Pharmaceutical Facilities Plumbing Systems

By Michael Frankel

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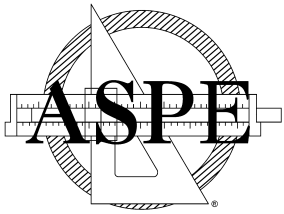

American Society of Plumbing Engineers
8614 W. Catalpa Ave., Suite 1007
Chicago, IL 60656
(773) 693-2773
E-mail: aspehq@aspe.org • Internet: www.aspe.org

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Preface

This book has been written to provide architects, contractors, owners and consulting engineers responsible for plumbing systems with a complete reference and design guide for the piping found in typical pharmaceutical facilities. All equipment and systems necessary for the proper operation and support of the process and production of the end product will be discussed. The actual process and product piping is outside the scope of this book.

It is intended as a practical book for the nonproprietary design of all of the support systems that allow efficient production of the end product. The functions of all relevant components are presented in language that is easy to understand for personnel that may not be familiar with all of the systems. Using a total systems approach, discussions progress from the fundamentals and component operation to a detailed procedure permitting a quick and accurate pipe sizing and equipment selection. Since much of the design criteria are empirical in nature, obtaining such criteria has been as a result of engineering over 45 years of experience. For all of the systems described, the reader will be able to understand the function and operation of the particular system and its relationship to other systems in the facility.

This book can be used effectively in schools teaching plumbing engineering since it is devoid of highly technical terms.

Since it is no longer possible for one individual to have an intimate knowledge of all subjects within any facility, I would like to give my most sincere thanks and acknowledgement to Tony Curaelie for his help. It was his knowledge about factors incorporated in modern facilities that proved invaluable in the writing of this book.

Michael Frankel, CIPE

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1 Codes and Standards

INTRODUCTION

Codes relating to piping provide specific design criteria, such as allowable materials, working stresses, seismic loads, thermal expansion and other imposed internal or external loads, as well as fabrication, installation, and testing for many other aspects of a total piping system. Code compliance is mandated by various federal, state, and local agencies that have jurisdiction and enforcement authority. Each code has precisely defined limitations on its jurisdiction. Familiarity with these limitations can be obtained only by a thorough reading and research of the applicable codes.

These codes often refer to standards prepared by other nationally recognized organizations. The term "nationally recognized" is meant to define a consensus group or organization composed of a membership that is representative of its members views. To achieve the status of national recognition, an association has to be in existence for a reasonable period of time, be active in research, testing, and other issues relating to its area of interest, and be generally thought of by its peers as scientifically accurate.

Standards can be separated into three broad categories: (1) The first is a technical category that determines dimensional and specific design criteria and rules for specific components or classes of components, such as valves, joints, and fittings. Dimensional standards provide control for components to ensure that components supplied by different manufacturers are physically interchangeable. Pressure-integrity standards provide performance criteria so that components supplied by different manufacturers will function and service as rated (for pressure and temperature) in a similar manner. Compliance with standards are usually required by construction or building codes as a reference or requirement or included within purchaser specifications. (2) The second category is compliance with federal, state, and local codes regulating plumbing and other health-related subjects. (3) The third is compliance with other codes and standards that relate to the manufacturing process concerning purity and with acceptable manufacturing processes that produce products of acceptable consistency and purity.

The applicability of various codes and standards must be ascertained prior to the start of a project, as the submission of plans for approval prior to the construction and installation of piping systems is often required. This necessitates a code search and consultation with the various authorities having jurisdiction. In the design of any piping system in accordance with any code or standard, when differing requirements are discovered, the most stringent requirements must be complied

with. Codes and standards for individual systems are listed under those systems later in this manual.

In the area of fire-protection standards, another consideration is fire-insurance carriers and underwriters. They very often have requirements that are more restrictive than the building and construction codes that normally apply to every project. This particularly applies to the area of water supply, storage, and distribution for fire-protection purposes, that also may be combined with the domestic water requirements and service.

CODES AND STANDARDS

Following is a partial list of the more important codes and standards uniquely impacting the materials, dimensions, and other general requirements for plumbing and other utility piping systems for pharmaceutical facilities.

American Welding Society (AWS)

This organization sets standards for materials and practices for the welding, soldering, and brazing of pipe joints.

Compressed Gas Association (CGA)

This association sets standards for the dimensions of gas piping and devices and provides purity standards for various compressed gases.

Current Good Manufacturing Practice (CGMP)

Design considerations for pharmaceuticals, devices, laboratories, and animal-care facilities are constantly evolving. The Food and Drug Administration (FDA) requires that facility design meet "current" good manufacturing and laboratory practice. As the technology of environment design and monitoring evolves, industry is expected to maintain facilities that conform to the best science available. For this reason, a design must be evaluated against the regulations, standards, and guidelines available at the time. Also included is the European Economic Community (EEC) *Guide to Good Manufacturing Practice for Medicinal Products*.

Code of Federal Regulations (CFR)

This document contains all of the varied rules and regulations concerning pharmaceutical facilities (among others) originated by the federal government.

International Standards Organization (ISO) 9000 Series

The United States is represented by the American National Standards Institute (ANSI)/American Society of Quality Control (ASQC).

1. **ISO 9000, ANSI/ASQC Q90.** Defines the terms and presents principal quality-management and quality-assurance practices used in the ISO 9000 series of standards and establishes guidelines for their selection and use. This standard is applicable to all industries.
2. **ISO 9001, ANSI/ASQC Q91.** Establishes models for quality assurance in the design, development, production, manufacture, installation, and service sectors of an organization. This standard, which is the most comprehensive of the three external quality assurance standards, is applicable to organizations that develop and produce their own products. It also applies to construction and engineering services.

3. **ISO 9002, ANSI/ASQC Q92.** Establishes models for quality assurance in production and installation. This standard is applicable to service industries and manufacturers that produce designs and specifications for other organizations.
4. **ISO 9003, ANSI/ASQC Q93.** Establishes models for quality assurance during final inspections and testing. This standard is applicable to testing laboratories, small shops, divisions within a firm, and equipment distributors that inspect and test supplied products.
5. **ISO 9004, ANSI/ASQC Q94.** This standard establishes internal organization management guidelines for designing and implementing quality systems and is applicable to all industries.

Manufacturers' Standardization of the Valve and Fittings Industry (MSS)

The MSS is an industry technical association organized for the development and improvement of industry, national, and international codes and standards for valves, valve actuators, pipe fittings, flanges, pipe hangers, and seals. Society membership is comprised of companies involved in the manufacturing of products covered by its activities. This society is recognized as the technical counterpart of the Valve Manufacturers Association and the American Pipe and Fittings Association, two nationally recognized trade associations.

National Institutes of Health (NIH)

The NIH, a division of the United States Public Health Service, is a government agency responsible for biomedical research and science. It is one of eight agencies, comprising twenty-four separate institutes, centers, and divisions, each devoted to a separate disease or disease group. Its mission is to uncover new knowledge, conduct and fund research, and train research personnel.

National Sanitation Foundation, International (NSF)

The NSF is an independent, not-for-profit organization of scientists, engineers, and educators. It is a trusted neutral agency serving government, industry, and consumers in achieving solutions to problems relating to public health and the environment. Services include development of consensus standards, voluntary product testing, and certification that products conform with NSF standards.

In general, compliance with NSF standards is required for any material or component that is intended to clean, process, or prepare food, clean the equipment and devices used to process and prepare food, and carry potable water.

3-A Standards

The purpose of the 3-A standard is to provide product-purity regulations pertaining to the design of adequate piping configurations, which allow acceptable piping network cleaning. It has been prepared by the following three organizations, with additional input from the Public Health Service.

1. International Association of Milk, Food, and Environmental Sanitarians.
2. The Milk Industry Foundation,
3. Dairy and Food Industries Supply Association.

REGULATING BODIES

A partial list of the more important regulating bodies and agencies impacting the plumbing and other general requirements for plumbing and other utility piping systems for pharmaceutical facilities.

Environmental Protection Agency (EPA)

The EPA is a government organization, created in 1970, that is responsible for the prevention of pollution of the environment. The EPA creates national pollution standards and criteria, creates compliance and enforcement plans, and performs research and development for identifying pollution-related risks. Criminal enforcement is also within the jurisdiction of the EPA.

Food and Drug Administration (FDA)

The FDA is a government agency originally created by the federal Food, Drug and Cosmetic Act and charged with the responsibility of seeing that all drugs are safe, effective, and properly labeled. The regulation implementing its authority is 21 CFR 211. CFR is published in the federal registry and is an acronym for "code of federal regulations."

Occupational Safety and Health Administration (OSHA)

The purpose of OSHA, a division of the United States Department of Labor, is to establish regulations that control and promote safety in the workplace. These regulations primarily concern the manufacturing, construction, transportation, and agricultural industries. OSHA also determines permissible exposure limits for chemicals and establishes norms for safety and monitoring procedures where workers are exposed to hazardous and toxic chemicals. These regulations require that all chemicals and hazardous materials be labeled and defined by Material Safety Data Sheets (MSDS).

2 Drainage Systems

SANITARY DRAINAGE AND VENT SYSTEMS

The design of the domestic sanitary-drainage and vent systems are standard plumbing systems, with effluent discharging directly into the public sanitary sewer. All plumbing fixtures and equipment and all sanitary-drainage piping shall be designed and installed in strict conformance with the applicable plumbing code for the project location. In terms of the design of these systems, there is nothing unique to pharmaceutical facilities that is not applicable to conventional plumbing systems.

It is good practice to have the sanitary house sewer and the discharge from an acid-neutralizing basin run separately outside the building then combine to dilute the neutralized acid effluent as much as possible prior to its discharge into a public sanitary sewer.

Special Plumbing-Fixture Requirements

One unique requirement of pharmaceutical clean rooms is a hand-washing sink in the gowning area at the entrance to the clean room. To be effective, the sink water-supply controls shall be capable of being operated without having hands touch them. Current practice uses proximity devices to turn the water on when hands are placed under the spout.

LABORATORY DRAINAGE AND VENT SYSTEMS

Introduction

A "laboratory" is generally considered to be any room or area within a building where investigation, testing, experiments, and/or research is conducted. Pharmaceutical facilities generally prepare, manufacture, and package drugs and devices of all kinds. "Manufacturing" is generally considered to be any facility where a product is the end result of having material or components packaged or assembled from parts obtained elsewhere or made within the facility.

The purpose of the drainage system installed in a typical chemistry or physics laboratory is to collect and transport liquid wastes from the laboratory fixtures and equipment for discharge into a facility chemical-waste treatment system for appropriate treatment and disposal or into the acid-waste treatment system for neutralization and eventual discharge into the public sanitary sewer. The acid vent system equalizes flow in the drainage system and maintains constant atmospheric pressure in the same manner as the sanitary drainage vent system does.

Laboratory waste consists primarily of dilute and concentrated mixtures of liquid chemical substances of mineral and organic origin and water. Acids of many types are usually present. Laboratory waste is discharged from sinks, cup sinks, fume hoods, and other similar fixtures and equipment. Discharge from floor drains,

autoclaves, and glass washers, and condensed water from various sources are also included. Except for exotic discharges, laboratory waste is assumed to have the viscosity of water. The drainage piping is sized based on that assumption.

The above definition of a laboratory and the classification of so-called "typical laboratory waste" is meant to be used only for this manual to distinguish this type of effluent from that of other waste-drainage systems.

pH Definition

Any dissolved impurity in water separates to form negative and positive charged atoms called "ions." Negative ions are called "cations" because they migrate to the cathode and positive ions are called "anions" because they migrate to the anode.

All acid compounds consist of hydrogen combined with an acid radical. In a mixture of acid and water, hydrogen ions result. pH is a measurement of the hydrogen ion concentration of a solution. Since the balance of hydroxyl (cation) and hydrogen (anion) ions must be constant, changes in one ion concentration produce corresponding changes in the other. The pH value is calculated from the logarithmic reciprocal of the hydrogen-ion concentration in water. The pH scale ranges from 0 to 14, with 0 being acid, 14 being alkaline, and 7.0 being neutral. A change of 1 unit represents a tenfold increase (or decrease) in strength. pH is not a measure of alkalinity.

Selection of Piping and Joint Material

The majority of the effluent from an "average" laboratory consists primarily of a mixture of water and acid. The chemicals used, if toxic to the staff, are confined to fume hoods. Information regarding the extent and concentration of all the chemicals expected to be used in the laboratory should be obtained from the end user. At one time or another, these chemicals will find their way into the drain pipe. The piping system and jointing method must resist them all.

An often-used material for piping above the floor drainage and vent piping from laboratory fixtures is fire-retardant polypropylene (PP), with either heat-fused socket or proprietary "screwed-mechanical" type joints. Other acceptable materials are glass with compression-sleeve joints and high-silicon cast-iron with caulked or compression-gasket joints. Although Polyvinyl Chloride (PVC) and Chlorinated Polyvinyl Chloride (CPVC) pipe have the lowest initial cost, they also have a limited range of chemical compatibility, with PVC having a low temperature rating. Polyvinylidene Flouride (PYDF) pipe had higher chemical resistancy and temperature ratings than PP, PVC or CPVC pipe but also has higher costs. Polytetrafluoroethylene (PTFE) is the most resistant to the widest variety of chemicals, has the highest temperature rating, and has the highest cost.

Piping underground could also be polypropylene with heat-fused socket joints or high-silicon cast iron with compression-gasket joints. Glass piping should be encased in a continuous sleeve of polyethylene for protection.

Vent pipe shall be the same material as the drain pipe. The vent shall be carried up to above the roof level. Vent piping penetrating the roof shall not be glass. An adapter can be used and any other acceptable acid-resistant pipe material can be provided through the roof penetration.

System Design Considerations

The same general system design considerations apply to the laboratory drainage system as apply to the sanitary drainage system, including placement of cleanouts. Each fixture shall be individually trapped and vented. Clean water, such as is discharged from air compressors and other condensate drains, could also spill into the laboratory drainage system when convenient. Because of possible stoppages that could flood all the pipe, the entire laboratory waste system shall be the of the same acid-resistant piping material.

Where the only waste discharge is from laboratory fixtures, the use of fixture unit schedules for pipe sizing is acceptable, except that simultaneous use should be factored into the sizing process. When the effluent is from a discharge whose flow is known (in gpm), base the size on that gpm and the equivalent gpm from the fixtures. The pipe shall be sized using the actual pitch and a half-full pipe. Table 2-1 gives the capacity of horizontal drainage piping flowing half full at various slopes. Table 2-2 gives the capacity of vertical stacks.

Table 2-1 Capacity of Horizontal Drainage Piping Flowing Half Full

Actual Inside Diameter of Pipe, in.	DISCHARGE RATE AND VELOCITY							
	1/16 in./ft Slope		1/8 in./ft Slope		¼ in./ft Slope		½ in./ft Slope	
	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps
1¼							3.40	1.78
1½					3.91	1.42	5.53	2.01
2					8.42	1.72	11.9	2.43
2½			10.8	1.41	15.3	1.99	21.6	2.82
3			17.6	1.59	24.8	2.25	35.1	3.19
4	26.70	1.36	37.8	1.93	53.4	2.73	75.5	3.86
5	48.3	1.58	68.3	2.23	96.6	3.16	137.0	4.47
6	78.5	1.78	111.0	2.52	157.0	3.57	222.0	5.04
8	170.0	2.17	240.0	3.07	340.0	4.34	480.0	6.13
10	308.0	2.52	436.0	3.56	616.0	5.04	872.0	7.12
12	500.0	2.83	707.0	4.01	999.0	5.67	1413.0	8.02

[a] Computed from the Manning Formula for ½-full pipe, n = 0.015. For ¼-full pipe, multiply discharge by 0.274; multiply velocity by 0.701. For ¾-full pipe, multiply discharge by 1.82; multiply velocity by 1.13. For full pipe, multiply discharge by 2.00; multiply velocity by 1.00. For smoother pipe, multiply discharge and velocity by 0.015 and divide by n value of smoother pipe.

Table 2-2 Drainage Capacity of Stacks

Pipe diameter, in.	1¼	1½	2	2½	3	4	5	6	8
Capacity, gpm	6.5	10.5	22.6	41	67.2	143	261	423	915

The laboratory drainage and vent system shall be separate from all other systems. The acid drainage shall be adequately treated and run separately outside the building, then combined on the site with the sanitary waste line.

Laboratory Acid-Waste Treatment

All acid waste requires neutralization to a pH of between 7.5 and 4.0 before it is permitted to discharge into any public sewer for disposal. Commonly accepted practice permits local authorities to allow primary treated effluent to discharge

directly into the public sanitary sewer system after only pH treatment. The most often-used primary procedures are direct, continuous contact with limestone chips in an acid-neutralizing basin or continuous or batch treatment in an automated neutralization system utilizing chemical-feed neutralizing.

An acid-neutralizing basin operates on the principle of a chemical reaction between the acid and the limestone chips. Each basin shall be designed by the manufacturer to allow sufficient contact time for the chemical reaction to accomplish complete neutralization based on the maximum flow rate anticipated. Actual tests have shown that 100 lb. of limestone chips treat 97 lb. of sulfuric acid and 75 lb. of hydrochloric acid. Effluent consisting mostly of sulfuric acid should be treated with dolomite limestone chips.

For general laboratory waste, several devices for treatment using limestone chips are available. For single, isolated sinks, an acid-neutralizing trap should be considered. For a small number of sinks in a cluster, a shelf-mounted, small-diameter basin could be used. It should be limited to the treatment of acids from a small number of fixtures and used only in remote locations. A larger basin, such as that illustrated in Figure 2-1, is available to treat the effluent from a large number of laboratory sinks. If the discharge of oil or grease is expected in the laboratory waste stream, the installation of an interceptor basin before the acid sump is recommended. Some objectionable contaminants can coat individual chips and prevent the proper chemical action required to neutralize the acid.

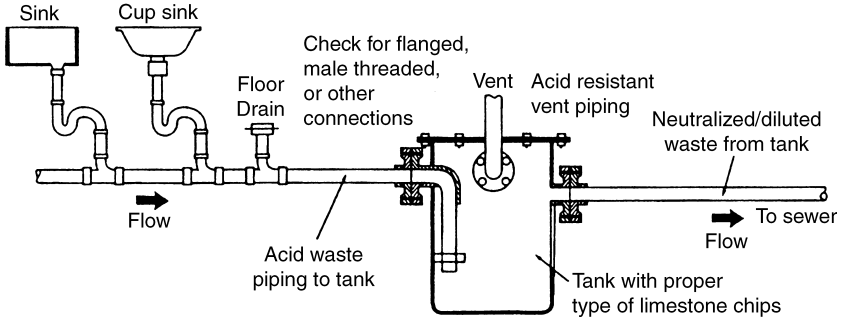


Figure 2-1 Large Acid-Neutralizing Basin

For a larger number of fixtures or equipment and where treatment by limestone chips alone is not practical, a system consisting of single or multiple basins and/or a mixing tank should be installed. If the system is located at a low level, a pump will be required to discharge up to the level of the sewer. A sophisticated arrangement of probes, chemical feed pumps, level indicators, and alarms will be required. An agitator or mixer may be installed in the basin to mix the acid with the caustic. The addition of a recorder may be desired. The acid-neutralizing system operates on the principle of automatically adding proper amounts of caustic to the incoming acid waste, thereby neutralizing the acid. The probe is connected to an automatic caustic feed pump that introduces the proper amount of neutralizing liquid into the basin or mixing tank. The most commonly used neutralizing chemical is caustic soda. Continuous treatment may also require additional downstream sensing probes and chemical additive locations to ensure that the discharge is within acceptable limits.

Figure 2-2 illustrates a typical continuous waste-treatment system. Various manufacturers have numerous proven and successful methods of acid treatment.

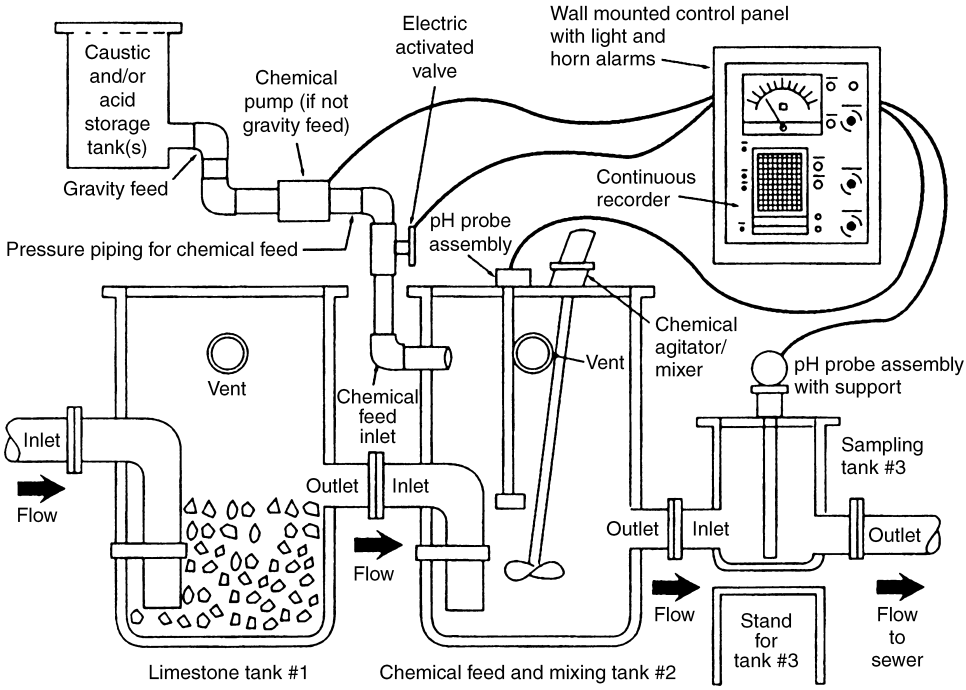


Figure 2-2 Continuous Acid-Neutralizing System

Note: Variations of this setup are available, including one large tank with three compartments instead of three separate tanks.

It is good engineering practice to have the discharge from the neutralizer routed separately into the sanitary house drain outside a building for dilution prior to its ultimate discharge into the public sewer. This may also be necessary for local authorities to monitor the waste stream without entering a building.

For a preliminary determination of the number of sinks required for an average laboratory, allow 1 sink for each 200 ft2 of laboratory area. Each sink will discharge 1 gpm. Cup sinks will discharge 0.5 gpm. For a maximum flow rate, assume that 50% of the sinks could discharge simultaneously.

ACID-WASTE DRAINAGE

Acid waste from pharmaceutical facilities consists of accidental spills originating from tanks and piping and anticipated waste from equipment discharging into drains. Very often, the drainage piping has to carry any of the acids used as part of the process. Where spills are directed into holding tanks, the drainage piping, tanks, pumps, and piping necessary to convey the effluent to treatment facilities is normally part of the plumbing engineer's responsibility.

The most important considerations in the selection of piping, valves, and tanks for acid are the concentration and temperature of the acid. Acid waste water from

chemical and other facilities must be neutralized to a pH of 4.0 or higher prior to discharge into the sanitary system.

Health and Safety Concerns

All grades and concentrations of acids can cause severe damage to the eyes and tissues of the body. Contact with the skin will cause irritation and burns. Contact with the eyes could cause blindness. Inhalation of the mist or vapors could cause lung irritation or burns. Ingestion will destroy the tissue of the mouth, throat, and stomach. Extreme care should be exercised in the handling and cleanup of all acids.

This mandates that emergency drench equipment be provided immediately adjacent to all hazards and locations where spills and other accidents could occur. If several people are normally present at a hazardous location, multiple drench equipment should be provided. Where fumes may be given off, emergency breathing apparatus shall be provided.

For the laboratory environment, emergency showers shall be provided immediately outside every room. Where rooms are adjacent, a single shower is accepted. Floor drains are not required but will prevent the floor surrounding the shower from becoming wet and a hazard to helping individuals. Every room shall have an emergency eyewash inside the room, usually mounted on a sink or free standing if sink mounting is not practical.

Where vapor is possible, fog nozzles using water to suppress the vapor and foam systems to prevent vapor from rising should be considered.

Common Acids

Acids are widely used in the pharmaceutical-processing industry. The acid most often used is sulfuric acid (H_2SO_4). Sulfuric acid is commercially available in many concentrations and as various percentages of oleum. Oleum is sulfuric acid containing sulfur trioxide dissolved in the acid; these grades are called “fuming” grades.

Selection of Equipment, Piping, and Joint Materials

Generally recommended piping materials for these acids at low temperatures (140°F and lower) and up to 90% concentration are PVC, CPVC, PP, Polyvinylidene Flouride (PVDF), Ethylenetetrafluoroethylene (ETFE) and High Density Polyethylene (HDPE) plastic, glass, alloy 20, duriron and Fiber Reinforced Plastic (FRP) piping with special resins. At 90% and higher concentration, carbon steel schedule 80 is often used. Stainless steel is generally unsuitable, except for olium greater than 103% concentration. Vent lines should be of the same material as the drain line.

Valve types include ball, gate, and diaphragm, with gate valves being the most commonly used. For low pressure and temperatures suitable for specific plastic pipe, plastic is often used. For higher temperatures and pressures, alloy 20 is preferred. In all cases, because of differences in manufacturing, pipe vendors should be consulted as to the suitability of materials for specific acid piping service.

Centrifugal pumps constructed of SS alloy 320 with Teflon packing are in common use. Other manufacturers use FRP and plastic pumps. Also available are metallic

pumps lined with plastic or glass. Temperature limits should be carefully checked for material suitability.

Accident Considerations

Spills of concentrated acids from tanks onto floors and equipment should be immediately washed off and flooded with water, which is then routed to the acid drainage system for neutralization. Tanks that contain this spillage should be of a suitable plastic. Since water reacts rapidly with the acid and splatters, caution should be exercised. Heat and fumes are also given off. Breathing the fumes will cause throat and lung injury. Where this situation is possible, suitable emergency breathing apparatus should be provided. An emergency shower should be provided in the immediate vicinity of acid storage and pipe routing.

Sulfuric acid is nonflammable but highly reactive. Below a concentration of 75% it reacts with carbon steel and other metals to form hydrogen. It is particularly hazardous when in contact with carbides, chlorates, nitrates, fulminates, picrates, and powdered metals. In higher concentrations it will ignite combustible materials such as oily rags and sawdust. Dry chemicals or carbon dioxide are the fire-suppression methods of choice.

Oleum spills, because of the danger of fumes, should be contained by curbs and the liquid diverted away from the area of a spill to a containment area where the liquid will be neutralized. The resulting liquid should be absorbed with diatomaceous earth, expanded clay, or another nonreactive material. This material should be carted away for suitable disposal.

RADIOACTIVE-WASTE DRAINAGE AND VENT SYSTEMS

General

Radioactive materials are used for various types of procedures. When pharmaceutical facilities use them, they generate low quantities of radioactive waste and use materials with low levels of radioactivity. Therefore, a less stringent set of regulatory requirements is necessary compared to those for facilities discharging or producing large quantities of radioactive wastes. The principles of drainage-system design apply to all kinds of systems, though some may have significantly higher levels of radiation than most. The design philosophy is the same, but the documentation that must be submitted for the protection of the public and workers in the event of any accident is considerably more complex for facilities having higher quantities of radioactive material and levels of radiation. Because of the small amount of radioactive material present at pharmaceutical facilities, larger storage and treatment systems are not provided and severe safety requirements are not necessary.

With the exception of providing radiation shielding where necessary, the requirements for the use of radioisotopes in laboratories are essentially no different than the requirements for other laboratories handling toxic chemicals or pathogens. The ideal objective is to keep the exposure of workers, staff, and the general public to zero. Since this is not realistic, it is required not only to prevent overexposure but to keep any exposure to radiation as low as is reasonably achievable. The design shall implement criteria that will eliminate or reduce to allowable levels the radiation exposure of workers and maintenance personnel and prevent exposure of the

general public to unacceptable amounts of radiation by waterborne radioactive waste (radwaste).

The Nature of Radiation

"Radioactivity" is the spontaneous emission of "harmful" particles from the unstable nucleus of an atom changing its atomic structure and creating a new element. There are many intermediate steps in the stabilization cycle that include the formation of other less complex radioactive byproducts called "isotopes." These byproducts in turn decay to form other unstable isotopes as the cycle continues. The end result is an element that is highly stable. As an example, the end product of uranium is lead. One of the intermediate byproducts of uranium is radon.

"Radiation" is a general term that means any or all of the following: alpha rays, beta rays, gamma rays, neutrons, x-rays, and other atomic particles. There are three general classifications of radiation of concern, namely alpha, beta and gamma. Alpha radiation is actually a helium atom with a high velocity. Beta radiation is an electron with a high velocity. Gamma radiation is a particle similar to a photon, which is light. Alpha and beta radiation can generally be stopped by the skin or clothing, paper, or another similar light material. Alpha loses energy very quickly in air and is no practical concern for distances greater than 12 in. High-energy beta radiation is commonly contained by only 1 in. of solid, dense plastic. Beta is denser, carries more energy greater distances than Alpha, and will burn bare skin and in particular, damage the eye, but will generally not penetrate into the body to cause any internal damage. The greatest danger with beta radiation is to the eyes, particularly when the eye is directly exposed close to the source.

Gamma radiation is electromagnetic in nature. It carries the most energy and therefore is the most dangerous to humans. Its wavelength is shorter than light waves. When generated, it is similar to x-rays and behaves in a manner similar to light waves. When released from a source, gamma rays have a mass and velocity that has a measurable energy potential.

Radiation Measurement

"Radioactivity" is a general term used for the total release of radiation of all types from a source. Its is measured in disintegrations per second (dps). This measurement is possible for gamma radiation because in most radioactive materials, dps also produces a known amount of gamma radiation. However, the best manner of measuring gamma radiation is from the energy it produces per kilogram of air. Because the instruments needed to measure radiation this way are very expensive, this method is not widely used outside the laboratory. The so-called "Geiger-Mueller counter" is the most common method of measuring radiation. It measures the penetration of ionizing radiation particles that enter a sealed tube where the particles strike the gas creating an electrical impulse between two electrodes connected to a suitable counting device. If an amplification device is used, the electrical impulses can be heard in the form of static. The more modern instruments have a digital readout.

Units of Radiation Dose

Particulate radiation is measured by the number of disintegrations per unit of time. A "curie" is equal to 3.7×10^{10} disintegrations per second. One "millicurie" is

0.001 curie, or 3.7×10^7 dps. One "rad" is defined as the dose corresponding to the absorption of 100 ergs/gram of tissue. A "roentgen" measures ions carrying a total of 2.58×10^4 coulombs of electrical energy.

Since the term "radiation" is a general one, a more specific method must be used to measure its effect on humans. That measurement is called a "dose." A "dose" is defined as the total quantity of radiation absorbed by the body or any portion of the body. Much of the time, the dose is modified by reference to a unit of time. This differs from radioactivity because all radiation is not absorbed by the body.

A rad is a measure of the dose to body tissue in terms of energy absorbed per unit mass. Gamma radiation is the most common type of radiation measured.

The most important measurement is the radiation equivalent to man, or "rem." A "rem" is the measure of ionizing radiation passing through or absorbed by the body in terms of the biological effect relative to a dose of 1 roentgen of x-rays. The relation of the rem to other dose units depends upon the actual biological effect to the particular part of the body being studied and the actual conditions and amount of time of the irradiation. One rem is the equivalent of 1 roentgen due to x or gamma radiation, and also 1 rad due to x, gamma, or beta radiation. One rem of high-flux neutrons is roughly equivalent to 14 million neutrons per cm^2 incident to the body.

Allowable Radiation Levels

There is no exact radiation level that is certain to cause any individual permanent harm. Many scientists believe there is no level below which radiation is harmless. There is a background level of radiation that exists all over the world. The most common source is the sun, which produces what is called "cosmic radiation." In addition, there are many substances that emit radiation, such as fly ash from burning organic fuels (particularly coal), granite, and many other natural substances that contain trace isotopes of elements. One of the most common of these trace elements is carbon 14, used by scientists to date many materials.

The Nuclear Regulatory Commission (NRC) is a governmental body that has the responsibility for establishing criteria for the field of radioactivity. These criteria appear in the federal government's *Code of Federal Regulations*.

All personnel working at any site that has a possibility of exposure to radiation are required to wear some type of exposure detection device that allows accurate determination of their actual exposure. The photographic badge is the most common device and is used where sensitivity is required. A pen-shaped device called a "dosimeter" is commonly used where there is less need for accuracy. It is used where the instantaneous determination of dose is necessary.

An "unrestricted area" is any area within a facility that is not specifically controlled for the purpose of protecting any individual from radiation or radioactive materials. A "restricted area" is access controlled. Another term, "environs," may also be used to describe areas adjacent to a restricted or high-radiation area.

A high-radiation area is defined as any accessible area within a facility that is capable of allowing the body to receive 100 millirem (mrem) of radiation in a 1-hour period.

Shielding

The purpose of shielding is to reduce or eliminate radiation emanating from any source within the facility. The greater the density, the more effective the material, so lead is universally used for this purpose. Another commonly used material is concrete. In terms of shielding, 0.1576 in. of lead is the equivalent of 12 in. of concrete. The basic philosophy is that concrete used as a structural element of the building serves a second purpose as a very good shielding material. It is up to the Radiological Safety Officer (RSO), whose responsibilities we discuss later, to determine the type and placement of shielding to lower radiation in specific areas. Radiation travels in a straight line, therefore, if a tank or a length of pipe has to be shielded, the proper manner is to form a labyrinth, so that the shine from the tank can't escape in a straight line.

The materials most commonly used for shielding purposes are concrete and sheet lead. Other materials that have proven effective include: (1) lead-lined concrete blocks, (2) lead-lined lath for plaster, and (3) lead-lined panels and gypsum boards.

Two levels of barrier are set up to reduce radiation levels: primary barriers, which are the first line of defense, and secondary barriers, which are used to eliminate leakage radiation and scattered radiation where it may possibly exist.

Radioactive Materials

Radioactive materials are used for the following five general purposes:

1. Imaging sciences.
2. Diagnostic purposes.
3. Treatment purposes.
4. Industrial uses.
5. Research.

Almost all of the materials used are isotopes. An "isotope" is a form of an element with a different (or excess) number of neutrons in its nucleus. Because of this difference, the atom is unstable. Isotopes are identified by their atomic weight, which is the number of neutrons and protons in the nucleus.

There are a great number of isotopes in use today. Some of the more common are:

1. Iodine 131 (8-day half-life).
2. Phosphorus 32.
3. Technetium 99 (6-hour half-life).
4. Calcium 45.
5. Carbon 14.
6. Strontium 90.
7. Radium 226.

Since radioactive materials of any given amount remain active for different periods of time, it is not possible to predict when any material will become completely stable. The method used is to determine when a specific material loses one half of its radioactivity. This is called its "half-life."

System Design

The Approval Process and Application Requirements

The use of any radioactive material requires the licensing of the site for a specific purpose, quantity, and amount of radioactive material. Application for this license is made to either the NRC or a particular state. Those states that have elected to adapt the NRC regulations and provide their own staff for the purpose of issuing and approving licenses are called "agreement states." In some cases, these states make additional regulations of their own. Those states that rely on the NRC to review and issue licenses are "non-agreement states." The application is made to the appropriate party.

The duties of the Radiological Safety Officer (RSO) include administration, monitoring personnel exposure limits, and controlling any release of radio nuclides to the sewer system. In addition, it is the RSO who usually works with engineers in the design phase of the facility to ensure that the piping runs and all other mechanical work will result in a low exposure to people within the facility. For the most part, this work is meant to ensure that facility personnel do not exceed the maximum permissible radiation dose allowed under the applicable codes for any particular type of radioactive material present and that non-staff members are not subject to unacceptable levels of radiation. The RSO is also responsible for the following:

1. Teaching facility staff of the potential dangers.
2. Keeping the necessary records for the facility.
3. Keeping inventory of material and records disposal.
4. The concentration of materials at the facility.
5. Assisting engineers in the design of mechanical systems.
6. Designating areas within the facility to be restricted.

General Design Criteria and Considerations

The prime consideration in the design of any facility is a concept concerning the exposure of personnel to radiation called "ALARA," which is an acronym for "as low as reasonably achievable." Adherence to this concept requires that in the design of the facility consideration must be given to every reasonable method to limit the possible exposure of personnel inside the facility and keep the presence of radioactivity in any unrestricted area to a level that is as low as reasonably achievable. The designer must take into account the current state of technology, the economics of further improvements in relation to benefits to the public health and safety, and other socioeconomic considerations relating to the utilization of radioactive material in the general public interest. The designer of the facility must also make a reasonable effort to eliminate residual radiation. One of the overriding concepts is the "worst-case" possibility, wherein the worst possible combination of circumstances is used to determine the possible level of radiation and the amount of exposure during a period of time. This concept should not be overused; a general rule is to have only one "accident" at a time. As an example, a serious spill and a fire would not be considered as likely to occur simultaneously.

Human or animal waste, even that contaminated with radioactivity, is exempt from all NRC regulations, requiring only compliance with local codes as far as disposal,

sizing, and all other criteria applicable to standard drainage systems. Also many isotopes are exempt from regulations regarding disposal into the public sewer.

Another requirement is that the liquid radwaste to be discharged shall be diluted with the ordinary waste effluent from the rest of the facility before being discharged to the public sewer system. This usually requires that the radwaste piping first be kept separate from the rest of the facility's effluent but then be combined before leaving the building for discharge into a public sewer. A method should be provided for the RSO to take a grab sample of the radwaste stream if desired, such as a valved outlet from both the radwaste line and the combined discharge.

The pitch of the piping should be kept as steep as possible in order to empty the pipe quickly and allow a scouring action to keep the radioactive solids in suspension.

It is common practice to have high levels of radiation confined to glove boxes or protected fume hoods. The small amount of liquid waste produced from this equipment would be stored in shielded containers below the equipment and removed periodically. If storage of larger quantities of low-level radwaste is required, the radwaste is piped to a holding tank. A common holding time is ten half-lives of the effluent. Usually, radwaste is stored for disposal on the site, outside of a building and where easy transfer of the radwaste is possible. The removal must be done by licensed waste-disposal contractors who remove the waste from the holding tank into a special truck, which transports the liquid waste to a designated site suitable for disposal of low-level radwaste. The solid wastes, such as gloves, wipes, and the like, are stored in special containers, which are removed to the disposal area with the liquid radwaste.

Floor drains are normally not desired in laboratories. If there is a spill of radioactive material, it is wiped up by hand using absorbent material, and the solid containing the spill is put in a special radwaste holding container within the lab. If, however, a floor drain is to be installed, all the major manufacturers make stainless steel drains. For testing purposes and to close off a drain when it is not expected to be used, each drain should be supplied with a closure plug. If there are areas that may have a spill, the floor must be pitched to a floor drain. A generally accepted value for the pitch of the floor is 1 in. per 20 ft. The thickness of the slab must be closely coordinated because the slab should be thinnest at the drain and thicker at the ends of the area served to make up the pitch. It is not practical to cast the slab evenly and add a topping because there is a tendency for thin set topping to crack and chip and create the possibility of a radioactive spill permeate the top coating. It is necessary to indicate the top of drain elevation at each drain since the slab depth is greater the longer the run to the drain. This also makes it easier for the shop fabricator to make up accurate pipe spools and floor drain extension collars.

Drains also require special treatment. They should also be manufactured of stainless steel. There will be different types of drains in different areas, and they may be installed at different elevations. Because of this and the probability that the piping will be made in spools (preassembled sections of piping), it is a good idea to number all the individual drains on the design drawings. A tag next to each drain can be used to provide information regarding type, number, and elevation.

Since fittings are a natural crud trap, avoid running piping in, under, over, or adjacent to unrestricted areas in a facility. If this is not possible, place the line where additional shielding can be added either at the time of construction or after the start of actual use, when the RSO may determine by survey that additional shielding is necessary. Much of the time, the ability to take apart the joint and flush out any crud is an advantage. Any of the popular joints for no-hub or grooved pipe are acceptable, as well as glass pipe if used in a laboratory for chemical resistance.

Be generous with cleanouts. They may be needed to flush out the line to reduce spot high radiation rather than having to rod it out.

Pipe Material Selection

The pipe selected for the radioactive drainage system depends upon the type of radiation and the level of radioactivity, which, in turn, depends upon the amount and type of radioactive material at the facility. In general, an ideal radwaste drainage pipe should have the following properties:

1. It must be nonporous.
2. It must be easy to clean and decontaminate.
3. It should be acid resistant.
4. It should be nonoxidizing.
5. The joints should not form crud traps.
6. Joint materials must not be affected by radiation exposure.

It is possible in very high radiation areas to have a pipe affected by the radiation present. The oxides of the pipe can become radioactive or the pipe itself could be weakened. Another consideration is the weakening of elastomeric seals or gaskets because of high levels of radiation. For this reason, Teflon is never used where anything more than a very low level of radiation is present. Other materials should be investigated regarding suitability of use for the levels anticipated.

All the commonly used materials (cast iron, ductile iron, copper, steel, and glass) and the joints normally used to put the pipes together fall far short of the ideal. However, they are all suitable for low-level waste and the radioactive source materials found in facilities with a low level of radiation. Plastic piping is not acceptable for radwaste systems due to the possibility that the plastic may be affected by the radiation. It is only when the radiation levels of the waste materials reach the "high radiation" category that they fail one or more of these conditions. As a result, stainless steel with welded joints has emerged as the material of choice for all "industrial" type waste products. Type 316L is the most commonly used.

A welded joint is the only type of joint that meets the criteria for not allowing a crud trap. The orbital welding process is often used since it produces the cleanest interior weld surface. The proper weld end preparation is critical to proper welding and must be diagrammed or described in the specifications.

There are two types of joint used for drainage pipe: butt welded and socket welded. "Butt welded" is a term used to describe two pipes placed end to end and joined with no overlapping. "Socket welded" describes the joint that results when one pipe is placed inside the other and only one end of the exposed pipe is actually welded around the exterior of the pipe. This is like a coupling, with only the joint on the

outside of the pipe welded. In general, only pipe 2 in. and less are socket welded. Pipe this small (2 in. and under) is called "small bore pipe."

Specifications for, and approval of, the entire welding process for both shop welding and field welding are necessary. It is also necessary to qualify welding personnel to ensure that they have sufficient training and knowledge to produce a weld of the required quality called for in the specifications. Qualifications of welding personnel are difficult to assess. High-temperature, high-pressure pipe is covered by ASME codes that specify the selection of successive welding type passes, filler metal composition, joint preparation, movement and handling of the pipe, tack welding and clamping, welding currents, metal deposit rates, and weld inspection. None of these code requirements apply to welded, non-pressure drainage pipe. If the engineer does not have the knowledge to specify the minimum requirements for welders and the welding process, it could be left to the contractor to determine the correct specifications for the project and recommend them to the engineer for approval. When this is done, the contractor establishes the minimum criteria that qualify any individual for welding on this particular project. It is then up to the contractor to test a welder's ability to make sound welds under the actual working conditions and using the same equipment expected to be used on the job and to certify that person as qualified. These criteria should be reviewed by the engineer for acceptability. It is common practice to use an outside, knowledgeable third party for this review process.

The defects in welded piping must be found and corrected. All of them center around the fact that the weld does not actually create a monolithic piece of pipe. The flaws are cracks or voids in the joint. The testing methods, which are of the nondestructive type (NDT), are as follows:

1. Visual inspection of the weld.
2. Dye penetrate.
3. Magnetic testing.
4. Ultrasonic testing.
5. X-ray.

INFECTIOUS AND BIOLOGICAL-WASTE DRAINAGE SYSTEMS

Introduction

Biological waste has the same basic characteristics as other laboratory and production facility waste but with the addition of biohazardous material. Biohazardous material consists of live organisms that are suspended in the waste stream and, if not contained, have the potential to cause infection, sickness, and other very serious diseases. This waste is discharged by gravity and under pressure from many sources, including:

1. Fermentation tanks and equipment.
2. Process centrifuges.
3. Sinks, both hand washing and process.
4. Containment-area floor drains.
5. Janitor closet drains.

6. Necropsy table drains.
7. Autoclave drains.
8. Contaminated condensate drains.

Containment is the method used to isolate and confine biohazardous material. The facility equipment and design shall conform to acceptable and appropriate containment practices based on the hazard potential. A containment category is used to describe an assembly of both primary and secondary preventive measures that provide personnel, environmental, and experimental protection. Primary barriers are specific pieces of equipment, such as the biological safety cabinet (which is the biologist's equivalent of the chemist's fume hood) and glove boxes. Secondary containment consists of features of the facility design that surround and support the primary containment. These features are described and classified in publications of the National Institutes of Health among other publications.

The classifications for biological containment in laboratories comprise four biosafety levels, BL1 through BL4. Publications describe the work practices, equipment, and BL selection criteria based on the activity of a particular laboratory. If the laboratory or production facility produces or uses greater than 10 L involving viable organisms, the facility may be classified as a "large scale" (LS) biosafety level. This is noted as "BL2 LS."

Manufacturing standards shall conform to good large scale production (GLSP) standards. The same standards apply to both small and large-scale facilities.

Facility types of work are outlined later in this chapter in a very abbreviated form.

CODES AND STANDARDS

Mandated guidelines and regulations include the following:

1. OSHA bloodborne pathogen regulations.
2. NIH guidelines for the use of recombinant microorganisms.
3. FDA cGMP regulations.
4. CDC/NIH guidelines for biosafety in microbiological and biomedical laboratories.

BIOLOGICAL SAFETY LEVELS

CDC/NIH guidelines for biosafety in microbiological and biomedical laboratories are summarized in the following laboratory containment levels.

- **Biosafety Level 1 (BL1) containment.** This classification is the typical biological research facility classification for work with low-hazard agents. Viable microorganisms not known to cause disease in healthy adults are used at this level. Work is done on an open bench and any hazard present can be controlled by using standard laboratory practice. Standard features consist of impervious and easily sanitized bench surfaces separated from general offices, animal rooms, and production areas. Contaminated liquid and solid waste shall be treated to remove biological hazards before disposal. Wastes containing DNA materials or potentially infectious microorganisms shall be

decontaminated before disposal. Hand wash facilities are required in each laboratory.

- **Biosafety Level 2 (BL2) containment.** Construction of this level facility is similar to that for a BL1 facility, except that the microorganisms may pose some risk and safety cabinets are often present. Equipment and work surfaces shall be wiped down with a suitable disinfectant. Sinks shall be scrubbed daily with a chlorine containing abrasive and flushed with a suitable disinfectant. All liquid waste shall be immediately decontaminated by mixing with a suitable disinfectant.

  Nearly all laboratories operate under levels 1 or 2 containment. At these levels, the facility is engaged in research, diagnostic, or production activities thought to pose little or minimal risk to workers.
- **Biosafety Level 3 (BL3) containment.** Level 3 activity involves organisms that pose a significant risk or represent a potentially serious threat to health and safety. Biosafety cabinets are required and all penetrations to outside the facility must be sealed to prevent leakage. These seals must be capable of being cleaned. Liquid waste is kept within the laboratory or facility and steam sterilized prior to discharge or disposal. Vacuum inlets must be protected by appropriate filters and/or disinfectant traps. Laboratory animals require special housing or, if conventional housing is used, personnel must be appropriately protected with full suits and respirators. A hand-washing sink that is routed to sterilization shall be located adjacent to the facility exit. Vents from plumbing fixtures must be filtered.
- **Biosafety Level 4 (BL4) containment.** This rarely used classification is reserved for facilities whose activities require a very high level of containment. The organisms have a life-threatening potential and may initiate a serious epidemic disease. All of the BL3 requirements apply. In addition, showers shall be provided for personnel at the airlock where clothes are changed upon entry or exit. Breathing air is generated outside the BL 4 unit and provided directly to full protective suits. Nothing is allowed outside the facility. A biowaste treatment system shall be provided within the facility to sterilize liquid waste.

