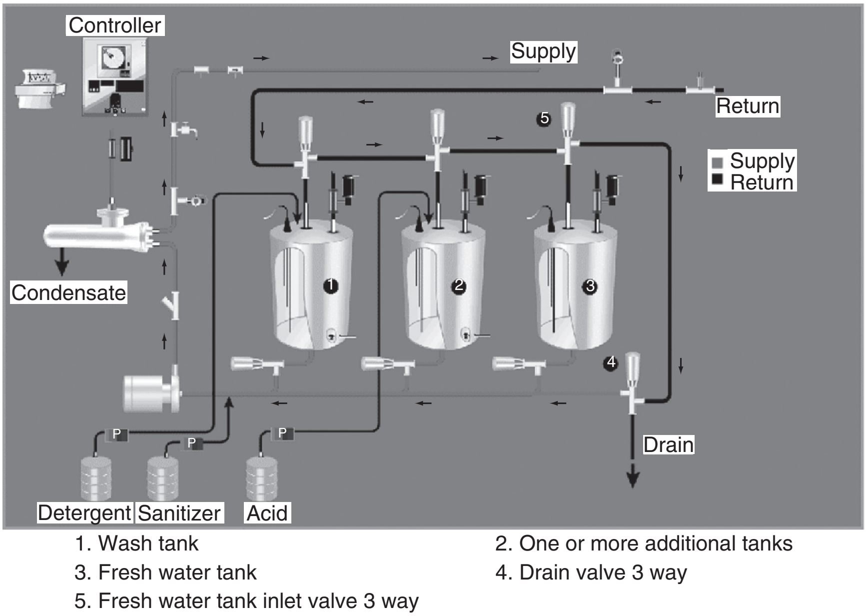

Fig. 8.11 Flow diagram for multi-use CIP system.

recovery. By using different programming techniques, selected programs can be run in any of the different modes (Fig. 8.11).

Advantages	**Disadvantages**
• Multi-use/Single use re-use/solution recovery • Circulate sanitizer/hot water • Optimize programs • Optimize water, energy, chemical use	• Higher equipment costs

8.5.3 CIP control and data acquisition

If the need is for one CIP system, multi-use is the best option. The controller will activate the pumps and valves control the heating, flow control, and safety interlocks. Controllers are available in several types, ranging from old-fashioned drums, cams, and electronic sequencing devices to Programmable Logic Controllers (PLCs) and dedicated PC microprocessors. A dedicated microprocessor has CIP logic programmed in, and recognizes, for example, what valves to open or close to accomplish each step. The latter are today's choices; with them, it is possible to record performance data – time, temperature, concentration, and mechanical action. The table in Appendix 2 poses some questions of relevance to help in choosing a dedicated controller or PLC based controller. The choice will depend on plant expertise available and/or local support for the controller requirements.

The wash program consists of clearly defined sequences or steps; for example, a "three-step" program consists of: (i) Pre-rinse; (ii)Wash; and (iii) Post-rinse. This could be hot or cold, depending on the utilities supplied to the CIP system.

8.5.4 CIP program and programming

During each CIP cycle, there is a subset of actions that must occur. In a rinse, the tank outlet valve (TOV) opens, the CIP supply pump turns on, the routing valves open so water goes down the designated pipe line, the return valves open to drain, the fresh water valve opens, level controls in the rinse tank turn on, etc. Keeping track of this activity is difficult, so it is advisable to use a pin chart and a drawing with the CIP circuits highlighted to see solution path and identify valves that need to be sequenced.

Pin charts generally contain: program, CIP function, CIP component (on/off), values (time, temperature, volume (water, cleaner, and sanitizer), and flow rate.

The example below is of a pin chart for a simple 4-step line wash. It is a combination of the 3 steps above, with a sanitizer step added (Table 8.5).

Along with the "pin chart", the programmer often provides a control description document, which provides a common language, and the example below is typical of the steps one would expect in a program. In most plants, these programs are more complex, and valve sequencing will be involved. If there are any sub-routes in the line circuits, each leg should run approximately 8 to 10 minutes at a concentration and temperature to ensure proper cleaning. A sanitizer step must be directed down each leg for the proper contact time recommended for the sanitizer.

In tank programs, the rinse part of the program is "pulsed" to ensure effective draining. Three pulses are recommended and this can be accomplished by shutting off the supply pumps while leaving on the tank return pump. This will evacuate all the water and remove any residual from the bottom of the tank.