LIQUID-WASTE DECONTAMINATION SYSTEM

A liquid-waste decontamination system (LWDS) collects and sterilizes (decontaminates) liquid waste. Effluent containing potentially hazardous biomatter is collected in a dedicated drainage system generally discharging by gravity into a sump below the floor level within the facility. From the sump, effluent is pumped into a "kill" tank where the actual sterilization occurs. A "kill tank" is a vessel into which steam or chemical disinfectant can be injected to kill any organism. The kill-tank system shall be qualified to the same biosafety level as the facility that it receives its discharge from. The kill-tank system must be a batch-process system, since time, based on the process used, is needed to complete the sterilization and decontamination.

System Components

In addition to piping, the system consists of the sump or tank to receive contaminated discharge from the drains and equipment of the facility, a pump to remove the contaminated effluent from the sump and into the kill tank(s), and the kill

tanks that will decontaminate and sterilize the effluent to a point permitting disposal into the same system as the sanitary waste from the facility, generally into a public sanitary sewer.

Sump Pit

The sump pit into which the effluent drains shall have a gasketed, waterproof cover. The controls are similar to those provided on a plumbing sump pump and shall be capable of being chemically or steam sterilized. The sizing of the pit is done in conjunction with the sizing of the pump so that the pump stays on for a minimum of 1 min to avoid frequent starting. Other considerations, such as having the pit contain one batch of product if necessary, may be considered.

Kill-Tank Assembly

The kill-tank component has a duplex-tank arrangement, which allows one batch to be decontaminated while the second tank is filling. The size of the tanks varies based on the individual facility, but common practice is to have each tank capable of containing one day's effluent plus the chemicals used for decontamination. Another consideration is to have sufficient size to hold a catastrophic spill. There is usually an agitator to mix the effluent with the deactivation chemicals to accelerate the treatment process. In addition to the kill tanks, tanks containing disinfectant chemicals to be injected are required. A fully automatic control system must be provided to ensure the timely addition of the required chemicals in the correct amounts and for the required duration of deactivation of the biomatter. Alarms and status shall be displayed on an appropriate panel located in a facility control room or monitoring areas.

Drainage System and Components

The drainage system must be closed, which requires sealed floor drains and valved connections to equipment when not in use, since the ventilation system maintains a negative pressure within the space. It is important that the trap on all floor drains have a seal 2½ in. deeper than the negative difference in air pressure. The traps of floor drains shall be filled with a disinfectant solution when not being used to discharge waste to eliminate the possibility of spreading organisms between different areas served by the same connected sections of the piping system.

The drainage piping material is based on the expected composition of effluent chemicals and the sterilization method to be used. If the local authorities determine that the biowaste is hazardous, a double-contained piping system with leak detection may be required. Stainless steel or PTFE pipe is usually chosen where higher-temperature effluent may be discharged or steam sterilization may be required. PVC, CPVC, polypropylene, or lined Fiber Reinforced Plastic (FRP) pipe could be used where effluent temperatures are lower and where chemicals will provide the method of sterilization.

If waste from pressurized equipment is discharged into a gravity system, the system must be adequately sized to convey the flow at the proposed flow rate with the gravity system pipe flowing half full, and adequate vents shall be provided to equalize and ensure the internal pressure of the pipe is always at atmospheric pressure.

Valves shall be of the diaphragm type and capable of being sterilized with the same method used for the pipe. After appropriate decontamination, the kill-tank effluent

shall be discharged to drain. This effluent also must be treated prior to discharge into a public sewer system for disposal.

Vents

A system vent from pipe, fixtures, sealed sump pits and kill tanks must be filter sterilized prior to leaving the system with a High Efficiency Particulate Air (HEPA) or a 0.2-μ filter.

In the event of an accident, OSHA has published rules to aid personnel responding to emergencies involving any hazardous material.

System Design Considerations

The treated discharge from any containment treatment shall be separately routed to the sanitary system outside the building to allow for monitoring and sampling.

CHEMICAL WASTE SYSTEMS

Chemical-waste drainage systems could contain a wide variety of waterborne wastes, including chemicals, solvents, suspended solids, flammable liquids, and waste water, many of which are considered hazardous. The purpose of the chemical-waste drainage system is to collect and transport these wastes from inside a facility to a point on site where treatment or disposal will be accomplished.

Codes and Standards

A great many regulations affect the design of any industrial drainage system. Among them are the federal Clean Water Act (CWA) and Resource Conservation and Recovery Act (RCRA), which are administered by the federal Environmental Protection Agency (EPA) as well as state and other local agencies. Local authorities are also empowered to enforce and legislate regulations that are stricter than the federal regulations. Where production and manufacturing facilities discharge waste, it is a general practice to engage the services of professionals experienced in waste-water treatment and environmental issues to ensure compliance with all the latest applicable regulations and an acceptable treatment system.

The major regulatory consideration to be determined is whether any particular waste stream is hazardous. If so, protective measures, such as double-contained piping systems and leak detection, may be required.

Pipe Material and Joint Selection

Because of the vast diversity of manufacturing processes, it is impossible to make any general characterizations of industrial waste water. It is common to have various areas within a plant or industrial complex discharge different types of effluent with greatly varying characteristics.

The largest quantity of effluent in an industrial facility originates from drains. Drains receive discharge from production equipment; floor wash down; process and production machines and other equipment, such as compressors and boilers. The floor drain and discharge pipe from the drain must be capable of resisting the chemicals discharged from the production equipment. Selection of the most appropriate piping material can be accomplished only if the nature of both present and future effluent is known and taken into account.

An often-used material is vitrified clay sewer pipe because of its resistance to most chemicals. Manholes are lined for protection against all possible acids or chemicals. A typical lined manhole is illustrated in Figure 2-3.

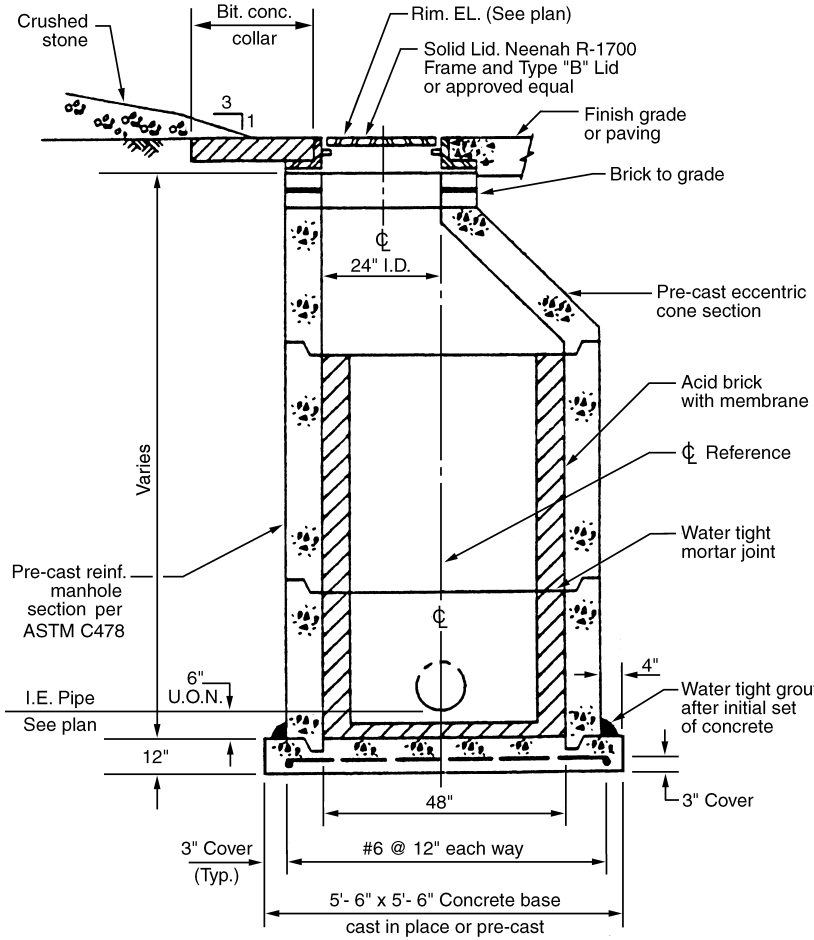


Figure 2-3 Lined Manhole

System Design Considerations

The design of the drainage system is dependent on the location, composition, and quantity of discharged effluent from all sources. The layout and engineering of a piping network requires ingenuity and attention to detail. Piping shall be sized based on the maximum possible flow (in gpm) and the slope of the pipe. Table 2-3 provides the information necessary to size drainage piping flowing full.

Selection of the type and location of floor drains is a major aspect of drainage system design. The following are general guidelines for doing this:

1. Wet floors are to be avoided. Drains should be located next to equipment and be large enough to allow multiple discharges to spill over them without spilling on the floor and running to the drain or requiring a run of pipe over the floor. If

large flow rates are expected, select a large drain.

2. The use of long trench drains in areas where there are several pieces of equipment will create easy access from the equipment to all the various drains. This arrangement is usually less costly than multiple drains.
3. In many cases, the discharge from a piece of equipment may be under pressure because of the head of water in the equipment, such as occurs when a tank is emptied. The drain should be large enough to accept the largest expected flow. The drain opening must be large enough to accept the maximum quantity flowing full by gravity without overflowing. An air gap shall be provided to prevent pressurizing the gravity-drainage system.
4. A funnel or open site type drain should be provided to accept a quantity of small-sized drainage lines from equipment. The top of the funnel should be as close to the floor as is reasonable in order for an air gap to be provided between the top of the floor drain and the end of the equipment drain. This air gap shall be twice the diameter of the drainage line.
5. Provide adequate cleanouts in drain lines. In lines that are at the ceiling of a high floor, extend the cleanouts to the floor above to avoid the need for maintenance personnel to climb ladders to clean stoppages.
6. To facilitate maintenance, the minimum size drain line under an isolated slab or underground should be 2 in. (50 mm). Floor drains should be a minimum size of 4 in. (100 mm).
7. Adequate venting of the drainage line must be provided to allow for smooth flow. Vents shall be connected to the top of the drain line in order to allow air at the top of the pipe to be either vented out (when there is a slug of liquid) or to admit air required by the flow of water or due to a partial vacuum created by the liquid flowing full. Vents shall be a minimum size of 2 in.
8. Local regulations may require the use of double-contained piping to prevent potential leakage from discharging into the environment. A leak-detection system should be provided that allows leakage to be annunciated.

Table 2-3 Capacity of Drainage Piping Flowing Full (n = 0.013)

Pipe Diameter, in.	Horizontal Piping, gpm Slope, in./ft			
	Stacks, gpm	⅛	¼	½
2	30	—	—	—
2½	54	—	—	—
3	92	36	51	80
4	192	77	110	174
6	563	220	315	449
8	1208	494	696	987
10	2600	943	1302	1800
12	6000	1526	2154	2800
15	—	2873	3500	4950

FIRE-SUPPRESSION WATER DRAINAGE

Introduction

For industrial facilities, the water used to suppress a fire could become contaminated with the products and raw materials it comes in contact with. It is required that any water, such as sprinkler and fire-hose discharge, that has the possibility of being contaminated in this manner, must be routed to holding basins for analysis and possible treatment before being discharged into the environment. If there are no materials capable of causing contamination, no special consideration is necessary except to protect other areas of the facility from possible flooding.

System Description

The components of the fire-suppresion drainage system are drains located in such a manner to intercept the flow of fire water, the drainage piping, a holding basin on site to contain and treat the total volume of water, and the necessary treatment system that will neutralize the water prior to discharge into the environment.

The amount of water discharged from the fire-suppression system is far greater than the amount of waste water discharged from the facility under normal operating conditions. Overflow floor drains large enough to take the design flow rate shall be installed at points where they can intercept the water before it flows out of doorways or drive bays and route it to holding basins. The placement of these overflow drains shall be selected to intercept all the water discharged and prevent it from damaging other parts of the facility, or escaping away from the property or into the ground.

The size of the drainage piping is based on flow rate and pitch from the facility to the detention basin. The effluent is essentially clear water with a few solids. The flow rate of the water that must be disposed of is determined by first calculating the sprinkler-water density over the area used for hydraulic calculations. Added to this is the average flow rate from the maximum number of fire standpipe hose streams in simultaneous use. Velocity in the drainage pipe is not a major consideration because the system will rarely be used. A shallow pitch will give a low velocity that may result in the deposit of some material that could be flushed out after the fire event. A high velocity will not affect the life of the piping system because of the short amount of time the system will be in operation. Pipe size is selected based on the actual pitch of the pipe and the capacity flowing full. Refer to Table 2-3 for sizing.

Venting the system is required to allow free flow of the effluent. Each individual drain need not be vented, but each branch should have a loop vent at least 2 in.(50 mm) in size. The vent could be connected to the sanitary vent system or carried through the roof independently.

The pipe material selected shall be compatible with the potential chemicals that might be carried.

FLAMMABLE AND VOLATILE-LIQUID DRAINAGE

Federal, state and local regulations have established standards for the discharge of volatile liquids, particularly oil, into storm-water and sanitary sewers. These standards vary, and the responsible enforcement and code authorities must be consulted to determine the level of treatment required.

The potential hazard created by volatile liquids could be either one of safety (since the vapors could create an explosive condition and oil will float on water and could be set on fire) or one of health (where the breathing of the vapors is dangerous to health and the substance is toxic if ingested by humans). The characteristic common to all these substances is that they are lighter than water. Their removal is similar to that of oil, which is the most common flammable liquid.

Oil in Water

Oil is considered immiscible since it cannot be mixed with water: Oil in water exists in several forms:

1. Free oil.
2. Mechanically dispersed oil, which consists of fine droplets ranging in size from microns to fractions of a millimeter. They are stable due to electrical charges and other forces but not due to the presence of surface active agents.
3. Chemically stabilized emulsions, which are fine droplets that are stable due to surface active agents.
4. Dissolved and dispersed oil is suspended in such a small size—typically 5 microns (μ) or smaller—that ordinary filtration is not possible.
5. Oil-wet solids, which are particulates that oil adheres to the surface of.

Methods of Separation and Treatment

Oil spills and leaks are best treated in their most concentrated state, which is at their source or as close as is reasonable to the source. The primary methods used to separate and remove free oil and oil-wet solids are flotation and centrifugation. Secondary treatments, such as chemical treatment/coalescence and filtration, are then used to break up oil/water emulsions and remove dispersed oil. Finally, tertiary treatments, such as ultrafiltration, biological treatment, and carbon adsorption, remove the oil to required levels prior to discharge. This chapter discusses only the general principles of primary and secondary separation methods and devices.

The American Petroleum Institute (API) has established criteria for the large-scale removal of globules larger than 150 μ. In abbreviated form, they are:

1. The horizontal velocity through the separator may be up to 15 times the rise velocity of the slowest-rising globule, up to a maximum of 3 ft/s (fps).
2. The depth of flow in the separator shall be between 3 ft 0 in. and 8 ft 0 in above the outlet.
3. The width of the separator shall be between 6 ft 0 in. and 20 ft 0 in.
4. The depth to width ratio shall be between 0.3 and 0.5.
5. An oil-retention baffle should be located no less than 12 in. downstream from a skimming device.

Gravity Separators

Gravity separation is the primary and most often-used separation method. It is based on the specific gravity difference between immiscible oil globules and water. Since all of these liquids are lighter than an equal volume of water, gravity separators operate on the principle of flotation. As the water and oil flow through the unit, the oil floats to the top and is trapped inside by a series of internal baffles. Since the oil remains liquid, it is easily drawn off via gravity. For larger-scale service, the rate at which oil and oil-wet solids float to the top of the separation chamber is enhanced by the attachment of small bubbles of air to the surface of the slow-rising oil globules. This is done by adding compressed air to the bottom of the flotation chamber. As the air saturated flow is brought back to atmospheric pressure, microscopic bubbles are formed that will mix with, and attach themselves to, the oil globules.

Centrifugal Separators

The centrifugal separator is used on large-scale services, also. This device operates on the principle of inducing the combined oil and water mixture to flow around a circular separation chamber. The lighter oil globules collect around the central vortex which contains the oil-removal mechanism and the clear water collects at the outer radial portion of the separation chamber. Methods have evolved that can produce effluent water with only 50 to 70 ppm of oil, and proprietary devices exist that can lower oil content to 10 ppm.

Filtration

Chemical methods used to break oil/water emulsions followed by the use of depth type filters to remove the destabilized mixture have proven effective in removing oil globules in sizes ranging from 1 to 50 μ. The velocity and flow rate of the mixture to be treated must be carefully controlled to achieve optimum performance of the system.

Methods for Smaller Systems

Oil separators for small flows usually take the form of a single unit consisting of a drain grating into which the effluent flows and in which the oil remains to be drawn off manually. Another type of unit uses an overflow arrangement that sends the trapped oil to a remote oil-storage tank.

Because there is a possibility that the vapor given off by the volatile liquid could ignite, it is important to provide a separator vent that terminates in the open air at an approved location above the highest part of the structure. Some codes require that a flame arrester be installed on the vent.

The material most commonly used for oil interceptors is cast iron, although steel can be used for less severe service. Gratings must have the strength to withstand the weight of the types of vehicle expected.

Figure 2-4 illustrates a typical small oil interceptor, Figure 2-5 the installation of a typical oil interceptor with gravity oil draw off for multiple floor-drain inlets.

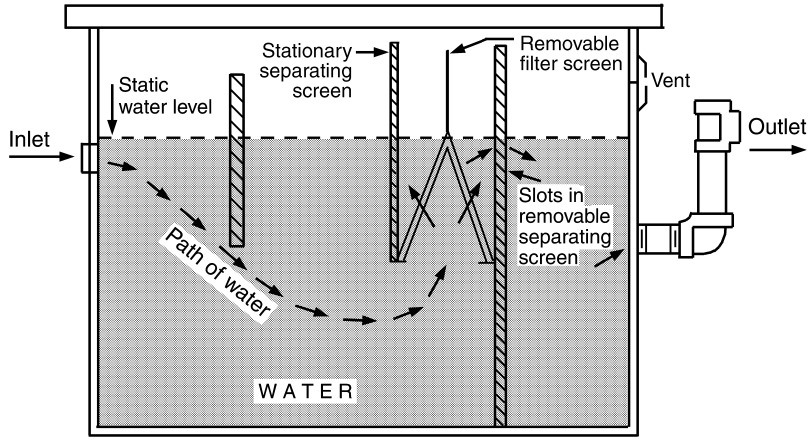
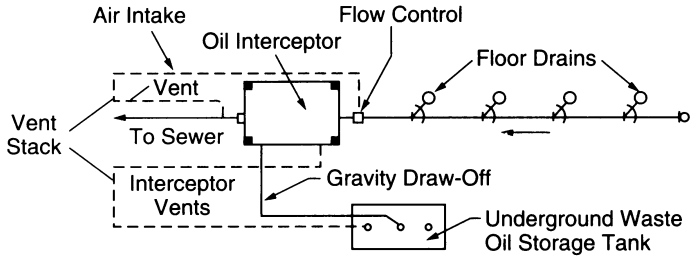
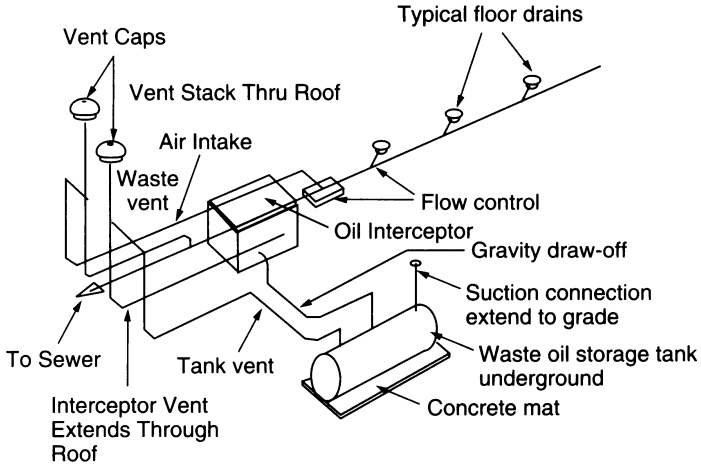


Figure 2-4 Typical Small Oil Interceptor



PLAN VIEW



ISOMETRIC VIEW

Figure 2-5 Installation of a Typical Small Oil Interceptor with Gravity Oil Draw Off

3 Water Systems

UTILITY-WATER SYSTEMS

Water from wells, rivers, lakes, and streams is commonly used for cooling of equipment or devices, process washing, and other purposes. The system that delivers this water is commonly called the "utility-water system" to differentiate it from the potable (city) water and pure-water systems. Clarifying and treating this water in order to meet the purity requirements of the proposed end use may be less expensive than potable or pure water systems, but requires good monitoring and quick reaction to raw and treated-water purity fluctuations. If the water is to be recirculated, the treatment methods are more stringent to avoid sedimentation. Local codes must be adhered to with regards to allowable chemical content present in the waste water if the bi-product of the treated water is to be discharged into the environment. This is necessary in order to avoid the need for waste treatment.

Initial Filtering

If the utility-water system source is surface water, a coarse or fine screen is usually placed at the intake to keep out fish and other large debris. Coarse screens are usually ½-in. diameter bars with a clear opening of 1 to 3 in. Fine screens can have openings of approximately ⅜-in.[2] by limiting water velocity through the screen to approximately 2 fps. If the quantity of water is small enough, basket strainers can be used. In climates where freezing may occur, the inlet should be placed far enough below the low-water level to prevent freezing.

Clarification

After the initial filtering, clarification is required to obtain water that meets the standards for the utilitarian use. The selection of the clarifier is based on the volume of water to be treated and the final quality desired. If the volume of water is small and the raw water is not very turbid, filters may be used.

Biological Control

To control fouling of the system by microorganisms, the microorganisms must be destroyed, if possible, or inactivated to keep them from reproducing then removed from the water stream. This is usually accomplished by chlorination, filtration, ultraviolet (UV) radiation, ozone generation, and special adsorbents.

Chlorination is the least costly and most often-used method. The action of chlorine requires a contact time and the establishment of a residual amount of chlorine. A range of 0.5 to 1.0 ppm is generally accepted for typical waters.

Water Softening

If the utility water system is used for recirculated cooling purposes, water softening should be considered to reduce hardness. For large-scale, raw-water treatment,

the lime soda ash method using either hydrated lime or quicklime along with soda ash should be considered. When added to water, these chemicals react with the dissolved calcium and magnesium carbonate to form insoluble compounds. These compounds precipitate out of solution and are passed through a filter for removal. They are then discharged to drain. This process is usually carried out during the clarification process rather than separately and is reserved for large volumes of water.

POTABLE WATER SYSTEMS

Potable water is used for human consumption, for various manufacturing and wash-down purposes, as feed water for pure-water systems, and to make hot water for cleaning. It is often called "city" water because it comes from the municipal water supply or "cold" water since the municipal water supply is as cold as it can be without refrigeration.

The design of the potable-water system and building service follows the standard procedures found in many engineering texts and is not unique to pharmaceutical facilities. Refer to standard engineering texts, such as the ASPE *Plumbing Engineering Design Handbook*.

Before the piping system can be sized, it is important to identify all the equipment that will use potable water as continuous or intermittant operation and to establish the flow rate of water. The continuous flow rate combined with the duty-cycle of the intermittant flow rate result in the highest value for instantaneous flow, to be used in establishing the size of service.

DOMESTIC HOT-WATER SYSTEMS

The domestic hot-water system provides and distributes hot water, which is used for human consumption as well as for washing and cleaning for various purposes throughout the facility. The system utilizes potable water, which may require water softening to reduce hardness and scaling of water heating elements.

Personnel Classification

Pharmaceutical production facilities are separated into shifts or workday hours of varying lengths depending on the nature of the workplace. A majority of the hot water use by personnel directly engaged in production within any facility is limited to the beginning and end of a shift or workday and to lunch time. The use of hot water for other general purposes are spread throughout the workday. Hot water is also used occasionally for emergency purposes, such as spill cleanup.

There are three general categories of personnel in any industrial facility: management/office personnel, production supervisors, and production personnel. Separate washrooms are often provided for each type of personnel, due primarily to physical location within the facility.

Specific Areas Within Facilities

Washrooms and Toilets

Washrooms and toilet rooms in separate areas are usually provided for the general production staff, the production staff supervisors, and the administrative/office staff of the facility.

The use of hot water in the toilet areas provided for the administrative/office personnel is the same as it is in office building, having the same characteristics of use. The type and number of fixtures required are governed by the applicable plumbing code.

The washrooms and toilets provided for production personnel and supervisors require different design criteria because of shift hours. The production personnel toilet area usually consists of locker rooms, toilet rooms, wash-up facilities, and showers. The number of various types of fixture is not usually covered in the applicable code, therefore, judgment and prior experience are often required. Consideration must be given to the number of people using the facilities at the end or beginning of a shift and to whether the type of work is "clean" or "dirty." Another consideration is whether code or client policy requires personnel to take a shower prior to leaving the facility.

Wash Fixtures Wash fixtures for production personnel often consist of a single, large fixture with multiple wash stations. Such fixtures are manufactured in various standard configurations, such as circle, semi-circle, and quarter circle, and in various sizes.

Spray heads are available for light and heavy industrial facilities, ranging from 0.5 to 0.75 gpm/station. Some individual wash-station faucets are not capable of independent operation, which means that the entire fixture must be turned on when only one person is washing. These multiple wash fixtures require a minimum of 20 psig for correct operation.

Where there is no client preference, the following general design criteria should be used to select fixtures:

1. Twenty minutes should be allowed at the end of a shift for wash up and showers.
2. Wash fixtures must be provided for all shift personnel. These fixtures can be either individual lavatories or group wash fountains. Where no guidance is given, a range of between 5 and 12 people per station should be provided for, depending on the number of people. The larger the number of people, the more people per station should be selected. A generally accepted figure of 1 wash station or lavatory for each 6 people should be used as a starting point to select the number of fixtures, with any fraction increasing the number by 1.
3. To determine the amount of space required, 24 in. for each lavatory is a generally used figure. A 20-in. section of curved wash-fountain rim is generally accepted as the equivalent of 1 lavatory.
4. Where individual wash up is anticipated, individual lavatories are preferable to group wash fountains because wash-fountain spray heads use much more water than 1 lavatory used by 1 person.

Showers Each shower head shall be limited to a flow rate of 2.75 gpm, if not governed by local code. Generally, the shower arrangement for males is a gang type shower, while females are given the privacy of individual shower stalls. These showers should have individual volume and temperature controls. The height of the shower head is between 6 ft 6 in. and 7 ft 0 in. above the floor. All new or renovated installations shall be handicapped accessible compliant.

The number of heads is based on the number of people expected to use the washroom on each shift. If no specific code figures are provided, client preference should be used. A suggested number would be 1 head for each 10 persons for "dirty" facilities and 1 head for 20 persons in cleaner facilities, allowing for a total of about 20 min for the shift to complete showering. For laboratories, suburban offices, and other similar facilities, when showers are provided in general-use toilet rooms (as compared to toilets adjacent to lockers and washrooms), they are most often used by personnel during lunch time and prior to going back to work after finishing some form of exercise, such as jogging or using facility-provided exercise equipment.

Wash Down

Hose stations are often provided in production rooms adjacent to equipment that requires cleaning and in rooms where it is required that the walls and floors be cleaned regularly. These hose stations are often provided with steam and cold water to make hot water, although many are also supplied with hot and cold water. The number of people simultaneously assigned to cleaning is an important factor to consider when calculating the maximum flow rate for the piping these fixutes can be identified as continuous use devices when determining hot water heater recovery capacities.

Guardhouses

A guardhouse is generally provided with toilet facilities unless it is close to an adjacent building that has a convenient toilet. The toilet shall have fixtures sufficient for the number of personnel on duty as required by code as if the guardhouse were a separate building. The most economical method of providing hot water is by installing a point-of-use, electric, instantaneous heater in or at the ceiling adjacent to each fixture requiring hot water. It should be sized to provide 140°F water at the flow rate of two-thirds the capacity of the faucet installed.

Service Sinks

Hot water from service sinks is used primarily to fill buckets for cleaning floors with mops. Where a service sink is provided in a location remote from other fixtures, a separate heater should be considered, since it is more cost effective than providing hot-water supply and return piping to a remote fixture. Service sinks are designated for maintenance applications therefore the spouts are fitted with hose threads and not water restricting aerators. Because of the lack of a restricting aerator, a large flow rate of hot water will be required. It is best to consider a small storage type water heater installed adjacent to the sink, on a shelf above the sink, or at the ceiling if there are space restrictions. The heating medium is usually electric because the initial cost is low, since no flue or ancillary furel piping is required.

Repair Areas

Repair areas within a facility are intended for maintenance of the production machinery and of the facility itself. Equipment typically includes wood and metal mills and lathes, welding apparatus, cleaning areas, and standard wood and metal working tools. Sinks are provided for rinsing and cleaning machine parts and for hand washing. They are not heavily used.

Electronic and instrument repair facilities have wash sinks provided to clean instruments brought in for repair. It is common practice to wash electronic equipment

with detergent and water to remove dust and other accumulated dirt after disassembly and prior to repair.

Cafeterias

The water-heating equipment for cafeterias within most industrial facilities is easier to size because the number of people using the facility is generally known, and the time allowed for eating is also limited.

An often-used method for calculating the water-heater size for a cafeteria serving production and administrative personnel is based on the number of people served and the range of time allowed for a meal. The executive dining room should be included when calculating the above figure if it is an adjacent facility. If it is remote, it should be considered completely separate and provided with its own water heater, the size of which is based on the same criteria. Refer to the ASPE *Domestic Hot Water Heating Manual* or other standard engineering texts for the sizing of water heaters for this purpose.

Sizing of Hot-Water Generators

General

Hot-water generators are either storage or semi-instantaneous type heaters. The semi-instantaneous type heaters are generally used because of the smaller space required and the lower cost. They usually use steam as the heating medium because it is plentiful, due to other manufacturing processes within the plant. To find the pounds of steam per hour required for the heater, use 50 lb/h for each gpm of hot water at 100°F rise.

Systems that require close temperature control coupled with a large amount of hot water at a steady flow rate over an extended period of time do not require a large storage tank. If a storage tank is provided there is a good probability that the temperature of the water will be lowered, which is unacceptable. The best selection would be a relatively small storage tank, which will act as a stabilizer; a water-heater recovery rate approximately equal to the demand; and a blending valve. This arrangement with a small tank will ensure a constant supply of hot water at a constant temperature, which will allow for good modulation.

When the requirements are for hot water boosted to a temperature of 180°F, keeping a constant distribution system temperature is even more critical. Such systems require either a quick recovery generator equal in capacity to the actual volume of instantaneous usage or a storage tank with sufficient volume to maintain stabilized water temperature with reduced recovery.

Sizing Procedures

Where an instantaneous system is selected, the maximum flow rate is the most critical factor in selecting a water heater capable of meeting the expected load.

The shower room is considered a "dump" load. Experience has shown that a 20-min period of time is enough for an entire shift to take a shower. This is the maximum amount of time that should be allowed. Each shower is assumed to last 5 min. The storage tank should have sufficient capacity to supply the entire shift, and the recovery should be sized to make up that amount of hot water before the next shift lets out. This figure should be adjusted if other fixtures are supplied from the same

tank. The water should be heated to a temperature of 140°F to eliminate pyrogen replication in the system but delivered to the shower stall at about 115°F to avoid the possibility of scalding.

Example 3-1
To provide an example of water-heater sizing, a pharmaceutical plant with 100 shift workers assigned to the area will be used to select both a storage and an instantaneous heater.

First we select the storage type heater. One hundred people require a wash fountain. Using 8 people per station, 12.5 or 13 stations are needed. For 12 stations (two 6-station units) and a 20-min timeframe, this gives 1.6 min of wash time per person—not quite enough to wash hands. Use two 8-station units because of the possibility of dirty working conditions. For the showers, it is assumed that 5% of the workers will take showers, which will require 5 heads. To calculate the heater capacity, add the two requirements. For a 20-min period, two 8-wash-station units require 5 gpm times 20 min equals 100 gal. Five showers at 2.5 gpm times 20 min equals 50 gal. The storage type water heater selected should be capable of makeup and storage capacity to deliver 150 gal in 20 min. The safest selection would be to store the entire required amount of water (with 30% additional to account for the cooling factor) in, say, a 200-gal storage tank, and make up the amount of water slowly over a 6-h period if this is the only purpose of the heater.

For an instantaneous heater, wash-station use equals 10 gpm and shower use equals 12.5 gpm. The instantaneous heater shall be sized for 22.5 gpm. Add to this total the requirements for all of the other equipment and wash-down.

PURE-WATER SYSTEMS

The purpose of pure-water systems is to provide water of the purity necessary for all the various laboratory and pharmaceutical production requirements of the facility. The purity of the different pure-water systems depends on the requirements of the end user. The various systems will be broadly defined and general guidelines for their production, storage, and distribution will be provided. Pure-water systems can be divided into two classifications: laboratory and pharmaceutical systems.

Laboratory Use

For laboratory work, all applications do not require the same purity. The American Society of Testing Materials (ASTM), the College of American Pathologists (CAP), the National Committee for Clinical Laboratory Standards (NCCLS), and the Association for the Advancement of Medical Instrumentation (AAMI) have all developed standards for water used in laboratories depending on its intended use. These standards are summarized in Tables 3-1 (CAP/ASTM), 3-2 (NCCLS), and 3-3 (AAMI/ANSI).

There are three pure-water categories in the NCCLS specifications:

- **Type I** Called "reagent grade water," this is used for analysis of trace matter and other critical applications. It is the purist water covered by any written standard. This water is free of organic and inorganic impurities, suspended solids, and microorganisms.

- **Type II** Called "analytical grade water," this is suitable for all but the most critical procedures.
- **Type III** Called "general laboratory grade water," this grade is suitable for most qualitative analyses, equipment rinsing, and as a supply for generating type I water.

Pharmaceutical Use

Pharmaceutical Water

In most countries, the pharmaceutical industry is regulated. In the United States, it is regulated by the FDA, which takes guidance from several sources, including the Pharmaceutical Research and Pharmaceutical Manufacturers of America (PhRMA), the United States Pharmacopeia (USP), and gets updates from the *Pharmacopeia Forum* (PF), which is published by the US Pharmacopeial Convention. Each

Table 3-1 CAP and ASTM Reagent-Grade Water Specifications

	CAP Type			ASTM Type			
	I	II	III	I	II	III	IV
Spec. conductance (μmho/cm)	0.1	0.5	10	0.056	1.0	0.25	5.0
Spec. resistance (MΩ · cm)	10	2.0	0.1	18	1.0	4	0.2
Silicate (μg/L)	50	100	1000	3	3	500	—
Heavy metals (μg/L)	10	10	10	—	—	—	—
Total organic carbon (μg/L)	—	—	—	100	50	200	—
Potassium permanganate reduction (min.)	60	60	60	—	—	—	—
Sodium (μg/L)	100	100	100	1	5	10	50
Chlorides (μg/L)	—	—	—	1	5	10	50
Hardness	neg	neg	neg	—	—	—	—
Ammonia	0.1	0.1	0.1	—	—	—	—
Bacterial growth (cfu/mL)	10	10^4	—	a	a	a	a
pH	—	—	5.0-8.0	—	—	—	5.0-8.0
CO_2 (μg/L)	3	3	3	—	—	—	—

a Microbiological contamination: When bacterial levels need to be controlled, reagent grade types should be further classified as follows:

	Type A	Type B	Type C
Maximum heterotropic bacteria count	10/1000 mL	10/1000 mL	100/10 mL
Endotoxin, endotoxin unit (EU)	<0.03	0.25	Not applicable

Table 3-2 NCCLS Reagent-Grade Water Specifications

Characteristics	Type I	Type II
Bacterial content (colony-forming units per mL, maximum)	10[a]	1000
pH	N/A	N/A
Resistivity, 25°C (MΩ/cm)	10	1.0
Silicate (mg/L max.)	0.05	0.1
Particulate matter[a]	0.22-μm filter	N/A
Organics[b]	Activated carbon	N/A

Source: Frankel 1996.

[a] Preferably, type I water should be bacteria free.

[b] These specifications are process specifications and are not measured by the end user.

Additional purification may be required for selected clinical laboratory procedures, such as:

1. Preparation of water with minimal pyrogen levels for cell culture.
2. Preparation of bacteria-free water for direct fluorescent detection of bacteria as in Legionella pneumophilia direct fluorescent antibody testing or direct fluorescent stains of mycobacteria.
3. Preparation of water with minimal organic content for HPLC.

country has its own governing and guiding agencies.

Information in this manual refers to standards of the United States. These standards include USP 24/NF 19, January 1, 2000.

Purified Water Types

1. **Compendial water.** This is a general term that includes all types of purified water and water for injection intended to be used in any final pharmaceutical drug-dosage form.
2. **Purified water (PW).** The quality of the feedwater shall meet drinking water standards. These standards are presented in Tables 3-4 and 3-5. The final product shall contain no added substances. The USP requirement regarding added substances has always referred to additions to the final product and not to the feedwater. It is commonly interpreted by the USP that substances may be added to the feedwater provided that they are removed to an acceptable level during the final treatment process. PW is used as the feedwater for the preparation of compendial water.
3. **Sterile purified water.** This type of purified water, including some sterile water for inhalation, is made using purified water as a raw-water source, sterilized and suitably packaged. It contains no antimicrobial agent.
4. **Bacteriostatic purified water.** This is PW, sterilized and suitably packaged. It contains no antimicrobial agent.
5. **Water for injection (WFI).** This type of purified water is made using PW as a raw-water source that must be further purified by distillation or RO. Bacteria and endotoxins must be reduced to the required level.
6. **Sterile bacteriostatic water for injection.** This is WFI, sterilized and suitably packaged. It contains no antimicrobial agent.
7. **Sterile water for inhalation.** This is WFI, sterilized and suitably packaged. It contains no antimicrobial agent except when used in humidifiers or similar devices subject to contamination or other added substances.
8. **Sterile water for irrigation.** This is WFI, steril-

Table 3-3 AAMI/ANSI Water-Quality Standards

Contaminant	Suggested Maximum Level (mg/L)
Calcium	2 (0.1 meq/L)
Magnesium	4 (0.3 meq/L)
Sodium	70 (3 meq/L)
Potassium	8 (0.2 meq/L)
Fluoride	0.2
Chlorine	0.5
Chloramines	0.1
Nitrate (N)	2
Sulfate	100
Copper, barium, zinc	0.1 each
Arsenic, lead, silver	0.005 each
Chromium	0.014
Cadmium	0.001
Selenium	0.09
Aluminum	0.01
Mercury	0.0002
Bacteria	200 (cfu/mL)

Source: Association for the Advancement of Medical Instrumentation (AAMI), 1990, *Hemodialysis Systems Standard*. Adopted by American National Standards Institute (ANSI), 1992.

Note: "meq/L" = mole equivalent/liter

Table 3-4 Current Standards for Purified Water and Water for Injection

Parameter	Standard
TOC	500 ppb carbon
Conductivity	1.3 µS/cm @ 25°C
	0.1 µS/cm @ 20°C
Bacteria	PW: 100 cfu/mL
	WFI: 10 cfu/100 mL
Bacterial endotoxins	WFI: 0.25 USP EU/mL

Note: µS/cm = microsiemens per centimeter
cfu/mL = colony forming units per milliliter

ized and suitably packaged. It contains no antimicrobial agent.

Table 3-5 Standards for Packaged PW, WFI, and Sterile PW

Parameter	Standard
pH	5.0-7.0
Chloride	0.5 mg/L
Sulfate	1.0 mg/L
Ammonia	0.03 mg/L
Calcium	1.0 mg/L
Carbon dioxide	5.0 mg/L
Oxidizable substances	pass USP permanganate test
Bacteria	
Purified Water	100 cfu/mL
WFI	10 cfu/100 mL
Sterile PW	pass the USP sterility test <71>
Endotoxin WFI	0.25 EU/mL

Source: U.S. Pharmacopeial Convention Inc.

Pharmaceutical Water-Treatment Process

Pharmaceutical water treatment takes raw water that meets drinking (potable) water standards and removes sufficient contaminants from that water in a treatment plant to meet the standards for the various types of compendial waters. A number of treatment steps are required in order to process raw water into PW and other subsequent pure-water types.

Each individual treatment plant has a different configuration. A typical configuration is illustrated in Figure 3-1. The intent of providing this figure is to show a process flow and include most of the equipment and general arrangement found in a typical plant. It is not intended to suggest that this is the best or only manner in which to arrange the process.

All pharmaceutical water shall start with potable water as a raw-water source. Potable water usually contains a residual of some oxidizing biocidal agent to control

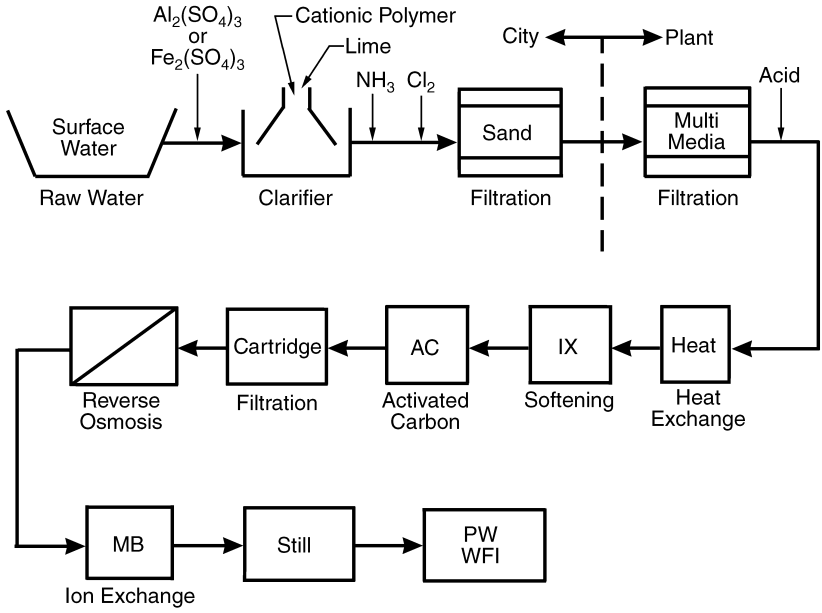


Figure 3-1 Typical Pharmaceutical Water-Treatment Flow Diagram

disease-causing microorganisms. Typically either chlorine or chloramine is the oxidizing agent, and it is used in sufficient quantities to achieve the free chlorine residual necessary to achieve its purpose. There are no requirements regarding the amount of total organic carbon (TOC) or endotoxins present. The TOC is subject to seasonal variances, with the lowest level usually occurring in the winter.

Typically, the steps in a pharmaceutical water-treatment process include the following:

- **Multimedia filtration.** This is one of the first steps commonly found in the treatment process. Its purpose is to remove the bulk of suspended contaminants larger than 30 μ.
- **Acid injection.** Some treatment plants must add acid injection somewhere in the system. The purpose of the acid is primarily for scale control. It is shown in Figure 3-1 before the heat exchanger because calcium carbonate is more likely to scale out when water is hot. If there is little hardness (calcium and magnesium ions) or alkalinity (hydroxide, bicarbonate, and carbonate ions) in the feedwater, acid may be eliminated. Another common reason to use acid is to minimize damage to cellulose acetate membranes if they are a downstream RO process component. These membranes are easily damaged at any pH level, but at a pH level of 5.5 to 6 the damage is minimized.
- **Heat exchange.** Feedwater is heated to lower the pumping costs for an RO unit because the warmer the water, the less pressure is required to pump water through an RO membrane. Another reason is that warmer water accelerates the rate of diffusion and chemical reactions. Generally speaking, for every 18°F (10°C) rise in temperature, the speed of chemical reactions doubles.
- **Softening.** A water softener controls scale by removing the hard, scale-forming cations like calcium and magnesium, and exchanging (replacing) them with non-scale-forming sodium ions.
- **Activated carbon units.** Often called "activated carbon beds" or "activated carbon filters," these filters remove chlorine or chloramine compounds from the feedwater to protect both RO membranes and deionization (DI) resins from the oxidizing action of the chlorine or chloramine compounds. A second, less common reason is to remove certain organic compounds. Organic compounds are molecules that always contain carbon, usually contain hydrogen, and frequently contain other atoms. They are called "organic" because prior to human intervention all organic compounds came from living organisms.
- **Cartridge filtration.** This filter is installed upstream of the reverse-osmosis units as an additional protection against suspended solids. Reverse-osmosis membranes will foul if sufficient suspended solids are not removed by the multimedia filter.
- **Reverse osmosis (RO).** RO is a process whereby a membrane removes the bulk of the suspended solids and contaminants, typically, 98 to 99+% of ionic contaminants and 95 to 99+% of dissolved TOC. A single pass through the RO membrane will typically not meet PW or WFI standards. A double-pass system, wherein the processed water from one RO unit is processed again through another unit, may be allowable. Distillation units are more commonly used to provide PW and WFI quality water.

- **Ion exchange.** Following RO, it is generally required to further reduce the contaminant level. This is typically done by a mixed-bed deionization unit. This unit could used in combination with electrodeionization (EDI) also known as "continuous deionization" (CDI) to further polish RO water. The resultant water is not pyrogen free.
- **Distillation.** In order to achieve PW and WFI quality, most treatment plants use distillation (stills) as a final step. A still heats the feedwater to the boiling point, and the resulting steam condensate typically meets required standards. Various types of still require different feedwater qualities, therefore, upstream requirements other than those shown in Figure 3-1 may be necessary. Distillation also produces water that is pyrogen free.

Codes and Standards

Pure-water treatment for laboratories shall comply with the following standards, depending on the purity of the water desired:

1. CAP and ASTM reagent grade water.
2. USP standards for water purity. Currently USP 23.
3. AAMI standards.
4. NCCLS standards.
5. SEMI and ASTM electronics grade water (outside the scope of this manual).

Pure-water treatment for pharmaceuticals shall comply with the following standards:

1. 21 CFR 210, cGMP for drugs.
2. 21 CFR 211, cGMP for finished pharmaceuticals.
3. USP/NF official water nomographs.
4. Federal Food, Drug and Cosmetic Act.

Water Impurities

Natural, or source, water is never pure. Water picks up impurities as it comes in contact with the ground surface or mineral formations when it is percolated through the earth. It also contains dissolved gases and dust picked up while falling through the air as rain, snow, or hail or as surface water in contact with the air above the water level. Water is classified as "surface water" when it is obtained from sources such as lakes and rivers and as "ground water" when it is obtained from streams, wells, or other aquifers originating underground.

One of the statements found in United States Pharmacopeia (USP) 23 in relation to purified water and water for injection used in pharmaceutical applications is that they contain "no added impurities." Some have taken this statement to mean that nothing shall be added to the raw, potable feed water. However, cGMP interpretation is that it was intended to concern only additions to the final pure-water product and not to feed water. Substances may be added during the processing of the water, but they must be removed to an acceptable level after being purified into the final product.

Suspended Matter (Particulates)

Turbidity "Turbidity," also called "suspended solids," is a general term used to describe any form of insoluble matter suspended in water. "Color" is another term

often used to describe turbidity and may be used when referring to water containing decaying vegetation. However, the term "turbidity" is most often used when referring to mineral particulates such as silt because they are usually the most plentiful. Other commonly occurring impurities are liquids, such as oil, and the residue caused by decaying vegetation. Coarse particles that settle rapidly when water is standing are referred to as "sediment," and fine particles that remain in suspension are called "silt."

Microorganisms Microorganisms are bacteria and viruses. They are living forms of particulate matter. Their unusual physiology allows them to grow and multiply in water containing only trace levels of nutrients. The presence of these nutrients in untreated water is an indicator of the possibility of microorganisms if the temperature for their growth is favorable. Although microorganisms are suspended solids, the treatment required for their removal or neutralization puts them in a separate category.

Pyrogens cause fever, and pathogenic organisms (such as Legionella pneumophila) cause diseases of any kind. Endotoxins, which are fragments derived from the cell walls of gram-negative bacteria, are considered the most important and widely occurring group of pyrogens. Other organic growths include algae (a primitive form of plant life), fungi (plants that lack the chlorophyll required for photosynthesis) and bacteria that exhibit both plant and animal characteristics. Bacteria are further subdivided into slime bacteria, which secrete slime; iron bacteria, which thrive on iron; sulfate-reducing bacteria, which live by consuming sulfate and converting it to hydrogen sulfide gas; and nitrifying bacteria, which use ammonia and whose byproduct results in the formation of nitric acid.

Several methods of measuring microorganisms are used, including viable-count essays, direct-count epifluorescent microscopy, scanning electron microscopy, and biochemical techniques. The most common means of measuring bacterial contamination is the viable-count method. This is done by passing the water being measured through a sterile nutrient medium and counting the number of colonies appearing on the medium after a period of time is allowed for growth. These colonies are called colony-forming units or CFUs. Endotoxins are measured in endotoxin units per milliliter (EU/mL). An often-used form of measurement for endotoxins is the limulus amoebocyte lysate (LAL) test, where a blood extract of the horseshoe crab becomes turbid in the presence of bacterial endotoxins. This detection technique uses the optical density (turbidity level) measured over a period of time.

Other Organisms This category of "impurity" is applied to larger living things such as clams, mussels, their larvae, and other forms of life. They tend to clog water inlets from salt and fresh bodies of water and also may find their way into the piping system of a facility. Additional discussion is found in utility-water Systems."

Dissolved Minerals and Organics

Organics Dissolved organic substances typically found in water include both man-made and natural substances. Man-made impurities include herbicides, pesticides, trihalomethanes, surfactants, and detergents. Naturally occurring impurities include lignins, tannins, humic and fulvic acid, and other products of bio-decomposition.

Alkalinity All natural water contains some alkalinity. "Alkalinity" is a measurement of the quantity of dissolved earth minerals in water and the water's ability to neutralize acids. It is mainly the sum of carbonate, bicarbonate, and hydroxide ions in water, with borate, phosphate, and silicate ions contributing to the total. It is reported as "ppm equivalent of calcium carbonate." Alkalinity is regarded as the most important characteristic of water in the determination of its scale-forming tendency.

Alkalinity is measured using two end-point indicators. The phenolphthalein or "P" alkalinity measures the strong alkali in the solution. The methyl orange or "M" alkalinity measures all of the alkalinity present in the solution. "M" alkalinity is often called "total alkalinity" because it also includes "P" alkalinity. Alkalinity is not a measure of pH.

Iron The most common form of iron is ferrous bicarbonate. It is also considered a form of hardness. Iron causes problems with many ion-exchange resins.

Magnesium The most common forms are magnesium carbonate, magnesium bicarbonate, and magnesium chloride. These impurities tend to deposit scale on surfaces they come in contact with.

Silica The three common kinds of silica are soluble, colloidal and particulate. Soluble silica is often referred to as "reactive silica," and colloidal silica is sometimes called "non-reactive" or "polymeric." The most common form in solution is silicon oxide, and in suspension it is found as a fine colloid. These impurities tend to deposit a scale on surfaces they come in contact with and form a gelatinous mass on reverse-osmosis (RO) membranes.

Sodium and Potassium Both elements form similar salts, with the most common being sodium or potassium chloride, sodium or potassium carbonate, and sodium or potassium bicarbonate.

Chlorides and Sulfates The most common forms are dissolved salts of sodium, potassium, calcium, and magnesium. These impurities tend to deposit a scale on surfaces they come in contact with.

Hardness Hardness is the total of calcium, magnesium, iron, and other metallic elements that contribute to the "hard" feel of water. Carbonate, sulfate, and chloride salts of these elements are responsible for most of the scaling deposited on pipe walls and boilers. Generally accepted practice limits the term "hardness" to include only calcium and magnesium. Hardness is usually expressed in terms of mg/L as $CaCO_3$.

Often, water is characterized in general terms by the amount of hardness, expressed as mg/L as $CaCO_3$, as follows:

Soft	0 to 75 mg/L as $CaCO_3$
Moderate	76 to 150 mg/L as $CaCO_3$
Hard	151 to 300 mg/L as $CaCO_3$
Very hard	Over 300 mg/L as $CaCO_3$

Trace Elements Trace elements are present in very small quantities and are only considered problems if the amount is above a level accepted for the purpose

of the water. Examples are lead, cadmium, copper, barium, silver, lithium, zinc, chromium, mercury, arsenic, and selenium.

Dissolved Gases

The dissolved gases that are most common in natural raw water are oxygen, carbon dioxide, nitrogen, and hydrogen sulfide. In addition, water obtained from a potable water supply usually contains chlorine and fluorides, which are added as an aid to public health. Of increasing concern is the presence of radon gas in many water supplies obtained from wells.

Oxygen must be present for the corrosion of metals, it is the basic factor in the corrosion process. Its removal or reduction reduces the corrosiveness of the water.

Carbon dioxide, nitrogen oxides, sulfur oxides, and hydrogen sulfide contribute to corrosion by making water acidic.

For chlorine, no pretreatment is usually necessary for a feed water with less than 1 ppm. When more than 1 ppm of chlorine is present, an activated carbon filter is recommended.

Water Analysis and Impurity Measurement

General

Analyzing a water sample is the process of finding the quantity of various impurities present. To accomplish this, the quantities must be presented in a logical and understandable manner to allow for easy and practical interpretation. It is of the utmost importance that the initial analysis of incoming water be accurate and contain a worst-case scenario, and that the desired output quality be established prior to the selection of any treatment system.

The most accurate analysis of a water sample is done by laboratories specializing in this type of work. Sterile containers must be used and several samples must be taken over a period of time to ensure that peak readings and average values are obtained. There are also many field tests of water samples that are not as accurate as those done in the laboratory but give an accuracy acceptable to the user.

The results of the analysis are expressed in many ways. A common method is to report the concentration of ions in solution as the weight of an element or compound per liter of water, expressed as milligrams per liter (mg/L) of water. Another method is to report it in parts per million (ppm). PPM can be expressed either by the weight of an impurity compared to the weight of water, abbreviated w/w (weight to weight), or by the volume of the impurity compared to the volume of water, abbreviated v/v. Other units are also used, such as grains per gallon (gpg) and equivalents per million (epm). Mg/L differs from ppm in expressing a proportion in weight per volume. This finds specific use in the analysis of saline waters. For common supplies where the specific gravity of the liquid is around 1, mg/L and ppm are equal. Grains per gallon (gpg) is a term often used in the discussion of ion-exchange equipment capabilities, where 1 gpg = 17.1 ppm.

As previously explained, compounds break down into ions when dissolved. Although chemists can measure the amounts of each ion present in a sample, it is not practical to find the total amount of each compound that actually went into solution. In practice, the actual method of analysis measures only ions. Using the

ionic form in measurement when reporting impurities makes it easier and more convenient to interpret the results.

To further simplify reporting, it is desirable to reduce all ions present in solution to a common denominator. The common denominator is calcium carbonate. This is accomplished by comparing the equivalent weight of all ions present and expressing them as the ppm anion and cation equivalent of calcium carbonate (CaCO3). The main reason is that the molecular weight of calcium carbonate is 100 and its equivalent weight is 40. This method of expression is a widely accepted—but not universal—standard for reporting a water analysis.

PH

When alkalines (bases) are mixed in water, hydroxyl ions result. In a mixture of acid and water, hudrogen ions result. PH is a measurement of the hydrogen ion concentration of a solution. Since the balance of hydroxyl (cation) and hydrogen ions (anion) must be constant, changes in one ion concentration produces corresponding change in the other. The pH value is calculated from the logarithmic reciprocal of the hydrogen-ion concentration in water. The pH scale ranges from 0 to 14, with 0 being acid and 14 being alkaline. 7.0 is neutral. A change of one unit represents a tenfold increase (or decrease) in strength. PH is not a measure of alkalinity.

Specific Resistance

Specific resistance is a measure of the amount of electrolytes in water. It measures the ability of 1 cm^3 of the sample solution at a given temperature to resist the flow of an electrical current. It is based on the activity of the compounds dissolved in water and is the most practical method of measuring impurities from a given sample. Resistance is given in ohms (Ω). The resistance is based on the amount of ionized salts only and varies with the temperature of the water. Pure water has a resistance of 18.3 megaohms (MΩ). Resistivity conversions are given in Table 3-3.

Specific Conductance

Specific conductance measures the ability of 1 cm3 of the sample solution at a given temperature to conduct an electrical current. It is the reciprocal of the resistance, in ohms. Since it is the opposite of resistance, it is given the name "mho," which is "ohm" spelled backwards. The actual conductance is so small it is measured in micromhos (μmho), which is one millionth of a mho. As an example, at 70°F (19°C) demineralized water with ½ ppm dissolved salt has a conductance of 1 μmho. Pure water has a conductance of 0.036 μmho. Conductivity conversions are given in Table 3-3. Specific conductance in actual practice is normally measured by probes suspended in the stream of water.

Total Suspended Solids

This figure is the sum of all of the suspended material found in the water sample and is commonly measured in either parts per million (ppm, w/w), or milligrams per liter (mg/L), which measures the weight of material per volume of the sample. For all practical purposes, these two forms of measurement are equal to each other (1 ppm = 1mg/L).

Turbidity in water is classified by the size of the particulates in microns (μ), which is $\frac{1}{1000}$ in. diameter, and tested by a light interference method, known as the "neph-

elometric" method. This test compares the water sample by color to a standard color scale; total suspended solids are indicated based on this comparison. The most common reporting method is the nephelometric turbidity unit (NTU). The higher the number is, the more turbid the water.

The nephelometric turbidity unit measures the color of a beam of light passed through the water sample. An often-used standard for potable water is the standard method for the examination of water and wastewater by the American Public Health Service, which uses formazin as the standard for producing a known volume of turbidity. The standard color scale to which it is compared is derived from the platinum cobalt unit (PCU). Other methods, which are used less frequently, are the comparator tube determination using formazin, called the formazin turbidity unit (FTU), and the original test, the Jackson turbidity unit (JTU), named for the man who developed a standard candle used for comparing the color of the candlelight through a sample to a color standard. The most accurate method of measuring solids is gravimeterically, in which a known quantity of water is evaporated and the resulting solids are weighed.

The most effective method of removing turbidity is by the use of filters and strainers. The equipment chosen to accomplish this task depends for the most part on the size and type of the solids to be retained. Other factors include the materials of construction of the device, the nature of the raw water, flow rate requirements, the particle removal target, initial and operating costs, and maintenance requirements.

Total Dissolved Solids (TDS)

TDS, often referred to as "dissolved inorganics and mineral salts," is generally the sum of all the dissolved minerals, including chlorides, sulfates, and carbonates. Dissolved solids contribute to scale deposit and the corrosion of piping and equipment. When dissolved in water, mineral salts form positively charged ions, mostly sodium and calcium, and negatively charged ions, mostly chlorides and sulfates.

Total Organic Carbon (TOC)

TOC is a measurement of the carbon level in water and is widely used to determine the contamination of water by organic compounds. These compounds contribute to corrosion, cause problems in manufacturing, and usually indicate the presence of endotoxins in water for pharmaceutical use.

The process of measurement is generally complicated and dependent on the expected level. For high levels, the organic compound is first converted to carbon dioxide, which is measured by infrared absorption. Gas stripping is required to remove other forms of carbon ions from dissolved mineral compounds. Forparts per billion (PPB) levels, photolytic oxidation is used and the resulting carbon dioxide is then measured.

Silt Density Index (SDI)

The SDI is a measure of the fouling potential of a feed-water source. Since colloids and other solids can be any size in the submicron range, there is no direct method to measure their concentration in feed water. The SDI is found by passing the feed water through a 0.45-μm rated Millipore filter at 30 psi (207 kPa). (A Millipore filter

is the only membrane currently approved by the ASTM for determining the SDI.) The SDI is found from the following formula:

Equation 3-1

$$SDI = \frac{1 - \left(\frac{t_1}{t_2}\right) \times 100}{T}$$

Where

t_1 = Initial time needed to collect a 500-mL sample of water through a fresh 0.45-μm filter 47 mm in diameter (s)

t_2 = Time to filter and collect a second 500-mL sample after exposing the same filter as above for 15 min to the flow of feed water (s)

T = Total test time (min, typically 15 min) (For high SDI, T may be less.)

The higher the number, the greater the potential for fouling. *Note:* For an accurate test, at the end of the elapsed time the filter should not be more than approximately 74% plugged. A Millipore filter is the only membrane currently approved by the ASTM for determining the SDI. If this figure is exceeded, the test should be repeated using a shorter overall elapsed time.

Many manufacturers of RO cartridges recommend allowable SDI figures for feed water. Typically, for hollow-fiber modules there is a maximum SDI of 3, and for spiral wound modules the allowable SDI figure is 4. For continuous deionization, an SDI of 4 or less is recommended. In practice, when water has an SDI greater than 4, a 4-μ depth prefilter is recommended. In addition to the 4-μ filter, an additional 1-μ filter is recommended downstream. The use of a 4-μm filter on the feed-water stream is always recommended as a precaution against fouling, regardless of the potential SDI.

Pure Water Technology and Component Description

Distillation

In its basic form, "distillation" is the boiling of feed water, the condensing of the steam produced from the feed water, and the collection of the condensate, which yields a product water theoretically free from nonvolatile impurities. There are three methods currently used to produce distilled water: single-stage distillation, vapor compression, and multieffect distillation.

Single-Stage Distillation Single Stage Distillation, for this type of distillation, is still the simplest. Feed water enters the still and is boiled, evaporated and condensed in a single stage. Cooling water is required to condense the steam produced. This type of still produces water with a purity of approximately 1 Mohm/cm, with higher purity possible with optional equipment that removes dissolved gaseous impurities. The still has a small footprint, is less labor intensive than the other processes, and will tolerate feed water with a high level of impurity.

Vapor-Compression Distillation Vapor compression, sometimes called "thermo-compression distillation," is a method of evaporation in which a liquid is boiled inside a bank of tubes. The vapor generated passes through a mist eliminator that removes any water droplets. The pure vapor is withdrawn by a compressor wherein the energy imparted results in a compressed steam with increased pressure and temperature. The higher-energy compressed steam is discharged into an evaporator. At this point, the steam gives up most of its energy (latent heat) to the

water inside the tubes. More vapor is generated and the process is repeated. The condensate (distilled water) is withdrawn by the distillate pump and discharged through a two-stream heat exchanger.

The excess feed water that did not evaporate is also pumped through an exchanger. Both the distillate and the blowdown are cooled, and the feed water is preheated prior to its entering the evaporator. These exchangers minimize the energy consumption of the system and eliminate the need for additional cooling water. The system operates continuously once it is started. Additional makeup heat, usually supplied by steam, is required for continuous operation. Vapor compression is generally considered economical when producing large quantities of water and does not require a high-quality feed water for proper operation. The vapor compression still is moderate in both first and operating costs.

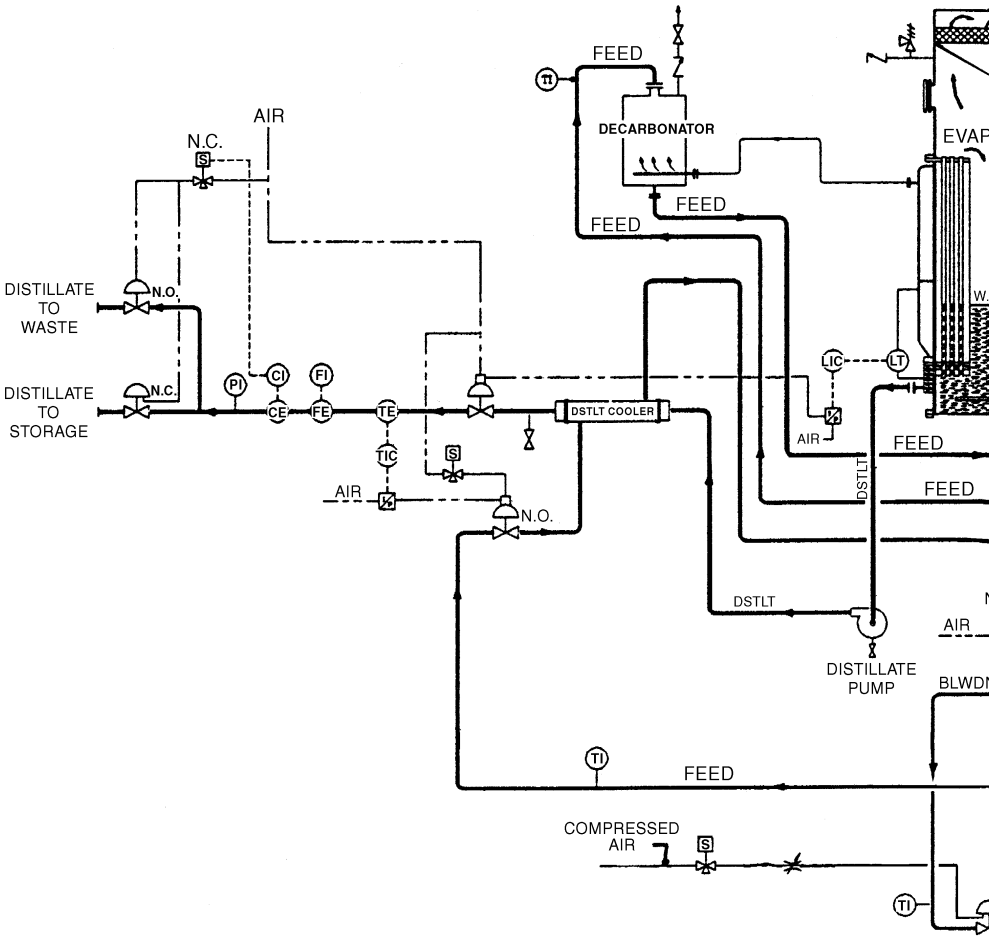
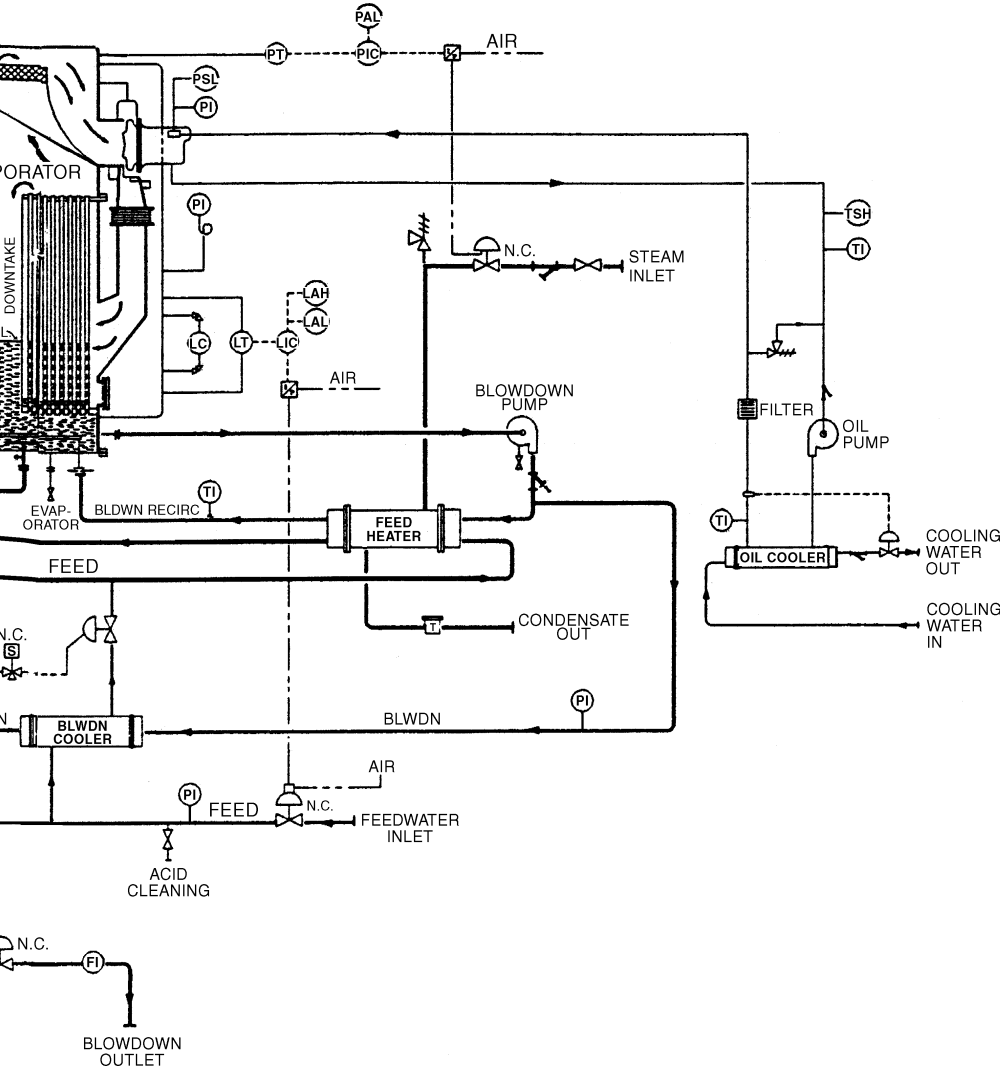


Figure 3-2 Vapor-Compression Distillation Unit

Refer to Figure 3-2 for a typical flow diagram of a vapor-compression distillation unit.

Multi-Effect Distillation Multieffect distillation units use the principle of staged evaporation and condensation to generate distilled water. Each stage is called an "effect." Distilled water is produced in each effect by condensation of the steam generated by the evaporation of high-purity feed water in the previous stage. The initial driving force for the evaporation is "power steam" applied to the shell side of the first effect vessel. The multieffect still has the highest initial cost and lowest operating cost and requires the highest-quality feed water of the stills discussed.

The feed water enters the vessel and its pressure is boosted by the feed pump. The feed water flows through a coil in the condenser, which allows it to pick up heat from the condensing steam. This preheated feed water flows through the feed-control



valve and into the tube side of the first effect. The first-effect level controller senses the feed-water level and signals the feed-control valve to maintain the desired level. Power steam is introduced into the unit and flows through the steam-control valve and into the shell side of the first effect.

Temperature sensors sense the temperature on the tube side of the first effect and signal the steam-control valve to maintain the required temperature. This steam condenses on the outside of the tubes of the first effect, giving up its latent heat of vaporization to the feed water inside of the tubes and causing it to boil and generate vapor.

The pure steam generated in the first effect is introduced into the shell side of the second effect. The pure steam condenses, producing distilled water while giving up its latent heat to the high-purity feed water inside the second-effect tubes, which causes the feed water to boil and generate vapor. Each effect operates at a lower pressure than the previous effect to provide the temperature difference that allows the transfer of heat. The pure steam generated in the tube side of the first effect by the condensing power steam passes through the mist eliminator to remove any entrained water droplets. Feed water from the first effect passes through an orifice and into the tube side of the second effect. The first-effect pure steam enters the shell side of the second effect and is condensed on the outside of the tubes.

The condensate (distilled water) passes through an orifice and enters the shell side of the third effect. Feed water in the second effect passes through an orifice and into the tube side of the third effect.

After passing through the mist eliminator, the last-effect pure steam enters the condenser and condenses on the outside of the condenser coils. This distilled water from the last effect and the distilled water from the previous effects are cooled by the cooling water of the condenser. The distilled water exits the condenser and enters the distillate pump. The distillate is pumped through the distillate-control valve and through the storage/dump valve. The condenser-level controller senses the distillate level and signals the control valve to maintain the desired level.

Noncondensable gases in the condenser are vented to the atmosphere. The condenser temperature is maintained at a predetermined level by the cooling water flow. The unit is protected by pressure-relief valves along with high and low-level alarms.

Refer to Figure 3-3 for a typical flow diagram of a multi-effect distillation unit.

Filtration

Deep-Bed Sand Filtration Deep-bed-sand filters are designed to remove coarse suspended particulates larger than 10 μ in size. They are pressure type filters that use either multi-graded sand or multimedia as the filter medium. Particulate removal in the order of 98% should be expected.

Sand-only filters for laboratory water systems should generally operate at a face velocity of about 4 gpm/ft^2 of cross-sectional bed area. Multimedia filters operate at about 6 gpm/ft^2 of cross-sectional bed area. The above values are general in nature; it is important to operate these units at the velocities recommended by the individual manufacturer.

The multimedia filter achieves a more uniform distribution of filter media throughout the bed and is considered a more effective filter than the sand-only filter. A typical multimedia filter for production of laboratory use pure water consists of a top layer of anthracite having a 1.1-mm grain size and 1.5 specific gravity, a middle layer of sand having a 0.5-mm diameter grain size and a specific gravity of 26, and a bottom layer of garnet having a 0.2-mm grain size and 4.2 specific gravity. Normal operational flow rate is from 6 to 15 gpm/ft^2 of bed area.

Backwashing is required to clean the filter, with the effluent discharged to the sanitary drainage system. A backwash flow rate of 10 to 15 gpm/ft^2 is generally required for effective cleaning.

Activated-Carbon Filtration Activated carbon is used to remove dissolved, nonionic organics, such as residual chlorine disinfectant, trihalomethanes, and chloramines, from municipal water supplies and also a major portion of naturally occurring dissolved organic material. The nonionic organics tend to coat ion-exchange resins and all types of membranes.

There is a reluctance on the part of system designers to use the activated-carbon filter in the generation of PW because the unit itself can develop significant levels of bacteria. This can be controlled by periodic sanitizing with pure steam or hot water with a temperature greater than 80°C. The need for sanitizing can be determined only by the testing of the water. Because of this sterilization, the interior of the filter housing should be lined or coated. When using potable water as feed water, stainless-steel housings should be avoided because of the possibility of chloride stress corrosion and chloride pitting resulting from the chlorine in the feed water.

MEMBRANE FILTRATION AND SEPARATION

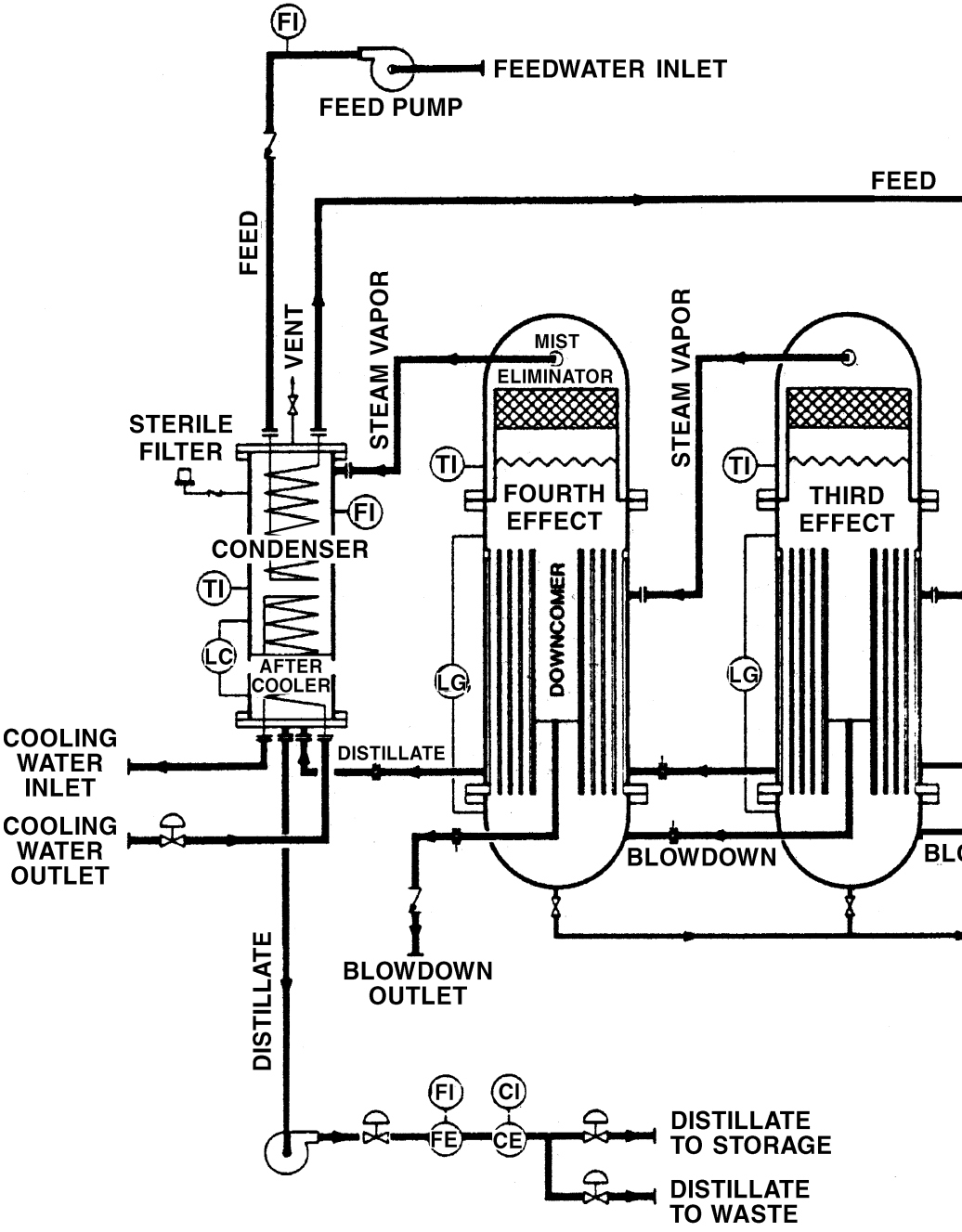
"Membrane filtration and separation" is a general term for a water-purification process that removes contaminants from feed water by means of a thin, porous barrier called a "membrane." When used as a filter, a membrane is capable of removing impurities of a much smaller size than other types of filter. Filters of this nature are often called "ultrafilters" and "nanofilters."

A semipermeable membrane limits the passage of selected atoms and/or molecules in a specific manner. When used to produce pure water, membrane filtration and separation is characterized by the feed-water flowing parallel to the membrane (often called "tangential flow"). Not all of the feed water is recovered. Many of the membranes used are also available as depth filters and in single thickness are used as disk filters.

There are two general categories of membrane filtration: reverse osmosis using a semipermeable membrane and filtration using ultrafiltration and nanofiltration membranes.

Reverse osmosis (RO) is a broad-based water-purifying process involving osmosis and ionic repulsion.

"Osmosis" is the spontaneous passage of nonvolatile solute molecules (impurities such as sodium chloride) in a solvent (such as water) through a semipermeable membrane. This membrane is called "semipermeable" because it allows the solvent to diffuse, or pass through, but is impervious to the solute.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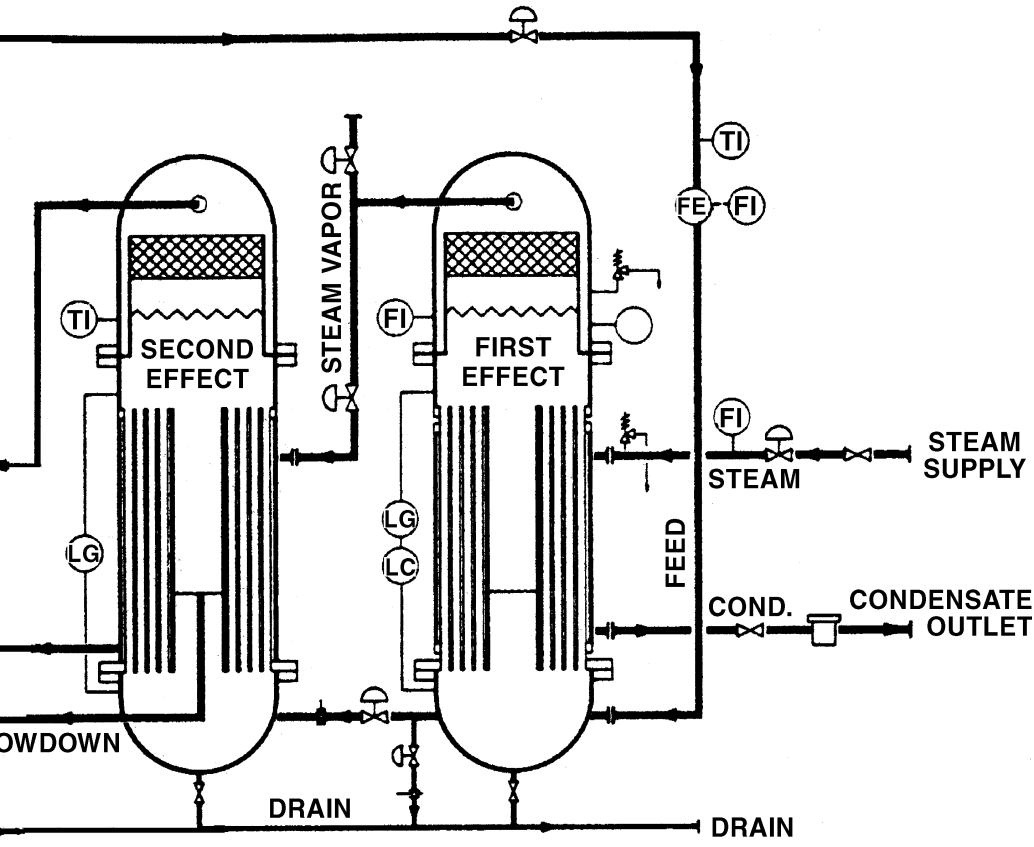


Figure 3-3 Multieffect Distillation Unit

In the natural osmosis process, when two solutions of different concentrations are separated by a semipermeable membrane, water molecules from the less concentrated solution will spontaneously pass through the membrane to dilute the more concentrated solution. This occurs until a rough equilibrium is achieved. The driving force is a difference of pressure called the "osmotic pressure" or "concentration gradient" that exists across the membrane and is based on the degree of concentration of contaminants. The pressure in the stronger solution is lower than that in the weaker solution. This pressure is what drives the flow of solvent. The flow, or flux, will continue until the osmotic pressure is equalized, which then results in a higher pressure on the concentrated solution side that is equal to the osmotic pressure.

Reverse osmosis is the flow of solvent in the direction opposite to that of natural osmosis. If enough pressure is applied to the more concentrated solution, which for the purpose of this discussion is water, pure water is diffused through the membrane leaving behind the bulk of the contaminants. This concentration of contaminants is continuously flushed to drain and thereby removed from the system. The purified water is called "permeate" and the contaminant containing water is called "reject" or the "reject stream." In some cases, the reject stream is referred to as "salt." The performance characteristics of the selected membrane determines how large a system is required. The flow rate is measured in membrane flux. "Membrane flux" is a measurement of the flow rate of permeate that will pass through a given area of the membrane at a specific temperature and pressure. The ratio of the purified-water flow to the feed-water flow is called the "recovery." Most applications require a minimum 40% recovery rate to be considered practical. Rejection characteristics are expressed as a percent of the specific impurities retained and depend on ionic charge and size.

Membrane Module Configurations — There are four types of membrane-module configuration used for RO applications: hollow fiber, spiral wound (SWRO), tubular (TRO), and plate and frame. Hollow fiber and spiral wound are the most commonly used configurations. In each design, maximum turbulence is necessary to avoid concentration polarization.

- **Hollow-fiber reverse osmosis.** The hollow-fiber configuration consists of a perforated tube manufactured from ceramic, carbon, or porous plastic with inside diameters ranging from ⅛ to 1 in. (8 to 25 mm). It requires rigid support when mounted inside the pressure vessel. Feed water could be introduced into either the center or the outside depending on the manufacturer of the RO module. Fouling resistance is low.
- **Spiral-wound reverse osmosis (SWRO).** This configuration typically achieves a large surface area per unit volume. In this design, a flat membrane is formed around a fabric spacer closed on three sides with the open side terminating in a perforated product-water tube. The unit is then placed in a pressure vessel. Feed water permeates through the membrane and flows radially inside the enclosure toward the product tube.
- **Tubular reverse osmosis (TRO).** This configuration consists of a perforated tube manufactured from ceramic, carbon, or porous plastic with larger inside diameters than those of the hollow-fiber configuration. The membrane is

installed on the inside of the tube. A number of tubes are installed inside a pressure vessel. Feed water enters the tube and permeates through the membrane to be collected on the outside. The feed-water channels are much more open than those of the SWRO and less subject to fouling.

- **Plate and frame.** This configuration consists of a membrane that is fixed to a grooved plastic or metal plate with several plates stacked together in a frame that includes feed water and drain ports. As the feed water flows across the membrane surfaces, the purified water penetrates the membrane and settles into the frame for collection. The retentate continues to flow and could be recirculated or directed to drain. This configuration is used mostly for filtration and rarely for RO systems. Packing density is low and resistance to fouling is very high. It is used for small to medium volumes, generally less than 20 gpm.

Membrane Selection—System performance is determined based on the following factors, which influence the capacity of the individual membranes selected:

1. Operating pH.
2. Chlorine tolerance.
3. Temperature of the feed water.
4. Feed-water quality, usually measured as SDI.
5. Types of impurities and prior feed-water treatment.
6. Membrane flux.
7. Number of operating hours.
8. Resistance to biodegradation and ability to be sanitized.
9. Rejection characteristics. Typical RO systems remove the following contaminants to the following levels:

Inorganic ions	93–99%
Dissolved organics (>300 MW)	>99%
Particulates	>99%
Microorganisms	>99%

The selection of a system configuration shall be based on the following considerations:

1. Maximum recovery.
2. Fouling properties and resistance.
3. Production rate per unit volume.

There are only a few polymers that have the necessary characteristics to function as a semipermeable membrane:

1. Thin film composite of various polymer materials.
2. Polyamide.
3. Cellulose acetate.
4. Cellulose tricetate.
5. Polysulfone.

Ultrafiltration and Nanofiltration Ultrafiltration and nanofiltration membranes are membranes that are categorized by their pore size. Ultrafiltration-membrane pore sizes range from 0.001 to 0.02 μm. Nanofiltration membranes have pore sizes that allow the passage of solids to 10,000-daltons. The 10,000-dalton cutoff

is recommended for the complete removal of pyrogens. Typical recovery rates for ultrafilters range between 95 and 98%, with the remainder flushed to drain.

The membranes are manufactured by bonding the membrane onto a porous, supporting substrate and then configuring it into a filter element. These filters are usually used as a pretreatment for the removal of colloids, bacteria, pyrogens, particulates, and high-molecular-weight organics. Spiral wound and hollow fiber are the two most often-used configurations.

Ion Exchange and Removal

Ion exchange is the basic process where specific ions in a feed-water stream are transferred onto an exchange medium called a resin and exchanged for different ions of equal charge. When the ion-exchange process is used to treat water only for the removal of hardness, it is generally known as "water softening." When the ion-exchange process is used to treat water for the removal of ions to produce pure water, it is often referred to as "deionization" or "demineralization."

The deionization/demine ralization process uses different types of resin to exchange first anions and then cations that will result in the removal of all ions from the feed water when it is carried to completion. When all the ionic components desolved in water are removed by ion exchange, the water is said to be "deionized" or "demineralized." The ion-exchange process is also used to remove dissolved inorganics. Water softening only exchanges some types of ions for others less detrimental for the intended end use of the water. Ion exchange will not remove significant amounts organics, bacteria, pyrogens, or turbidity.

Regenerable Ion Exchange Regenerable ion exchange is a batch process where ions in raw water are transferred onto a resin medium in exchange for other ions bonded to that medium as the raw water percolates through them. This is accomplished by having the ions in the raw water adsorbed onto a bed of exchange resins and replaced with an equivalent amount of another ion of the same charge. This action continues until the medium has reached its exchange capacity and is no longer capable of exchanging ions. Water softening and deionization are the two most common regenerable ion-exchange processes.

There are two general types of deionizer: the working type and the polishing type. The working type is used for the initial removal of the bulk of ions from the feed water or as an ion-exchange process (such as hardness removal) only if the purification is a single process. The polishing type is used to purify feed water after an initial run through a working ion-exchange system.

Resins Resin-exchange media include natural inorganic aluminum silicates (sometimes called "zeolites" or "green sands"), bentonite clay, and synthetic gelatinous and synthetic organic resins. Most processes use the synthetic resins. Resins are graded by purity and consistency in the size of the resin.

Resin is manufactured in the form of a large number of spherical beads, typically about 0.4 mm in diameter. These beads have weakly bonded ions present on their surfaces, which are used for the exchange process. Because the process must exchange ions of the same charge, ion-exchange resins are either anion or cation-

exchange resins. Manufacturers are constantly making new resins for different ion-removal purposes. This is a constantly changing technology.

Traditional deionization exchanges cations with hydrogen (H^+) ions (an acid) and anions with hydroxyl (OH^-) ions (a base). Although not 100% effective, these two exchange processes together combine the ions remaining in the feed water to create water as the end product. When all the ionized impurities are removed, the water is said to be "deionized" or "demineralized."

Many ion-exchange resins are available. Each is formulated to obtain optimum performance for different impurities. The term for a resin's affinity for different ions in solution is its "selectivity coefficients." The number of charges (valence) available on a particular ionic medium is a major factor in the selection of specific resins to remove the desired impurities. The resins are contained in a vessel, often referred to as a "column." The actual resin bed could be supported by a mat of graded gravel, screen-wrapped ,or perforated plates, which also act to evenly distribute feed water over the entire resin bed. The size of the resin beads in the vessel also creates an effective depth filter. This filtering action leads to fouling and unpredictable operating runs because of an accumulation of particulates.

Anion resins are classified as either a strong or a weak base. An often-used anion resin is divinyl benzene, a gelatinous bead. Anion resin type 1 premium has a very close tolerance of bead size. Anion resin type 1 regular is generally used for maximum silica reduction. Resin type 2 is used most often unless type 1 is specifically requested. There is a difference in cost and a difference in capacity between the two resins. In general, the higher cost of the type 1 resin is considered acceptable in order to obtain a more efficient and longer-lasting resin. Weak-base exchangers are not effective in the removal of carbon dioxide or silica. They remove strong acids more by adsorption than by ion exchange. The end result is the same, and the weak-base regeneration's efficiency for acid-salt removal is far superior to that of the strong base material. Thus, weak-base units are superior when the feed water is high in sulfates and chlorides.

The two most often-used cation-exchange resins are strong and weak acid. Strong cation resins remove all cations regardless of the anion with which they are associated. These resins have a moderate exchange capacity and require a strong acid regenerant such as hydrochloric or sulfuric acid.

The deionization process can be arranged as either a two-step (dual-bed) or a single (mixed-bed) process. In the dual-bed process, one vessel contains the anion-exchange resins and a second vessel contains the cation-exchange resins. In the mixed-bed unit, a single vessel contains a mixture of both resins. The dual-bed arrangement produces water that is less pure than that produced by the mixed-bed arrangement, but it has greater removal capacity. A typical mixed bed contains 40% cation resins and 60% anion resins. Dual beds are easier to regenerate. It is not uncommon to have a dual-bed exchanger, often referred to as a "working exchanger," installed before a mixed bed to remove the bulk of the impurities, then have the mixed bed, often called a "polishing exchanger," further purify the water to the desired high purity. A typical single-bed ion-exchange unit is illustrated in Figure 3-4. A typical dual-bed ion-exchange unit is illustrated in Figure 3-5. A typi-

cal mixed-bed ion-exchange unit is illustrated in Figure 3-6. The piping and valve arrangements of different manufacturers may vary.

Regeneration Cycle The ion-exchange process is reversible. Over time, as water passes through the ion-exchange resin beds, the number of ions on the resin beads available for exchange declines and gradually becomes exhausted. The process starts at the water entry to the vessel and progresses down the bed. When the resin has reached the limit of exchange, the bed is said to have reached its maximum "exchange capacity." It is then necessary to take the column out of service to be regenerated.

"Regeneration," which is the reverse of deionization, is the displacement of the ions removed from the feed water. Regeneration generally consists of three steps: (1) backwashing, (2) application of regenerating solution, and (3) rinsing. Regeneration can be performed either co-currently (in the same direction as the flow of feed water) or counter currently (in the opposite direction of the flow of feed water). All the water used for regeneration must be routed to a drain of adequate size. In addition, the acid and caustic must be neutralized prior to discharge into a public sewer system. It is common practice to combine the acid and caustic waste streams to neutralize the effluent to the greatest extent possible. Additional acid or caustic may have to be added to the final effluent to produce a pH acceptable to the local authorities.

Backwashing is a counter-current operation that accomplishes two purposes. The first is to remove any particulates that have accumulated in the resin bed and on the beads. The second is to regrade the resin beads so that new beads are on the top of the bed, which is where the heaviest duty from the beads is required. This is done by having the resin bed, which is normally packed during use, expanded by the reverse flow of water. The manufacturer establishes the flow rate of backwash that should be maintained. The flow rate of water should be enough to scrub the beads, increasing the cleaning action. More than the recommended flow will only waste water and provide no additional benefits. Too high a flow rate will blow resin out of the tank and into the drain.

The two chemicals that can be used to regenerate cation resin beds are a 93% solution of sulfuric or a 30 to 32% solution of hydrochloric acid, also called "mureatic acid." As these chemicals flow through the columns, they replace the retained cations with hydrogen ions from the acid. Hydrochloric acid is used most often because it has the greatest efficiency, and only one quarter of the amount of hydrochloric acid is used compared to the amount of sulfuric acid. Sulfuric acid is much lower in cost and is used when there is a large quantity of resin to be regenerated, which makes its lower cost practical. The most often-used chemical for regenerating anion resins is a 40% mixture of sodium hydroxide, which replaces the retained anion ions with hydroxyl ions. For mixed-bed units, the resins must be separated prior to regeneration.

The quality of the chemicals used for regeneration has an important effect on the maintenance of exchange capacity. Although chemically pure ingredients are not required, some contaminants found in these chemicals collect on the resins and eventually will cause difficulty in operation.

Technical-grade acids, free of oils and other organic materials, are acceptable for the regeneration of cation resins. They should be 66° Baume, free of suspended matter, and light in color. They should mix freely with water and not form any precipitate. Acid containing inhibitors should not be used. Sulfuric acid is usually the most economical choice for large-scale use. Hydrochloric acid should be technical grade and a minimum of 30% HCl by weight (18° Baume) and shall not contain excessive amounts of iron and organic materials. HCl obtained by the salt-aid or hydrogen-chlorine process has been found satisfactory. HCl obtained by the hydrolysis of chlorinated organic chemicals should be avoided, particularly if it is to be used to treat potable water.

Anion-exchange resins are regenerated with 76% sodium hydroxide, which shall be low in iron, chlorides, and silica to avoid fouling the strong-base anion exchangers. Weak-base anion exchangers are most economically regenerated with technical-grade flake sodium hydroxide. Strong-base exchangers are best regenerated using nylon or rayon-grade sodium hydroxide, also 76%. If it is purchased in a 40% solution, use the same technical grade indicated in the previous paragraphs. All caustic shall have a maximum of 2 ppm chlorates.

The flush cycle is the shortest one in the regeneration process. It is a co-current process whose purpose is to flush any remaining residue of the regeneration liquids to drain and to repack the bed in preparation for the new run.

The entire regeneration cycle typically takes about 1 hour. If the process requires continuous operation, a duplex set of equipment should be installed so that one is in use while the other is being regenerated.

To estimate the frequency of regeneration, first get, from the manufacturer, the exchange capacity, in grains, of the selected resin bed. Next, determine, from the analysis of the raw water, the average level of TDS, and convert this figure into grains per gallon. Dividing the flow rate, in gpm, into the grain capacity of the resin bed will give the time it takes to saturate the resin bed before regeneration is required.

Service Deionization Service deionization is not another form of deionization but, rather, a different type of equipment arrangement. With the regenerable type, the deionization (DI) equipment is permanent and the regeneration is done on site by operating or maintenance personnel. They must handle and store the chemicals used for regeneration. With the service type, the supplier replaces cartridges of exhausted resins with regenerated ones.