The chemical supplier may have standardized checks that both they and the plant operators can use. Chemical suppliers should train plant employees in testing so that the right detergent and sanitizer concentration is used in each circuit.

What data should be collected from CIP systems, and how, is sometimes determined by the regulatory agencies under which the plant manufactures. In general, all plants will benefit from knowing the date, circuit ID or name, operator, time, temperature, flow rate, concentration, and pressure. In addition, other components may be added to the system, such as a flow meter, conductivity sensor, and pressure gauge. Some of the data from these devices can be recorded with a simple chart recorder, showing time, temperature, and

Table 8.5 Pin chart of a line program for a re-use CIP system.

CIP PIN Chart - Line Program Re-Use CIP System								X = Active/On				
Function	**Value per segement**	**Fresh water tank – outlet valve N.C.**	**Fresh water valve**	**Alkaline tank – outlet valve N.C.**	**Alkaline tank – inlet valve N.C.**	**CIP supply pump**	**Steam valve**	**Retum pump**	**Drain valve N.O.**	**Detergent control system**	**Sanitizer pump**	**Valve sequence progm**
Rinse to drain	2 min.	X	X			X						X
Pause	Re-start					“MANUAL PREPARATION”						
Rinse to drain	2 min.	X	X			X						X
Alkaline wash	10 min.			X	X	X	X		X	X		X
Rinse to drain	4 min.	X	X			X						X
Sanitize	2 min.	X	X			X					X	X
Shut down												

pressure; the operator is required to fill in date and circuit information and sign at the end of each shift. They can also record chemical concentrations on the chart, which should be reviewed daily by management and then filed. By doing this the plant will have a history of the system and performance data on wash frequencies.

Today's modern PLC and dedicated processors can also perform data acquisition, and the plant will want to look at the regulatory guidelines for electronic data collection to make sure it is in compliance; in the USA, 21 CFR part 11 is a good starting place. The list below is not all-inclusive, but gives a general idea of what to look for in electronic data acquisition and management:

- direct wiring to PLC;
- automatic report generation upon conclusion of CIP;
- ability to have printed statement of what is being cleaned (e.g. Tank 1, Transfer Line, etc.);
- graphical representation of conductivity, supply temperature, return temperature, and flow rate, with some markers showing the initiation and conclusion of distinct steps;
- summary stating CIP start time, finish time, total cycle time, time since last CIP completed, and for caustic circulation, acid circulation, and final rinse: average flow rate, average conductivity, and average return temperature;
- ability to show any alarms (e.g. CIP aborted, steps skipped, exceed of maximum time for temperature, conductivity, cycle time;
- historical data back-up via a memory card or PLC.

The CIP System in bottled water facilities today is a matter of routine. There are many choices, from the design of the transfer piping to the right system and controls. However, no matter what is chosen, it is only as good as the operator's ability to run and maintain it properly. The operators need to know the system and programs well enough to monitor the results. Performance checklists should include but are not limited to CIP performance checks for lines and CIP performance checks for vessels. Without well-trained, well-motivated employees, no sanitation program will ever be successful.

8.5.5 Hot CIP safety precautions

- Never operate the CIP system in a manner for which it is not designed. Always operate well within safe parameters. Always verify that all equipment to be cleaned can tolerate the temperature, concentration, pressure, and flow rates generated by the units. Always be cautious to allow proper venting of atmospheric tanks by opening the manway during the CIP process. Never allow microfilters and UV lights to be subject to water hammer or high pressures.
- The CIP system uses highly corrosive chemicals as a cleaning medium that can cause burns to the skin and eyes. Always wear personal protective equipment (chemical resistant gloves, apron, goggles or face shield, and boots) when making and breaking flow panel connections or removing equipment for maintenance. This is especially important when opening and handling chemical drums and taking samples.
- Be careful when maneuvering chemical drums, portable return pumps, and other heavy objects/equipment. Always get help or use proper equipment such as forklifts to prevent back strains and other forms of personal injury.
- Never by-pass the safety features of an electrical panel while the unit is in operation, and obtain the help of a qualified electrician when troubleshooting electrical panels.