The service DI system uses individual cartridges or tanks for the anion, cation, and mixed beds. When the individual cartridges are exhausted, they are replaced by the supplier with recharged units on site and the exhausted cartridges are removed to be regenerated at the supplier's premises. This arrangement reduces the initial cost of the equipment considerably, eliminates the need to store chemicals, and frees the operating or maintenance personnel from the time required for regenerating the units. In addition, it saves water that would be used for backwash. The operating costs to a facility for service DI are higher than they are for permanent bed type equipment.

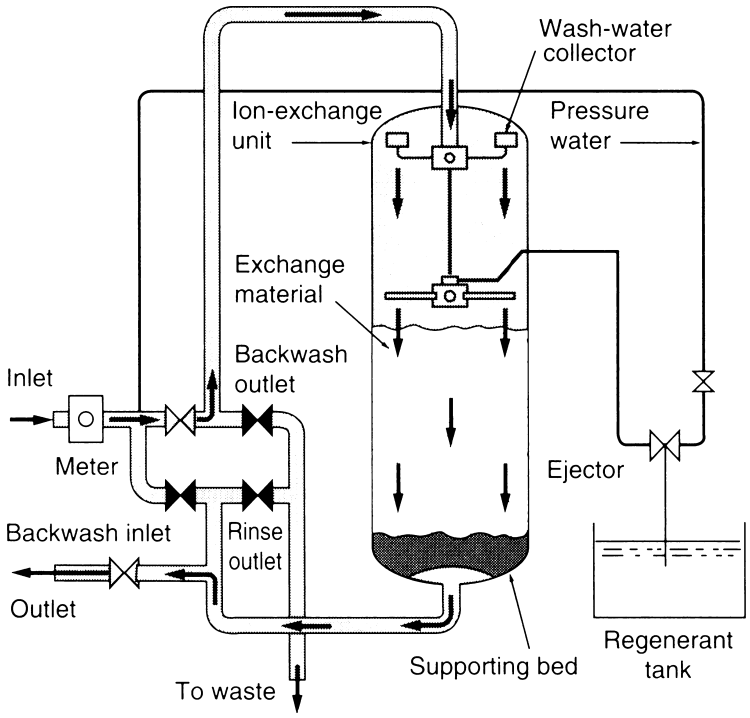


Figure 3-4 Single-Bed Ion Exchanger

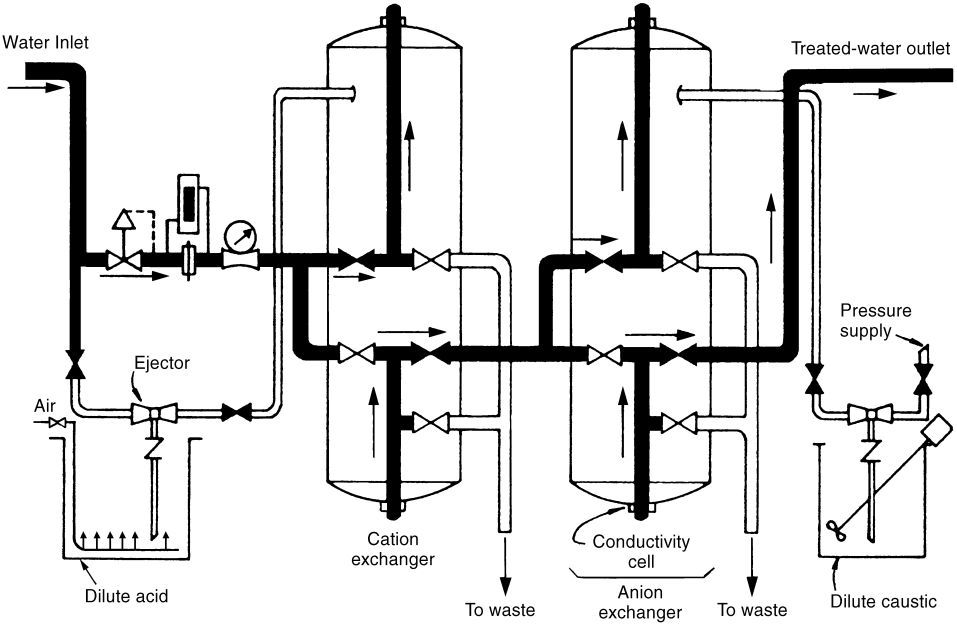


Figure 3-5 Dual-Bed Ion Exchanger

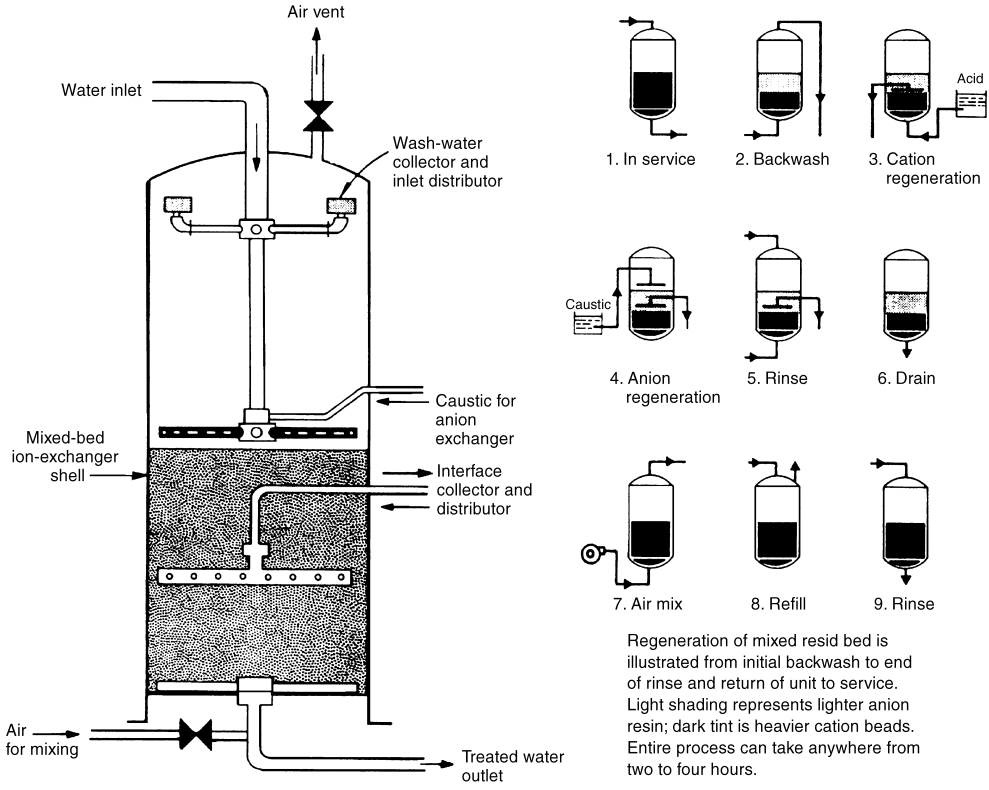


Figure 3-6 Mixed-Bed Ion Exchanger

Continuous Deionization Continuous deionization (CDI), also known as "electrodeionization," is a continuous water-purification process that uses direct current (DC), an alternating arrangement of cation and anion-permeable ion-exchange membranes forming parallel-flow compartments (concentrating compartments) on either side of an additional flow compartment containing a thin layer of mixed-bed ion-exchange resin (diluting compartment). The components, called a "cell pair," are installed in a plate-and-frame device where the flow compartments form various flow paths for the product and waste water. This arrangement is schematically illustrated in Figure 3-7.

The feed water flows through the diluting compartment. When a DC field is applied across the pair of membranes, ions move from the diluting stream, through the ion beads and the membrane into the concentrate stream, thereby producing separation. With an alternating arrangement of cell pairs, the cations and anions are trapped in the concentrate stream, where they are routed to drain. The resin bed serves as a highly conductive medium through which the ions flow because of the electric field. The various flow streams are hydraulically independent, allowing a high volume of high-purity water (product) and a low volume of concentrate (waste).

The resin-filled diluting compartment (cell) creates a low-level resistance path for ions. At the outlet of the diluting cell under the proper combination of flow, tem-

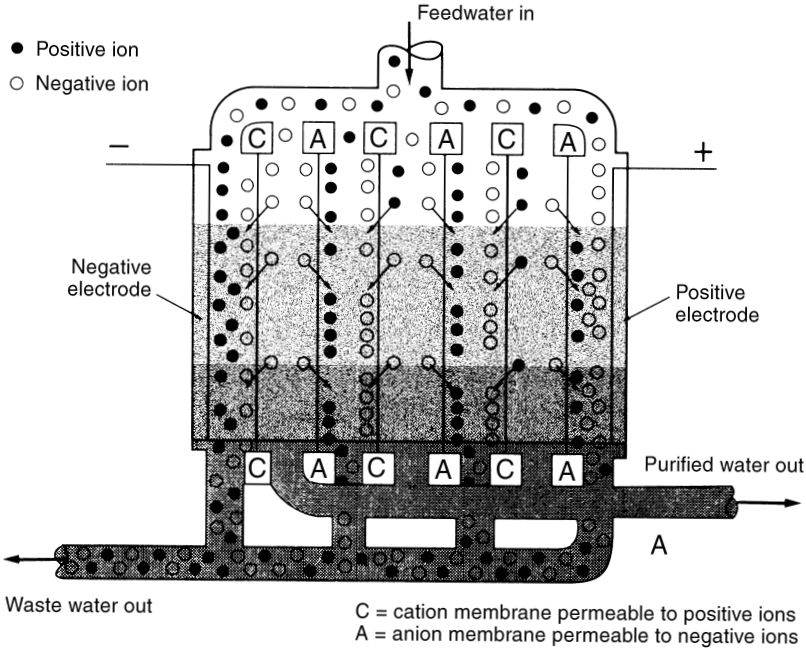


Figure 3-7 Continuous Deionization Unit

perature, water conductivity, and voltage, the ion-exchange resins will regenerate automatically without the use of added chemicals. This process is continuous and results in a steady supply of high-purity water from the diluting compartment.

CDI is very sensitive to feed-water impurities. Experience has shown that very few natural or potable feedwater supplies can meet the required feed-water specifications without softening. Typical system feed-water requirements are the same as those for potable water. Individual manufacturers may have other specific requirements. Because of these requirements, most processes that purify water for pharmaceutical purposes use CDI for polishing after RO. Another disadvantage of this process is that the membrane used is incompatible with standard chemical sanitizing agents and sensitive to frequent sanitizing.

Water Softening Water softening is a process that reduces or removes dissolved impurities causing hardness in water. This is commonly done by either of two methods: passing the raw water through an ion-exchange process: passing the raw water through an ion-exchange process or adding lime-soda ash to the raw water (for very large volumes).

Ion Exchange—Water softening using the ion-exchange process is a cation exchange that removes insoluble and scale-forming iron, calcium, and magnesium carbonate, and other multivalent cations, which are the primary causes of hardness, and replaces them with sodium ions, which do not contribute to hardness. Removal of these impurities will prevent the buildup of insoluble scale precipates on piping and the reverse-osmosis membrane. This is accomplished by passing

the water through a bed of granular, sodium, cation-exchange resin. This process is commonly called "sodium-cycle ion exchange."

The resin bed typically occupies about two-thirds of the tank. The other one-third is needed for expansion of the resin bed during backwash. A generally accepted range of between 0.4 and 3 gpm/ft3 of resin is used to determine the volume of resin and the cycle time of the unit.

Microbial growth inside the unit is a concern in softening systems used for pharmaceutical and some laboratory purposes. The water softener is regenerated with a brine solution, which does not destroy bacteria. The liquid brine solution storage and regeneration equipment also allow microbial growth in storage tanks that are exposed to the atmosphere. An alternative is to use a dry storage system, which generates salt solution from water that is mixed with salt pellets only when necessary for regeneration. This type of system controls microbial growth better than a wet system does, but constant maintenance is required to monitor the brine tank. The quality of the salt in all systems should be periodically determined to ensure that there are "no added substances" present.

The water softener regeneration cycle of the water softening process is similar to that previously discussed. The difference is that salt is used to regenerate the resin bed. Industrial water softeners use rock salt for economy. Because of its high mineral content, rock salt requires a special tank called a "desolver" to desolve the rock salt in water prior to use. The water softener is similar to the schematic single-bed ion exchanger illustrated in Figure 3-4.

Ion-Exchange System Design Considerations One of the major decisions that must be made when selecting an ion-exchange system is allowable leakage. Leakage is the presence of undesired ions in the final treated water. The amount of leakage is a function of the level of completeness of regeneration of the resin. For water softening, generally accepted leakage amounts range between 0.1 and 1 ppm. Since total regeneration of the resin bed is inefficient and very costly, most water softeners operate at one-half to two-thirds of the ultimate capacity of the softener. There is sodium leakage from cation exchangers and silica leakage from anion exchangers. Normally, mixed-bed units have negligible leakage.

In general, passing the water through one time does not give adequate purification of the water stream for high-purity applications, therefore, a polisher is necessary. In general, a mixed-bed ion-exchange system has a 74% lower initial cost than a two-bed system when used as a polisher. A single-pass RO system is about equal to a two-bed ion-exchange system.

Usually, if the water demand for a facility is less than about 40 gpm, the greatest benefit will be derived from simpler, less costly equipment at the expense of higher operating costs. For this quantity of water, it is usual to have a mixed-bed unit without a degasifier, which is not required. For facilities with a requirement of 200 gpm or more, a majority of the systems installed have multiple-bed units and a degasifier. Manufacturers must be contacted for specific system and resin selection and required equipment.

Where applicable, the use of weakly acidic and weakly basic resins minimizes chemical costs and reduces losses to waste because of high regenerative capacity.

There are some problems, such as microbial growth, associated with water softeners. Sanitization is usually accomplished during regeneration. Iron buildup in the unit could pass through to downstream purification equipment unless operating personnel constantly monitor the water quality.

Microbial Control

Chemicals The most often-used disinfection method is the addition of oxidizing or nonoxidizing chemicals. The chemicals could be either biocides, which are substances that kill microbes, or biostats, which prevent the further growth of microbes. Commonly used chemicals are chlorine and chlorine compounds, hydrogen peroxide, and acid compounds.

To be effective, a chemical must have a minimum "contact time" in the water. In addition, a residual amount of the chemical must be present to maintain effectiveness.

Chemicals add impurities to the water and generally are not suitable for a pure-water environment. They are used mostly to disinfect potable and process water and equipment by injection directly into the fluid stream by means of a metering pump. When they are present in the feed water used for purification, they must be removed. Chlorine may produce trihalomethanes.

Ultraviolet Radiation Ultraviolet radiation is an in-line process. UV light is generated using mercury vapor lamps. Two different wavelengths that produce the intensity and energy output necessary for the intended germicidal treatment requirements are available. The 254-nm wavelength operates in the germicidal region, sterilizing by destroying bacteria, mold, viruses, and other microorganisms. This wavelength is preferred for pure-water systems; it significantly reduces the multiplication of organisms. The 185-nm wavelength operates in the ozone-forming region, where it has the ability to break down organic molecules to carbon dioxide by the photooxidation process. It slowly breaks the bonds in organic molecules by direct radiation and oxidizes organisms by the formation of hydroxyl radicals.

Flow rates of approximately 2 fps are a general industry standard for the effective sanitizing of purified water. The flow rate through the UV device should be reduced compared to that of the circulation loop to extend contact time. The recommended location of the UV device is prior to the deionization equipment.

Problems with UV radiation include the generation of ions that lower the resistivity of water and the possible leaching of silica from the quartz sleeve of the UV device. Glass, plastic, rubber, and similar materials exposed to UV radiation over time crack, etch, discolor, and flake. Tests show that only 50% of the energy used by the bulb is actually transmitted to the water, and that over time the output of a bulb dissipates by 25%. Federal standard 209E and aseptic guidelines issued by the FDA provide some guidance for the use and application of UV irradiation.

Filtering A filter removes organisms from the fluid stream. Generally accepted practice is to use a 0.2-μm absolute filter for the removal of bacteria, although some authorities question the effectiveness of this practice. Recommended cur-

rent practice is to use a membrane filter with an absolute rating (cutoff) of 10,000 daltons. Cartridge filtration is the most common method of filtration. Additional discussions can be found under the filtration section within this chapter.

Heat Heating to 175°F (80°C) effectively sanitizes water under pressure. This can be accomplished by the use of a steam, electric, or other type of heat exchanger. It is common practice to circulate purified water at this temperature and use heat exchangers to lower the water temperature at each point of use as necessary.

Ozone Ozone (O_3) is an oxidizing gas generated from gaseous oxygen or catalytically from water. The most often-used method of producing ozone is by a corona-discharge generator, which converts the oxygen in air to ozone. The air is passed between two electrodes, where an electrostatic discharge across the gap converts oxygen to ozone.

The ozone system consists of a feed-gas treatment unit, an ozone generator, a water-ozone contact mechanism, and a destruction unit to eliminate any residual ozone.

1. **Feed-gas treatment.** The gas reaching the generator must have all the particles larger than 0.3 μm and 95% of those larger than 0.1 μm removed. In addition, aerosols, moisture, and hydrocarbons shall be removed as required by the manufacturer. This purification is usually done as part of a pre-fabricated treatment package.
2. **Ozone generator.** The three basic types of generator are the Lowther plate, Otto plate, and tube units. They differ only in the manner in which they are cooled. Ozone generators use large amounts of electrical power, generally between 15 and 26 kWh/kg of O_3.
3. **Water-ozone contact mechanism.** Ozone and water are mixed in direct contact with one another by the use of static or mechanical mixers, injectors, or columns that optimize the dissolution of the gas.
4. **Ozone destruction unit.** Depending on the generator, ozone concentrations can vary from 100 to 3000 ppm. Because high concentrations are harmful to humans and metals, ozone should not be allowed to escape to atmosphere without being treated to reach a level below 0.1 ppm. Destruction can be accomplished by catalytic, thermal, and activated carbon. Thermal units operate at a temperature of 300°C and generally require a 3 to 5-min contact time to be effective.

The mechanism for ozone oxidation is the generation of hydroxyl radicals. The gas is injected directly into the water stream.

Problems with ozone treatment include the inability to oxidize all organic compounds, slow action, and, in some cases, the formation of stable and refectory compounds.

Effects of Various Treatments

The general impact of various treatments on the quality of water is summarized in Table 3-6.

Table 3-6 How Treatments Affect Water Quality

Piece of Equipment	Positive Contribution	Negative Contribution
Activated carbon (AC) bed	Removes certain organic and chlorine compounds	Sheds bacterial particles and AC granule particles
Scale inhibitor injection	Controls scaling	Adds TOC and may add bacterial particles
Sulfite compound injection	Removes oxidizing compounds	Adds and may add bacteria
Reverse osmosis unit	Removes most dissolved and suspended contaminants	Sheds TOC compounds an bacteria
Mixed-bed ion exchange	Removes most dissolved contaminants	Adds bacterial and resin particles
Germicidal UV unit	Kills or inactivates most microorganisms	Decomposing micro-organisms add TOC and may increase bacteria downstream
TOC destruct UV unit	Destroys many TOC compounds	TOC compounds convert to ions that reduce the resistivity
Polishing mixed bed	Removes most dissolved contaminants	Adds bacterial and resin particles
Final filter	Removes most particles	Bacteria grow on filter, liberating TOC
Piping	Conducts water	Sheds bacterial and piping particles
Valving	Controls flow rates	Sheds bacterial and valving particles

4 Compressed Gas Systems

INTRODUCTION

This chapter describes design criteria, production, storage, and central-piping distribution methods for various compressed-gas systems. Some of the gases discussed may be stored as cryogenic liquids and converted to gases at the storage location. The storage and vaporization of these gases are discussed in Chapter 6. Compressed air used to supply breathing apparatus is discussed in Chapter 8.

FUNDAMENTALS

General

Air is a fluid as compared to a solid. The two kinds of fluid are liquid and gas. In a gas, the molecular structure does not have a lattice arrangement and the cohesive forces that bind the molecules together are not as strong as those of a solid. This means that the molecules are quite mobile, allowing a gas to take the shape of its container. This mobility also allows a gas to expand through space and mix with the other gases that are present.

The volume of the atomic structure a gas in relation to the total volume of a gas molecule is quite small, so gases are mostly empty space. This is why they can be compressed.

Pressure is produced when the molecules of a gas in an enclosed space rapidly strike the enclosing surfaces. If the gas is confined into a smaller and smaller volume, the molecules strike the container walls more frequently, producing greater pressure.

For most purposes, air is compressed by the adiabatic process, wherein the heat of compression helps raise the pressure. Because of this, more horsepower is required to obtain the same outlet pressure than is required under ideal isothermal conditions. Therefore, manufacturers use different methods to reduce power consumption. Intercoolers to reduce the temperature during the compression process is the most common method used.

Definitions

Compressed Gas A "compressed gas" is any gas stored or distributed at a pressure greater than atmospheric pressure.

Isobaric Process This is a basic compressed-gas process that takes place under constant pressure.

Isochoric Process This is a basic compressed-gas process that takes place under constant volume.

Isothermal Process This is a basic compressed-gas process that takes place under constant temperature.

Polytropic Process This is a generalized expression for the three previously listed processes when variations in pressure, temperature, or volume are allowed to occur during the compression cycle.

Adiabatic Process This process of gas compression allows no heat to be transferred to or from the gas during compression.

UNITS OF MEASUREMENT

Pressure measurements are given in terms of the force acting upon an area. The most common unit of pressure measurement in IP units is pounds per square inch (psi). In SI units it is kilopascals (kPa). Another common unit of measurement for low-pressure systems is inches of water column (in. wc).

Standard Reference Points and Pressure Measurement

The two basic reference points for measuring pressure are standard atmospheric pressure and a perfect vacuum. When the pressure is measured from standard atmospheric pressure to a specified higher pressure, it is called "gauge pressure," expressed as pounds per square inch gauge (psig). If the pressure level is measured from a perfect vacuum, it is called "absolute pressure," expressed as pounds per square inch absolute (psia). Local barometric pressure, which is the prevailing pressure at any specific location, is variable and should not be confused with standard atmosphere, which is the mean theoretical barometric pressure at sea level. Theoretical standard atmospheric pressure at sea level is equal to 14.696 psia (101.4 kPa), 0 psig, and 29.92 in. Hg (760 mm Hg). A perfect vacuum has a value of 0 psia (0 kPa) and 0 in. Hg. Refer to Figure 4-1 for the relationship among the various methods of measuring air pressure.

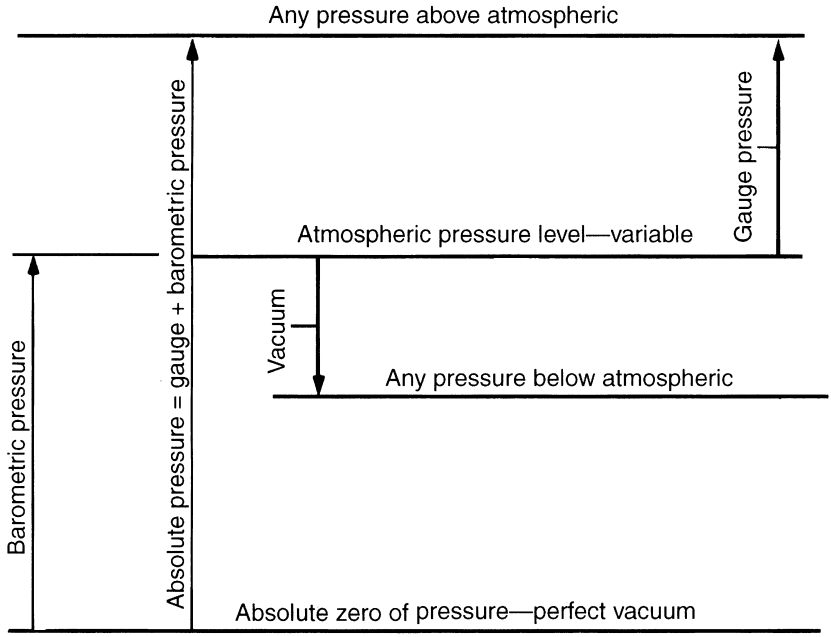


Figure 4-1 Relationship Between Gauge and Absolute Pressure

For ease of calculation, 14.7 psig is often adjusted to 15 psig and 29.92 in. Hg is often adjusted to 30 in. Hg. These minor deviations yield results that are well within the accuracy required for most engineering calculations.

Theoretical standard atmospheric temperature is 60°F (15.6°C).

"Standard air" is considered to have a relative humidity of 0.0 %, a temperature of 60°F (15.6°C), and a pressure of 14.7 psig (101.4 kPa).

"Free air" is air at ambient conditions at a specific location. Its temperature, barometric pressure, and temperature may be different than those of standard air. The term "free air" may not be used unless the ambient temperature, humidity, and barometric pressure conditions at the compressor location are stated.

Flow-Rate Measurement

The most common measurement of flow rate in IP units is cubic feet per minute (cfm). If the flow rate is low, it is commonly expressed in cubic feet per hour (cfh). For SI units, liters per minute (L/min) and liters per second (L/s) are used. The flow rate must reference scfm or acfm (sL/min or aL/min).

"Standard cubic feet per minute (scfm) [standard liters per minute (sL/min)]" is a volume measurement of air at standard conditions. One cubic foot of standard air weighs 0.764 lb.

"Actual cubic feet per minute (acfm) [actual liters per minute (aL/min)]" is a volume measurement of standard air after it has been compressed. To find the acfm equivalent of scfm at pressure, refer to Figure 4-2. The term "acfm" is meaningless unless the pressure is stated.

"Inlet cubic feet per minute (icfm)" is the actual flow rate of free air entering the inlet flange of the compressor, not considering losses through any installed inlet devices or piping. This term is meaningless unless the ambient temperature, humidity, and barometric pressure conditions at the compressor location are stated.

"Free air delivered (FAD)" is the actual volume rate of free air produced at the outlet flange of the compressor when referenced to icfm.

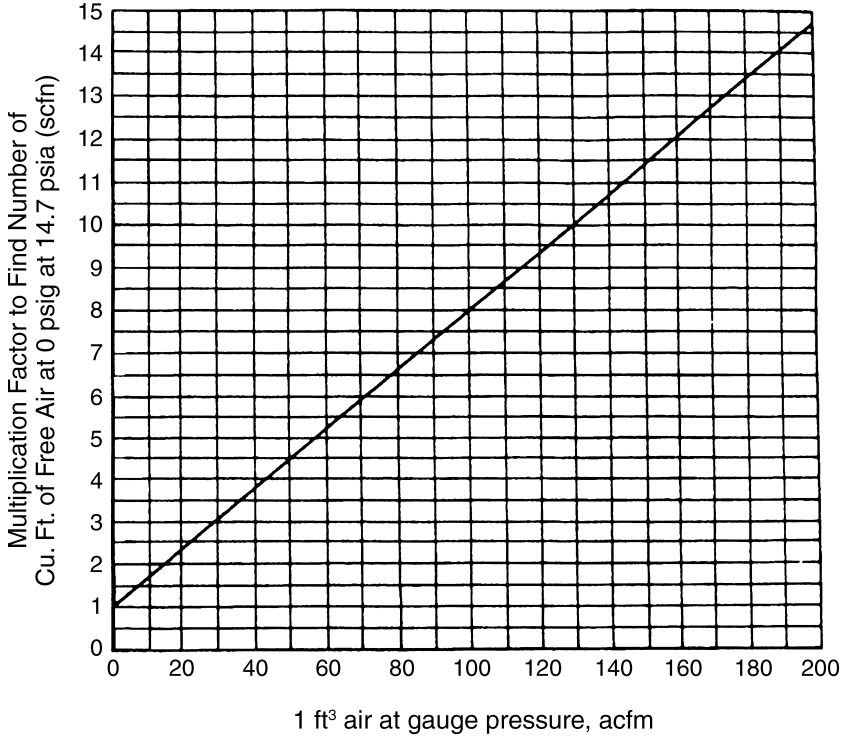
PHYSICAL PROPERTIES OF AIR

"Air" is the atmosphere surrounding the earth. It is a mixture of many elements and compounds. Pure air is odorless and tasteless unless some foreign matter is suspended in the mixture. The air pressure exerted at the earth's surface is due to the weight of the column of air above that point and is measured barometrically.

Because free air is less dense at higher elevations, a correction factor must be used to determine the equivalent volume of air at the higher elevation. The elevation correction factors are given in Table 4-1. By multiplying the volume of air by the correction factor, the actual quantity of air can be found.

Table 4-1 Elevation Correction Factor

Altitude, ft. (m)	Correction Factor
0 (0)	1.00
1600 (480)	1.05
3300 (990)	1.11
5000 (1500)	1.17
6600 (1980)	1.24
8200 (2460)	1.31
9900 (2970)	1.39



Ratio of free air to compressed air. To find the free air equivalent for 1 acfm at 130 psig pressure, find 130 at the bottom, go up to the diagonal, then horizontal to the left, to find the multiplier of 9.8. Then 1 acfm will equal 9.8 scfm.

PSIG x 7 = KPa SCFM x 0.5 = L/s

Figure 4-2 Conversion of ACFM to SCFM

Temperature is also a consideration. Because a volume of free air at a higher temperature will exert a higher pressure than an equal volume at a lower temperature, a correction factor must be used to determine equivalent volumes of air at different temperatures. The temperature correction factors are given in Table 4-2. By multiplying the volume of air by the correction factor, the actual quantity of air can be found.

Water Vapor in the Air

Both temperature and pressure can affect the ability of air to hold moisture. When a given volume of air is compressed, an increase in temperature occurs. An increase in temperature results in an increased ability of the air to retain moisture. Conversely, a decrease in pressure results in a decreased ability to hold water. With each 20°F increase in temperature, the ability of air to accept water vapor doubles. When air is compressed, the rise in temperature is more critical than the pressure rise. Because of the high temperature given to air during the compression cycle, water is precipitated not inside the compressor but rather after the cycle has been completed.

Air contains varying amounts of water vapor, depending on its temperature and pressure. Various methods are used to express the amount present.

Table 4-2 Temperature Correction Factor

Temperature of Intake, °F (°C)	Correction Factor	Temperature of Intake, °F (°C)	Correction Factor
-50 (-46)	0.773	40 (4)	0.943
-40 (-40)	0.792	50 (10)	0.962
-30 (-34)	0.811	60 (15.6)	0.981
-20 (-29)	0.830	70 (21)	1.000
-10 (-23)	0.849	80 (27)	1.019
0 (-18)	0.867	90 (32)	1.038
10 (-12)	0.886	100 (38)	1.057
20 (-6.7)	0.905	110 (43)	1.076
30 (-1)	0.925	120 (49)	1.095

"Relative humidity" is the amount of water vapor present in the air expressed as a percent of the amount present when the air is saturated. Relative humidity is dependent on pressure and temperature. To determine the moisture content of saturated air based on its temperature, refer to Figure 4-3.

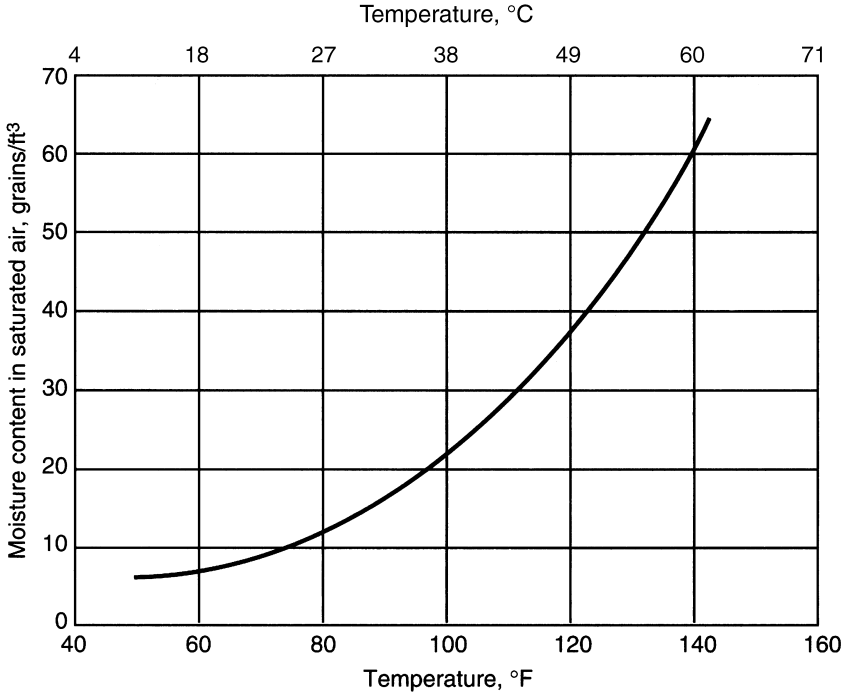
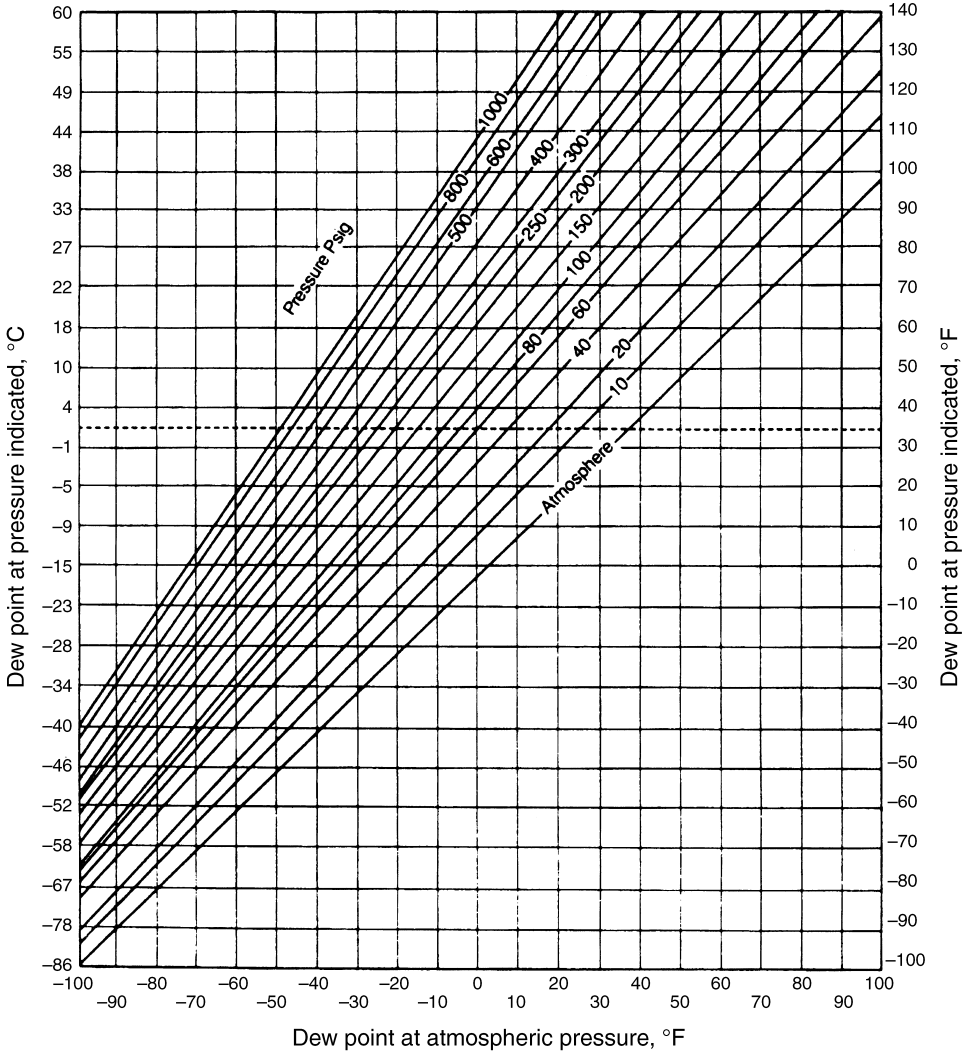


Figure 4-3 Moisture Content of Saturated Air

The "dew point" is that temperature at which water in the air starts to condense on a surface; it is a method used to express the dryness of compressed air. The lower the dew point, the dryer the air. Since the dew point of air varies with the air pressure, it must be referred to as the "pressure dew point." Air at different temperatures but

the same pressure has different dew points. To find the dew point of air at different temperatures, refer to the dew-point conversion chart, Figure 4-4.



Note: Multiply pressure in PSIG by 6.9 to obtain KPa

DEW POINT CONVERSION:
To obtain the dew point temperature expected if the gas were expanded to a lower pressure, proceed as follows:

1. Using “dew point at pressure indicated”, locate this temperature on scale at right- or left-hand side of chart.
2. Read horizontally to intersection of curve corresponding to the operating pressure at which the gas was dried.
3. From that point, read vertically downward to curve corresponding to the expanded lower pressure.
4. From that point, read horizontally to scale on right- or left-hand side of chart to obtain dew poinnt temperature at the expanded lower pressure.
5. If dew point temperatures at atmospheric pressure are desired, after step 2 above read vertically downward to scale at bottom of chart, which gives “Dew point at atmospheric pressure.”

Figure 4-4 Dew Point Conversion Chart

Source: Courtesy Hankison Corp.

Table 4-3 Weight of Water Vapor in Air

Temperature,		Relative Humidity (%)								
°F	(°C)	10	20	30	40	50	60	70	80	90
30	(-1)	3	5	7	9	12	14	17	19	21
40	(4)	4	7	10	14	16	18	20	22	24
50	(10)	6	10	14	20	26	32	38	42	48
60	(15.6)	8	16	22	30	39	48	54	62	70
70	(21)	11	21	34	44	55	66	78	88	100
80	(27)	16	30	46	62	78	92	108	125	140
90	(32)	21	42	65	85	108	128	158	173	195
100	(38)	29	58	87	116	147	176	208		

Note: Weights are in grains of moisture/lb of dry air at standard barometric pressure.

Table 4-4 Moisture Content of Air at 1 Atmosphere

Dew Point, °F	Grains Moisture/ lb Air	Pounds Moisture/ lb Air	Grains Moisture/ ft^3 Air	ppm	Volume (%)
110		0.0600		60,000	
	400		25		9
		0.0500		50,000	8
					7
100	300		20		
		0.0400		40,000	
					6
			15		
90					5
		0.0300			
	200				
					4
80					
	150	0.0200	10	20,000	
			9		3
70			8		
	100	0.0150		15,000	
	90		7		2
	80		6		
60					
		0.0100		10,000	
	70	0.0090		9,000	1.5
	60	0.0080		8,000	
50					
	50	0.0070		7,000	1
	40	0.0060	3	6,000	0.9
40					
		0.0050		5,000	0.8
	30	0.0040	2	4,000	0.7
					0.6
30					
	20	0.0030	1.5	3,000	0.5
					0.4
20					
		0.0020	1	2,000	0.3
	10		0.8		

(continued)

Table 4-4 Moisture Content of Air at 1 Atmosphere (continued)

Dew Point, °F	Grains Moisture/ lb Air	Pounds Moisture/ lb Air	Grains Moisture/ ft^3 Air	ppm	Volume (%)
10					
	8	0.0010	0.6	1,000	0.2
	6	0.0080		800	
0					
		0.0006	0.4	600	0.1
	4				0.08
-10					
		0.0004		400	0.06
	2		0.2		
-20					0.04
		0.0002		200	
-30	1		0.1		
	0.8		0.08		0.02
	0.6	0.001	0.06	100	
-40		0.00008		80	
	0.4	0.00006	0.04	60	0.01
					0.008
-50		0.00004		40	
	0.2		0.02		0.006
					0.004
-60					
		0.00002		20	
	0.1		0.01		
	0.08		0.008		0.002
-70		0.00001		10	
	0.06	0.000008	0.006	8	
	0.04	0.000006	0.004	6	0.001
-80					0.0008
		0.000004		4	0.0006
	0.02		0.002		0.0004
-90					
		0.000002		2	
	0.01		0.001		0.0002
-100	0.008				
		0.000001	0.0008	1	

Source: Courtesy of Hankison Corp.

Notes: 1) There are many ways of expressing moisture content of air. This accompanying chart provides a quick comparison of the more frequently used methods. Read straight across to find equivalent moisture contents at 1 atmospheric pressure.

2) A pressure correction is necessary for all other measurements listed. For a convenient means of converting dew points measured at atmospheric pressure to those measured at an elevated pressure, refer to Figure 4-4. Use the latter dew point on the moisture content chart to read grains per pound, pound per pound, ppm, and volume percent. On the other hand, if moisture content is expressed in these units, read the expanded dew point from the moisture content chart and refer to Figure 4-4 to convert the dew point reading to elevated pressure.

3) The relationship of dew point to grains per cubic foot does not change much with pressure in the range of 0 to 300 psig. Consequently, grains per cubic foot for elevated pressures can also be read directly from the chart, remembering that actual cubic feet are used.

The relationship of the dew point to the weight of water per cubic foot of air at a constant temperature is about the same for all different pressures in the range common to facility compressed-air systems. Refer to Table 4-3 for the weight of water vapor in the air at different temperatures and relative humidity values. For a conversion table giving different methods expressing moisture content of air, refer to Table 4-4.

Impurities and Contamination

Knowledge of the various pollutants in the air is helpful in deciding what equipment is required to effectively reduce or remove them. The required level of protection from the various contaminants depends on the intended purpose of the air. The identification and quantification of pollutants must be done and the performance criteria for each individual system must be determined prior to the selection of any equipment.

There are four general classes of contamination:

1. **Liquids (oil and water).** Water enters a system with the intake air, passes through the compressor as a vapor, and condenses afterwards into liquid droplets. Most liquid-oil contamination originates at the intake location or in an oil-lubricated compressor. As these contaminants are swept through the system at velocities approaching 4000 ft/min (fpm), they gradually erode obstructions in their path by repeated collisions. When water settles on pipes, corrosion begins; at the end use, it ruins machinery and tools and causes product rejection and product contamination. At high temperatures, oils break down to form acids. With particulates, oil forms sludge. Oil can also act like water droplets and cause erosion. Liquid chemicals react with water and corrode surfaces. Water also allows microorganisms to grow.
2. **Vapor (oil, water, and hydrocarbons).** Oil, water, and chemical vapors enter the system in the same manner that liquids do and contribute to the corrosion of surfaces in contact with the air. Oil vapor reacts with oxygen to form varnish buildup on surfaces. Various chemicals cause corrosion and are often toxic.
3. **Gas.** Gases such as carbon dioxide, sulfur dioxide, and nitrogen compounds react with heat and water to form acids.
4. **Particulates.** Particulates enter the system at the air intake, originate in the compressor due to mechanical action, or are released from some air-drying systems. These particles erode piping and valves or cause product contamination. The most harmful effect, however, is the clogging of orifices or passages (of tools, for instance) at end-use points. These particulates include metal dust, carbon and Teflon particles, pollen, dust, rust, and scale. Bacteria enter through the inlet and reproduce in a moist, warm environment.

Air-Purification Design Considerations

There is no single type of air-purification equipment or device that can accomplish the job of removing 100 % of all impurities. Objective performance criteria must be used to select air-purification components that will accomplish the desired reduction level. Such criteria must include pressure drop, efficiency, dependability, service life, energy efficiency, and ease of maintenance. Contaminant removal processes are discussed further under individual components.

1. There is no safe level of liquids in the airstream. They should be removed as completely as is practical.
2. The level of acceptable water vapor varies with end-use requirements. A dew point of –30°F is required to minimize corrosion in pipelines. For critical applications, a dew point of –100°F may be required. Oil vapor remaining in the air should be as close to zero as is practical. Chemical concentration should be reduced to zero, where practical.
3. Gases in any quantity that are potentially harmful to the system or risk of contamination of the end product should be reduced to zero or to a point that will cause no harm or contamination, depending on practical considerations. Condensable hydrocarbons should be removed as completely as is practical.
4. Particulate contamination must be reduced to a level low enough to minimize end-use machine or tool clogging, product rejection, or process contamination. These values must be established by the engineer and client; they vary widely. The general range of particles in a typical system is between 0.01 and 10 μ in diameter.

PRODUCTION COMPRESSED-AIR SYSTEMS

Equipment

Air Compressors

The selection of an air compressor for any specific application depends primarily upon a knowledge of its performance characteristics as applied to the particular system being designed. Cost, space requirements, and efficiency are other considerations. Increasing awareness of energy costs also requires evaluation of total operating costs and ease of maintenance for an extended period of time. A carefully selected air compressor will satisfy the system design and performance criteria while operating in the most cost-efficient manner.

Air compressors are divided into two general categories: displacement and dynamic compressors. Displacement compressors can be further separated into reciprocating and rotary machine catagories. Typical reciprocating compressors include piston and diaphragm types. Rotary compressors include such types as the sliding vane, liquid ring (or liquid piston), and screw. The most widely used types of dynamic compressors include centrifugal and axial flow.

Compressor Regulation If the total system demand for both air pressure and volume exactly matched the compressor output for as long as the compressor operated, no regulation would be required. Since this does not usually happen, whenever system demand varies it is necessary to regulate the compressor. Some manner must be found to adjust output to match the variable demands of the system. The ideal method would be to have an infinitely variable compressor to provide the exact volume and pressure required to satisfy all demands. Again, this is not realistic. Following is a discussion of the commonly used methods to achieve varying volume of air while maintaining adequate system pressure.

Compressor capacity can be regulated by either continuous or discontinuous methods. Continuous means require control of the compressor by using either an adjustable speed coupling or a control of the drive motor speed. Another method

is to bleed compressed air from the discharge either to atmosphere or back into the inlet. This is called "unloading" or "blow-off" and is wasteful of energy. Finally, the internals of a compressor can be altered to be less efficient by the adjustment of valves, clearances etc. This last method is the least desirable of all, because the correct speed and the internal adjustment of the compressor for specific projects can only be determined and accomplished by the manufacturer. This makes it almost impossible for maintenance personnel to repair in the field. Blowoff, however, has several alternatives.

In general, unloading is best used when the compressor operates more than 50% of the time or where continuous operation of a motor is desirable. For applications requiring constant compressor speeds, a pilot unloader, pressure sensing device, or trigger valves can be used. The pilot unloader operates in one of three ways—it may adjust compressor cylinder suction valves, close valves on the compressor inlet line, or open a bypass in the main discharge line. To summarize, a constant compressor-speed unloader operates when upper pressure is reached but the motor continues to run. At the lower pressure limit, the pilot stops working and allows air to be delivered. Of course, the motor is still running.

Discontinuous regulation is the most common method of controlling compressor capacity. This is accomplished by using a pressure-regulating device (either mechanical or electromechanical) arranged to stop the compressor at a preset high pressure and start it again a preset low pressure. A receiver (tank) is used to store air. This gives a reserve capacity to keep the compressor from starting too often. Receivers are discussed later.

There are circumstances when both kinds of regulation may prove beneficial. It is possible to have both types acting together. This is referred to as "dual" regulation or control.

Speaking in general terms about continuous regulation, the reciprocating compressor uses the inlet suction valve most often. It is possible to obtain this type of unloader in from one to three gradually increasing stages of operation. Sliding-vane and screw type compressors commonly use the modulating suction valve, with dual control and a receiver if demand permits. Centrifugal compressors should not be run outside their range, so a blowoff to atmosphere is used.

Silencers

When sound is too loud, it becomes noise. This noise, depending upon location and circumstances, can be very objectionable. With today's emphasis on noise control, the installation of an intake silencer is probably necessary for most projects.

There are two types of silencer: reactive and absorptive. The reactive type is used to attenuate (reduce) low-frequency sound up to approximately 500 Hertz (Hz), which is most often found on reciprocating compressors. The absorptive type is often used on centrifugal and screw type compressors where frequencies are above 500 Hertz (Hz). There is no practical limit in cubic feet per minute (cfm) for either type.

The selection of a silencer should be made in conjunction with the manufacturer. To accomplish this, it is first necessary for the engineer to determine two things: the sound power level of the compressor (which must be obtained from the com-

pressor manufacturer) and the highest level of sound permitted by OSHA, local authorities, or facility personnel. With the establishment of these design criteria, selection of a silencer can be made if the final level of sound desired is included in the specifications. This allows the various manufacturers to suggest the correct silencer for that purpose, for final acceptance by the engineer.

OSHA has established maximum acceptable sound levels to prevent hearing loss. These levels are generally regarded as excessive. That noise level, if accepted, usually disturbs facility workers in adjacent and surrounding areas.

Silencers may be combined with the inlet filter for a more economical installation. They can also be mounted directly on the compressor or at the roof level as separate units.

Aftercoolers

An "aftercooler" is a device used to lower the temperature of compressed air immediately after the compression process. In doing so, it liberates large amounts of water. The primary function of an aftercooler is to remove water vapor rather than to lower the temperature of the compressed airstream.

Air leaving the compressor is very hot. It is desirable to reduce the temperature of air discharged to a range of between 70 and 110°F. A primary reason the temperature is lowered is to remove moisture that would otherwise condense elsewhere in the system as the air cools to ambient conditions. It is considered good practice to install an aftercooler as close to the compressor discharge as is practical for that reason. An aftercooler is also useful to precondition air where additional conditioning is necessary.

There are three general types of aftercooler:

1. Water cooled.
2. Air cooled.
3. Refrigerant.

If a facility has a plentiful supply of reusable and/or recirculated cooling water, the first choice would be a water-cooled aftercooler. These units are selected on the basis of maximum inlet compressed-air temperature, highest temperature and quantity of cooling water available, desired outlet compressed-air temperature, and maximum flow, in cfm, of compressed air. A typical cooling capacity will bring the compressed air to within 10 to 15°F of the water temperature used for cooling.

Air-cooled units are less efficient than water-cooled ones. They are selected on the basis of maximum inlet compressed-air temperature, highest ambient-air temperature, approach temperature desired, and maximum flow, in cfm, of compressed air. A typical cooling capacity will bring the compressed air to within 20 to 30°F of the air used for cooling.

A refrigerant type of aftercooler is rarely used. If one is required due to job conditions, consult the manufacturer's literature for applications. Used for this purpose, a refrigerated aftercooler will follow the same principles used by air dryers, which are discussed later in this chapter.

Since large amounts of water are usually removed from the air in an aftercooler, a moisture separator is usually provided. The separator could be either an integral part of the aftercooler or a separate unit. A typical aftercooler and separator are illustrated in Figure 4-5.

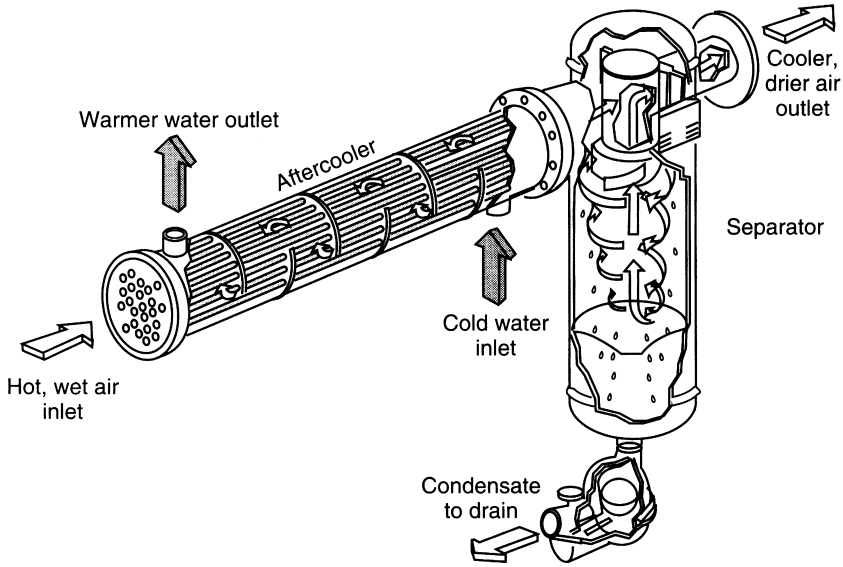


Figure 4-5 Aftercooler and Moisture Separator

Additional factors to be considered when selecting an aftercooler are pressure drop through units, space requirements, operation costs, and maintenance.

Filters

The purpose of any filter is to reduce or remove impurities or contaminants in the airstream to an acceptable, predetermined level.

Contaminants are removed by mechanical separation (interception), coalescence, adsorption, or a combination of these principles.

1. **Mechanical separation.** Mechanical separation is used to remove solid particles from the airstream. The filter element is a thin sheet or membrane whose passages are smaller than the particles to be retained. They intercept and hold dirt, scale, dust, and other solid particles in the matrix of the filter element.
2. **Coalescing.** Coalescing filters are used to remove aerosols from the airstream. This is accomplished by impingement of the small-diameter aerosols onto a passive portion of the device, which causes them to randomly collide and merge into larger droplets, which drain from the filter by gravity.
3. **Adsorption.** Adsorption is used to remove vapors from the airstream by causing the contaminant molecules to be trapped into the small pores of the filter medium. This medium has a very high surface-to-volume ratio.

4. **Combination.** Combination filters use two or more filtration principles in a single unit. Manufacturers should be consulted to obtain the most effective combinations to remove specific contaminants.

Filter nomenclature has been developed based on the individual type of filter medium and generally where it is placed in a compressed-air system. Inlet filters, prefilters, after-filters, and point-of-use filters are some examples of filters designated by their placement whereas particulate, coalescing, and carbon filters are designated by type of medium. Generally speaking, nothing prevents any kind of filter from being used for any application, provided that the required reduction of contaminants is achieved and it is suitable for the purpose intended. Following is a brief discussion of various types of filter.

- Inlet filters remove large amounts of contaminants at the inlet to the air compressor.
- Prefilters are generally used before air enters a dryer to remove various contaminants that might foul the unit. These filters are usually of the coalescing type so they can remove particulates and vapors, such as oil, hydrocarbons, and water. When combined with separators at this point, these filters may be called "separator/filters."
- After-filters are generally used after the drying process to remove smaller particulates than those removed by a prefilter. Some dryers produce a very small-diameter dust (fines) that must be removed from the airstream. These filters remove particulates only.
- Point-of-use filters are generally used immediately prior to any tool or individual piece of equipment that requires removal of particulates to a greater extent than that provided by an after-filter.
- Oil-removal filters are special filters used only for the removal of unwanted amounts of oil aerosols that are too small to be removed by a coalescing filter.
- Activated carbon filters are used to remove gaseous oil and other hydrocarbons as well as small particulates that are too small to be removed by a coalescing filter.

Specialized Filters

Intake-Air Filters — Intake-air filters are required for every installation to protect the compressor from damage. A properly selected air filter will return dividends in the form of reduced wear and maintenance by ensuring that sufficiently clean air is supplied to the compressor.

Intake air must be clean and free of foreign matter, such as leaves or insects; solid and gaseous impurities, and abrasive dust particles. In addition, the air should be as cold as is possible in order to increase compressor efficiency. In certain urban and industrial locations, air is often contaminated with corrosive and acid gases, which might damage the compressor. Unusual volumes of any objectionable contaminant gas in vapor or aerosol form must be considered. Filters should have the following characteristics:

1. **High efficiency** The filter should remove large amounts of particulates from the intake air and allow the particulates to accumulate on the filter elements while keeping a low pressure drop.

2. **Large storage capacity** It should be able to store large amounts of particulates before requiring replacement due to the reduced flow of intake air.
3. **Low resistance** It should have a low resistance to the flow of intake air.
4. **Mechanical and structural soundness** Filters must be capable of withstanding any possible air-pressure surge as well as resisting physical damage.

Filters for intake air fall into the following general categories:

1. **Paper filters** These are dry and disposable, consisting of corrugated paper, usually impregnated by some material to improve performance. Filter efficiency is high with low pressure drop when new. Paper is not recommended for inlet air temperatures greater than 150°F or where strong air pulsations may occur, as may occur with some piston compressors. They are recommended for air compressors of any capacity.
2. **Felt filters** These are dry, reusable, pleated felt elements, often reinforced with wire screens. These filters have a large particulate capacity. They are cleaned either by using compressed air or by washing as per manufacturer's instructions. These are recommended for oil-free air and other compressors of any capacity.
3. **Oil-wetted labyrinth filters** These are reusable and of metal construction. They use the principle of separating particulates by rapid changes of direction, which cause particles to adhere on surfaces wetted by a film of oil. These filters require careful maintenance to ensure that the oil surface has not dried out or become saturated. They are recommended for small-capacity units (up to about 100 cfm) and where large amounts of particulates are present at the inlet.
4. **Oil-bath filters** These filters are reusable, with an improved type of wetted labyrinth that uses a surface of liquid oil to trap particulates. This type of filter has a large capacity for particulates, usually equal to the weight of oil in the filter. Careful maintenance is required to regularly change the oil. If an unloader is used on the air compressor, there is a potential for the oil to be blown out of the filter. These filters are recommended where large amounts of particulates are present at the inlet.

For most installations, the design engineer selects the inlet location and investigates known and potential pollutants. This information is ideally obtained from many tests of air at the proposed intake location taken over several months in all the different seasons and at different times of the day. This kind of testing is rarely possible. In some urban areas, tests are taken by some authority, such as the state or federal EPA or a health department. In actual practice, tests can be taken and analyzed during the design phase of a project. Then the purity of the air for final use can be determined. With this criterion, the inlet filter can be selected based on the type of compressor used. Manufacturers, who have a knowledge of their own product line, should be consulted to recommend filter types capable of meeting the established criteria. The filter best suited for the system under design can then be selected.

For outdoor installations, provide a weatherproof rain cap and an insect screen around and over the actual inlet. Do not locate the compressor inlet close to any

exhausts or vent pipes in order to avoid contaminants. The inlet should be mounted no less than 3 ft 0 in. above roof or ground level or the possible snow level.

Separators — A "separator" is a type of filter used to remove large quantities of liquid water or oil, individually or in combination, from the airstream. Often, oil and water form an emulsion inside the compressor and are discharged together.

Since suspended liquids are present after the air leaves the aftercooler or compressor, the most common location is at that point. The general design of these units should allow for the removal of between 90 and 99%, by weight, of liquids.

There are two general types of separator: passive and active. The passive type uses no moving parts and depends on the impaction of the liquid on internal surfaces, along with coalescence, for its effectiveness. Active units use moving internal parts (often centrifugal action) to remove liquid drops.

The purpose of an oil separator is to remove oil present in the airstream, regardless of the quantity or form (drops, aerosol, or vapor). An oil separator can be selected to obtain any degree of removal.

Separators can be combined with integral air filters to increase the efficiency of the combined unit. They can also be provided with integral drain traps. If not, a separate drain trap must be provided.

Oil and moisture separators should never be considered similar types of units, as their functions are quite different.

Filter Selection Just as the degree of contamination in compressed air varies, so do the requirements for purity of the entire system and at various points of use. These requirements must be established prior to the selection of filters for the system.

Filters should be selected based on their ability to meet established design criteria. The manufacturer, who is knowledgeable about specific conditions, should be consulted as part of the selection process. The following items must be considered:

1. Maximum flow rate expected.
2. Desired pressure drop across the filter.
3. Temperature of the airstream.
4. Contaminants to be removed (a requirement for filter type and housing material).
5 Pressure rating. (Is the ASME stamp required?)
6. Is a drain trap required (automatic type preferable)?
7. Is a sampling port required?
8. Filter efficiency.

The following procedure should be followed in filter selection:

1. Calculate the maximum flow rate of air expected. This figure should be in the same unit as the manufacturer's rating unit, usually scfm (sL/min).
2. Determine the lowest pressure with which the filter can be expected to operate. This pressure must be used in conjunction with the pressure lost in other system equipment.

3. Based on the filter's position in the system, determine the contaminant or contaminants to be removed.
4. Determine the maximum pressure drop across the filter. Manufacturers often use such values as "wetted pressure drop" and "dry pressure drop," which do not take into consideration dirty elements. Average conditions use a range of between 6 and 10 psig.
5. Will monitoring of the filter element for replacement, such as by a color change, be required?
6. Select the appropriate filter from a manufacturer's catalog.

Drain Traps

Separators and aftercoolers are not capable of directly discharging any water or oil removed from compressed air to drains. The purpose of a drain trap is to allow for the collection and removal of liquids that have separated from the airstream with little or no loss of line pressure or compressed air.

Drain traps fall into two general types, manual and automatic. Automatic traps are by far the more common type. A manual trap is simply a drip leg on piping, with a valve that is opened by hand to drain the liquid that has accumulated in the length of pipe making up the drip leg.

Automatic drains fall into three categories:

1. Float.
2. Bucket.
3. Electronic.

Float traps operate on the principle of a sealed float connected to a valve that opens when the float rises and reaches a predetermined level. Bucket traps use an unsealed bucket that moves due to the displacement of water either in or around the bucket. This opens a valve to allow the accumulated liquid to discharge. The electronic type is a solenoid valve set to open at predetermined programmable intervals for a programmable period of open time. Selection of an automatic drain valve is based on line pressure, the quantity of liquid stored, the consistency of stored liquid, and the rate of liquid discharge required.

Float traps generally allow for higher discharge rates and greater contamination of stored liquid with oil sludge and solid particles than do bucket traps. Bucket traps are usually tighter sealing and can be used for high-pressure applications. They also cost less than float traps. Some facilities have a preference for using a particular type of trap. If traps must be placed outdoors and there is a potential for freezing, integral heaters are available to keep the stored liquid above freezing. Some traps require a small equalization line from the trap to the compressed-air piping to allow for reliable float operation.

Compressed-Air Dryers

"Air dryers" are devices used to remove water vapor from the airstream.

Large volumes of water consisting of larger droplets are removed by a moisture separator. If additional reduction of water vapor content is desired, it must be accomplished by the use of an air dryer. There are five methods generally used:

1. High pressurization of the compressed air.

2. Condensation.
3. Absorption.
4. Adsorption.
5. Heat-of-compression drying.

High Pressurization High pressurization reduces water vapor by compressing air to far greater pressures than those required for actual use. When pressure is increased, it decreases the ability of air to hold moisture. Since pressurization requires great amounts of energy, this process is rarely used.

Condensation Condensation utilizes the principle of lowering the temperature of the airstream through a heat exchanger, thereby producing a lower dew point. The lower dew point reduces the capacity of air to retain moisture. Moisture then condenses out of the air onto the coils of the dryer. A moisture separator removes the condensate. The cooling medium in the coil could be chilled water, brine, or a refrigerant. The most common type uses a refrigerant, and is called a "refrigerated dryer."

The greatest limitation is that they cannot practically produce a pressure dew point lower than 35°F. Otherwise, the condensed moisture would freeze on the coils. Advantages are that they have the lowest operating cost and they do not introduce impurities into the airstream. Initial cost is mid-range compared to the different dryer types. General pressure loss through a refrigerated dryer is approximately 5 psi.

Absorption Absorption dryers use either a solid or a liquid medium and operate on the principle of having the airstream pass through or over a deliquescent material. This medium changes state in the presence of water. The solvent is then drained away, removing the water and reducing the amount of material available for absorption. Solid absorbers are much more common than liquid ones.

The liquid absorber is usually a glycol compound. The airstream passes over the liquid, and the water combines with the glycol. The glycol-water solution must be regenerated by having the water distilled off.

This system will produce a 20°F dew-point reduction below inlet air temperature as a general rule. The greatest advantage of this type of dryer is that it requires no external connections, except a drain, for the system to operate. It has the lowest initial cost. It is generally used for intermittent flows where a high degree of drying is not required. Disadvantages are that some material used as a medium may be corrosive to the vessel; special treatment of the disposed liquid may be necessary; there is limited dew-point reduction; and, since a small amount of glycol is lost in this process, some replacement is periodically required.

Adsorption Adsorption dryers use a porous, nonconsumable material that causes water vapor to condense as a very thin film on the material's surface. This material is called a "desiccant." There is no chemical interaction, and the adsorption process is reversible. Desiccant dryers are capable of producing a pressure dew point as low as –100°F. The method of regeneration is the primary way of distinguishing between types of desiccant dryers.

Desiccant materials include silica gel, activated alumina, and aluminosilicate (molecular sieve). Each material also has applications for the removal of specific impurities other than water. Desiccant materials age in use over a period of years, which may affect capacity. In addition, care must be taken to avoid contamination of the material, particularly by oils. If adequate protection is not provided, the material may have to be replaced, although, if the contamination is not extensive, it might be brought back by the removal of the impurities.

The two general types of regeneration method for desiccant dryers are pressure swing (heatless) and heat activated (internal or external type heaters).

Pressure-swing systems regenerate the material by using a portion of dry air from the system to flow in a reverse direction, thus purging the desiccant bed of water. This operation is completed in a short period of time, usually no longer then 10 min. This purge air must be discharged to the atmosphere and thus is lost. The compressor must be oversized, therefore, to accommodate the additional air required for drying.

Thermal-swing regeneration using internal heaters is commonly used for units up to 1000 scfm and 100 psi. Purge air from the system is directed to flow in a reverse direction through the unit, with the purge air heated by internal heating elements. The purge air may be as much as 30% of the air-compressor capacity.

External-heat regeneration uses a purge blower, atmospheric air, and an external heater to fulfill regeneration-process requirements. The use of system air is not necessary. Because of the external heater, larger units can be selected for faster regeneration time.

In general, pressure-swing dryers are the lowest in initial cost and among the lowest in operating costs, and produce the most consistent dew point. In addition, they are more efficient in systems where high contamination may be a problem. Both adsorption and absorption dryers require an after-filter to trap particles (fines) that escape from the dryer into the piping network.

Heat-of-Compression Drying This recent development uses a desiccant to adsorb the moisture in the compressed airstream. The desiccant is continuously regenerated using the hot air discharged directly from the compressor before it goes into the aftercooler. The air used to regenerate the desiccant is now returned into the main airstream. There are no regeneration air losses or electric heaters used. This dryer could be cooled by a fan (air cooled) or water cooled. Air cooling with air at 95°F often gives a pressure dew point of –15°F.

Dryer Selection Procedure The single most important requirement in the selection process is to determine the lowest required pressure dew point for the intended application. This may eliminate some types of dryer. An excessive flow rate may eliminate other dryer types. The variations in initial and operating costs among units is another determining factor.

The following information must be obtained or calculated in order to select a dryer.

1. The lowest required pressure dew point. This information is usually supplied by the facility based on the equipment that will be used.
2. The temperature of the air at the inlet of the dryer. Obtained from the compressor manufacturer.
3. Maximum system pressure.
4. Maximum flow rate for the system.
5. If electrical power is available where the dryer is to be installed.

Refer to a manufacturer's catalog to select a dryer capable of meeting these requirements. Consideration should be given to initial and operating costs.

Lubricators

Lubricators are used to lubricate individual pieces of equipment during operation. There are three basic methods of lubrication, each for unique applications.

Fixed-feed lubricators are used for individual tools only and provide oil at a fixed rate (drops per minute). The amount is controlled by the air velocity. This type of lubricator must be adjusted while the tool is running. Any filter and/or regulator must be compatible with the individual installation. This system is best used where there are long operating periods with constant air flow.

Demand-feed systems use a wick saturated with oil. As the airstream passes the wick, lubricant is carried into the air. This type of lubricator should not be used where there is either low air velocity or low volume.

Positive displacement methods use a pneumatic piston to force lubricant to the point of application whenever there is flow. This type of lubrication is regarded as the most accurate and dependable, but it is also the most costly. It is best used for equipment with short operating cycles.

Air-Compressor Drives

Electric motors are the predominant motive force for air compressors. Other methods of powering compressors are diesel, gasoline, and steam engines. Since electric motors are so predominant, however, our discussion is limited only to that type of drive.

Motors are coupled to compressors either by belt drive, direct coupling, adjustable-speed couplings, flexible coupling, or flange coupling. For typical systems, belt drives are commonly used. Belt drive couplings lose approximately 4% of their power through the drive connection.

The starter used for an electric drive is based on the type and size of the motor. Magnetic, across-the-line starters are most common. When an across-the-line starter is used with an induction motor, the starting inrush of current is 5½ times the running current. If this is too much current, and the initial load needs to be reduced, a step starter (reduced voltage) can be used. This type of starter has a series of taps or steps to reduce voltage (and therefore current) to the motor. Care must be taken to select a reduced-voltage starter that provides the necessary torque to start the compressor, which is usually 110% of running torque. Consult an electrical engineer and manufacturer to check correct selection. The synchronous motor has a starting inrush of 3½ times the running current. Make sure all the necessary

overload protection is provided to prevent damage to the motor in case the compressor fails to start.

The power factor, which is a charge made by a utility company for peak energy demand, may be a criterion in the selection of an appropriate type of drive motor for larger sizes. The synchronous motor has a lower power factor than an induction motor does.

Starting Unloader

The starting unloader is used only when starting a compressor. After pressure has been initially established in the system, when the compressor stops the system remains pressurized. When the compressor must start again, it has to overcome the force exerted by the air still under pressure in the casing. There is not enough power in the drive motor to overcome this pressure. Therefore, a means must be provided to vent the air under pressure in the compressor casing to atmosphere, allowing the compressor to start under no load conditions. This is done with a starting unloader.

There are two types of starting unloader—centrifugal and pressure switch. The pressure-switch type operates by using a separate switch to open a valve type mechanism installed in the cylinder head. The centrifugal type is an integral part of the compressor and is activated by connection to the camshaft. The centrifugal type is generally preferred because it is more reliable.

Compressed-Air Receivers

The primary purpose of a receiver is to store air. Determination of the need for a receiver is always based on the type of regulation the system will use. If the compressor will run 100% of the time and have constant blowoff, an air receiver is not required.

For most applications, an air compressor is regulated by starting and stopping, with a receiver used to store air and prevent the compressor from cycling too often. Generally accepted practice for reciprocating compressors is to limit starts to about ten per hour and maximum running time to 70%. Centrifugal, screw, and sliding-vane compressors are best run 100% of the time.

An air receiver serves the following purposes:

1. Storage of air.
2. Equalization of pressure variations (pulsations).
3. Collection of residual condensate.

Piping connections should be made in such a way that the incoming air is forced to circulate and mix with the air inside the tank before being discharged.

Receivers should be ASME stamped for unfired pressure vessels. They should be sized on the basis of system demand and compressor size, using the starts per hour and running time best suited for the project. The design engineer must keep in mind that the compressor will operate to satisfy the pressure switch rather than the use of air and that the receiver is an integral part of a system that must function with respect to load conditions, amount of storage, and pressure differential.

Cooling Water

Water is used to cool air-compressor jackets and the air passing through intercoolers and aftercoolers. The use of water to cool compressors results in lower horsepower motors than would be required for similar-capacity air-cooled units. Water may also be used to cool the oil used for compressor lubrication.

It is no longer acceptable to waste the water used for cooling under current energy policies and regulations. In most cases, this water is fairly expensive if treated. Another consideration is that the discharge must also also be treated. If river water is used with only filtering, it could be discharged back into the source, if that is acceptable to the local authorities. The use of cooled or chilled water is preferred.

Water temperature is an important consideration. The coldest water should go first to the intercooler and aftercooler, because the lower the cooling-water temperature, the more efficient that stage is. If the cooling water supplied to a reciprocating-compressor jacket is too cold, it may cause water vapor to condense inside the cylinders and thus wash away some lubrication. This accelerates the wear of pistons, rings, and cylinder walls. A good rule to remember is that the water temperature should be the same or slightly higher than the temperature of the desired discharged air. In general, water over 110°F should not be considered for cooling purposes. A 10°F rise inside the compressor is a common average temperature rise. The following should be considered when providing cooling water:

1. Generally, a 5 psi pressure drop can be expected when cooling compressor jackets.
2. A strainer should be provided on the water supply to compressor jackets.
3. Minimum supply pressure of 10 psi should be available.
4. A solenoid valve should be provided to start water flow only when the compressor starts.
5. Thermometers should be provided on the inlet and outlet for ease of trouble-shooting.
6. A sight glass or drain funnel should be provided to monitor actual flow.
7. A figure of ½ gpm/hp is the average requirement for cooling water quantity to an air compressor.

The amount of cooling water required for all purposes may be determined from the following formula:

Equation 4-1

$$\text{gpm} = \frac{\text{BHP} \times \text{H}}{\text{T} \times 8.33}$$

Where

BHP = Brake horsepower
H = Heat dissipation, °F (°C)
T = Selected temperature rise of cooling water (usually 10°F), °F (°C)

Hose and Fittings

Most tools use flexible hose for the connection to the piping system. The hose used is usually larger than the air inlet port on the tool it serves. Table 4-5 indicates generally accepted hose length and air-flow parameters for the selection of supply hoses based on the size of inlet ports.

Table 4-5 Friction Loss for Hose (psi)

Free Air Flow, scfm	6 ft 1/8 in.	8 ft 5/32 in.	8 ft 1/4 in.	8 ft 5/16 in.	8 ft 3/8 in.	12½ ft ½ in.	25 ft ½ in.	50 ft ½ in.	25 ft ¾ in.	50 ft ¾ in.	8 ft, 5/32 in. 25 ft, ½ in.	8 ft, ¼ in. 50 ft, ½ in.	12½ ft, ½ in. 25 ft, ¾ in.	12½ ft, ½ in. 50 ft, ¾ in.
2	3.5	1.2	—	—	—	—	—	—	—	—	1.3			
3	7.3	2.7	—	—	—	—	—	—	—	—	2.8			
4	12.5	4.4	—	—	—	—	—	—	—	—	4.6			
5	—	6.7	—	—	—	—	—	—	—	—	6.9			
6	9.3	9.3	—	—	—	—	—	—	—	—	9.7	1.2		
7	—	12.4	1.3	—	—	—	—	—	—	—	12.9	1.6		
8	—	—	1.6	—	—	—	—	—	—	—	—	2.1		
10	—	—	2.5	—	—	—	—	—	—	—	—	3.2		
12	—	—	3.5	1.3	—	—	—	—	—	—	—	4.5		
15	—	—	5.3	2.0	—	—	—	1.1	—	—	—	6.9		
20	—	—	9.0	3.4	1.4	—	1.0	1.9	—	—	—	11.8		
25	—	—	13.8	5.1	2.2	—	1.5	3.0	—	—	—	—	1.3	1.5
30	—	—	—	7.3	3.1	1.1	2.1	4.2	—	—	—	—	1.8	2.1
35	—	—	—	9.8	4.1	1.5	2.9	5.6	—	—	—	—	2.5	2.8
40	—	—	—	12.5	5.3	2.0	3.7	7.1	—	1.0	—	—	3.2	3.7
45	—	—	—	—	6.6	2.5	4.6	8.9	—	1.2	—	—	4.0	4.6
50	—	—	—	—	8.1	3.0	5.6	10.9	—	1.5	—	—	4.9	5.6
55	—	—	—	—	9.7	3.6	6.7	13.0	—	1.8	—	—	5.9	6.8
60	—	—	—	—	11.5	4.3	7.9	—	1.1	2.1	—	—	7.0	8.0
70	—	—	—	—	—	5.7	10.6	—	1.4	2.8	—	—	9.4	10.7
80	—	—	—	—	—	7.3	13.6	—	1.9	3.6	—	—	12.1	13.9
90	—	—	—	—	—	9.2	—	—	2.3	4.5				
100	—	—	—	—	—	11.2	—	—	2.8	5.5				
120	—	—	—	—	—	—	—	—	4.0	7.7				
140	—	—	—	—	—	—	—	—	5.4	10.3				
160	—	—	—	—	—	—	—	—	6.9	13.3				
180	—	—	—	—	—	—	—	—	8.7					
200	—	—	—	—	—	—	—	—	10.6					
220	—	—	—	—	—	—	—	—	12.7					

Notes: 1) Based on 95 psig air pressure at hose inlet, includes normal couplings (quick connect couplings will increase pressure losses materially). Hose is assumed to be smooth. Air is clean and dry. If an airline lubricator is upstream from the hose, pressure loss will be considerably higher. Pressure loss varies inversely as the absolute pressure (approximately). Probable accuracy is believed to be ±10 percent.
2) psi × 7 = kPa

Where the length of hose may extend more than 20 ft, hose one size larger than normal should be used to compensate for additional line friction loss. It is good practice to limit hose friction loss to 5 psi.

Compressed-Air System Design

General

The compressed-air system must be controlled, regulated, and sized to ensure that an adequate volume of air, at a pressure and purity necessary to satisfy user requirements, is delivered at any outlet during the period of heaviest use.

The design process is an iterative one, because the performance of one or several components may have an effect on the performance of other equipment. Therefore, various adjustments are necessary as the design progresses.

The entire system is separated into three individual systems:

1. Air compressor, including regulation, intake, and receiver.
2. Compressed-air conditioning equipment.
3. Piping distribution network.

Design Sequence

Following are the design sequence and a discussion of the items in the design sequence:

1. Locate and identify all processes, work stations, and pieces of equipment using compressed air. They should be located on a plan, and a complete list should be made to simplify record keeping.
2. Determine the volume of air used at each location.
3. Determine the pressure range required at each location.
4. Determine conditioning requirements for each item, such as allowable moisture content, particulate size, and oil content.
5. Establish how much of a 1-min period of time the individual tool or process will be in actual use. This is referred to as the "duty cycle."
6. Establish the maximum number of locations that may be used simultaneously on each branch, on each main, and for the project as a whole. This is known as the "use factor."
7. Establish the extent of allowable leakage.
8. Establish any allowance for future expansion.
9. Make a preliminary piping layout and assign preliminary pressure drop.
10. Select the air-compressor type, conditioning equipment, equipment location, and air inlet, making sure that scfm (sL/min) or acfm (aL/min) is used consistently for both the system and compressor capacity rating.
11. Final step: Produce a design including a piping layout, pipe sizes, and component configurations within the system.

Project Air-Consuming Device Location This speaks for itself. To accomplish this task and to facilitate the branch piping layout, it is recommended that the location of all air-consuming devices and their requirements be marked on a plan. Prepare a list, for future reference, of all devices noted on the plans, their location, and their actual flow rate.

Pressure and Volume Requirement The information relative to pressure and volume parameters for individual equipment and tools is usually obtained from the end user, facility planner, or owner. It is quite common for these facts to be incomplete, with additional investigation required to find the specific values needed. It is often useful to assign preliminary pressure and flow-rate requirements for the system, in order to arrange equipment space and give preliminary mechanical data to other disciplines. Table 4-6 lists general air requirements for various tools. Although the tools listed are not generally found in pharmaceutical facilities, they may be used for maintenance and as a comparison for tools not listed.

Compressed-Air Conditioning The selection of conditioning equipment depends upon end-use requirements, usually obtained when items 2, 3, and 4 are received. Conditioning equipment includes dryers, filters, lubricators, and pres-

Table 4-6 General Air Requirements for Tools

Tools or Equipment	Size or Type	Air Pressure, psi	Air Consumed, scfm
Hoists	1 ton	70-100	1
Blow guns		70-90	3
Bus or truck lists	14,000-lb cap	70-90	10
Car lifts	8,000-lb cap	70-90	6
Car rockers		70-90	6
Drills, rotary	¼-in. cap	70-90	20-90
Engine, cleaning		70-90	5
Grease guns		70-90	4
Grinders	6-in. wheel	70-90	50
Grinders	4-in. wheel	70-90	20
Paint sprayers	Production gun	40-70	20
Paint sprayers	Small hand	70-90	2-10
Spring oilers		40-70	4
Riveters	Small to large	70-90	10-35
Drills, piston	½-in. cap, 3-in. cap	70-90	50-110
Spark plug cleaners	Reach 36-45	70-90	5
Carving tools		70-90	10-15
Rotary sanders		70-90	50
Rotary sanders		70-90	30
Tire changers		70-90	1
Tire inflaters		70-90	1½
Tire spreaders		70-90	1
Valve grinders		70-90	2
Air hammers	Light to heavy	70-90	30-40
Sand hammers		70-90	25-40
Nut setters and runners	¼-in. cap to ¾-in. cap	70-90	20-30
Impact wrenches/ screwdrivers	Small to large	70-90	4-10
Air bushings	Small to large	80-90	4-10
Pneumatic doors		40-90	2
File and burr tools		70-90	20
Wood borers	1-2 in.	70-90	40-80
Rim strippers		100-120	6
Body polishers		70-90	2
Carbon removers		70-100	3
Sand blasters	Wide variation	90	6-400

sure regulators. Additional discussions can be found in previous sections under air purification design considerations.

Dryer Selection — Dryer selection is based on the most demanding user requirement except where special, dedicated equipment may be required. If a very low dew point is required, the only selection possible is a desiccant type dryer. If, however, a high dew point is acceptable, several different types of dryer can be considered.

- **Deliquescent dryers.** The deliquescent dryer is the least efficient dryer, but it requires no power to operate and its initial cost is the lowest of all the types of dryer. It has a moderate operating cost, since only the drying medium must be replenished at regular intervals. This type of dryer loses efficiency if the inlet air temperature is over 100°F, so an efficient aftercooler is mandatory. The type of deliquescent material used will affect the quality of air. Salt type materials normally reduce dew points about 12°F to 20°F, while potassium carbonate lowers the dew point about 30°F. A filter is necessary after the dryer to remove any chemical carry-over (fines) from the system.
- **Refrigerated dryers.** The most often-used type of dryer is the refrigerated dryer. It produces pressure dew points as low as 33°F, but, for practical purposes, a general figure of about 38°F has been used. The general operating cost is moderate. External requirements are floor drains and electric power. In some cases, reheating of the dried air may be necessary because the low air temperature may produce condensation on the discharge pipe exterior. The initial cost is moderate.

  All cycling, refrigerated-air dryer ratings and capacities are based on the National Fluid Power Association recommended Standard T/3.27.2 with saturated entering inlet air at 100°F and 100 psig, with a 100°F ambient temperature. At these standard conditions, the dryer must be capable of producing outlet air with a dew point in the range of 33°F to 39°F and a pressure drop of 5 psig or less.

  To select a dryer based on pressure drop and rated flow, refer to Figure 4-6, entering with the actual pressure.

  For correction factors based on temperatures other than 100°F, inlet air temperature other than 100°F and an ambient air temperature other than 100°F, refer to Table 4-7.

Table 4-7 Correction Factors for Refrigerated Air Dryers

Inlet Air Pressure		Inlet Air Temperature		Ambient Air Temperature	
Pressure psig[a]	Correction Factor	Temperature °F (°C)	Correction Factor	Temperature °F (°C)	Correction Factor
50	1.19	80 (27)	0.66	80 (27)	0.92
75	1.06	90 (32)	0.82	90 (32)	0.95
100	1.00	100 (38)	1.00	100 (38)	1.00
150	0.95	110 (43)	1.21	110 (43)	1.07
175	0.94				
255	0.92	120 (49)	1.42	120 (49)	1.16

a psig × 6.9 = kPa

- **Desiccant dryers.** Desiccant dryers produce the lowest dew points. They are the highest in initial costs and the highest in operating costs. Of the three purging methods used, the vacuum type is the most energy efficient. The

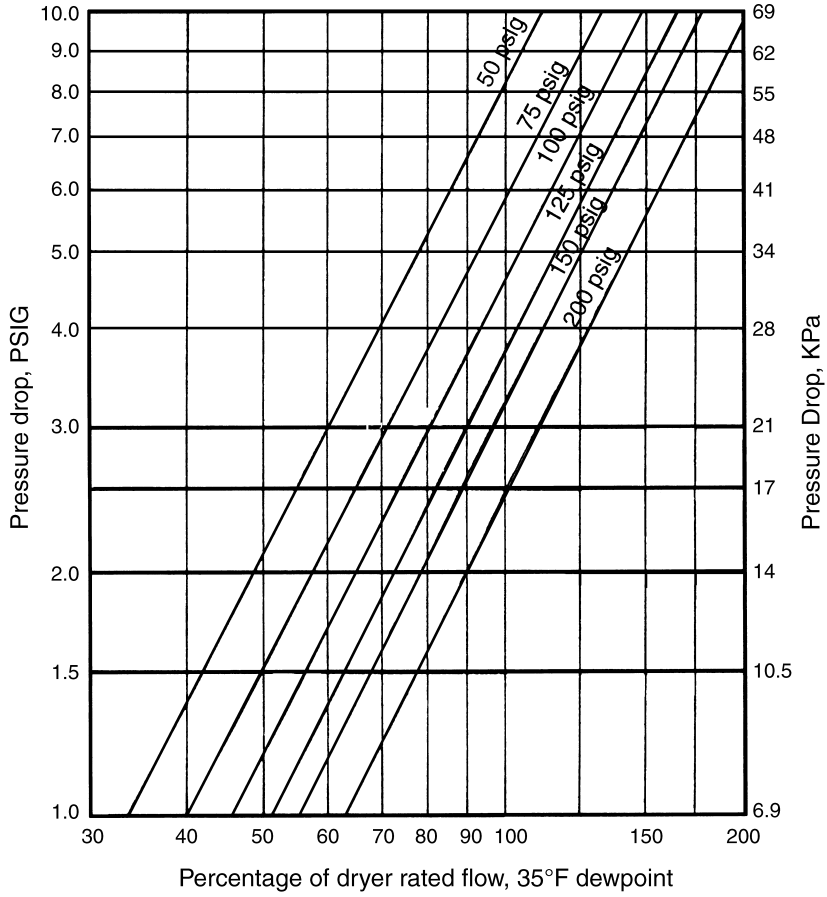


Figure 4-6 Capacity of Refrigerated Air Dryers

unheated purge is the fastest, but it uses about 15% of system air for purging. Too high an incoming air temperature is detrimental to the desiccant material. An aftercooler is usually recommended for most dryer installations because it is an economical way to reduce the moisture content of air; it should be selected in conjunction with the dryer. The aftercooler adds cost to the project, however, and is not often used.

Filter Selection—Two factors are used to select a filter: effectiveness and pressure drop. Do not specify a filter that produces air that is cleaner than actually necessary. If one station or process requires a much higher purity than all other points do, use a point-of-use filter for that area only and a less restricted filter for the main supply. It is possible for a filter to have the largest pressure drop of all the equipment in the system. In general, a filter produces a 3 to 10-psig pressure drop when dirty. If the actual figure proves to be too high, it is a good idea to oversize the filter to lower the pressure drop. In most cases, it is more economical to pay the added

initial cost of a larger filter than to increase energy requirements to compress air to a higher pressure for the life of the system.

General Considerations — It is considered good practice to provide pressure gauges on either side of main filters to determine filter condition.

Lubricators are selected based on the manufacturer's requirements for tool operation. The manufacturer must be consulted for type.

Pressure regulators are selected based on cfm and pressure-drop requirements.

Duty Cycle Users should be consulted to determine the duty cycle because, in most cases, they are the only authorities capable of discussing the actual operations of the project. In most industrial applications, tasks of a similar nature are usually grouped together. This allows sections or branches to be calculated independently.

Use Factor Experience indicates that it is almost impossible to determine a use factor accurately. Therefore, there must be sufficient receiver capacity or larger compressor capacity to allow for possible variances. In laboratories, air is used mostly for chemical reactions and is not used as much as it is in industrial applications. The exceptions are classrooms, some research facilities, and some areas within hospitals, where the use factor may be quite high. Laboratories are discussed later in this chapter.

Allowable Leakage There is no method to determine a reasonable figure accurately. Leakage is a function of the number and type of connections, the age of the system, and the quality of the pipe assembly. A system with many smaller tools and operations generally has a greater leakage of air than one with a few larger use points. Generally, a well-maintained system generally has a leakage of about 2% to 5%. Average conditions incur a 10% leakage. Poorly maintained systems have been known to have a 25% leakage factor. The facility maintenance department should be consulted when selecting a value.

Future Expansion The owner of the project must give guidance as to the possibility and extent of any future expansion. Consideration should be given to oversizing some components, such as filters, dryers, and main pipe sizes, in anticipation of expansion to avoid costly replacement in the future and to save downtime while expansion is underway. There is no loss in component efficiency incurred by doing this.

Piping System Design Piping layout on the plans should now be reasonably complete, with checking for space, clearances, interferences, and securely anchored drops to equipment. Also, the following information must be available:

1. A list of all air-consuming devices.
2. Minimum and maximum pressure requirements for each device.
3. Actual volume of air used by each device.
4. Duty cycles and use factors for each piece of equipment.
5. Special individual air-conditioning equipment requirements.

It is now possible to start sizing the piping using the following sequence:

1. In order to use pressure drop tables, it is necessary to find the equivalent length to run from the compressor to the farthest point in the piping system. The reason is that the various pipe sizing tables are based on a pressure drop developed using friction loss for a given length of pipe. Measuring the actual length is the first step. In addition to the actual measured pipe length, the effect of fittings must be considered. This is because fittings and valves create an obstruction to the flow of air. For design purposes, the addition of 50% of the actual measured run gives an approximation of the total equivalent run and, therefore, the means to select a pipe size.

Table 4-8 Pressure Drop of Air (in psi) through 100 ft of Pipe

	Pipe Diameter, in.										
	½	¾	1	1¼	1½	2	2½	3	4	5	6
scfm[a]	Schedule 40 Steel Pipe, 50 psig										
2	0.024	0.006									
3	0.055	0.012									
4	0.098	0.022	0.006								
5	0.153	0.034	0.009								
6	0.220	0.050	0.013								
8	0.391	0.088	0.023	0.006							
10	0.611	0.138	0.036	0.009							
15	1.374	0.310	0.082	0.020	0.009						
20	2.443	0.551	0.146	0.035	0.016						
25	3.617	0.861	0.227	0.055	0.024	0.007					
30	5.497	1.240	0.328	0.079	0.035	0.010					
35	—	1.688	0.446	0.108	0.047	0.013	0.005				
40	—	2.205	0.582	0.141	0.062	0.017	0.007				
45	—	2.791	0.737	0.178	0.078	0.021	0.009				
50	—	3.445	0.910	0.220	0.097	0.026	0.011				
60	—	4.961	1.310	0.317	0.140	0.038	0.016	0.005			
70	—	—	1.783	0.432	0.190	0.052	0.021	0.007			
80	—	—	2.329	0.564	0.248	0.068	0.028	0.009			
90	—	—	2.948	0.713	0.314	0.086	0.035	0.011			
100	—	—	3.639	0.881	0.388	0.106	0.044	0.014			
125	—	—	5.686	1.376	0.606	0.165	0.068	0.022			
150	—	—	—	1.982	0.872	0.238	0.098	0.031	0.007		
175	—	—	—	2.697	1.187	0.324	0.133	0.043	0.010		
200	—	—	—	3.523	1.550	0.423	0.174	0.056	0.013		
225	—	—	—	4.459	1.962	0.536	0.220	0.070	0.016		
250	—	—	—	5.505	2.423	0.662	0.272	0.087	0.020	0.006	
275	—	—	—	—	2.931	0.801	0.329	0.105	0.024	0.007	
300	—	—	—	—	3.489	0.953	0.392	0.125	0.029	0.009	
325	—	—	—	—	4.094	1.118	0.460	0.147	0.034	0.010	
350	—	—	—	—	4.748	1.297	0.533	0.170	0.039	0.012	
375	—	—	—	—	5.451	1.489	0.612	0.195	0.045	0.014	0.005
400	—	—	—	—	6.202	1.694	0.696	0.222	0.051	0.015	0.006
425	—	—	—	—	—	1.912	0.786	0.251	0.057	0.017	0.007
450	—	—	—	—	—	2.144	0.881	0.281	0.064	0.019	0.006
475	—	—	—	—	—	2.388	0.982	0.313	0.072	0.022	0.009
500	—	—	—	—	—	2.646	1.068	0.347	0.079	0.024	0.010
550	—	—	—	—	—	3.202	1.317	0.420	0.096	0.029	0.012
600	—	—	—	—	—	3.811	1.567	0.500	0.114	0.035	0.014
650	—	—	—	—	—	4.473	1.839	0.587	0.134	0.041	0.016

Table 4-8 Pressure Drop of Air (in psi) through 100 ft of Pipe (continued)

	Pipe Diameter, in.										
	½	¾	1	1¼	1½	2	2½	3	4	5	6
scfm[a]	Schedule 40 Steel Pipe, 75 psig										
2	0.018										
3	0.040	0.009									
4	0.070	0.016									
5	0.110	0.025									
6	0.159	0.036	0.009								
8	0.282	0.064	0.017								
10	0.441	0.099	0.026								
15	0.991	0.224	0.059	0.014							
20	1.762	0.398	0.105	0.025	0.011						
25	2.753	0.621	0.164	0.040	0.017						
30	3.965	0.895	0.236	0.057	0.025						
35	5.396	1.218	0.322	0.078	0.034	0.009					
40	7.048	1.590	0.420	0.102	0.045	0.012					
45	8.921	2.013	0.532	0.129	0.057	0.015					
50	—	2.485	0.656	0.159	0.070	0.019	0.008				
60	—	3.579	0.945	0.229	0.101	0.027	0.011				
70	—	4.871	1.286	0.311	0.137	0.037	0.015				
80	—	6.362	1.680	0.407	0.179	0.049	0.020				
90	—	8.052	2.126	0.515	0.226	0.062	0.025	0.008			
100	—	—	2.625	0.635	0.280	0.076	0.031	0.010			
125	—	—	4.101	0.993	0.437	0.119	0.049	0.016			
150	—	—	5.906	1.429	0.629	0.172	0.071	0.023			
175	—	—	8.039	1.946	0.856	0.234	0.096	0.031			
200	—	—	—	2.541	1.118	0.305	0.126	0.040	0.009		
225	—	—	—	3.216	1.415	0.387	0.159	0.051	0.012		
250	—	—	—	3.971	1.747	0.477	0.196	0.063	0.014		
275	—	—	—	4.804	2.114	0.577	0.237	0.076	0.017		
300	—	—	—	5.718	2.516	0.687	0.283	0.090	0.021		
325	—	—	—	6.710	2.953	0.807	0.332	0.106	0.024		
350	—	—	—	7.782	3.425	0.935	0.385	0.123	0.028	0.008	
375	—	—	—	8.934	3.932	1.074	0.441	0.141	0.032	0.010	
400	—	—	—	—	4.473	1.222	0.502	0.160	0.037	0.011	
425	—	—	—	—	5.050	1.379	0.567	0.181	0.041	0.013	
450	—	—	—	—	5.662	1.546	0.636	0.203	0.046	0.014	
475	—	—	—	—	6.308	1.723	0.706	0.226	0.052	0.016	
500	—	—	—	—	6.990	1.909	0.785	0.251	0.057	0.017	
550	—	—	—	—	8.458	2.310	0.950	0.303	0.069	0.021	0.008
600	—	—	—	—	—	2.749	1.130	0.361	0.082	0.025	0.010
650	—	—	—	—	—	3.226	1.326	0.423	0.097	0.029	0.012

2. Determine the actual pressure drop that will occur only in the piping system. Generally accepted practice is to allow 10% of the proposed system pressure for pipe friction loss. So, for a 125-psi system, a figure of 10 to 12 psi is allowed. Since the air compressor has not been selected yet, this figure is variable. A smaller pipe size may lead to higher compressor horsepower. It is considered good practice to oversize distribution mains to allow for future growth and the future addition of conditioning equipment that may add a pressure drop not anticipated at the time of original design.