- Always keep guards on rotating equipment in place. Never operate any equipment without proper safety precautions in place. Never allow any CIP circuit to be operated, knowing that there is damaged or defective equipment in line.
- Never operate the CIP system prior to proper calibration of all instrumentation. Never adjust or "tweak" any equipment or instrumentation without completely reading and understanding the maintenance and operating manual first.
- Communicate to all personnel that a CIP cycle is running and minimize excess employee traffic in the area where CIP circuits and equipment are located.
- Remember that the CIP system can start and stop remote equipment automatically without warning. Never do maintenance or place yourself in a dangerous situation without following appropriate equipment electrical isolation procedures.
- Always completely walk the CIP circuit during the pre-rinse to identify potentially dangerous leaks prior to chemical addition and heat-up.
- Never enter the tank of a CIP system or place any part of your body inside without following your plant's confined space entry procedures. Never open the manway of any CIP tank or tank to be cleaned while the unit is running.
- The CIP system may use high temperatures to aid in the cleaning process. Always be cautious of hot surfaces and never touch any CIP equipment unless the unit is shut down and allowed to cool. Always be extremely cautious of steam piping. Wear suitable clothing when working with hot CIP surfaces, circuit piping, and equipment.

8.6 GENERAL GUIDELINES FOR CONDUCTING A CLEANING AND SANITATION VALIDATION

Cleaning and sanitation is an important process step, validation ensures that the cleaning and sanitation cycles effectively remove residues to a predetermined level of acceptability and in an efficient manner. Validation must take into account the worst case scenario, i.e. new line, new process, or lines have not been validated for a long time. Validation is essential to ensure food safety for the following reasons:

- to ensure a consistent product quality by optimal cleaning and sanitation process;
- to reduce the use of chemicals, water and energy;
- to adjust the cleaning approach to new technologies;
- to increase the understanding of cleaning;
- to increase the safety of the personnel carrying out cleaning tasks.

The mindset about importance of cleaning and awareness needs to be developed at all levels. Factors for a successful validation:

(i) *Planned allocation of time*: the validation of cleaning is not a quick one-day study. Factory complexity has an influence on time and number of people required.
(ii) Clearly defined responsibilities.
(iii) A validation team with an expert as leader.
(iv) Provision of adequate monitoring tools.

(v) Use of the operators' input during the prerequisite study time.
(vi) Coaching of people involved in cleaning.

Phase 1 is planning and preparation of the validation study with personnel, communicate with sanitation manager and to explain the purpose of the validation. During the planning stage, availability of any necessary modification must be confirmed. Everyone involved must understand the basic concepts of cleaning validation.

The preparatory step is to collect the necessary information on all elements of the CIP process and to document these elements. This should include the mapping of the CIP circuits for both product and chemical lines with all details of valves and pumps listed, and review of the instrument calibration, history of the CIP circuits, and documentation.

Phase 2 is performance qualification, in which it is verified that the selected cleaning system delivers and circulates cleaning solutions according to the pre-selected parameters in the standard operating procedure. The sanitation schedule is reviewed to confirm that all equipment is soaked, cleaned, and sanitized. The appropriateness and effectiveness of the cleaning equipment and chemicals are assessed by monitoring the flow rate, chemical concentration, contact time and temperature for cleaning and sanitation, the effectiveness for both alkaline cleaner, and sanitizer steps can be evaluated. This will confirm, for example, whether the water temperature for the alkaline rinse step achieves 60–71°C (140–160°F) necessary for the prevention of any biofilm formation.

Phase 3 of the validation study is a synthesis of the results and the establishment of an action plan. All results of the validation study need to be evaluated, to check if they comply with the acceptance criteria and to identify deviations or problems, and to correlate observations with documentation of problems and microbiological counts. The following types of sampling are appropriate:

- *Direct surface sampling*: physical with swab methods for wet cleaning and visual inspection for all cleaning. The swab method is useful for difficult to clean parts.
- *Indirect sampling*: use of rinse solutions post CIP.
- Time, temperature, concentration, and flow rate are within the operating parameters.

If the results comply with the acceptance criteria, the CIP is validated and the routine monitoring and verification are scheduled. If deviations or problems are found, an action plan is prepared to correct potential sources of problems, with dates and plans for re-validation.

Phase 4 is the follow-up after validation; this should be an agreed plan between production and quality assurance to develop the daily or routine monitoring plan. Operators should be trained to ensure they understand tests and deviations to report.

Validation of cleaning and sanitation needs to be followed up by regular monitoring and by verifying at least once a year if the results of the standard operating procedures are consistent and meet the acceptance criteria. The involvement of chemical suppliers is recommended, as their experience and expertise can complement the in-house knowledge. The supplier can also give advice on the compatibility of chemicals with a particular material or equipment parts, or provide key monitoring tools specifically required for the validation.