Table 4-8 Pressure Drop of Air (in psi) through 100 ft of Pipe (continued)

	Pipe Diameter, in.									
	½	¾	1	1¼	1½	2	2½	3	4	5
scfm[a]	Schedule 40 Steel Pipe, 100 psig									
2	0.014									
3	0.031									
4	0.055	0.012								
5	0.086	0.019								
6	0.124	0.028								
8	0.220	0.050	0.013							
10	0.345	0.078	0.021							
15	0.775	0.175	0.046	0.011						
20	1.378	0.311	0.082	0.020						
25	2.153	0.486	0.128	0.031	0.014					
30	3.101	0.700	0.185	0.045	0.020					
35	4.220	0.952	0.251	0.061	0.027					
40	5.512	1.244	0.328	0.079	0.035					
45	6.976	1.574	0.416	0.101	0.044	0.012				
50	8.613	1.943	0.513	0.124	0.055	0.015				
60	12.402	2.799	0.739	0.179	0.079	0.021				
70	—	3.809	1.006	0.243	0.107	0.029	0.012			
80	—	4.975	1.314	0.318	0.140	0.038	0.016			
90	—	6.297	1.663	0.402	0.177	0.048	0.020			
100	—	7.774	2.053	0.497	0.219	0.060	0.025			
125	—	12.149	3.207	0.776	0.342	0.093	0.038	0.012		
150	—	—	4.619	1.118	0.492	0.134	0.055	0.018		
175	—	—	6.287	1.522	0.670	0.183	0.075	0.024		
200	—	—	8.211	1.987	0.875	0.239	0.098	0.031		
225	—	—	10.392	2.515	1.107	0.302	0.124	0.040		
250	—	—	12.830	3.105	1.367	0.373	0.153	0.049	0.011	
275	—	—	—	3.757	1.654	0.452	0.186	0.059	0.014	
300	—	—	—	4.471	1.968	0.537	0.221	0.071	0.016	
325	—	—	—	5.248	2.309	0.631	0.259	0.083	0.019	
350	—	—	—	6.086	2.678	0.731	0.301	0.096	0.022	
375	—	—	—	6.987	3.075	0.840	0.345	0.110	0.025	
400	—	—	—	7.949	3.498	0.955	0.393	0.125	0.029	
425	—	—	—	8.974	3.949	1.079	0.443	0.142	0.032	
450	—	—	—	10.061	4.428	1.209	0.497	0.159	0.036	0.011
475	—	—	—	11.210	4.933	1.347	0.554	0.177	0.040	0.012
500	—	—	—	12.421	5.466	1.493	0.614	0.196	0.045	0.014
550	—	—	—	—	6.614	1.806	0.743	0.237	0.054	0.016
600	—	—	—	—	7.871	2.150	0.884	0.282	0.064	0.020
650	—	—	—	—	9.238	2.523	1.037	0.331	0.076	0.023

3. Size the piping using the appropriate charts, having calculated the cfm and the allowable friction loss in each section of the piping. Since all pipe sizing charts are formulated based on the loss of pressure per some length of piping (usually 100 ft), it is necessary to arrive at the required value for the chart you are using. Table 4-8 presents friction loss of air in psi for a 100-ft length of pipe and from 50 to 125 psi line pressure. Use the lowest system working pressure to determine pipe size. The temperature used to calculate the friction loss is 60°F. For 100°F, increase the drop figures in the table by 7.7% for greater accuracy.

Table 4-8 Pressure Drop of Air (in psi) through 100 ft of Pipe (continued)

	Pipe Diameter, in.									
	½	¾	1	1¼	1½	2	2½	3	4	5
scfm[a]	Schedule 40 Steel Pipe, 125 psig									
3	0.025									
4	0.045									
5	0.071	0.016								
6	0.102	0.023								
8	0.181	0.041								
10	0.283	0.064	0.017							
15	0.636	0.144	0.038							
20	1.131	0.255	0.067	0.016						
25	1.768	0.399	0.105	0.025						
30	2.546	0.574	0.152	0.037	0.016					
35	3.465	0.782	0.206	0.050	0.022					
40	4.526	1.021	0.270	0.065	0.029					
45	5.728	1.292	0.341	0.083	0.036					
50	7.071	1.596	0.421	0.102	0.045					
60	10.183	2.298	0.607	0.147	0.065	0.018				
70	13.860	3.128	0.826	0.200	0.088	0.024				
80	—	4.085	1.079	0.261	0.115	0.031	0.013			
90	—	5.170	1.365	0.330	0.145	0.040	0.016			
100	—	6.383	1.685	0.408	0.180	0.049	0.020			
125	—	9.973	2.633	0.637	0.281	0.077	0.031			
150	—	14.361	3.792	0.918	0.404	0.110	0.045	0.014		
175	—	—	5.162	1.249	0.550	0.150	0.062	0.020		
200	—	—	6.742	1.632	0.718	0.196	0.081	0.026		
225	—	—	8.533	2.065	0.909	0.248	0.102	0.033		
250	—	—	10.534	2.550	1.122	0.306	0.126	0.040		
275	—	—	12.746	3.085	1.358	0.371	0.152	0.049		
300	—	—	15.169	3.671	1.616	0.441	0.181	0.058	0.013	
325	—	—	—	4.309	1.896	0.518	0.213	0.068	0.016	
350	—	—	—	4.997	2.199	0.601	0.247	0.079	0.018	
375	—	—	—	5.736	2.525	0.689	0.283	0.090	0.021	
400	—	—	—	6.527	2.872	0.784	0.323	0.103	0.024	
425	—	—	—	7.368	3.243	0.886	0.364	0.115	0.027	
450	—	—	—	8.260	3.635	0.993	0.408	0.130	0.030	
475	—	—	—	9.204	4.050	1.106	0.455	0.145	0.033	
500	—	—	—	10.198	4.488	1.226	0.504	0.161	0.037	
550	—	—	—	12.340	5.430	1.483	0.610	0.195	0.044	0.013
600	—	—	—	14.685	6.463	1.765	0.726	0.232	0.053	0.016
650	—	—	—	—	7.585	2.071	0.852	0.272	0.062	0.019

a Ft3 of free air at 60°F, 14.7 psia.

The charts were calculated using the following formula:

Equation 4-2

$$P = \frac{Q\,FV^2}{2GD}$$

Where

P = Pressure loss due to friction (psf = 144+ psi)
F = Friction factor (Use 4000 as an average figure.)
V = Velocity (fps)
G = Acceleration due to gravity (32.2 fps)

D = Pipe diameter (ft).
Q = Specific weight of air (lb/ft^3)

The following general design parameters can be used as a guide when calculating a piping system's total pressure drop:

1. Equipment drop leg: 2 psi loss (1 psi if possible).
2. Hose allowance: 2–5 psi loss.
3. Quick disconnect coupling: 4 psi loss.
4. Lubricator: 1–4 psi loss.
5. Point-of-use filter: ½–2 psi loss.

Table 4-5 gives the recommended hose sizes and friction loss of air through hose used to connect tools to the main piping system.

Air-Conditioning Equipment Selection The specific performance characteristics of various dryer types have previously been given. Following is a discussion of all the other equipment in this network.

The selection of a cooling medium for aftercoolers has been discussed previously. There are, however, additional points concerning aftercoolers to be considered. Some aftercoolers have a high pressure drop at the rated flow. Consider oversizing the unit. Some dryers require inlet air at a low maximum temperature. Selection must be made with this in mind. Provide a bypass around the aftercooler for ease of servicing.

Moisture separators are designed for specific flow conditions and so should be selected based on the actual design of the system. If marginal conditions are encountered, go to the next larger size unit, but be sure the specified unit is compatible with the actual volume. The pressure drop through a properly sized unit is about 3 psi.

The filter selection guidelines were discussed earlier in this part, under "Compressed-Air System Design." The sizing parameters must include maximum oil content of the air, maximum particulate size, and the actual cfm the filters must handle. Pressure loads are also a prime consideration. The magnitude of contaminants depends on the following:

1. Choice of air compressor.
2. Presence or absence of an aftercooler.
3. Type of dryer used.
4. Quality of inlet air.

Valves are an often-overlooked component of a compressed-air system. The selection of valve type and material is important to efficiency and operating life. The following should be considered when selecting valves:

1. The most important valve feature is minimum flow restriction (pressure drop) when the valve is open full. Ball, gate, and plug valves have the lowest pressure drop. It is extremely rare to use a valve for flow restriction, therefore, this is not a consideration.
2. Pressure rating suitable for maximum operating pressure rating of the compressor.

3. Valve body and seat materials compatible with expected trace gases and contaminants.
4. Positive shut-off.
5. Minimum leakage through the valve stem.
6. Use of valves designed for compressed-air service. Be careful to examine valve specifications for airway ports or openings smaller than the nominal size indicated or expected.

Selecting the Air-Compressor Assembly There is now enough information to size the compressor assembly. This includes the intake system, compressor and compressor installation, and receiver. To start, the following information must be available:

1. Total connected cfm of all air-using devices, including flow to the air dryer system if applicable.
2. Maximum pressure all air-using devices require.
3. Duty and use factors giving maximum expected use of air by devices.
4. Leakage and future expansion allowance, in scfm.
5. Allowable pressure drops for the entire system, including piping and conditioning equipment.
6. Altitude, temperature, and contaminant removal corrections.
7. Location of air compressor and all ancillary equipment.

Having completed the above work, first design the inlet piping system. Since air-compressor performance depends on inlet conditions, this system deserves special care. The air intake should provide a supply of air to the compressor that is as clean, cool, and dry as possible. The proposed location should be studied for the presence of any type of airborne contamination, and positioned to avoid the probability of contaminated intake. Whenever possible, use fresh outside air.

For an external installation, the inlet should have a rain cap and a screen. An inlet filter should always be provided inside the building. If the manufacturer of the selected compressor indicates that noise may be a problem, a silencer must be installed. If a duplex is used, each compressor should have an independent air intake.

Table 4-9 Air Inlet Pipe Size

Maximum Free Air Capacity, scfm	Minimum Size, in.
50	2½
110	3
210	4
400	5
800	6

Source: Courtesy of James Church.

Uncontrolled piping pulsations can harm inlet piping, damage the building structure, and affect compressor performance. Air flow into a reciprocating compressor pulsates because of the cyclic intake of air into the compressor cylinder. The variable pressure causes the air column in the pipe to vibrate, which creates a traveling wave in the pipe moving at the speed of sound. The inlet pipe itself vibrates at some natural frequency depending on its length. If the air column vibrates at or near the same frequency as the length of pipe, the system is said to be "resonant." Large pressures could result when this occurs. Resonant pipe lengths can be calculated by the compressor manufacturers, and the critical length given to the engineer. As an example,

with a 600-rpm compressor, avoid a length of pipe 3.2 to 12.5 ft, 16.8 to 26.2 ft and 32.3 to 41.5 ft. A surge chamber can also be used to eliminate this problem.

The pressure loss of air through the intake piping should be held to a minimum. Suggested inlet pipe size is given in Table 4-9. The velocity of intake air should be limited to about 1000 fpm and friction loss should be limited to about 4 in. wc to avoid noise problems. Inlet louver velocity should also be low enough to avoid drawing in rainwater. Standard round-duct charts can also be used for sizing. In general, if air requirements are less than 500 scfm, the intake can be indoors. Provide an automatic drain on the line leading to the compressor, and pitch the intake piping to the drain point. If indoor air temperature is usually higher than 100°F, the intake should be outdoors.

Many different factors are involved in the selection of a compressor type:

1. Space limitations.
2. Noise limitations.
3. Compressor pressure capability.
4. Capacity.
5. Availability, cost, and quality of cooling water.
6. Need for oil-free air.
7. Electrical power limitations.
8. Cost—both initial and long term.

The following reasons for using a duplex unit should be considered when unsure whether to select a duplex rather than a simplex unit.

1. The cost of downtime. The owner may request two 100%-capacity machines to eliminate the possibility of a shutdown.
2. Where a facility has a steady requirement (called a base load) and in addition, there are substantial variations due to periodic or intermittent use, it is best to select a duplex unit.
3. When electrical starting requirements would overload the system, two units starting at different times will eliminate the problem.
4. Where floor space is not available for one large compressor and ancillary equipment.
5. Where widely separated concentrations of heavy use exist, two compressors are a good idea.

Experience has shown that a properly sized, constantly working compressor usually requires less maintenance than one running intermittently.

Most of the power input to a compressor is rejected through the various cooling systems into the space where the compressor is located. This information must be relayed to the HVAC systems engineer for space conditioning if necessary. Good ventilation is mandatory in the area of the compressor.

Selection of the proper type of pump foundation and mounting depends upon the lowest frequency and magnitude of pump vibration and the load-bearing requirement of the slab upon which the compressor rests. Metal, rubber, coils, and spring type materials are available for use as isolators. The manufacturers

of isolators should be consulted to confirm the proper type for the purpose and conditions expected.

Vibration isolation is achieved by the proper selection and placement of resilient devices between the pump base and the building structure. This is accomplished by placing isolators between the pump and the floor, flexible connections on all piping from the compressor, and spring type hangers on the piping around the compressor for a distance of about 20 ft.

Sizing Receivers — Air receivers are used to keep compressors from working continuously. They store air at a higher pressure, allowing the compressor to shut down until the volume used causes the pressure to drop. Then the compressor starts the cycle again.

Air receivers should be placed as close to the compressor as is possible. A flexible connection should be used to isolate the vibration of the compressor from the receiver.

The size of the receiver is a function of time and pressure. One formula commonly used to determine size is the following:

Equation 4-3

$$T = \frac{V\,(P_1 - P_2)}{C\,P}$$

Where

T = Time receiver will supply air from upper pressure to lower pressure (min)
V = Volume of receiver under design (ft^3)
P_1 = Upper pressure of air in receiver (psia)
P_2 = Lower pressure of air in receiver (psia)
C = System air requirements (scfm)
P = Atmospheric pressure at receiver location (psia) (14.7 psia)

The average value for T should be about 10 min. Then solve for the volume, selecting a standard tank as listed in a manufacturer's catalog. If the calculated size is too large, use a smaller T and consult the manufacturer. The receiver should be provided with an automatic drain trap and a pressure-relief valve.

Another commonly used approach is to have the receiver capable of providing a 1 minute supply of air at the pump's rated capacity, using the following formula:

Equation 4-4

$$V = C \times \frac{P}{P_1}$$

Instrumentation Pressure and temperature gauges located in the system can help identify problems and signal the need for maintenance. Put temperature gauges on the discharge of both the aftercooler and the dryer and on the cooling water inlet and outlet. Pressure gauges on each side of both filters and dryers and on the compressor discharge are useful for determining buildup and deposits.

Miscellaneous Design Considerations

1. Provide for the thermal expansion of pipe due to the possibility of 350°F air.
2. Take all branch connections from the tops of mains.

5 Vacuum-Air Systems

INTRODUCTION

This chapter describes criteria, production, and the piping distribution network for various vacuum-air systems. Because of the diverse uses and different design criteria for each type of vacuum-air system, this chapter is divided into the following separate sections: laboratory systems applications, and central vacuum-cleaning systems.

FUNDAMENTALS

"Vacuum" is defined as an air pressure that is less than atmospheric pressure. The vacuum level is the difference in pressure between the evacuated system and the atmosphere. Vacuum pressures generally used in the United States fall into three basic categories:

1. Rough (or coarse) vacuum, up to 28 in. Hg.
2. Medium (or fine) vacuum, up to 1 μ.
3. Ultra-high vacuum, greater than 1 μ.

In other parts of the world, the categories are often classified as follows:

1. Rough vacuum, 760 to 1 torr.
2. Medium vacuum, 1 to 10^{-3} torr.
3. High vacuum, 10^{-3} to 10^{-7} torr.
4. Ultra-high vacuum, greater than 10^{-7}.

The performance of any vacuum-air system is based on two factors: the flow volume, measured in cfm (L/min), and the maximum vacuum maintained in the system. For most vacuum systems to function, air becomes the transporting medium for any gas or suspended solids, and the pressure provides the energy for transportation. These two essential factors operate in inverse proportion—as the airflow increases, the vacuum pressure decreases. The various systems must be designed to produce specific vacuum pressure and airflow levels that have been determined, often by experience and experimentation, to be most effective in performing their respective tasks. The exception is where vacuum pressure is intended to produce a force used to lift objects or simply to evacuate an enclosed space. For these uses, airflow is only a function of how long it takes the system to achieve its ultimate vacuum pressure.

PRESSURE MEASUREMENT

While the definition of vacuum is straightforward, measuring a vacuum level (or force) is not. Several methods of measurement are used, with each depending on a different reference point.

To compute work forces and changes in volume, conversion to negative gage pressure (psig) or absolute pressure (psia) is required. The units used are inches of mercury (in. Hg) and the millibar (mb). These units originate from the use of a barometer. The basic barometer is an evacuated vertical tube with its top end closed and the open bottom placed in a container of mercury open to the atmosphere. The pressure, or "weight," exerted by the atmosphere on the open container forces the mercury up into the tube. At sea level, this pressure will support a column of mercury 29.92 in. high. In pressure units, this becomes 14.69 psi (99.89 kPa).

The two basic reference points for measuring vacuum are standard atmospheric pressure and a perfect vacuum. When the point of reference is standard atmospheric pressure, the vacuum pressure is called "gauge pressure." If the pressure level is measured from a perfect vacuum, the term is "absolute pressure." Local barometric pressure, which is the prevailing pressure at any specific location, should not be confused with standard atmosphere, which is mean barometric pressure at sea level.

At standard atmospheric pressure, 0 in. Hg is equal to 14.7 psig (101.4 kPa) and 29.92 in. Hg. For the ease of calculations, 14.7 psig is adjusted to 15 psig and 29.92 in. Hg is adjusted to 30 in. Hg. These minor deviations yield results well within the range of accuracy required for engineering calculations in this handbook. At the opposite end of the scale, 0 psia (a perfect vacuum) has an absolute value of 0 in. Hg and 29.92 in. Hg at sea level. Table 5-1 compares vacuum pressure from the two most commonly used reference points. Figure 5-1 gives conversions from one pressure unit to another. Table 5-2 gives numerical conversion multipliers for converting torr into various other vacuum-pressure units. Table 5-3 gives numerical conversions from in. Hg. to psia and in. Hg. absolute. Table 5-4 gives conversions from kPa to in. Hg.

On the dials of most pressure gauges, atmospheric pressure is assigned the value of 0. Vacuum measurements must have a value of less than 0. Negative gauge pressure is the difference between the system vacuum pressure and atmospheric pressure. Absolute pressure is the pressure (in psi) above a perfect

Table 5-1 Basic Vacuum-Pressure Measurements

Units			
Negative Gauge (psig)	Absolute Pressure (psia)	Inches of Mercury (in. Hg)	KiloPascals Absolute (kPa)
0	14.7	0	101.4
Atmospheric pressure at sea level			
-1.0	13.7	2.04	94.8
-2.0	12.7	4.07	87.5
-4.0	10.7	8.14	74.9
-6.0	8.7	12.20	59.5
-8.0	6.7	16.30	46.2
-10.0	4.7	20.40	32.5
-12.0	2.7	24.40	17.5
-14.0	0.7	28.50	10.0
-14.6	0.1	29.70	1.0
-14.7	0	29.92	0

Perfect vacuum (zero reference pressure)

Table 5-2 Conversion Multipliers for Vacuum Units

0.0010 torr = 1 micrometer mercury (μm Hg)
0.0075 torr = 1 pascal (Pa)
0.7501 torr = 1 millibar (mbar)
1.000 torr = 1 mm mercury (mm Hg)
1.868 torr = 1 in. water at 4°C (in. H_2O)
25.40 torr = 1 in. mercury (in. Hg)
51.71 torr = 1 lb/in.^{2} (psi)
735.6 torr = 1 tech. atmosphere (at)
750.1 torr = 1 bar
760.0 torr = 1 standard atmosphere (atm)

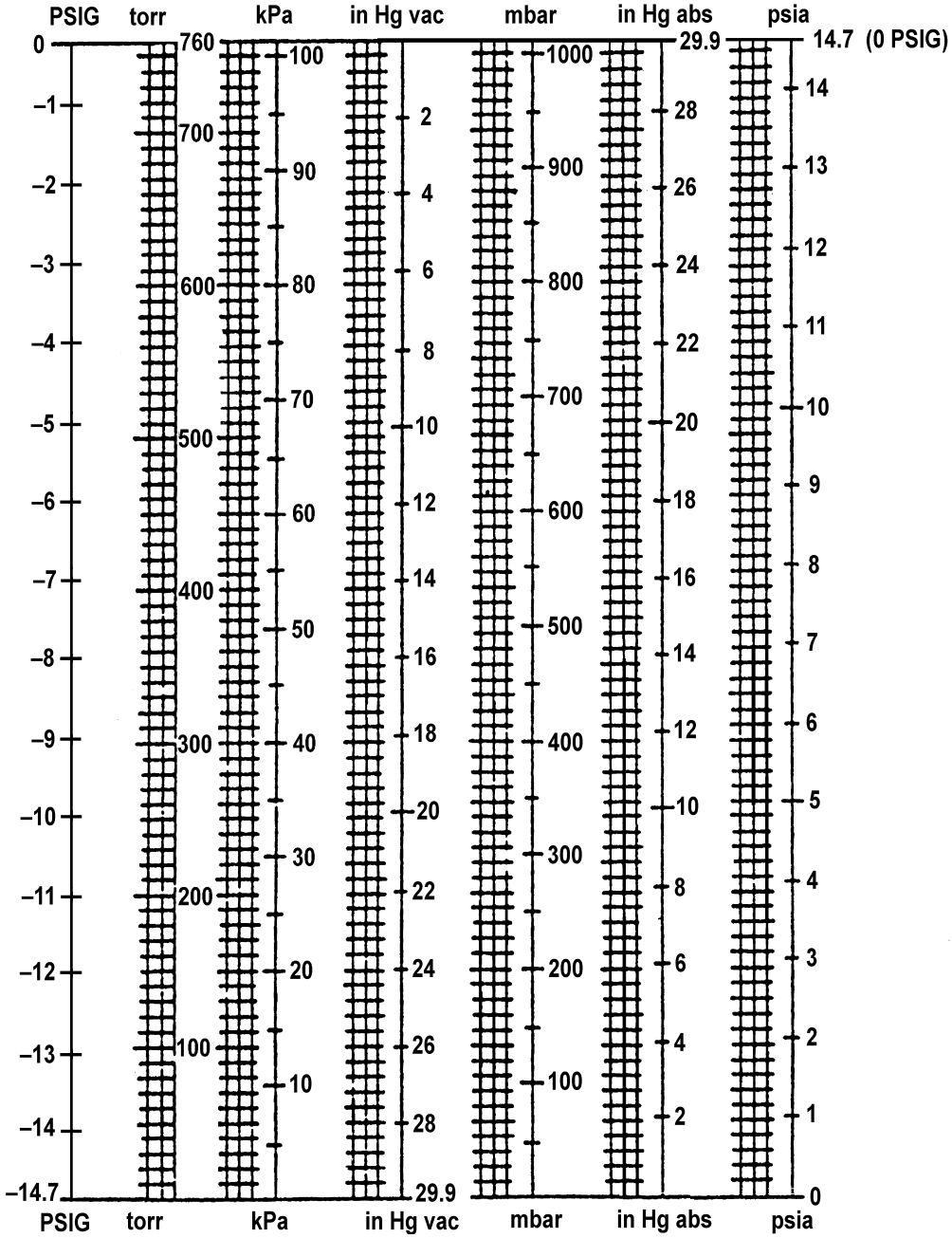


Figure 5-1 Conversion of Vacuum-Pressure Measurements

Table 5-3 Conversion of in. Hg to psia and in. Hg abs

in. Hg	in. Hg abs.	psia	in. Hg	in. Hg abs.	psia
0	29.92	14.70	24	5.92	2.9085
1	28.92	14.2086	25	4.92	2.4172
2	27.92	13.7173	26	3.92	1.9259
3	26.92	13.2260	27	2.92	1.4346
4	25.92	12.7347	28	1.92`	0.9433
5	24.92	12.2434	29	0.92	0.4520
6	23.92	11.7521	29.12	0.80	0.3930
7	22.92	11.2608	29.22	0.70	0.3439
8	21.92	10.7695	29.32	0.60	0.2947
9	20.92	10.2782	29.42	0.50	0.2456
10	19.92	9.7869	29.52	0.40	0.1965
11	18.92	9.2955	29.62	0.30	0.1473
12	17.92	8.8042	29.72	0.20	0.0982
13	16.92	8.3129	29.82	0.10	0.0491
14	15.92	7.8216	29.83	0.09	0.0442
15	14.92	7.3303	29.84	0.08	0.0393
16	13.92	6.8390	29.85	0.07	0.0344
17	12.92	6.3477	29.86	0.06	0.0295
18	11.92	5.8564	29.87	0.05	0.0246
19	10.92	5.3651	29.88	0.04	0.0197
20	9.92	4.8738	29.89	0.03	0.0147
21	8.92	4.3824	29.90	0.02	0.0098
22	7.92	3.8911	29.91	0.01	0.0049
23	6.92	3.3998	29.92	0.00	0.00

Table 5-4 Basic Vacuum Pressure Conversion

kPa abs	in. Hg	in. Hg abs	psia
101.4	0	29.92	14.70
97.9	1	28.92	14.2086
94.5	2	27.92	13.7173
91.5	3	26.92	13.2260
87.77	4	25.92	12.7347
84.39	5	24.92	12.2434
81.01	6	23.92	11.7521
77.63	7	22.92	11.2608
74.19	8	21.92	10.7695
70.81	9	20.92	10.2782
67.43	10	19.92	9.7869
64.05	11	18.92	9.2955
60.67	12	17.92	8.8042
57.29	13	16.92	8.3129
53.91	14	15.92	7.8216
50.54	15	14.92	7.3303
47.09	16	13.92	6.8390
43.71	17	12.92	6.3477
40.33	18	11.92	5.8564
36.95	19	10.92	5.3651
33.57	20	9.92	4.8738
30.20	21	8.92	4.3824
26.82	22	7.92	3.8911
23.27	23	6.92	3.3998
19.99	24	5.92	2.9085
16.61	25	4.92	2.4172
13.23	26	3.92	1.9259
9.85	27	2.92	1.4346
6.48	28	1.92`	0.9433
3.10	29	0.92	0.4520
2.36	29.22	0.80	0.3930
1.35	29.52	0.70	0.3439
0.61	29.72	0.60	0.2947
0	29.92	0	0

vacuum and is equal to atmospheric pressure less negative gauge pressure.

Other vacuum units are atmospheres, torrs, and microns (μ). One standard atmosphere equals 14.7 psi, or 29.92 in Hg. Any fraction of an atmosphere is a partial vacuum and would equal negative gauge pressure. To calculate atmospheres knowing absolute pressure in psi, divide that figure by 14.7. A torr is $\frac{1}{760}$ of an atmosphere, and a micron is 0.001 torr. These units of measurements are very high vacuum pressures and so are generally used for research, industrial, or laboratory use.

GENERAL VACUUM CRITERIA

Conversion of scfm to acfm

Vacuum is used by having air at atmospheric pressure enter a piping system that has a lower pressure. Gas at atmospheric pressure will expand to fill the piping system. The air at standard, atmospheric pressure is called “standard cubic feet per minute” (scfm), otherwise known as “free” air, and the expanded air in the piping system is called “actual cubic feet per minute” (acfm). Another term used to indicate acfm is “inlet cubic feet per minute” (icfm). The acfm is greater than the scfm.

To convert scfm to acfm with a given pressure (in. Hg) and temperature (°F), use the following formula:

Equation 5-1

$$\text{acfm} = \text{scfm} \frac{29.92}{P} \times \frac{T + 460}{520}$$

Where

P = Actual pressure for the scfm being converted, in. Hg
T = Actual temperature for the scfm being converted, °F

For practical purposes, a numerical method for solving Equation 5-1 can be used if the temperature is always 60°F. At that temperature, the second part of the equation becomes unity. Table 5-5 gives numerical values for 29.92/P. To find acfm, multiply the scfm by the value found in Table 5-5 opposite the vacuum pressure.

A direct ratio for converting scfm to acfm for various pressures is given in Table 5-6.

Table 5-5 Numerical Value to Determine acfm from scfm

P	29.92 / P	P	29.92 / P
29.92	1.00	10.92	2.7399
28.92	1.0345	9.92	3.0161
27.92	1.0716	8.92	3.3542
26.92	1.1114	7.92	3.7777
25.92	1.1543	6.92	4.3236
24.92	1.2006	5.92	5.0540
23.92	1.2508	4.92	6.0813
22.92	1.3054	3.92	7.6326
21.92	1.3649	2.92	10.2465
20.92	1.4302	1.92	15.5833
19.92	1.5020	0.92	32.5217
18.92	1.5813	0.80	37.40
17.92	1.6696	0.70	42.0742
16.92	1.7683	0.60	49.8667
15.92	1.8793	0.50	59.84
14.92	2.0053	0.40	74.80
13.92	2.1494	0.30	99.7334
12.92	2.3157	0.20	149.60
11.92	2.5100	0.10	299.20

Notes: 1) Expanded air ratio, 29.92/P, as a function of pressure, P, (in. Hg).
2) 1 in. Hg = 3.38 kPa

Table 5-6 Ratio for Converting scfm to acfm (sL/s to aL/s)

in. Hg	kPa abs	Factor	in. Hg	kPa abs	Factor
1	97.9	1.05	16	47.09	2.15
2	94.5	1.1	17	43.71	2.3
3	91.15	1.1	18	40.33	2.5
4	87.77	1.15	19	36.95	2.73
5	84.39	1.2	20	33.57	3
6	81.01	1.25	21	30.20	3.33
7	77.63	1.3	22	26.82	3.75
8	74.19	1.35	23	23.37	4.28
9	70.81	1.4	24	19.99	5
10	67.43	1.5	25	16.61	6
11	64.05	1.55	26	13.23	7.5
12	60.67	1.62	27	9.85	10
13	57.29	1.75	28	6.48	15
14	53.91	1.85	29	3.10	30
15	50.54	2.0	29.92	0	60

Adjusting Vacuum-Pump Rating for Altitude

The rating of a pump at altitude is diminished from its full capacity rating at sea level. For each 1000-ft increase in altitude, atmospheric pressure drops by approximately 1 in. Hg. Refer to Table 5-7 for actual barometric pressure at various altitudes. As an example, for the city of Denver (at 5000 ft), the local atmospheric pressure is 24.90 in. Hg. Dividing 30 into 24.90 gives 83.3%. If a pump is rated at 25 in. Hg at sea level, 83.3% of 25 equals 20.8 in. Hg at 5000 ft. This is the vacuum pressure that would equal 25 in. Hg at sea level.

At altitudes above sea level, there is a reduction in the scfm delivered because of the difference between local pressure and standard pressure. The scfm must be increased to compensate for this difference. Table 5-8 presents a multiplication factor to accomplish this. To find the adjusted scfm, multiply the actual scfm by the factor found opposite the altitude where the project is located.

Table 5-7 Barometric Pressure Corresponding to Altitude

Altitude[a]		Barometric Pressure	
ft	m	in. Hg	kPa
-10,000	-3040	31.00	104.5
-500	-152	30.50	102.8
0	0	29.92	100.8
500	152	29.39	99.0
1,000	304	28.87	97.3
1,500	456	28.33	95.5
2,000	608	27.82	93.7
760	760	27.31	92.0
3,000	912	26.81	90.3
3,500	1,064	26.32	88.7
4,000	1,216	25.85	87.1
4,500	1,368	25.36	85.5
5,000	1,520	24.90	83.9
5,500	1,672	24.43	81.9
6,000	1,824	23.98	80.8
6,500	1,976	23.53	79.3
7,000	2,128	23.10	77.8
7,500	2,280	22.65	76.3
8,000	2,432	22.22	74.9
8,500	2,584	21.80	73.4
9,000	2,736	21.39	72.1
9,500	2,888	20.98	70.7
10,000	3,040	20.58	69.3

[a] Sea level = 0.

Table 5-8 Factor for Flow Rate Reduction Due to Altitude

Altitude		Factor Used for Required scfm
ft	m	
0	0	1.0
500	152	1.02
1,000	304	1.04
1,500	456	1.06
2,000	608	1.08
2,500	760	1.10
3,000	912	1.12
3,500	1,064	1.14
4,000	1,216	1.16
5,000	1,520	1.20
6,000	1,824	1.25
7,000	2,128	1.30
8,000	2,432	1.35
9,000	2,736	1.40
10,000	3,040	1.45
11,000	3,344	1.51

Note: 1 scfm = 0.472 sL/s

Time for Pump to Reach Rated Vacuum

The time a given pump will take to reach its rated vacuum pressure depends on the volume of the system, in cubic feet, and the capacity of the pump, in cfm, at the vacuum rated pressure. But simply dividing the system volume by the capacity of the pump will not produce an accurate answer. This is because the vacuum pump does not pump the same quantity of air at different pressures. There is actually a logarithmic relationship that can be approximated by the following formula:

Equation 5-2

$$T = \frac{V}{Q} N$$

Where

T = Time, min
V = Volume of system, ft^3
Q = Flow capacity of pump, cfm

N = Natural log, constant

Note: For vacuum up to 15 in. Hg, N = 1
For vacuum up to 22.5 in. Hg, N = 2
For vacuum up to 26 in. Hg, N = 3
For vacuum up to 28 in. Hg, N = 4

For the most accurate answer, obtain pump curves from the manufacturer and substitute the cfm capacity for the pump at each 5 in. Hg increment. Add them together to find the total time. The selection of the value for N depends on the highest level of system vacuum pressure and is constant throughout the several calculations.

Adjusting Pressure Drop for Different Vacuum Pressures

The chart for friction loss in a vacuum pipe presented later in this section (Table 5-11 and Table 5-12) is based on 15 in. Hg. For a given scfm and pipe size, the pressure loss at any vacuum pressure other than the 15 in. Hg the chart was developed for, can be found by dividing the pressure drop in the chart by the factor found from the following formula:

Equation 5-3

$$F = 30 - \frac{\text{new vacuum pressure(psi)}}{15}$$

Where
F = Factor to be multiplied by values in Table 5-11 and Table 5-12

Simplified Method of Calculating Velocity

Use the following formula to find the velocity of a gas stream under a vacuum:

Equation 5-4

$$V = C \times Q$$

Where
V = Velocity, fpm
C = Constant based on pipe size (Refer to Table 5-9.)
Q = Flow rate based on an absolute vacuum pressure, acfm

Example 5-1

Calculate the velocity of 100 scfm through a 2-in. pipe with a pressure of 20 in. Hg.

1. First, find the equivalent absolute pressure of 20 in. Hg. Using Table 5-9, read 9.92 in. Hg abs.
2. Convert 100 scfm to acfm at a pressure of 9.92 in. Hg abs. by using Table 5-6. Opposite 10 in. Hg read 1.5.
   $100 \times 1.5 = 150$ acfm
3. Refer to Table 5-9 to obtain C. This table has been developed from the flow characteristics of air in Schedule 40 pipe. Opposite 3-in. pipe read 19.53.
4. $V = 150 \times 19.53$
   V = 2930 fps

Table 5-9 Constant for Finding Mean Air Velocity

Sched. 40 Pipe Size, in. (NPS)[a]	DN	Constant	Sched. 40 Pipe Size, in. (NPS)[a]	DN	Constant
⅜	12	740.9	2½	65	30.12
½	15	481.9	3	75	19.53
¾	20	270.0	3½	90	14.7
1	25	168.0	4	100	11.32
1¼	32	96.15	5	125	7.27
1½	40	71.43	6	150	5.0
2	50	42.92	8	200	2.95

a 1 in. = 25.4 mm

Vacuum Work Forces

The total force of the vacuum system acting on a load is based on the vacuum pressure and the surface area on which the vacuum is acting. This is expressed in the following formula:

Equation 5-5

$$F = P \times A$$

Where

F = Force, psi
P = Vacuum pressure, psig
A = Area, $in.^2$

Since the above formula is theoretical, it is common practice to use a safety factor that is in the range of 3 to 5 times the calculated force to compensate for the quality of the air seal and other factors, such as the configuration of the load, and outside forces, such as acceleration.

SYSTEM COMPONENTS

General

Vacuum is produced by a single or multiple vacuum pump source drawing air from remote vacuum inlets or equipment. Except for some industrial applications, vacuum pumps withdraw air from a receiver to produce the vacuum. The piping distribution system is connected to the receiver. The pump(s) are also connected to the receiver and maintain the desired range of vacuum as the demand rises or falls, depending on the number of inlets that open or close. When the system vacuum pressure drops to a predetermined level, additional pumps are started. When the desired high level of vacuum is reached, the pumps could be shut off. Larger units may be constantly operated, loading, unloading, or bypassing on demand. Often, there is a timer on the system that allows the pumps to run for a longer time than is required by system pressure to prevent rapid cycling.

Air exhausted from the system must be discharged to the atmosphere by means of an exhaust piping system. The pipe size shall be large enough so as not to restrict the operation of the vacuum pump. To size the exhaust piping, refer to Table 5-10, using the equivalent length of exhaust piping as the length of piping.

Table 5-10 Vacuum-Pump Exhaust Pipe Sizing

Total Vacuum Plant Capacity, All Pumps		Equivalent Pipe Length, ft (m)						
		50 (15.2)	100 (30.4)	150 (45.6)	200 (60.8)	300 (91.2)	400 (121.6)	500 (152)
scfm	sL/s	Pipe Size, in. (DN)[a]						
10	4.72	2 (50)	2 (50)	2 (50)	2 (50)	2 (50)	2 (50)	2 (50)
50	23.6	2 (50)	2½ (65)	3 (75)	3 (75)	3 (75)	3 (75)	3 (75)
100	47.2	3 (75)	3 (75)	3 (75)	4 (100)	4 (100)	5 (125)	5 (125)
150	71	3 (75)	4 (100)	4 (100)	4 (100)	5 (125)	5 (125)	5 (125)
200	55	4 (100)	4 (100)	4 (100)	5 (125)	5 (125)	5 (125)	5 (125)
300	142	4 (100)	5 (125)	5 (125)	5 (125)	6 (150)	6 (150)	6 (150)
400	189	5 (125)	5 (125)	6 (150)	6 (150)	6 (150)	8 (200)	8 (200)
500	236	5 (125)	6 (150)	6 (150)	6 (150)	8 (200)	8 (200)	8 (200)

[a]1 in. = 25.4 mm

Alarms are required for maintenance purposes or to annunciate trouble in the system (generally inadequate vacuum pressure). Specific alarms are mandated by code for health-care facilities.

Vacuum Pumps

The principal types of vacuum pump are divided into two general groups: gas transfer and capture. Capture pumps are not used in pharmaceutical facilities and are, therefore, outside the scope of this handbook.

Gas-Transfer Pumps

Gas-transfer pumps are essentially air compressors that use the vacuum system as their inlet and discharge "compressed" air to the atmosphere. The great majority of pumps used for most applications are gas-transfer pumps. They operate by removing gas from the lower-pressure system and conveying it to the higher pressure of the free air environment through one or more stages of compression provided by a vacuum pump. These pumps, also known as "mechanical rotary type pumps," are those used most often for industrial and laboratory purposes. Examples of gas-transfer pumps include:

1. Rotary vane (once-through-oil [OTO] type or oilless).
2. Reciprocating (rotary) piston pump.
3. Rotary lobe (roots) (ordinary lobe or claw type).
4. Screw.
5. Liquid ring.
6. Diaphragm.
7. Centrifugal (turbo).

Gas-transfer pumps are divided into positive displacement and kinetic types.

Seal Liquids

For liquid-ring pumps, a circulating liquid in the pump casing is an integral part of the pump operation. Commonly known as "seal liquid," it is not intended to refer to shaft or any other kinds of sealing.

Water used for sealing purposes must be continuously replaced. With no conservation, approximately 0.5 gpm/hp is used. Manufacturers have developed proprietary water conservation methods that typically reduce the usage to approximately 0.1 gpm/hp. Specific information about any water usage and additional space required must be obtained from each manufacturer.

Oil used for sealing purposes is recirculated and may have to be cooled. The pump does not require any water to operate. The oil eventually becomes contaminated and must be replaced on a regular basis. Typically, a running time of 1500 to 2000 hrs is the useful life of the seal oil. Specific information about additional space required must be obtained from each manufacturer. It may be necessary to install a running-time meter on these pumps to aid in maintenance. Pumps that use oil often require more installation space than those that don't.

Vacuum-Pressure Gauges

Manometer

A manometer is used to measure relative pressure between the system and local barometric pressure. It consists of a cylindrical "U" tube partially filled with liquid. One end is connected to the system being measured and the other end could be open or closed. The difference between the liquid levels in each vertical leg of the "U" tube is used to calculate the pressure.

Bourdon Gauge

An often-used type of mechanical gauge is the Bourdon gauge. This type of gauge is used to measure the difference between the system vacuum pressure and local barometric pressure and is the most widely used type of gauge.

Diaphragm Gauge

The diaphragm gauge measures the pressure difference by sensing the deflection of a thin metal diaphragm or capsular element. Similarly to the Bourdon gauge, its operation relies on the deformation of an elastic metal under pressure.

Strain Gauge

Strain gauges also use the deflection of a diaphragm to produce a change in electrical resistance of the attached strain gauge.

Ancillary Equipment

A coalescing, or oil-mist, filter should be used on the exhaust of any pump that uses oil to prevent the discharge of that oil into the atmosphere. It can also be used to recover solvents from the discharge airstream.

A "knockout pot" is a device that removes entrained liquid or slugs of liquid, preventing them from entering the inlets of mechanical pumps used in industrial applications. It can be combined with an inlet filter in one housing.

Inlet filters are used to remove solids or liquids that may be present in the inlet airstream just prior to the air entering the pump. Various filter elements are available to remove particulates approximately 0.3 μ in size.

In some cases where the system as a whole has a high vacuum pressure, it is desirable to lower the vacuum pressure to a branch. This is done with an air-bleed valve on the branch where the lower vacuum pressure is desired. The valve is opened and air is allowed to enter the system. For precise control, a needle type valve is used.

LABORATORY VACUUM SYSTEMS

The laboratory vacuum system serves general chemical, biological, and physics laboratory purposes, principally drying, filtering, fluid transfer, and evacuating air from apparatus. The usual working pressure of standard vacuum systems is in the range of 15 to 20 in. Hg. In some cases, there is a need for "high" vacuum in the range of 24 to 29 in. Hg, which is usually produced with a separate vacuum pump. The major difference between laboratory and surgical/medical systems is that the laboratory vacuum system does not normally carry liquids, though some invariably are introduced into the system. Rather, it is used primarily for pumping down and maintaining a vacuum rather than transporting air or solids back to the source.

Codes and Standards

There are no codes and standards required to be used directly in the design of vacuum systems for laboratories. The most important requirements are those of the end user and good engineering practice.

Laboratories conducting biological work where airborne pathogens could be released are required to follow the appropriate biological-level criteria established by the NIH. For most biological installations, it is recommended that check valves be installed in each branch line to every room or area to prevent any cross discharge. In addition, the vacuum pump exhaust shall be provided with duplex 0.02-μ filters on the exhaust to eliminate all pathogenic particulates.

Vacuum Source

The vacuum source usually consists of two or more pumps designed to operate as system demand requires, a receiver used to provide a vacuum reservoir and to separate liquids from the vacuum airstream, the interconnecting piping betweem the pumps and receiver, and alarms. A duplex pump arrangement is usually selected if the system is critical to the operation of the laboratory. In some smaller installations where the vacuum system is not critical, it may be acceptable to have a single vacuum pump. The pumps selected should be oil free.

The two most comonly used pump types are the liquid ring and the sliding vane. A detail of a typical laboratory vacuum-pump assembly is illustrated in Figure 5-2.

Distribution Network

Piping for the distribution system shall be a corrosion-resistant material such as copper tube types K, L, or M; stainless steel; or galvanized steel pipe (usually schedule 40 ASTM A-53). Copper tube shall be hard temper except when installed underground, in which case, soft temper should be used. Whenever piping passes under areas subject to high surface loads, such as roadways and parking lots, it shall be protected by ducts or secondary containment. Although cost has a major influence on the selection of the piping material, the most commonly used material is copper tube type L, ASTM B-88 up to 4 in. in size, with soldered joints. Pipe 5 in. and larger is usually schedule 40 galvanized-steel pipe with threaded joints. Fittings shall have an extra long-turn radius pattern so as not to impede the flow of fluids in the pipe.

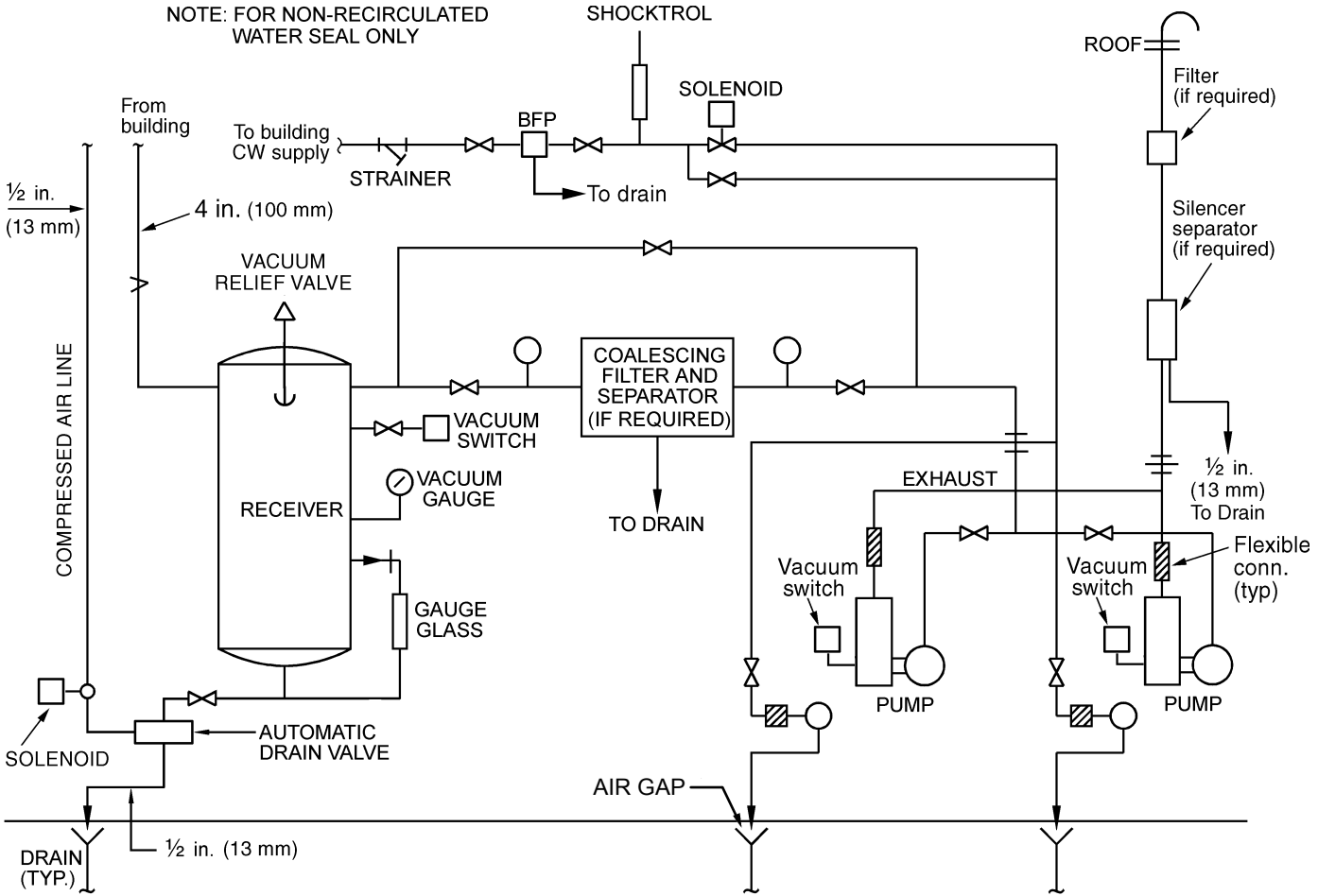


Figure 5-2 Typical Laboratory Vacuum Source

Sizing Criteria

Number of Inlets

There are no codes or other mandated requirements specifying the locations of laboratory vacuum inlets. The number of inlets is determined by the user, based on a set of program requirements for all rooms, areas, and equipment used in the facility. Inlets for laboratory stations, fume hoods, etc. shall be appropriate for the intended use, based on the requirements of the end user.

Flow Rate

The basic flow rate from each laboratory inlet shall be 1.0 scfm. This is a number based on experience. This flow rate is used in conjunction with the diversity factor.