8.7 THE DO'S AND DON'TS OF CLEANING AND DISINFECTION

THE DO'S

1. Become familiar with products and their applications, because misapplication can cause explosive chemical reactions or discharge dangerous vapors.
2. Read the labels on all products, and become familiar with their applications and properties, so that you will be aware of their compositions and potentially hazardous capabilities.
3. Know what antidotes to use when someone becomes injured so you can assist in directing immediate first aid and minimize injury.
4. Know the limitations and capabilities of products so you will understand the seriousness of injury that could occur when skin tissue is brought into contact with specific detergents.
5. Know the maximum operating temperature of products so that when preparing cleaning procedures or observing cleaning operations you will know when temperatures exceed that maximum.
6. Know which products are acidic or alkaline so that instant first aid action can be taken in case of injury.
7. Always mix detergents in "use" dilution – not their concentrates.
8. Wear and instruct employees to wear necessary protective clothing, such as goggles and/or facemasks, when dispensing detergents.
9. Wear footwear appropriate to the environment, which protects from moisture and provides non-skid soles.
10. Always provide detailed written instructions when training personnel on the safe use of products to minimize misunderstanding and prevent unsafe action.
11. Teach safety by example, as a picture is worth a thousand words.
12. Use equipment that allows safe sampling and dispensing into test equipment when sampling solutions that usually are at elevated temperatures.
13. Check solution temperatures with a thermometer, which gives maximum protection to its user from high solution temperatures.
14. Know the conditions of application and chemical characteristics of sanitizers you are using to prevent injury to personnel and equipment.
15. Know safety as applied to Bulk Handling Programs so that you can observe an installation and know that safety is being practiced concerning eyewashes, showerheads, and bulk tank labeling.

THE DON'TS

1. Do not mix acid and chlorine products, because this releases poisonous chlorine gas.
2. Do not use a liquid chlorinated cleaner on an automated OVERRIDE program, because of the potential release of chlorine gas.
3. Do not permit "override" cleaning without instructions, because of the possibility of damage to equipment or personal injury from chemical reaction.
4. Do not add water to a pail of powdered caustic to dissolve the powder because of flashback, caused when water is added to powder. Rather, add caustic to a pail of cold water.
   NEVER ADD WATER TO CONCENTRATED CHEMICALS!
5. Do not use a lightweight plastic pail when dissolving caustic chemicals, because heat generated by the action of water and caustic will soften the pail.
6. Do not use hose stations where hot water is produced by mixing cold water and steam unless you have knowledge of the hot water generation process, because this can pose a real danger of blowing live steam.
7. Do not try to remove caked powders from shipping containers, because of the hazard of product flying into the eye or making contact with the skin.
8. Do not mix wetting agents and nitric acid products in concentrated form, because the oxidizing reaction of acids and wetting agents can cause a violent chemical reaction and flashback.
9. Do not charge detergent reservoirs that are at or above eye level, because of the danger of splash back of product or product spilling back on the person.
10. Do not mix detergents without knowledge of their compatibility, because of the danger of reaction and flashback.
11. Do not dispense products from shipping containers that are not labeled, because of the possibility of misapplication of detergent, causing personal injury or damage to equipment.
12. Do not store products in unlabeled containers, because any person cleaning up may not know what product is in use, resulting in misapplication.
13. Do not use a drum pump for dispensing two different products, because the pump may not have been properly rinsed, resulting in the possible mixing of two incompatible products, causing a chemical reaction or flashback.
14. Do not pressurize a shipping container for dispensing product, as no shipping container is designed to withstand more than atmospheric pressure.
15. Do not dispense highly concentrated caustics or acids into open containers, but rather into a closed system to prevent personal injury from splashed products.

(*continued*)