Diversity Factor

The diversity factor established for general laboratories is based on experience. It has been found to be slightly more than that used for compressed air because the vacuum is often left on for longer periods of time. Refer to Figure 5-3 for a direct reading chart to determine the adjusted general laboratory vacuum flow rate using the number of connected inlets.

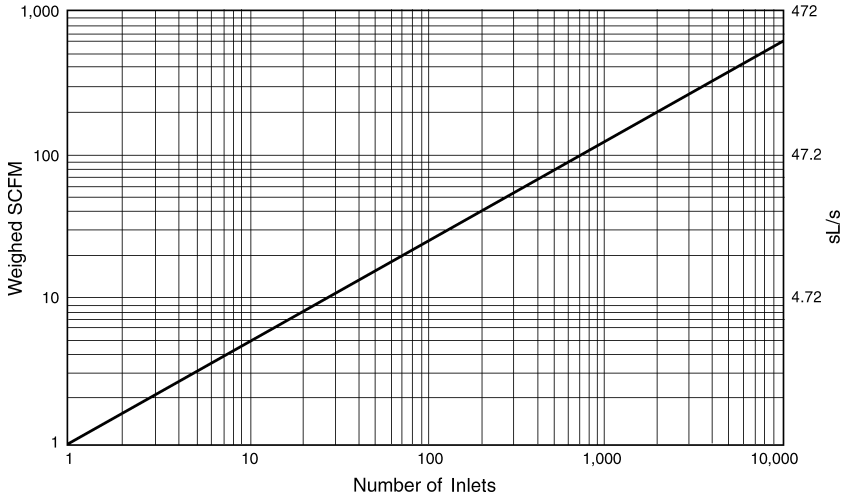


Figure 5-3 Direct Reading Vacuum Flow Rate Chart

For the design of classrooms, the diversity factor for one and two classrooms on one branch is 100%. For more than two classrooms, use a diversity factor that is double that for compressed air in Table 13-13 but never less than the largest scfm calculated for the first two rooms. Since the above flow rates and diversity factors are based on experience, they must be used with judgment and modified if necessary to adjust for special conditions and owner requirements. Always consult the user for definitive information regarding the maximum probable simultaneous usage.

Allowable Friction Loss

A generally accepted figure used to size a piping system is to allow a friction loss of 3 in. Hg for the entire system (after the source assembly) and a maximum velocity

of 5000 fpm. If noise may be a problem, use 4000 fpm. For smaller systems, use a figure of 1 in. Hg for each 100 ft of pipe.

Vacuum-Pump Sizing

The source pump for laboratories is selected using the flow rate of gas calculated using all inlets, the diversity factor for the whole facility, and the required vacuum pressure. It has been found that in most facilities vacuum pumps are oversized.

If the pump manufacturer expresses the flow rate in acfm, scfm is calculated from the total connected inlets, the diversity factor, and Equation 5-1. The stopping point of the pump is the required vacuum level to support all processes. The exhaust and interconnecting piping is similar to a surgical/medical vacuum system.

Piping-Network Sizing

The following method is used to size the pipe at each design point:

1. Calculate the adjusted scfm at each point, using the connected scfm reduced by the diversity factor at each point.
2. Calculate the allowable friction loss/100 ft of pipe.
3. Enter Table 5-11 for copper tube or Table 5-12 for steel pipe with the adjusted scfm and the allowable friction loss. Find the value equal to or less than the previously determined allowable pressure loss. Read the size at the top of the column where the selected value is found.

Table 5-11 Vacuum Pipe Sizing, Type L Copper Tubing

Maximum Velocity: 5000 fpm (25 m/s)		Pipe Diameter, in. (DN)							
		¾ (20)	1 (25)	1¼ (32)	1½ (40)	2 (50)	2½ (65)	3 (80)	4 (100)
scfm	sL/s	Pressure Drop, in. Hg / 100 ft[a]							
1	0.472	0.08							
2	0.944	0.27	0.08						
3	1.41	0.53	0.15						
4	1.9	0.88	0.25	0.09					
5	2.36	1.3	0.36	0.14					
6	2.83	1.8	0.50	0.19					
7	3.30		0.65	0.24	0.11				
8	3.77		0.82	0.30	0.13				
9	4.25		1.01	0.37	0.16				
10	4.72		1.22	0.45	0.20				
15	7.0			0.91	0.40	0.11			
20	9.5				0.66	0.18			
25	11.8					0.26	0.09		
30	14.1					0.36	0.13		
35	16.5					0.47	0.17		
40	18.9						0.21	0.09	
45	21.2						0.26	0.11	
50	23.6						0.32	0.14	
60	28.3						0.44	0.19	
70	33.0							0.25	0.06
80	37.7							0.31	0.08
90	42.5								0.10
100	47.2								0.12
125	59.0								0.18
150	71.0								0.25

a 1 in. Hg = 3.37 kPa

Table 5-12 Vacuum Pipe Sizing, Sched. 40 Steel Pipe

Maximum Velocity: 5000 fpm (25 m/s)		Pipe Diameter, in. (DN)							
		¾ (20)	1 (25)	1¼ (32)	1½ (40)	2 (50)	2½ (65)	3 (80)	4 (100)
scfm	sL/s	Pressure Drop, in. Hg / 100 ft[a]							
1	0.472	0.07							
2	0.944	0.22	0.07						
3	1.41	0.45	0.14						
4	1.9	0.75	0.24	0.06					
5	2.36	1.1	0.35	0.09					
6	2.83	1.56	0.48	0.13					
7	3.30		0.63	0.17	0.08				
8	3.77		0.81	0.21	0.10				
9	4.25		1.00	0.26	0.13				
10	4.72		1.21	0.32	0.15				
15	7.0			0.66	0.31	0.09			
20	9.5				0.52	0.15			
25	11.8				0.78	0.23	0.10		
30	14.1					0.32	0.14		
35	16.5					0.42	0.18		
40	18.9					0.54	0.23	0.08	
45	21.2						0.28	0.10	
50	23.6						0.34	0.12	
60	28.3						0.47	0.16	
70	33.0							0.22	0.06
80	37.7							0.28	0.07
90	42.5							0.34	0.09
100	47.2								0.11
125	59.0								0.17
150	71.0								0.23

a 1 in. Hg = 3.37 kPa

VACUUM-CLEANING SYSTEMS

This section discusses vacuum systems used for removing unwanted solid dirt, dust, and liquids from floors, walls, and ceilings. This can be accomplished by the use of either a permanent, centrally located system or portable, self-contained, electric-powered units. The central system transports the dirt to a central location where it can be easily disposed of or recovered.

Portable units can be easily moved throughout all areas of a facility. Their most common use is for clean rooms; a portable unit is kept within a clean room to handle spills. Another use is where controlled substances are used and must be accounted for. If there is a spill, the easiest method of cleanup is to have a portable unit brought to the accident area. The containment bag is weighed before the cleanup begins and again after the cleanup is completed. The difference is the weight of the controlled substance.

Types of System and Equipment

There are three types of permanent system: dry, wet, and a combination system. The dry system is intended exclusively for free-flowing, dry material. It is the most commonly used type, with cleaning capabilities ranging from cleaning carpets to removing potentially toxic and explosive product spills from floors in an industrial

facility. Equipment consists of a vacuum producer, one or more separators that remove collected material from the airstream, tubing to convey the air and material to the separator, and inlets located throughout the facility. There is a wide variety of separators to allow disposal and recovery of the collected material.

The wet system is intended exclusively for liquid handling and pickup. It is commonly found in health-care, industrial, and laboratory facilities where sanitation is important and frequent washings are required. Equipment consists of a vacuum producer, a wet separator constructed to resist the chemical action of the liquids involved, piping or tubing of a material resistant to the chemical action of the liquid, and inlets located throughout the facility.

A combination system is capable of both wet and dry pickup. Equipment consists of a vacuum producer, a wet separator constructed to resist the chemical action of the liquid mixtures involved, pipe or tubing of a material resistant to the chemical action of the combined solid/liquid, and inlets located throughout the facility.

Codes and Standards

There are no codes and standards governing the design and installation of vacuum-cleaning systems.

System Components

Vacuum Producer (Exhauster)

Vacuum producers for typical vacuum-cleaning systems consist of a single or multi-stage centrifugal type units powered by an electric motor. The housing can be constructed of various materials to handle special chemicals and of non-sparking aluminum for potentially explosive dust. The discharge of the unit can be positioned at various points to accommodate the requirements of the exhaust piping system.

Separators

Separators are used to remove the solid particulates in the airstream generated by the vacuum producers.

For dry type systems, tubular bag and centrifugal type separators can be used. If only dust and other fine materials are expected, a tubular bag type is adequate. The bag(s) are permanently installed and cannot be removed. They function as air filters for fine particles and collect a majority of the dirt. This dirt eventually falls into a hopper or dirt can at the bottom of the unit. To empty the entire unit, the system must be shut down. The bag(s) must be shaken to remove as much of the collected material as is practical and emptied into the dirt can. The dirt can is removed (or the hopper is emptied into a separate container) in order to clean out the unit. The dirt can should be sized to contain at least one full day's storage. Units are available with multiple bags to increase filter-bag area. Shaking can be done either manually or by motor operation. The motor-operated shaker has adjustable time periods to start operation after a variable length of time from shutdown of the system and for a variable length of time for the bags to be shaken. If continuous operation is required, dry compressed air can be used to blow through the bags and remove the dirt without requiring a shutdown.

The centrifugal type separator is designed to remove coarser, dry particles from the airstream. It is also recommended when more than six simultaneous operators are anticipated to remove the bulk of the dirt. The air enters the separator tangentially to the unit, forcing the air containing particulates into a circular motion within the unit. Centrifugal force accomplishes separation.

The wet separator system collects the liquid, separates the water from the airstream, and discharges the waste to drain. This type of separator can be equipped with an automatic overflow shut-off that stops the system if the water level reaches a predetermined high-water level and with automatic emptying features.

Immersion type separators are used to collect explosive or flammable material in a water compartment. If there is a potential for explosion, such as exists in a grain or flour-handling facility, the separator shall be provided with an integral explosion-relief/rupture device that is vented to the outside of the building.

Filters

Vacuum producers are normally exhausted to the outside air and usually do not require any filtration. However, when substances removed from the facility are considered harmful to the environment, a High Efficiency Particulate Air (HEPA) filter must be installed in the discharge line to eliminate the possibility of contamination of the outside air. The recommended location is between the separator and vacuum producer, but an alternate location immediately prior to penetration of the building wall or roof is also acceptable.

Silencers

When the exhaust from the vacuum producer is considered too noisy, a silencer shall be installed in the exhaust to reduce the noise to an acceptable level. Pulsating air flow will require special design considerations. Connection to silencers shall be made with flexible connections. Additional support for silencers is recommended. Filters and silencers can be economically combined into a single, integral unit.

Inlets

Inlets are female inlet valves and are equipped with self-closing covers. They provide a quick connection for any male hose or equipment. The cover can be locked as an option. Many different inlet types are available, in sizes ranging from 1½ to 4 in. and in various materials.

Control and Check Valves

Valves for the vacuum-cleaning system are different than standard valves. They are used to control the flow or stop the reverse flow of air in the vacuum-cleaning system. When used only fully open or closed, they are generally referred to as "blast gates." When used as regulating valves, they are called wafer "butterfly valves." A less costly substitute for a blast gate is an air-gate valve, which operates using a sliding plate in a channel. An air gate is illustrated in Figure 15-16B. The plate has a hole that matches the size of the opening in the channel, with room to close off the opening completely. Air gates can only be used in low-pressure systems and are generally available in sizes ranging from 2 to 6 in.

Air-Bleed Device

If the exhauster is constantly operated with low or no inlet air, there is a possibility that the exhauster motor will become hot enough to require shutdown due to

overheating. To avoid this, an air-bleed device can be installed on the inlet to the exhauster that will automatically allow air to enter the piping system. If the facility indicates that this may be a possibility, the manufacturer of the unit should be consulted to determine the need for this device for the system selected.

Pipe and Fittings

The most often-used pipe material is thin-wall tubing, generally in a range of 12 to 16 gauge. This tubing is available in plain carbon steel, zinc-coated steel, aluminum, and stainless steel. Fittings are specially designed for the vacuum-cleaning system. Tubing is normally joined using shrink sleeves over the joints. Compression fittings and flexible rubber sleeves and clamps are also used.

Tubing shall be supported every 8 to 10 ft, depending on size, under normal conditions.

Standard steel pipe is often used in areas where the additional strength is required. In special areas where leakage and strength are mandatory, the tubing joints can be welded if required.

Detailed System Design

Inlet Location and Spacing

The first step in system design is to locate the inlets throughout the facility.

The spacing of inlets depends on the length of hose selected for use. After this is decided, the inlet locations shall be planned in such a manner that all areas are capable of being reached by the selected hose length. This must take into account furniture, doorways, columns, and all obstructions. Some small overlap must be provided to allow for hose not being able to be stretched to the absolute end of its length. Consideration should be given to providing a 25 ft 0 in. spacing for areas where spills are frequent, heavy floor deposits may occur, and frequent spot cleaning is necessary.

Generally, there are several alternate locations possible for any given valve. Inlets should be placed near room entrances. Wherever possible, try to locate inlets in a constant pattern on every floor. This allows for the location of common vertical risers since the distance between floors is less than the distance between inlets. In any system, minimizing piping system losses by a careful layout will be reflected in a reduction in the power requirements of the exhauster.

The inlets should be located between 24 and 36 in. above the floor.

Determining Number of Simultaneous Operators

This is another major consideration for design purposes because an under-designed system will not produce the desired level of vacuum and an oversized system will be costly.

The maximum number of simultaneous operators is decided by the housekeeping or maintenance department of the facility and depends on a number of factors:

1. Is the preferred method to have gang cleaning? Is it possible to alter this practice in order to produce a less costly system?
2. What is the maximum number of operators expected to use the system at the same time?

3. Is the work done daily?

For commercial facilities where there may be no available information, the following guidelines, which are based on experience, can be used to estimate simultaneous use based on productivity. These figures consider the greater efficiency of a central system compared to portable units, often in the order of 25%. They must be verified and based on actual methods anticipated.

1. For carpets, 1 operator is expected to cover 20,000 ft^2 of area for regular carpeting in an 8-hr shift. For long or shag carpets, the figure is about 15,000 ft^2. Another generally accepted figure for short time periods is 3000 ft^2/hr for standard floors and 2500 ft^2/hr for shag and long carpets.
2. For hotels, an average figure of 100 rooms, including adjacent corridors, per 8-hr shift is expected. For long or shag carpets, the figure is about 75 rooms.
3. For theaters, use the number of seats divided by 1000 to establish the number of simultaneous operators.
4. For schools, 12 classrooms/day is an average figure for a custodian to clean in addition to other duties normally accomplished.

Inlet Valve and Hose Sizing

Experience has shown that 1½ in. is the most practical size for hose and tools used for cleaning floors, walls, and ceilings. Smaller, 1-in. size tools are used for cleaning production tools, equipment, and benches. Larger hose and tools are used for picking up large spills and cleaning large tanks, boxcars, and the holds of ships. Refer to Table 5-13 for general recommendations for tool and hose sizes.

Standard hoses are available in 25, 37.5, and 50-ft lengths. For general cleaning, the location of inlet valves should allow for convenient cleaning with a maximum of 50 ft 0 in. of hose. This represents a labor savings by halving the times an operator has to change outlets with a 25-ft hose. This length should not be exceeded, except for occasional cleaning, because of excessive pressure drop.

Table 5-13 Recommended Sizes of Hand Tools and Hose

Nominal Size		Average Floor Cleaning and Moderate Spills	Close Hand Work	Removing Heavy Sills or Large Quantities of Materials	Overhead Vacuum Cleaning	Standard Hose Length	
in.	DN					ft	m
1	25	Not used	Yes	Inadequate	Not used	8	2.4
1½	40	Excellent	Yes	Fair	Preferred	25 and 50	7.5 and 15
2	50	Good	No	Good	Poor	25 and 50	7.5 and 15
2½	65	Not used	No	Excellent	Not used	25 and 50	7.5 and 15

Source: Courtesy of Hoffman.

Locating the Vacuum-Producer Assembly

The vacuum-producer assembly consists of the vacuum producer, commonly called an "exhauster," and separators. The following shall be considered when locating the vacuum equipment:

1. Provide enough headroom for the piping above the equipment and to allow the various pieces to be easily brought into the room or area where they are to be installed.

2. An ideal location is on the floor below the lowest inlet of the building or facility and centrally located to minimize the differences at remote inlet locations.
3. A convenient means to dispose of the dirt should be close by. If a separator is used, an adequately sized floor drain is required.
4. Enough room around the separators shall be provided to allow for easy inspection, and, where the dirt bins must be emptied, room must be provided for the carts needed to move it. Dry separators could also be located outside the building for direct truck disposal of the dirt if they are sufficiently protected.

Sizing the Piping Network

General After the inlets and vacuum equipment have been located, the layout of the piping system accomplished, and the number of simultaneous operators decided upon, the process of system sizing can begin.

Cleaning systems using hose and tools shall have sufficient capacity so that only one pass over the area being cleaned is necessary. With adequate vacuum, light to medium dirt deposits shall be removed as fast as the operator moves the floor tool across the surface. The actual cleaning agent is the velocity of the air sweeping across the floor.

Inlet Tool Size The recommended inlet sizes for hand tools and hose are given in Table 5-13.

Vacuum-Pressure Requirements and Hose cfm In order to achieve the necessary air velocity, the minimum recommended vacuum pressure for ordinary use is 2 in. Hg. For hard-to-clean and industrial type materials, 3 in. Hg vacuum pressure is required. The flow rate must be enough to bring the dirt into the tool nozzle. Refer to Table 5-14 to determine the minimum and maximum recommended flow rates of air and the friction losses of each hose size for the flow rate selected. For ordinary carpeting and floor-cleaning purposes, a generally accepted flow rate of 70 scfm is recommended.

Recommended Velocity The recommended velocity in the vacuum-cleaning piping system depends on the orientation of the pipe (horizontal or vertical) and the size. Since the velocity of the air in the pipe conveys the suspended particles, it should be kept within the recommended range. Refer to Table 5-15, which indicates recommended velocity based on pipe size and the horizontal or vertical orientation of the pipe.

It is the air velocity that moves the dirt in the system. Oversizing the pipe will lead to low velocity and poor system performance.

Pipe Sizing

Selecting the Simultaneous Number of Outlets in Use — Facilities may have many inlet valves, but only a few will be used at once. Under normal operating conditions, these inlets are chosen at random by the operators. As an aid in the determination of simultaneous usage, the following conditions should be expected:

1. Adjacent inlet valves will not be used simultaneously.

Table 5-14 Flow Rate and Friction Loss for Vacuum-Cleaning Tools and Hoses

Use	Nominal Size of Tools and Hose	Minimum Volume and Pressure Drop[a]		Maximum Volume and Pressure Drop[a]	
		Volume, scfm	Pressure Drop, in. Hg	Volume, scfm	Pressure Drop, in. Hg
Bench use	1-in. diam., 8-ft 1-in. flexible hose	40	1.20	50	1.90
White rooms or areas with very low dust content	1½-in. diam., 50-ft 1½-in. flexible hose	60	2.25	90	4.10
Usual industrial	1½-in. diam., 50-ft 1½-in. flexible hose	70	2.80	100[b]	4.80
Fissionable materials or other heavy metallic dusts and minute particles of copper, iron, etc.	1½-in. diam., 50-ft 1½-in. flexible hose	100	2.50	120	4.20
Heavy spills, cleaning railroad cars and ship holds	2-in. diam., 50-ft 2-in. flexible hose	120	2.60	150	3.80

Source: Courtesy of Hoffman.
Note: 1 scfm = 0.5 sL/s; 1 in. Hg = 3.4 kPa
a The pressure drop in flexible hose is 2½ times the pressure drop for the same length and size of Schedule 40 pipe.
b Can be exceeded by 10% if necessary.

Table 5-15 Recommended Velocities for Vacuum-Cleaning Systems

Nominal Tubing Size		Horizontal Runs of Branches and Mains and Vertical Down-Flow Risers		Vertical Up-Flow Risers	
in.	DN	Minimum Velocity, ft/min	Recommended Max. Velocity, ft/min	Minimum Velocity, ft/min	Recommended Max. Velocity, ft/min
1½	40	1800	3000	2600	3800
2	50	2000	3500	3000	4200
2½	65	2200	3900	3200	4700
3	75	2400	4200	3800	5100
4	100	2800	4900	4200	6000
5	125	3000	5400	4800	6500
6	150	3400	6000	5000	7200

Source: Courtesy of Hoffman.
Note: 1 ft/min = 0.3 m/min

2. For the purpose of calculating simultaneous use, the most remote inlet on the main, the inlet closest to the separator, and other inlet valves between these two will be assumed to be in use.
3. Where mains and outlets are located on several floors, the use of inlets will be evenly distributed along a main on 1 floor or on different floors.
4. For long horizontal runs on 1 floor, allow for 2 operators on that branch.

Sizing the Piping Network—Refer to Table 5-16 for selecting the initial pipe size based on the number of simultaneous operators. This table has been calculated to achieve the minimum velocity of air required for adequate cleaning. In this table, the term "line" refers to permanently installed pipe from inlet to separator and "hose" is the hose connecting the tool to the inlet. One-and-a-half-in. hose is recommended, except where the size of the material to be cleaned will not pass through the hose or a large volume of material is expected.

Table 5-16 Pipe Diameter Based on Simultaneous Operators

Line Diam.		Number of Operators	Number of Operators
in.	DN	70 scfm, 1½-in. hose	140 scfm, 2-in. hose
2	50	1	—
2½	65	2	1
3	75	3	2
3½	90	4	2
4	100	5	3
5	125	8	4
6	150	12	6
8	200	20	10

Source: Courtesy of Spencer Turbine.
Note: 1 scfm = 0.5 sL/s

After the initial selection of the pipe sizes, the actual velocity and friction loss based on anticipated flow rates in each section of the piping system should be determined using Figure 5-4. This chart is a more accurate method of determining the pipe size, friction loss, and velocity of the system. Enter the chart with the adjusted scfm and allowable pressure loss. Read the pipe size at the point where these two values intersect. If this point is between lines, use the larger pipe size. If any parameter is found to be outside of the calculated ranges, the pipe size should be revised.

Pipe sizing is an iterative procedure, and the sizes may have to be adjusted to reduce or increase friction loss and velocity as the design progresses.

Piping System Friction Losses With the piping network sized, the next step is to precisely calculate the worst-case total system friction losses, in in. Hg, to size the exhauster. This is calculated by adding together all of the following values, starting from the inlet that is most remotely located from the exhauster and continuing to the source.

1. Initial level of vacuum required. For average conditions the generally accepted figure is 2 in. Hg. For hard-to-clean material, industrial applications, and long shag type carpet, the initial vacuum should be increased to 3 in. Hg.
2. Pressure drop through the hose and tool. Refer to Table 5-14 for the friction loss through individual tools and hose based on the intended size and length of hose and the flow rate selected for the project.
3. Loss of vacuum pressure due to friction of the air in the pipe. Losses in the straight runs of the piping system are based on the flow rate of air in the pipe at the point of design. Refer to Figure 5-4. Fittings are figured separately, using an equivalent length of pipe to be added to the straight run. Refer to Table 5-17 to determine the equivalent length of run for each type and size of fitting. Starting from the farthest inlet, use the cfm, the pipe size, the fitting allowance, and the pipe length along the entire run of pipe to find the total friction loss.
4. Loss through the separator. A generally accepted figure is 1 in. Hg loss through all types of separators. The exact figure must be obtained from the manufacturer.
5. Exhaust line loss. This can usually be ignored except for long runs. Allow 0.1 in. Hg as an average figure for a run of 100 ft.

Table 5-17 Equivalent Length of Vacuum Cleaning Pipe Fittings

Nominal Pipe Size		Equivalent Length of Pipe Fittings (ft)[a]	
in.	DN	90° Change in Direction	45° Change in Direction
1¼	32	3	1½
1½	40	4	2
2	50	5	2½
2½	65	6	3
3	75	7	4
4	100	10	5
5	125	12	6
6	150	15	7½
8	200	20	10

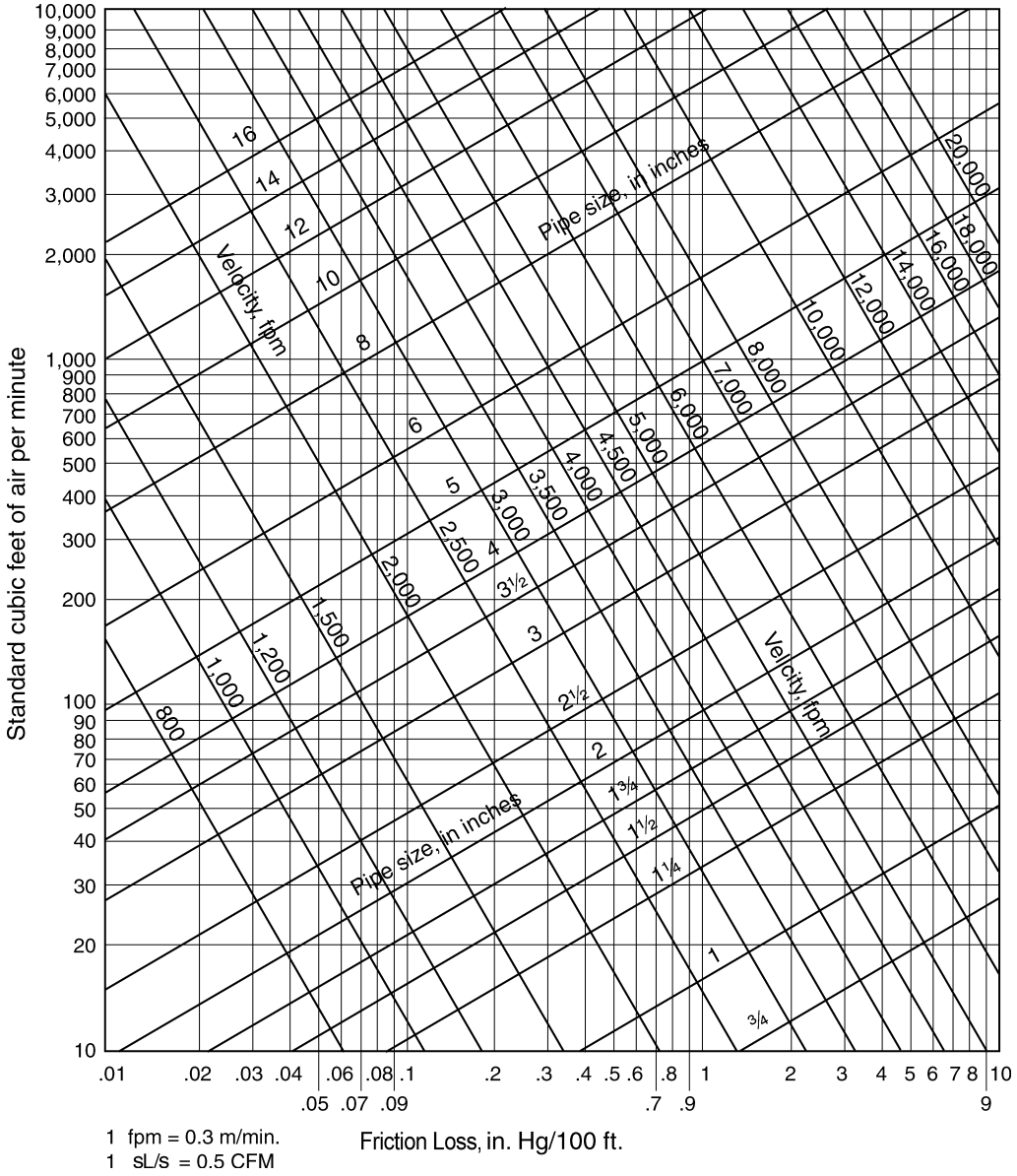
Notes: 1) For smooth-flow fittings, use 90% of these values.
2) 1 ft = 0.3 m
a Lengths based on use of cast-iron drainage fittings.

Vacuum-Producer (Exhauster) Sizing

Exhauster-Inlet Rating Determination It is now possible to size the exhauster. Two exhauster ratings must be known in order to select the size and horsepower: 1) the worst-case piping-system vacuum pressure losses and 2) the flow rate of air, in scfm, required by the system.

The vacuum pressure required from the exhauster is the total necessary to overcome all piping-system losses. This consists of the total pressure drop from all components in the piping network from the inlet farthest from the exhauster to the source. These include the initial inlet vacuum level required; the pressure lost through the tool and hose selected; the friction loss of air flowing through the piping system; the pressure lost through separators, filters, and silencers; and finally the exhaust pressure to be overcome, if required. These values are added together to establish the vacuum rating of the exhauster.

The flow rate of air entering the system, in scfm, is calculated by multiplying the number of simultaneous operators by the scfm selected as appropriate for the intended cleanup requirements. For smaller, less-complex systems, it is sufficient to use only the actual selected inlet cfm.



1 fpm = 0.3 m/min.
1 sL/s = 0.5 CFM

Figure 5-4 Vacuum Cleaning Pipe Sizing Chart
Friction loss, in in. of mercury per 100 ft of line with inlet air at 70°F and 14.7 psia

Source: Courtesy of Spencer Turbine.

Separator Selection and Sizing The separator is sized based on the cfm of the vacuum producer and the type of material expected to be collected. Refer to Table 5-18 for classification of the material that is expected to be collected.

For dry separators, a starting point for sizing would provide a ratio of filter bag area to bag volume of 6:1 for smaller volumes of coarse material and of 3:1 for fine dust and larger quantities of all material. Wet and centrifugal separator sizing

Table 5-18 Classification of Material for Separator Selection

Size of Material	Very Fine		Fine		Granular		Lumpy		Irregular
	Recommended Sep. (S)	Ratio Vol. Bag Area	Recommended Sep. (S)	Ratio Vol. Bag Area	Recommended Sep. (S)	Ratio Vol. Bag Area	Recommended Sep. (S)	Ratio Vol. Bag Area	Separator Selection & Bag Area
Small	Cent.	Not appl.	Cent.	Not appl.	Cent.	Not appl.	Cent.	Not appl.	dependent on material
Medium	TB	6:1	Cent. and TB	6:1	Cent.	Not appl.	Cent.	Not appl.	
Large	Cent. and TB	3:1	Cent. and TB	6:1	Cent. and TB	6:1	Cent.	Not appl.	

Source: Courtesy of Spencer Turbine.

Notes: 1) Centrifugal separators do not utilize bags.

2) Definition of terms:
Small: Light accumulations, such as those found in clean rooms, white rooms, laboratories, and so on.
Medium: Average accumulations, such as those found in classrooms, motels, assembly areas, and so on.
Large: Heavy accumulations, such as those found in foundries, spillage from conveyor belts, waste from processing machines, and so on.
Fine: 100 mesh to 8 in. (3.2 mm).
Very fine: Less than 100 mesh.
Granular: 8 to ½ in. (3.2 to 12.7 mm).
Lumpy: Lumps ½ in. (12.7 mm) and over.
Irregular: Fibrous, stringy, and so on.

3) Abbreviations: Cent. = centrifugal; TB = tubular bag.

is proprietary to each manufacturer and dependent on the quantity and type of material expected to be removed.

Some automatic separator cleaning systems use compressed air to aid in dislodging the dust. The air pressure recommended is generally in the range of 100 to 125 psig.

Exhauster Discharge The discharge from the exhauster is usually steel pipe routed outside the building. It is also possible to route the exhauster discharge into an HVAC exhaust duct, which is routed directly outside the building.

For a piped exhaust, if the end is elbowed down, it shall be a minimum of 8 ft 0 in. above grade. If the end is vertical, an end cap shall be installed to prevent rain from entering the pipe. A screen will prevent insects from entering. The size shall be equal to or 1 size larger than the size of the pipe into the exhauster. Use HVAC ductwork sizing methods to find the size of the exhaust piping while keeping the air-pressure loss to a minimum.

The pressure loss through the exhaust pipe shall be added to the exhauster inlet pressure drop, the total of which will be calculated into the pressure that the exhauster must overcome. For short runs of about 20 ft 0 in., this can be ignored.

Exhauster Rating Adjustments

CFM Adjustment for Long Runs — For systems with very long runs or complex systems with both long and short runs of piping, some adjustment in the selected inlet cfm shall be made. This is necessary because the actual cfm at the inlets closest to the exhauster will be greater than the cfm at the end of the longest run due to the lower friction loss. The adjustment will establish an average inlet cfm flow rate for all inlets that will be used for sizing instead of the selected inlet cfm.

In order to establish the adjusted cfm, it is necessary to calculate separately the total system friction loss for the branch lines containing the inlets nearest and farthest from the exhauster. Following the procedures previously explained will result in minimum and maximum system friction loss figures. The following formula is used to calculate the adjusted cfm:

Equation 5-6

$$\text{adjusted cfm} = \frac{\text{farthest inlet friction loss (in. Hg)}}{\text{closest inlet friction loss (in. Hg)}} \times \text{selected cfm}$$

The adjusted cfm figure is used instead of the selected cfm and is multiplied by the number of simultaneous operators to size the exhauster.

Adjustment Due to Elevation — All of the above calculations are based on scfm. If the project location is above sea level, the scfm should be adjusted to allow for the difference in barometric pressure. Refer to Table 5-8 for the correction factor. This factor shall be multiplied by the scfm figure to calculate the adjusted cfm, which is used in sizing the exhauster.

Adjustment for Different CFM Standards — Another adjustment to the scfm figure used to size the exhauster may be required if the equipment manufacturer uses the inlet cfm (icfm) instead of the scfm. "Inlet cfm" is the actual volume of air at the inlet

of the exhauster determined using local temperature and barometric conditions. Previously discussed temperature and barometric conversions shall be used.

To convert scfm to acfm, refer to Equation 5-1.

General Design Considerations

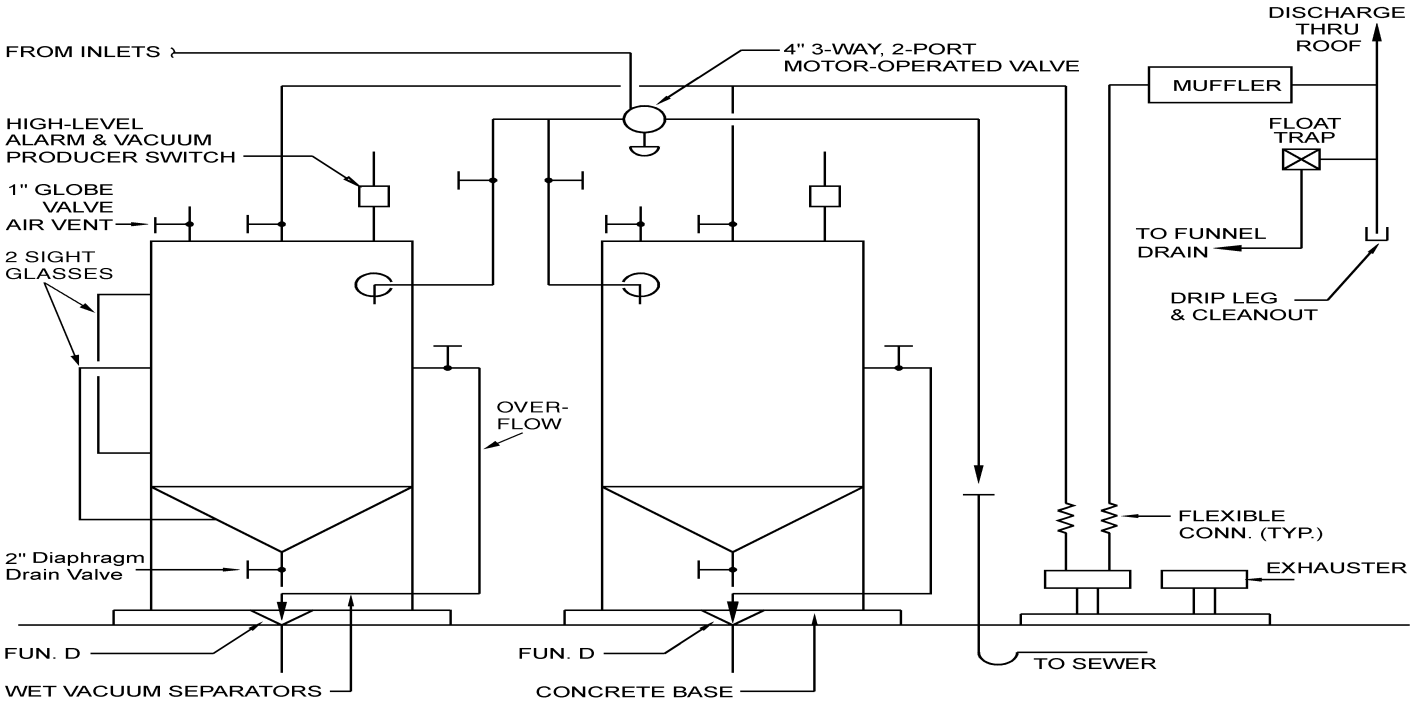
"Abrasion" is the wearing away of the interior of the pipe wall by large, hard particles at the point where these particles strike the pipe. The effects are greatest at changes in the direction of the pipe, such as at elbows and tees and under the bag plates of separators. When abrasive particles are expected, it is recommended that either cast-iron drainage fittings or schedule 40 steel pipe fittings using sanitary pattern sweeps and tees be substituted for the normally used tubing materials.

It is good practice to provide a safety factor of extra cfm to ensure that additional capacity is available from the exhauster without its affecting the available vacuum. This safety factor should not exceed 5% of the total cfm and is used only when selecting the exhauster, not for sizing the piping system. Select the exhauster size and then add the safety factor. The unit selected should have the extra flow available.

The piping shall be pitched toward the separator. Install plugged cleanouts at the bases of all risers and at 90° changes in direction to allow any blockages to be cleared easily.

Piping geometry in the design of wet system piping could become critical. Every effort shall be made to keep the piping below the inlet valves to prevent any liquid from running out of the inlet after completion of the cleaning routines and to ease the flow of the liquid into the pipe. The wet system pipe should pitch back to the separator at about ⅛ in./ft. All drops should be no larger than 2 in. in size and only 1 inlet shall be placed on a single drop. Each drop should terminate in a plugged tee facing down. This allows any liquid still clinging to the sides of the pipe to collect at the bottom of the riser and be carried away the next time the system is used.

A typical schematic of a wet vacuum-cleaning source is illustrated in Figure 5-5.



SCHEMATIC OF TYPICAL WET VACUUM CLEANING PUMP ASSEMBLY

Figure 5-5 Schematic of a Typical Wet-Vacuum Cleaning Pump Assembly

Source: Courtesy of Spencer Turbine.

6 Cryogenic Storage of Gases

INTRODUCTION

This chapter describes the bulk storage of cryogenic liquids used for laboratory purposes. For the purposes of this manual, the definition of a "cryogenic gas" is any gas in a liquid state at a temperature of –20°F (–28.9°C) or lower. There are two reasons to consider the cryogenic storage of gases. The first is where a facility uses a large volume of gas and desires storage on site for practical and economical reasons. The second is where a cold liquid is required for research, cooling, and other purposes.

BULK STORAGE

When the volume of gases expected to be used is large enough, it is often economical and practical to store these gases as cryogenic liquids. The reason for this is volume. The cold liquid occupies considerably less volume than a comparable quantity of compressed gas. The most commonly used gases stored as cryogenics are nitrogen, argon, and oxygen. Also available but less commonly used are carbon dioxide, hydrogen, and helium.

CODES AND STANDARDS

The following codes are used in the fabrication of cryogenic liquid storage tanks:

1. Underwriters Laboratories, UL-644.
2. ASME *Code for Unfired Pressure Vessels*.
3. NFPA 50, 50A, and 50B.
4. NFPA 99, *Health Care Facilities,* is often used as a standard for laboratories.

SYSTEM COMPONENTS

The major components of a cryogenic storage system include the bulk-storage tank that contains a gas in liquid form, a vaporizer if a gas is desired, and the piping network conveying either gas or liquid to the point of use. A vaporizer is directly connected to the storage tank and is used to convert the liquid gas to its gaseous state. Storage tanks are categorized as either large bulk tanks or smaller dewers.

TANKS

LARGE BULK TANKS

Refer to Table 6-1 for standard large-tank sizes. Large tanks are highly insulated and can be installed either horizontally or vertically. The vertical position is most common because the vertical tank occupies less site area than a horizontal one does. Another reason is that the vertical tank presents less wetted area for the liquid to vaporize, and it is desirable to keep the stored liquid in that state as long as it is possible. Tank dimensions vary slightly depending on horizontal or vertical

installation, but the greatest difference is only about 6 in. in length for the largest tanks. The horizontal tank is slightly smaller and lighter. All capacities are given in gallons of water. Many manufacturers have similar lines of tanks, with some standard sizes having a capacity as low as 300 gal. All tanks are ASME rated as unfired pressure vessels.

In locating the tanks on a facility site, enough room must be allowed for a delivery truck to approach the tanks closely. There must be easy access to the tank because an operator must vent gas from the hose connection of the truck to the storage tank by means of a manual vent before filling can start. Two connections to the cryogenic tank are provided. One is to the top of the tank in the vapor space and the other is in the lower portion of the tank in the liquid space. This allows the operator to adjust the pressure in the tank during filling. Filling from the bottom compresses the vapor at the top, increasing pressure. Filling from the vapor space lowers the pressure because some of the vapor condenses and turns back to liquid, thereby reducing the volume of vapor. If filling to a specific pressure, a pressure gauge shall be provided.

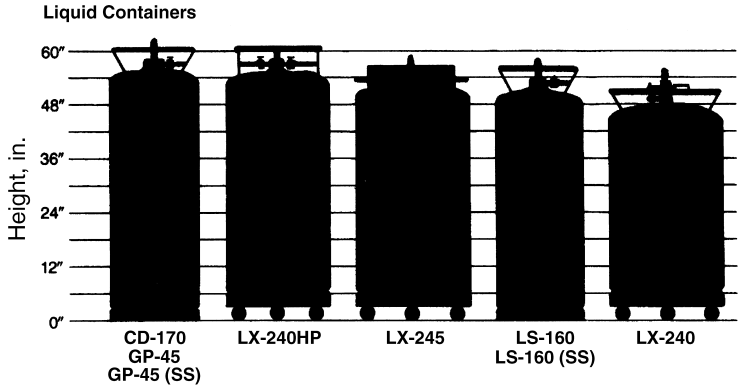
One important factor to consider is that there will be leakage of gaseous product from the cryogenic tank if no liquid product is withdrawn for a period of time.

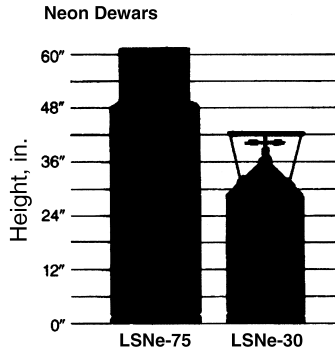
Table 6-1 Cryogenic Storage Tank Dimensions

Nominal Capacity, gal	Diameter	Height	Working Pressure, psig	Nominal Tare Weight, lb	Normal Evaporation Rate, %/day LOX
315	4'	8' 1"	250	2,600	0.90
525	4'	11' 1"	250	3,600	0.55
900	5'	11' 7"	250	5,500	0.40
1,500	5' 6"	15' 0"	250	9,100	0.35
1,500	5' 6"	15' 8"	150	10,800	1.5
1,500	5' 6"	6' 6"	150	11,000	1.5
3,000	8'	16' 7"	50	14,900	0.17
3,000	8'	16' 7"	250	20,360	0.50
3,000	8'	16' 4"	250	17,340	0.17
6,000	8'	9' 0"	250	34,500	0.30
6,000	8'	27' 0"	50	19,900	0.15
9,000	9' 6"	30' 9"	250	53,500	0.26
9,000	9' 6"	30' 9"	250	51,300	0.10
11,000	9' 6"	35' 7"	75	34,900	0.10
11,000	9' 6"	35' 7"	250	65,900	0.25
11,000	9' 6"	35' 7"	250	60,000	0.10
13,000	10'	36' 7"	72	41,000	0.10
13,000	10'	36' 7"	250	68,300	0.10
13,000	10'	36' 7"	250	74,100	0.25

Source: Minnesota Valley Engineering, Inc.
Note: LOX = Liquid oxygen

Each tank is insulated and is not intended to have a high internal pressure. The rising of pressure inside the tank resulting from internal vaporization of product will raise the pressure higher than the working pressure and will have to be vented to atmosphere from the relief vent. For comparison purposes only, the percent of liquid oxygen (LOX) lost in 1 day is included in Table 6-1.





Container Style	Outside Diameter (in.)	Overall Height (in.)	Average Tare Wt. (lbs.)
CD-170	20	63	280
GP-45	20	63	250
GP-45 (SS)	20	63	250
LSHe-30	20	48	120
LSHe-60	24	51	190
LSHe-100	24	59	220
LSHe-250	32	66	450
LSHe-500	42	74	675
LSNe-30	17	43	128
LSNe-75	20	62	225
LS-160	20	58	210
LS-160 (SS)	20	58	205
LX-240	26	56	250
LX-240HP	24	61	310
LX-245	26	59	265

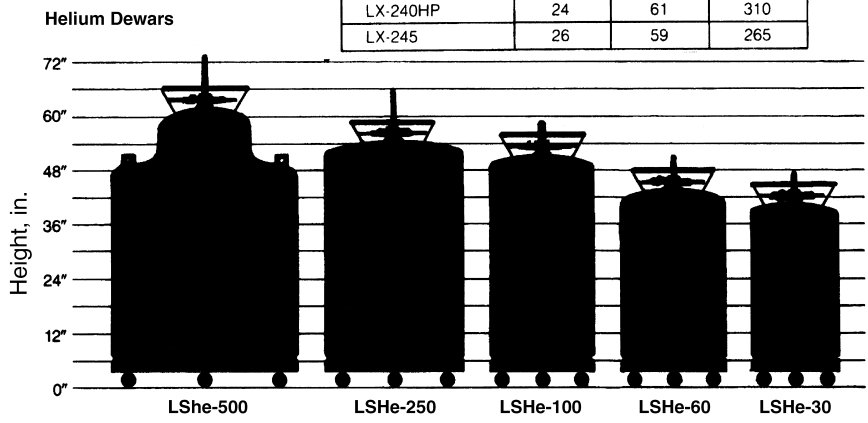


Figure 6-1 Cryogenic Container Dimensions

Dewers

"Dewers" are smaller, insulated tanks used to store smaller quantities of cryogenic gases in individual laboratories or outdoors if required for reasons of space. They can be manifolded together for larger storage capacities if desired. Standard-size dewers are illustrated in Figure 6-1 listed under "low-pressure stainless-steel drums."

Sizing the Large Bulk Tank

The amount of liquid to be stored is based on the volume of gas expected to be used between deliveries. The delivery schedule is a compromise between that preferred by the supplier and that preferred by the client. The most often suggested period of time between deliveries ranges from once to twice a month. Proceed with the sizing as outlined below:

1. Determine the proposed usage of each gas per day, shift, or week as closely as possible. This is best done based on past experience. If the installation is new, or this information is not available, calculate the expected usage based on the total number of outlets and connected equipment, the quantity of gas used by each, and the amount of time each day each is expected to be used.
2. Contact the intended supplier (or interview several if one supplier is not being used at the present time) to obtain the intended delivery schedule and price. Agree on a tank size based on a trade-off between keeping the tank as small as possible and having a reasonable supply between deliveries. A minimum of 2 weeks between supplies is a good starting point. Once a month is also a commonly used period of time.
3. Calculate the actual usable capacity of the storage tank(s) based on the proposed usage per day multiplied by the time, in days, between deliveries. Use Table 6-2 to convert gallons of liquid to cubic feet of gas.
4. Add 25% to the actual usable capacity found in step 3. This figure allows 15% for additional empty volume used as vaporization space above the allowable high liquid level when the tank is full and 10% for the additional volume occupied by the liquid gas present as a reserve capacity. This 10% should allow for a 2-day reserve supply of liquid to be in the tank when the low-level alarm point is reached, giving enough time for the supplier to send more product. An absolute low-level point should be 5% of capacity, which will trigger an emergency call to the supplier.
5. Another point to consider when filling a tank is that the pressure of nitrogen varies with temperature. Refer to Figure 6-2 for the relationship of density and pressure. The higher the pressure, the more liquid nitrogen can be loaded into the tank.
6. Vertical tanks must be installed on a concrete pad. The strength of the concrete should be a minimum of 3000 psi. The size of the pad should be a minimum of 6 in. larger than the diameter of the tank, and if there is additional equipment (e.g., a vaporizer), the pad should be enlarged accordingly. Manufacturers' recommendations indicate that the minimum bearing strength of the soil should be 2000 psi. In addition, the concrete should be

Table 6-2 Conversion of 1 Gallon of Liquid to Gas

Gas	Ft^3/ Gal
Nitrogen	93
Oxygen	115
Argon	112
Carbon dioxide	92
Helium	100
Hydrogen	113

Note: At atmospheric pressure.