16. Do not transport liquid products, especially highly corrosive types, in open containers, because of splashing and spillage potential.
17. Do not add detergents to hot water unless procedures are written with precautions, because of the potential hazard of flashback.
18. Do not start circulating hot water containing detergent without establishing circulation and checking for leaks, as leaks in such systems are dangerous.
19. Do not add concentrated detergents directly to processing equipment. Rather pre-dissolve, or have water in a vessel, because of the potential for chemical reaction with product contact surfaces of equipment.
20. Do not enter any closed vessel immediately after cleaning, before venting, or changing the air supply within. Use the "buddy system", because of the potential presence of carbon monoxide gas.
21. Do not use detergents at concentrations in excess of recommendations, because of the potential for damage to equipment and personnel.
22. Do not use cleaning solutions above recommended temperatures, because of the potential of pumping problems and splashing of solution causing injury.
23. Do not dispense a detergent from a shipping container or into a point of application without protective goggles and clothing.
24. Do not perform a hazardous task without a planned route of exit to a safe area, in case unexpected things happen.
25. Do not substitute detergent unless you have a thorough knowledge of the substitute product as equipment damage, cleaning failure, or personal injury may occur.
26. Do not wear pant legs on the inside of boots. Rather wear them outside of boots to prevent detergent from going into an open top boot in case of spillage.
27. Do not give verbal instructions on cleaning procedures, because of the potential for misunderstanding. In addition, verbal instructions leave no document for future reference or review.
28. Do not dispense used solutions at the end of a cleaning cycle to the floor where flooding will occur, because floors become slippery when detergents are discharged to them and not properly rinsed.
29. Do not swing discharge lines carelessly to the floor or drain when discharging spent solution, because of the danger to other employees who may not be expecting your action.
30. Do not manually clean equipment when it is operating.

ACKNOWLEDGMENTS

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"Make the Right Choice" Ecolab Training Series

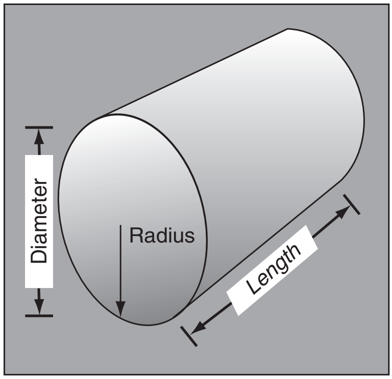
APPENDIX 1 – CALCULATIONS FOR ESTABLISHING MINIMUM FLOW RATES FOR CLEANING CYLINDRICAL VESSELS

Horizontal tanks or vessels: cleaning flow rate – 0.12–0.30 gpm/sq ft of surface area

- *Cylindrical tanks*: use the following formula to calculate surface area:

  π (3.14) × r^2 (radius) = area of one end
  π (3.140 × d (diameter) × l (length) = area of wall

  For example: the surface area of a cylindrical tank 7 ft in diameter (3.5 radius) and 10 ft long is equal to
  Ends: 3.14 × 3.5 × 3.5 = 38.5 × 2 = 77 sq ft
  Wall: 3.14 × 7 × 10 = 220
  Total surface = 297 sq ft × 0.12 gpm/sq ft
  Recommended minimum flow rate = 36 gpm.

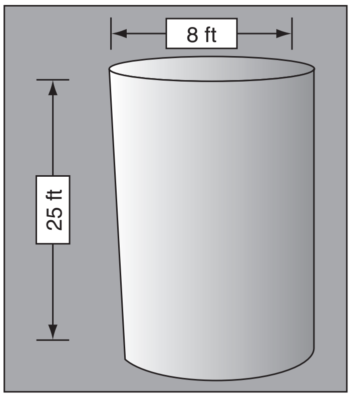


- *Vertical tanks or vessels*: cleaning flow rate – 2.5–3.5 gpm/ft of linear circumference

  Circumference: π (3.14) × diameter = circumference

  For example: a silo that is 25 ft high with diameter of 8 ft

  Circumference: 3.14 × 8 = 25.12 ft
  25.12 ft × 2.5 gpm/ft
  Recommended minimum flow rate = 62.8 gpm



APPENDIX 2 – QUESTIONS TO ASK WHEN CHOOSING BETWEEN A DEDICATED CONTROLLER AND A PLC BASED CONTROLLER

What level of internal expertise/support available?

- A PLC requires an individual with expertise, programming software, and PLC communication hardware to a laptop or a PC.
- Dedicated is easy for a non-programmer to support.

Do you need the ability to fine-tune CIP cycles?

- A PLC can have CIP step variables made on the keypad; however, a remote PC with programming software is required for significant revisions.
- Dedicated can have all CIP cycles fine-tuned from either a touch-screen or from a remote PC.

What control flexibility is required?

- PLC controls the CIP unit and can control return pumps and line valve sequencing. Standard controls do not include process control.
- Dedicated controls the CIP unit and can control return pumps and line valve sequencing. It cannot control process operations.

Are interlocks required between process and CIP?

- PLC can have starter run interlocks programmed and alarmed. These must be specified for proper design and programming.
- Dedicated can have start or run interlocks programmed and alarmed. These must be specified for proper design and programming.

Will the CIP controller need to interface to other controllers?

- PLC can interface via DH+ standard or RIO/Ethernet system selections.
- Dedicated can interface via DH+ system selection.

What communication protocol?

- PLC can communicate via DH+, RIO, or Ethernet by system selection.
- Dedicated can communicate via DH+ standard system selection. Other communication options require Electrical Design review.

Will CIP controller pulses process equipment?

- PLC controls process valve sequencing via communication with process controller or custom programming per application requires Electrical Design review.
- Dedicated control process valve sequencing via discrete I/O or communication with process controller.

APPENDIX 3 – GLOSSARY OF TERMS

Antimicrobial agent: a chemical agent that kills or suppresses the growth of micro-organisms.

Biofilms: are composed of a collection of bacteria that have attached to surfaces and have excreted an extracellular polysaccharide, or slime layer. This slime layer protects the cells from adverse environmental conditions.

BOD (biological oxygen demand): a measure of the pollution present in water, obtained by measuring the amount of oxygen absorbed from the water by the micro-organisms present in it.

Chelate or Chelators: chemicals that are incorporated into the detergent formulation and that prevent scale build-up, i.e. the precipitation of calcium and magnesium salts onto the equipment surfaces.

Cleaner: a substance that breaks the bond between the soil and the surface being cleaned. Not only must it remove the soil, it must hold it in suspension and allow it to be flushed away.

Cleaning: the process that will remove soil and prevent accumulation of residues, which may decompose to support growth of disease or nuisance causing organisms. It must be accomplished with water, mechanical action, and detergents.

Denaturization: the process that changes the form of proteins, hardening them and making the protein less soluble. An example is the way that heat acts on egg white, causing it to solidify.

Detergent: see Cleaner.

Disinfectant: a chemical agent that is capable of destroying disease causing bacteria or pathogens, but not spores and not all viruses. In a technical and legal sense, a disinfectant must be capable of reducing the level of pathogenic bacteria by 99.999 % during a time frame of more than 5 but less than 10 minutes, as tested by the Association of Analytical Communities (AOAC) method. The main difference between a sanitizer and a disinfectant is that at a specified use dilution, the disinfectant must have a higher kill capability for pathogenic bacteria than that of a sanitizer.

Disinfection: the killing or inactivation of all micro-organisms, except for some spore forms. The efficacy of disinfection is affected by a number of factors, including the type and level of microbial contamination, the activity of the disinfectant, and the contact time. Organic material and soil can block disinfectant contact and may inhibit activity. Therefore, cleaning must precede all disinfection.

EDTA (Ethylenediaminetetra-acetic acid): a molecule that can bind to metal ions; used as a chelator in detergent chemistry.

Emulsification: a measure of a detergent's ability to break down fats and oils into smaller particles that are removed more easily during rinsing.

EPA – Environmental Protection Agency: the Unites States agency that it is responsible for the actual definition and regulated uses of both sanitizers and disinfectants.

Peptize: mechanical action combined with a surfactant, resulting in two immiscible liquids. Peptizing breaks down the protein bond and stabilizes it in suspension.

pH scale: a logarithmic scale, which is used to measure the acidity or alkalinity of a solution. The pH of pure water is 7, with lower values indicating acidity and higher values indicating alkalinity.

Pin chart: pin chart refers to a chart used in programming. Historically, electrical controllers used pins to turn on electrical switches and a grid was used to assign the steps in order of operation, so that a programmer knew where to put the pins in the sequence. The term pin chart has carried over as a programming term in CIP applications.

QAC (Quaternary ammonium compounds): sometimes referred to as Quat sanitizers.

Sanitation: the term used to describe the complete plant cleaning and sanitizing program protecting public health.

Sanitize: to reduce the number of micro-organisms to a safe level.

Sanitizer: the AOAC test method requires that a sanitizer is capable of killing 99.999 % (5 log reduction) of a specific bacterial test population, (*Staphylococcus aureus* and *Escherichia coli*) within 30 seconds at 25°C (77°F). A sanitizer may or may not necessarily destroy pathogenic or disease-causing bacteria, as is a criterion for a disinfectant.

Sterilant: an agent that destroys or eliminates all forms of life, including all forms of vegetative or actively growing bacteria, bacteria spores, fungi, and viruses.

Sterilization: is the complete destruction of all forms of life.