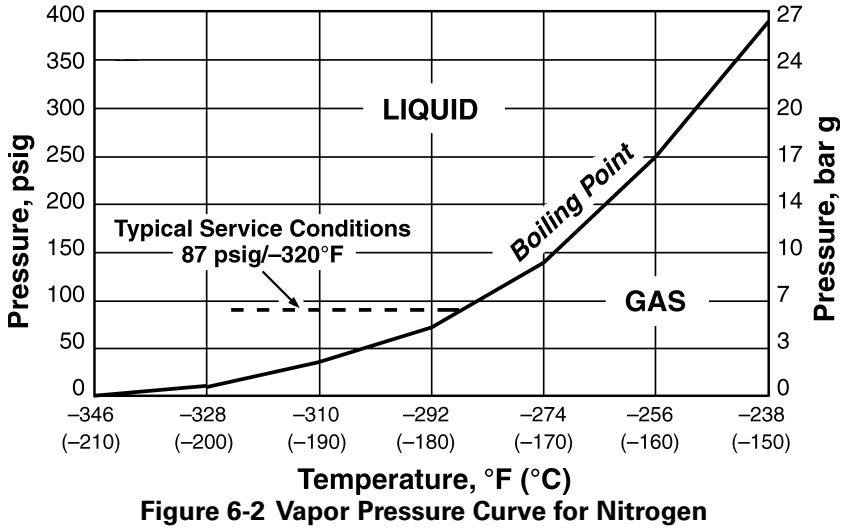


Figure 6-2 Vapor Pressure Curve for Nitrogen

poured over a 6-in. layer of crushed stone or gravel. The thickness of the pad depends on the capacity of the tank, and the pad should be reinforced. The reinforcement should be wire mesh for small pads and rebar each way (top and bottom) for larger pads. Since it may be required that the tanks be tested with water at some time during their lives, water weight must be used to determine the weight of the filled tank, which in turn is used to determine the tank foundation requirements. To estimate the total weight required to be supported, find the tare (empty) weight of the tank and use the capacity as if it is filled with water. For a quick estimate, multiply the capacity, in gallons, by 15.

Tank-pad thickness should conform to these minimums:

Less than 900-gal capacity	12 in. thick
1500 to 3000-gal capacity	15 in. thick
6000 to 9000-gal capacity	18 in. thick
11,000-gal capacity	21 in. thick
13,000-gal capacity	24 in. thick

Large horizontal tanks usually have piers located 8 ft 0 in. from each end of the tank. Smaller tanks have supports located ¼ of that distance from each end. It is necessary to design foundations based on the weight of the tank and contents spread between the two piers.

Vertical tanks are attached to their foundations by bolts connecting the legs on the tanks to the concrete pad. The bolts are supplied by the manufacturer and installed by the contractor supplying the pad. The specifications should require that the contractor install the tanks based strictly on manufacturers' requirements and under their supervision.

7. Cryogenic storage tanks are actually two tanks, one inside the other. The annulus is filled with insulation and a vacuum in order to provide a high degree of insulation. Storage tanks used only for gas supply are normally constructed for a working pressure ranging between 150 and 250 psig, with a pressure-relief valve set to 10% over the working pressure. If the low temperature were

not maintained, the liquid gas introduced into the tank during filling would vaporize instantly and the pressure inside the tank would quickly rise above the working pressure. If a filled tank is not used for a period of time, usually about 2 days, approximately ½ of 1% of the contents of the tank per day will be lost through the relief valve in order to maintain the set pressure.

Another option for having a storage-tank system installed is to allow the supplier to size, design, and install the tank based on a performance specification. It is then the responsibility of the supplier to size the storage system based on the provided usage criteria; if any mistake is made, it is the supplier's, assuming the usage information is correct. In many cases it is also possible to have the installation of the storage tank and equipment paid for by the supplier and the cost paid out over 7 to 10 years along with the cost of the gases.

The information required is as follows:

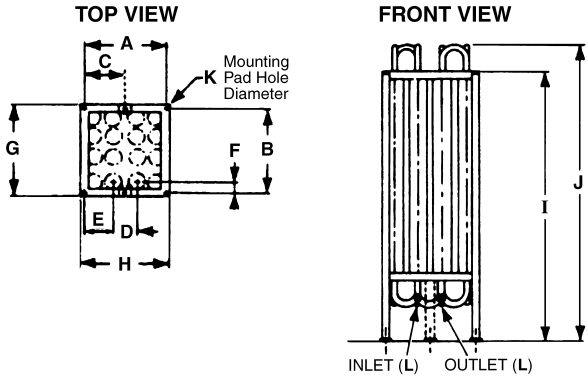
1. Location of the facility to determine outside air conditions. If site temperature ranges are available, provide this also.
2. Peak quantity of gas to be used in cfm and cfh (L/min or L/h). Indicate peak usage per day and week if possible. If this quantity is not obtainable, then indicate the use to which the gas will be put and the total number of outlets or stations in the facility.
3. Will the use of gas be constant or intermittent? If only a portion of the use is constant, the use is considered constant. This information is used to determine if a vaporizer is necessary and to size it based on usage.
4. Required pressure range of the gas.
5. The proposed location of the tank on the site. In determining this location, consideration must be given to easy road access to the location by the supply truck.
6. If the gas is flammable or reactive, separation of the tank from the building and any other material storage must be allowed for.

The Vaporizer

Bulk gases are stored as liquids and must be converted to gases prior to use. If the volume used by the facility is large, not enough liquid can be converted to gas inside the insulated storage tank to satisfy demand. To convert the necessary volume of liquid to gas, a device called a "vaporizer" is required.

The most often-used vaporizer has no moving parts and uses ambient air to warm the cryogenic liquid as it passes through a long length of finned tubing. The vaporizer is installed close to the storage tank, usually on the same pad as the storage tank. Each manufacturer has standard size units that are selected by the scfh, type of cryogenic liquid to be vaporized, and the lowest expected outdoor temperature. For typical sizes of atmospheric vaporizers, refer to Figure 6-3. If the expected volume is large, a vaporizer using an additional source of heat obtained from steam, electricity, or fuel gas may be required.

The most common material for the vaporizer is aluminum. If high purity is required, stainless steel is used. For preliminary sizing, based on a temperature of 70°F and 70% relative humidity, each 8 ft 0 in. length of 8-in. aluminum tubing with 8 fins/ft will vaporize 500 cfh. Manufacturer's have multiple methods of sizing vaporizers. Two items are necessary for sizing; the lowest mean ambient outside temperature



Model No. Nominal Flow Capacity	250 SCFH	500 SCFH	1000 SCFH	1500 SCFH	2000 SCFH	5000 SCFH
Part No. Drwg. No.	97-1450-9 D-9427	97-1451-9 C-9414	97-1454-9 C-12996	97-1452-9 D-9246	97-1453-9 D-12993	97-1455-9 D-12757
No. and Length of Elements	Four 3'	Four 6'	Six 6'	Nine 6'	Twelve 6'	Thirty 6'
Shipping Wt.	80#	150#	175#	250#	310#	510#
Maximum Working Pressure	350 psig	350 psig	350 psig	350 psig	350 psig	350 psig
Material	6063 Aluminum	6063 Aluminum	6063 Aluminum	6063 Aluminum	6063 Aluminum	6063 Aluminum
A	7½"	8⅛"	10⅜"	14⅜"	20⅝"	35⅜"
B	14"	10⅜"	14⅜"	16⅝"	16⅝"	29⅛"
C	—	—	—	—	—	17⅝"
D	6¼"	6¼"	6¼"	12½"	6¼"	18¾"
E	⅝"	15⁄16"	2 1⁄16"	15⁄16"	7 3⁄16"	8 1⁄16"
F	3⅞"	2 1⁄16"	15⁄16"	2 1⁄16"	2 1⁄16"	1 13⁄16"
G	11 7⁄16"	12¼"	18⅜"	18⅜"	18⅜"	30⅞"
H	11 7⁄16"	12¼"	12⅛"	18⅜"	24⅝"	37⅛"
I	42"	84 3⁄16"	84⅜"	84⅜"	90⅜"	90 3⁄16"
J	48"	89 9⁄16"	89¾"	89¾"	95¾"	95 9⁄16"
K	7⁄16" dia.	17⁄32" dia.	17⁄32" dia.	17⁄32" dia.	17⁄32" dia.	17⁄32" dia.
L	⅜" MPT Female coupling, located on top of unit	1" NPT Male half nipple	1" NPT Male half nipple	1" NPT Male half nipple	1" NPT Male half nipple	1" NPT Male half nipple

Figure 6-3 Ambient Air Vaporizers

for 72 hr and the flow rate of the gas. Aluminum vaporizers are rated at 400 psig, with stainless steel being rated higher.

The area under the vaporizer is constantly wet. This is due to the ice formed on the fins melting and dripping to the ground. Because of this, the immediate area must have good drainage or be provided with a drainage inlet.

A typical schematic detail of a bulk storage tank and vaporizer installation is shown in Figure 6-4.

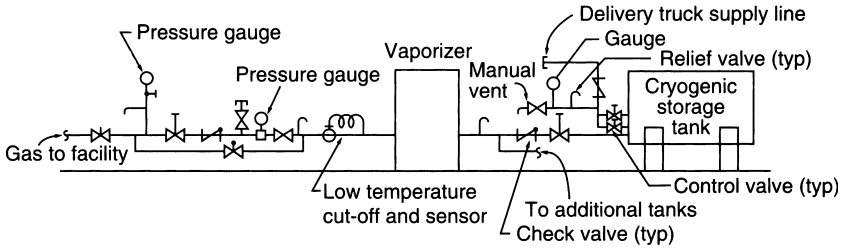


Figure 6-4 Detail of Large-Scale Storage Tank

Pressure-Relief Valves

Pressure-relief valves for over-pressure protection must be provided in all cases where gases or cryogenic liquids could become trapped between valves. For oxygen service, a condition known as "adiabatic compression" could occur. This is a situation where a gas at high pressure escapes into a region or pipe at a lower pressure then encounters an obstruction; the temperature of the gas suddenly rises to a very high temperature. This could cause auto-ignition of the pipe. For noncombustible or nonflammable gases, the pressure of the liquid turned to gas by absorbing heat could exceed the burst pressure of the pipe.

Pressure-relief valves shall be installed on a thermal standoff. They must be sized to vent the amount of gas needed to lower the pressure inside the tank or piping system. A pressure-relief valve shall be installed between any two valves. When the PRV goes off, it does not reset at the set pressure but, rather, at a pressure about 20 psig lower. This may cause excessive loss of gas if it is allowed to happen regularly. Another type of relief valve found on storage tanks is a rupture disk. This device is set to break at a predetermined pressure and cannot be reset; it is considered an emergency vent and is used when all other pressure-relief devices have failed to relieve pressure. All the contents of the tank are lost when the rupture disk is used.

Pipe Materials and Insulation

When a cryogenic liquid is desired, it must be piped from the point of origin to the point of use with the least amount of heat loss possible. In cryogenic work, it is impossible to separate the piping material from the insulation because, in most cases, the method of retarding heat loss from the network is an integral part of the pipe. The material of the piping system and the insulation used to keep the heat loss to a minimum must be a major consideration.

There are two general classes of preinsulated piping: double-wall piping with the annulus vacuum insulated and the single-wall piping with the pipe exterior thermally insulated. Vacuum-insulated piping is double walled. The vacuum could be either a static vacuum, where the annulus vacuum is factory accomplished during manufacturing, or a dynamic vacuum applied to the annulus by continuous vacuum pumping.

- **Double-wall piping with annulus under static vacuum** This double-wall system is usually manufactured from schedule 40, 304 SS with nonmetallic spacers used to keep the piping apart. The pipe is manufactured in sections with the vacuum applied to the annulus during the manufacturing process and simultaneously sealed. Pipe joints are assembled using a mechanical "bayonet" joint with an O ring to connect the sections, which consist of a long male section inserted into a female section and physically connected with a bolted flange. This provides a long heat-leakage path.
- **Double-wall piping with annulus under dynamic vacuum** This double-wall system is often manufactured from corrugated copper tube with nonmetallic spacers used to keep the piping apart. Pipe joints are assembled using a bayonet joint as previously discussed or a brazed joint using a silver brazing alloy. A connection to the outer double-wall pipe provides the inlet to a vacuum pump, which is used to produce the vacuum-insulating pressure.
- **Single-wall pipe with exterior thermal insulation** Typical pipe is most often made up of copper water tube (ASTM B88), type K or L, or stainless steel (type ASTM 304 or 316) preinsulated with high density Polyethylene (PE) of 2 lb/ft^2 from 1½ to 6 in. in thickness. Fittings are wrought copper. The pipe is jacketed with PVC 0.06 in. thick. The piping is preinsulated with space left between pipes so joints can be observed. Additional insulation is added after the pipe has completed testing. Copper pipe is joined by brazing, SS pipe by welding.

Pipe Sizing Methods

Cryogenic piping is sized based on the flow rate and head loss for the liquid. Because the specific gravity of the liquid is almost, but not always, less than that of water, water charts can be used for velocity and friction loss with the assurance that there is a slight safety factor. As an example, the specific gravity of liquid nitrogen is 0.81.

The available vapor pressure in the storage tank can be adjusted by setting the relief valve to a higher pressure, which is often required to overcome any static lift and friction loss through the piping. The vapor-pressure curve for nitrogen is given in Figure 6-2.

A combination of vapor and liquid in the same pipe is called a "two-phase flow." The flow rate of a two-phase flow is reduced compared to that of liquid flow alone. For laboratories that use small amounts of cryogenic liquid for freezer cooling or to fill dewers, two-phase flow is not important because only a small amount of liquid is desired after the gas is eliminated. There is a special fitting available for installation on the discharge pipe to separate the vapor from the liquid. It is important for facilities where there is an open-end discharge to provide adequate ventilation in the room to avoid an accumulation of gas.

A typical detail of a large-scale cryogenic storage tank is illustrated in Figure 6-4.

7 Animal-Care Facility Piping Systems

INTRODUCTION

This chapter discusses various piping systems uniquely associated with the physical care, health, and well-being of laboratory animals. Included are various utility systems for animal watering, water treatment, room and floor cleaning, equipment washing, cage flushing and drainage, and other specialized piping required for laboratory and experimental work within the facility. Other systems involved with general laboratory and facility work, such as those for compressed gases and plumbing, are discussed in their respective chapters.

GENERAL

It is expected that a facility involved with long-term studies will have different operating and animal drinking-water quality requirements than one used for medical research. For critical studies, the various utility systems shall incorporate design features necessary to ensure reliability and provide a consistent environment. As many variables as are practical (or desirable) shall be eliminated to ensure the accuracy of the ongoing experiments being conducted. Regardless of the facility type, different users and owners have individual priorities based on experiences, operating philosophies, and corporate cultures that must be established prior to the start of the final design phase of a project.

CODES AND STANDARDS

1. The local codes applicable to plumbing systems must be observed in the design and installation of ordinary plumbing fixtures and potable water and drainage lines for the facility.
2. 10-CFR-58 is the code (by the agencies of the federal government) for good laboratory practice for nonclinical laboratory studies.
3. 21-CFR-211, cGMP, requires compliance with FDA protocols for pharmaceutical applications.
4. NIH publication 86-23, *Guide for the Care and Use of Laboratory Animals.*
5. American Association for Accrediation of Laboratory Animal Care (AAALAC). Inspection and accreditation by the AAALAC is accepted by the NIH as assurance that the facility is in compliance with Public Health Services (PHS) standards.

ANIMAL DRINKING-WATER SYSTEMS

The purpose of the animal drinking-water system is to produce, distribute, and maintain an uninterruptible supply of drinking water with a specific and consistent range of purity to all animals in a facility. There are two general types of systems: an automated central-distribution system and individual water bottles.

System Types

The great majority of animals used by laboratories for medical and product research are mice, rats, guinea pigs, rabbits, cats, dogs, and primates. Smaller animals and primates are kept in stacked cages, often on racks. Medium-sized animals, such as dogs, goats, and pigs, are kept in kennels or pens. Larger floor areas are required for barnyard animals such as cows. Watering can be done either by an automatic, reduced-pressure, central system, which pipes water from the source directly to each cage, kennel or pen; or by separate drinking bottles or watering devices manually placed in individual cages or pens.

Automated, Central Supply-and-Distribution System

The purpose of an automated, central, drinking-water supply system is to automatically treat and distribute drinking water. Ancillary devices are used to flush the system and maintain a uniform and acceptable level of purity.

The system consists of a raw or treated water source, a purification system, medicinal and disinfection injection equipment if necessary, pressure-reducing stations, and a distribution piping network consisting of a low-pressure room-distribution piping system and a rack-manifold pipe terminating in a drinking valve for each cage or pen for the animals. Also necessary is an automated flushing system for the room-distribution piping activated by a flush-sequence panel, and a monitoring system to automatically provide monitoring of such items as drinking-water pressure, flow, and possible leakage.

Animals in cages are kept in animal rooms. Cages are usually placed in multi-tiered, portable or permanent cage racks, which contain a number of cages. The cage rack has an integral piping system installed, called a "rack manifold," that distributes the water to all cages. The rack manifold could be installed by the manufacturer or in the facility by operating personnel. The rack manifold receives its water from the room-distribution piping. The connection between the room-distribution piping and the rack manifold is made by means of a detachable recoil hose generally manufactured from Polypropylene (PP), nylon, or Ethylene-Propylene Diene Monomer (EPDM). This hose is flexible, generally ⅜ in. (12 mm) in size and coiled to conserve space. It will stretch to a length of about 6 ft 0 in. (2 m). Each end is provided with a quick-disconnect fitting used to attach the hose to both the room-distribution piping and the rack manifold.

To maintain drinking-water quality, a method of flushing the room-distribution piping and the rack manifold shall be provided. Ancillary equipment includes flushing and sanitizing systems to wash the recoil hose and the cage rack-piping interior.

Water Bottles

Drinking water bottles are individual units with an integral drinking tube that are placed by hand on a bracket in each cage. These bottles could be filled either by hand or automatically via a bottle filler.

Automatic bottle fillers should be considered to reduce the time necessary to fill bottles and minimize water spillage. Bottle fillers are available with manifolds to fit any size bottles. They can be supplied with purified water from a central water

supply and—with separate, programmable proportioners—could acidify, chlorinate, and medicate the water as required. The bottle filler automates the filling procedure so that the bottles are correctly positioned during filling and stops the flow when the water reaches a predetermined level.

Flushing System

In order to maintain drinking-water quality, the drinking-water distribution system should be flushed periodically. This is accomplished by having the same drinking water that is normally distributed to the animals flow through the piping system at an elevated flow rate, pressure, and velocity. The water is sent to drain and not recovered. This is initiated automatically at the drinking-water pressure-reducing station by the addition of separate regulating valves and pressure-regulating arrangements.

Different flushing arrangements are possible, depending on the cost, facility protocol, and purity desired. One method flushes only the main runs by the addition of a solenoid valve at the end of the main run and the provision of a return line to drain from this point. Another method is to flush the mains and the room-distribution piping by adding the solenoid valve at the end of each room-distribution branch with the return line to drain from each room. A third method flushes the entire system, including the rack manifold, by adding a solenoid valve on each cage connection to the room-distribution pipe, which flushes the recoil hose and the rack manifold.

It is accepted practice to replace all the drinking water in the room-distribution piping system at regular intervals, a minimum of twice daily. To approximate the amount of water in the pipe, allow 1 gal (4 L) for each 33 ft 0 in. (10 m) of pipe. General practice is to flush the system with water at about 15 psi (90 kPa) at a rate of 15 gpm (60 L/min). If the drinking water is not purified, it is recommended that the piping be flushed at least twice daily for about 2 min. For purified water, flush once daily for about 1 min. Flushing can be done manually by means of a valve in the pressure-reducing station enclosure or automatically by the addition of a bypass and solenoid valve around the low-pressure assembly to the pressure-reducing station. The sequence and duration of the automatic flush cycle is controlled from a flush-sequencer panel.

DRINKING-WATER TREATMENT SYSTEMS

The purpose of the drinking-water treatment system is to remove impurities from the raw-water supply to achieve the water quality required by the animals in the facility. In addition, disinfectant and medication can be added to the water during treatment if required.

Systems Description

There are no generally recognized and accepted standards for animal drinking-water quality. Purity and consistency requirements depend on the incoming water quality, the established protocol of the end user, the importance of either the initial or the operating cost of the proposed system, the species of animals housed in the facility, and the animal-housing methods. The overall objective is to eliminate as

many variables as possible for the entire period of time the studies or experiments are conducted.

The most often-used treatment for drinking water is reverse osmosis. Other possible treatment methods are distillation and deionization. A discussion of these purification methods appears in the chapter "Water Systems."

Reverse Osmosis

When a higher-quality water is required and other types of purified water are not available in a facility, reverse osmosis (RO) is normally selected. Since the amount of water is usually small, a package type unit mounted on a skid is provided and connected directly to the water supply. The RO system is flexible and, when used in combination with DI water supply, will provide water that is virtually contamination free.

Disinfection and Medication of Drinking Water

Disinfection chemical mixtures are added to the animal drinking-water supply to eliminate and control bacterial contamination in the central and room-distribution piping system. Medication is added to conform with experimental protocols if necessary. These mixtures are usually introduced into the piping system by a self-contained, central, proportioning (injector) unit using facility water pressure. Medication is added to the drinking water using the same proportioning equipment that adds disinfectant. All equipment is available in a wide range of sizes and materials. A schematic detail of a typical central proportioner is illustrated in Figure 7-1.

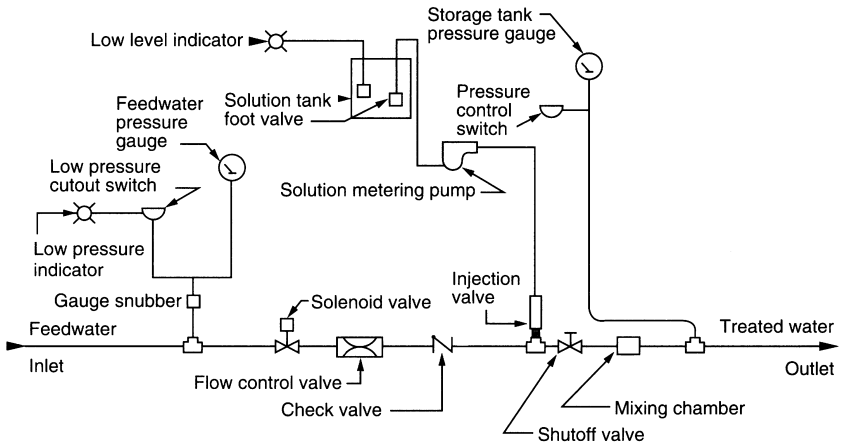


Figure 7-1 Typical Central Proportioning Unit

Chlorination Chlorination is a recognized biocidal treatment that leaves a residual of chlorine in the entire central-distribution system. Hyperchlorinated water is not as corrosive as acidified water and could be used with brass/copper distribution system components. Accepted practice is to provide a pH higher than 4, with a residual range of free chlorine between 5 and 12 ppm. Free chlorine in water dissipates in time with light, heat, and reaction with organic contaminants,

making it ineffective when water bottles are used. Chlorine creates toxic compounds in reaction with some water contaminants and medications.

Acidification Acidification has an advantage over chlorination in that it is more stable and lasts longer in the system. The disadvantage is that corrosion-resistant materials must be used. The pH range should be between 2.5 and 3 in order to be effective. A pH lower than 2.5 will cause the water to become "sour" and the animals will not drink it. At a pH above 3, the mixture is not considered an effective germicide.

DRINKING-WATER SYSTEM COMPONENTS AND SELECTION

Pressure-Reducing Station

The pressure-reducing station reduces the normal pressure of the raw-water supply to a level required for the animal-room drinking-water distribution system. As an option, a secondary system can be added to provide a higher pressure in the room-distribution system for flushing.

The pressure and flow rate depend on the type and number of animals to be supplied. Also usually included are a 5-μ water filter, a pressure gauge, and a backflow preventer. Timing devices that automatically control flushing duration are controlled by a remote flush-sequencer panel, which controls all flushing sequencing operations. The recommended pressures for animal-room piping distribution to various animals are as follows:

Small animals, such as	
Rats and mice	3-5 psig (20.4-34 kPa)
Primates	3-5 psig
Dogs and cats	3-5 psig
Swine and piglets	6-12 psig (41-81.6 kPa)

The secondary pressure-reducing assembly used to provide automatically room-distribution pipe-flushing water operates at a pressure of 15 psig (102 kPa). This assembly is installed as a bypass around the low-pressure assembly. Manual operation at a lower cost could also be provided. This additional pressure for a short period of time will not cause the animals any difficulty if they decide to drink during the flushing cycle.

One pressure-reducing station can be connected to as many as 35 interconnect stations to small animal-rack manifolds, often referred to as "drops." This allows 1 station to control more than 1 animal room.

The pressure-reducing station is a preassembled unit complete with all the various valves, fittings, and reducing valves required for a specific project. All the components are installed in a cabinet, which requires only mounting and utility connections.

Drinking Valves

Drinking valves are used by the animals to obtain water from the distribution-system piping. An internal mechanism keeps the valve normally closed; the animal drinking from the valve must open it by some action, such as moving the entire valve or operating a small lever inside the body of the valve with the tongue. Many

different kinds of valve are available to supply any type of animal that may be kept in the facility. The valves can be mounted on cages, on the rack manifold, or on the walls of pens and kennels at varying heights with the use of special brackets.

Animal-Rack Manifold Configurations

The configuration of the piping on the animal rack plays an important part in the effectiveness and efficiency of the filling and flushing of the drinking-water system. The two most often-used configurations are the reverse "S" and the "H."

The reverse "S," illustrated in Figure 7-2, is the most often-used configuration. It has two basic styles based on the valve location in the flush drain line. One style has a supply control valve at the top and the other has a drain valve at the bottom. Either location is acceptable, with the deciding factor being the ease of operating the valve where the rack is installed. This configuration has the advantage of eliminating dead legs and offers more convenience to facility personnel when they fill the piping after washing. The vent is a manually operated air bleed used when the cage rack is reconnected to the room-distribution pipe. It is opened until water is discharged, thereby eliminating any air pockets in the manifold. This manifold style provides a positive exchange of water during flushing with a minimum usage of time and water. This configuration is used far more than any other manifold style. It is easily converted to automatic flushing by the installation of solenoid devices on the valve. It is recommended when micro-isolator cage systems are installed. The complete, on-line, rack-manifold flushing system is illustrated in Figure 7-3. This cage system has the advantage of the complete isolation of individual cages, with the accompanying capability for additional flushing and disinfection of the piping system.

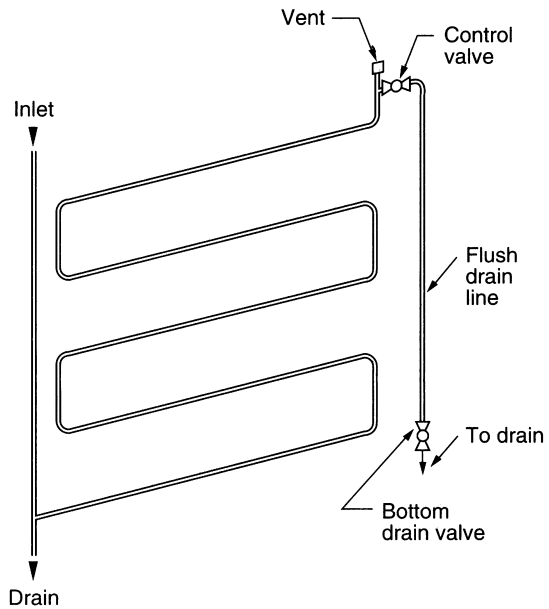


Figure 7-2 Reverse "S" Configuration Watering Manifold

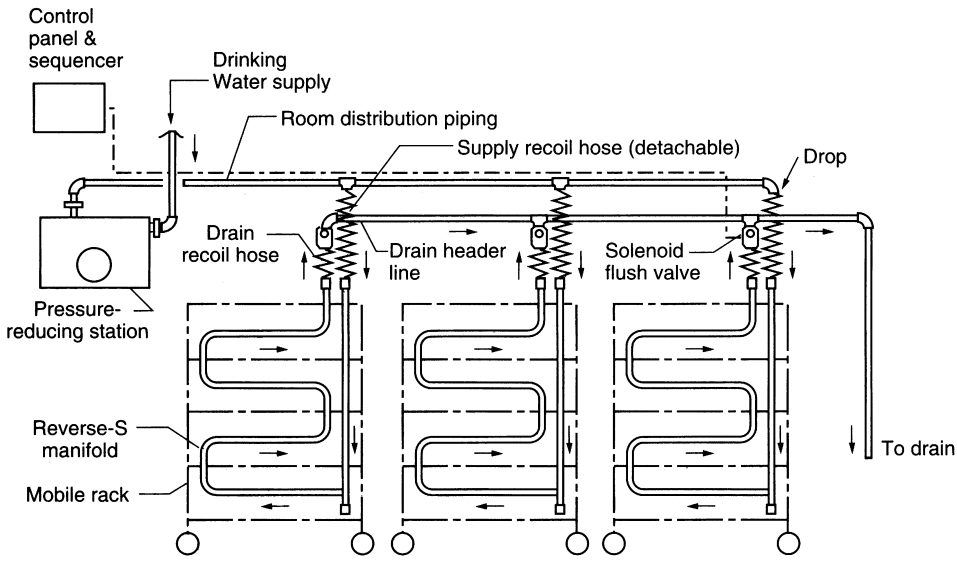


Figure 7-3 Typical Room Distribution, On-Line, Rack Manifold Flushing System

Source: Courtesy of Edstrom Industries.

One variation of the reverse "S" is the standard "S," illustrated in Figure 7-4. This configuration has the advantage of complete on-line flushing and lower initial cost of the manifold. Disadvantages are the need for extra supports on the cage rack and the need for venting to be done manually or by the animals after being placed in service. This configuration is no longer recommended.

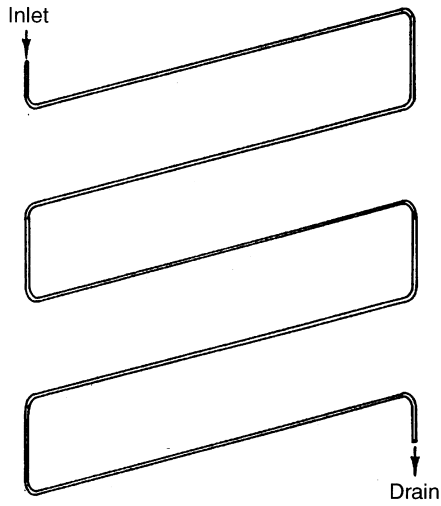


Figure 7-4 Standard "S" Configuration Manifold

The "H" style, illustrated in Figure 7-5, although rigidly installed and with positive venting, is not suitable for on-line flushing. Because of this, it is rarely used except for larger animals, which will consume all the water in the rack piping manifold.

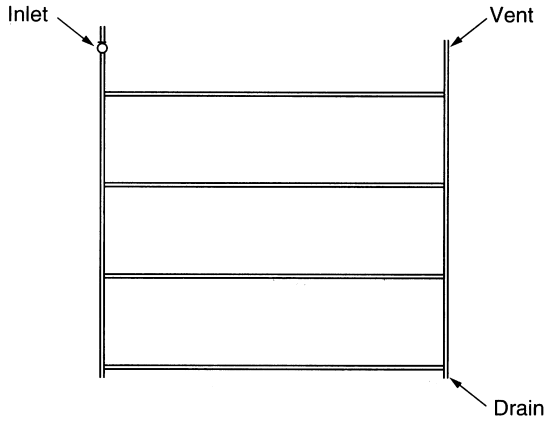


Figure 7-5 Standard "H" Configuration Manifold

The most common piping materials are CPVC and 304L stainless steel. CPVC conforms to ASTM D 2846, is 0.875 outside diameter (OD) with 0.188 in. minimum wall thickness. Joining process is done with solvent cement socket joints. The drinking valves are installed with a proprietary, drilled and tapped fitting. The 304L stainless steel tubing is 0.50 OD with a 0.036 in. minimum wall thickness. Fittings are made with O-ring joints and socket fittings or compression type fittings. The mounting of both pipe materials is accomplished by the use of 304 SS stainless-steel clamps and fasteners.

System Sizing Methods

The water consumption of small animals in cages is very low. It is also probable that the animal room will not be used to full capacity. Because of this low consumption flow rate, the flushing-water flow rate of the system is the critical factor in sizing the piping. Typically, the animal-room piping distribution network is a header uniformly sized at ½ in. (50 mm) throughout the animal room.

The pipe sizes in other areas of the animal facility are determined based on the requirements of maximum flow rate at the necessary pressure to supply the flushing velocity. Maximum flow rate depends on the flush sequencing, and the pressure drop depends on overcoming pressure loss through the equipment connected to the branch being sized—such as pressure-reducing stations, solenoid valves, and recoil hoses—and friction loss through the piping network. Allowance must be made to provide a sufficiently high flow rate and water velocity to efficiently provide the flushing action desired.

CLEANING AND DRAINAGE SYSTEMS AND PRACTICES

General

Keeping the animal rooms and cages clean is an extremely important facet of facility practice. The cleaning of the animal room is accomplished either by sponging the walls, floors, and ceiling or by hosing down the room. Cage racks can be cleaned by washing them with a hose or by placing them in a large washing machine. Cages are cleaned in a cage washer. Pens and kennels are hosed down. Floors in pens are cleaned with hoses and the bedding with feces is pushed into trenches with floor drains.

In specialized areas, such as holding or isolation rooms where only small animals are kept, it is common practice to have permanent cage racks or have the portable racks remain in the animal room. The litter is put into bags and brought to other areas for disposal. The cage racks are manually wiped down and no rack washer is required. A sink is usually provided in the animal room for the convenience of the cleaning personnel. Individual water bottles, if provided, could be washed in the sink. The cages are removed and washed separately in a cage washer. This type of animal room usually does not require a floor drain if the entire room will be sponged down. If hosing is practiced, a floor drain is required.

Rabbits and guinea pigs have a tendency to spray urine and feces. This requires that the racks be hosed down in the room. A wash station with a hose reel and detergent injection capability to hose down the cage racks and the room itself is usually placed in individual rooms. Citric acid is often used as a cleaning agent for rabbits.

Hose Stations

Hose stations usually consist of a mixing valve with cold water and steam to make hot water or hot water alone, a length of flexible hose, and an adjustable spray nozzle. Hot and cold water are also used. It can be exposed or provided with an enclosure when an easily cleaned surface is required.

Cleaning-Agent Systems

Cleaning agents are used to clean and/or disinfect the walls, ceiling, and floor of a room and to add agent to the cage wash water. When used to clean rooms, the equipment used for this purpose is commonly called a "facility detergent system." When used to add agent to the cage washing water it is often called a "cage-washing detergent system." These are separate systems and are not capable of providing agent to each other.

A single-station detergent-dispensing system is used when rooms are cleaned with mops or squeegees. It consists of a wall-mounted unit having a holder for detergent concentrate and an injector unit. A container filled with detergent concentrate is placed in the holder and is used to supply agent to the injector that dispenses a metered amount of agent when a hose bibb is opened to fill the pail or container. These rooms usually have sinks and mop racks inside to be used only for these rooms. A typical schematic detail of a single-station detergent system is illustrated in Figure 7-6.

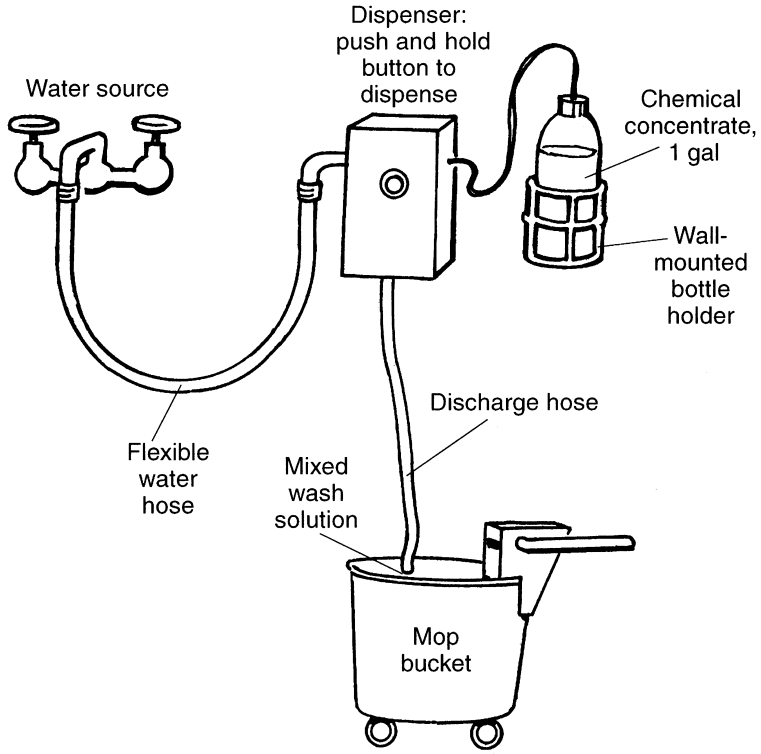


Figure 7-6 Single-Station Detergent System

When used to supply a single or multiple-spray hose for cleaning floors and walls, a central system could be installed to supply several rooms within a facility by means of a detergent pump that dispenses agent. A 55-gal drum of agent should be used to reduce the number of times the supply has to be changed. A typical central-supply detergent-dispensing system is illustrated in Figure 7-7.

The cage-washing detergent system is usually located in the wet area of the cage-washing facility and, with the use of a detergent pump, could be used as a central system to supply cage and bottle washers. A typical schematic detail of a cage-washing system is illustrated in Figure 7-8.

It is common practice to have a central system or a wall-mounted cleaning-agent dispenser unit along with the hose station. Separate, portable units could be used when cross contamination between animal rooms is a consideration. A typical, wall-mounted, cleaning-agent system consists of separate water and cleaning-agent tanks; a water pump; and a special, coaxial hose that sprays a proportioned mixture of the water and cleaning agent. Compressed air is often used to provide pressure.

Cage-Flushing Water System

The removal of animal waste from cages can be done by several methods. One method removes the waste along with the bedding at the time cages are removed from the animal room to be washed. Another method uses an independent rack-

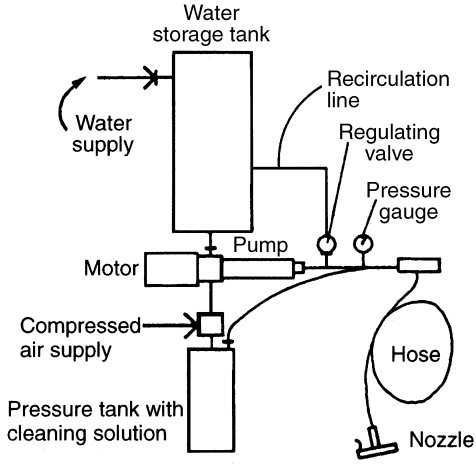


Figure 7-7 Central-Supply Detergent System

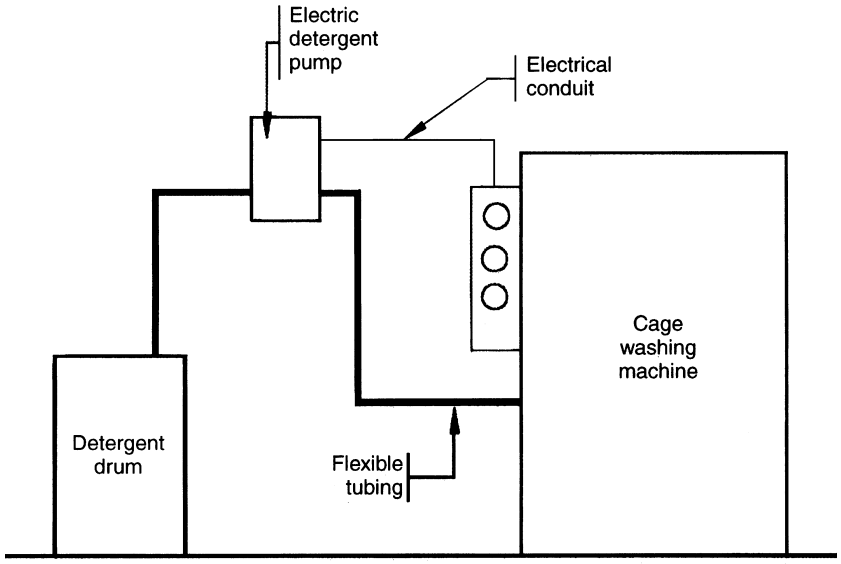


Figure 7-8 Typical Cage-Washing Detergent System

flush system to automatically remove animal waste from cages on racks while the animals and cages remain in the animal room.

The independent rack flush is a separate system that uses chlorinated water automatically distributed to each animal room. The cages and racks are constructed so that the animal droppings fall through the cage floor onto a sloping pan below each tier of cages. Each tier is cascaded at the end onto the sloping pan below. Eventually, the lowest pan spills into a drain trough in the animal room. The flushing schedule is decided by facility personnel.

The water supply could be a reservoir placed on the rack that is filled with water and automatically discharged onto the pans at preset intervals. These preset intervals are determined based on experience and generally range from once to three times daily. Another method uses a solenoid valve to automatically discharge water onto the pans; the valve is sequenced by a timer set to alternate fill and dump cycles. The timer could be either centrally located or installed separately in each animal room. Larger cages, such as those for primates, are usually stacked no more than two cages high. Current practice is to have these cages manually cleaned by personnel who hose down the pans directly into floor or wall troughs.

Water is supplied to each cage rack by means of a recoil hose, which has a different quick-disconnect end than that of the drinking water recoil hose to avoid cross connection. Refer to Figure 7-9 for a detail of a typical cage-rack utility connection arrangement.

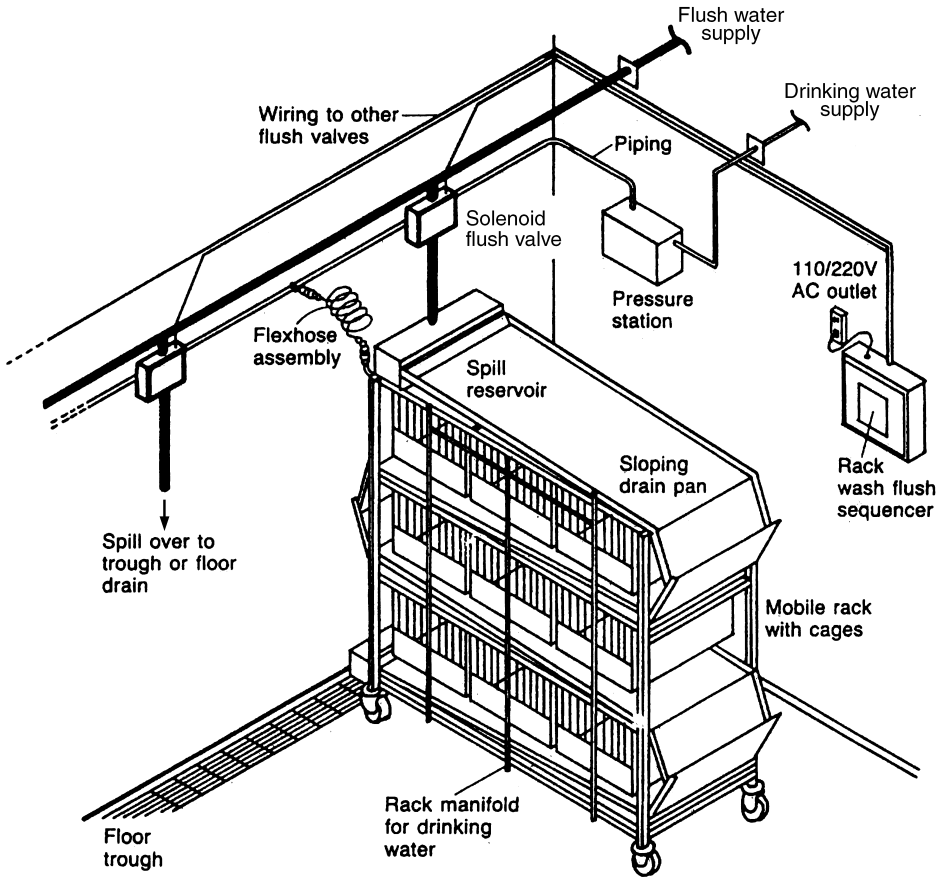


Figure 7-9 Typical Cage-Rack Utility Connections

Solid-Waste Disposal

Solid waste consists of bedding, feces, animal carcasses, and other miscellaneous waste, including straw and sawdust used for larger farm animals. Bedding comprises the largest quantity of this solid waste. It is necessary to determine the quantity of bedding before a decision can be made as to the most cost-effective method to dispose of it.

Bedding can be disposed of by incineration, as regular garbage, or into the sewer system. Incinerators are costly, require compliance with many regulatory agencies and multiple permits, and often result in objections from adjoining property owners. Incineration is the preferred method of disposing of carcasses and large quantities of contaminated waste. Carcasses could also be autoclaved and disposed of as regular garbage. Regular garbage disposal is the most common method of disposal. It involves collecting, moving, and storage of the waste into large containers until regular garbage collection is made. This is very labor intensive.

Discharge into the drainage system must first be accepted by the local authorities and responsible code officials. This requires the bedding to be water soluble, that it shall not float, and provision be made to thoroughly mix the bedding with water. This mixture is called a "slurry." Experience has shown, if done properly, discharge into an adequately sized drain line—minimum size 6 in. (150 mm)—has caused no problems, since the effluent has the same general characteristics of water.

A self-contained waste-disposal system is available that is capable of disposing of animal bedding and waste. The system consists of a pulping unit to grind the waste into a slurry and sanitize it, a water extractor to remove most of the water from the slurry, and the interconnecting piping system that transports the slurry from the pulper to the extractor and recirculates the water removed from the extractor back to the pulping unit for reuse. The solid waste is removed as garbage. Manufacturers are available for assistance in the design and equipment selection for this specialized system. The system has the advantages of reducing water use, reducing operating costs by eliminating the handling of the waste by operating personnel, compacting the waste to about 20% of the space required for standard garbage not compacted, and reducing the possibility of contamination by isolation of the disposal equipment. The disadvantage is its high initial cost.

This system could consist of single or multiple units of different capacities. It requires water intermittently for pulping at the rate of about 10 to 30 gpm (63 to 190 L/min). Hose bibbs should be installed for washdown. The pipe should be sized for a maximum velocity of 8 fps (1.75 m/s), with typical slurry lines ranging between 2 and 4 in. (50 and 200 mm) and return lines generally 2 in. (50 mm) in size. The extractor discharges into a drain that should be 4 or 6 in. (100 or 150 mm) depending on the flow. A typical schematic diagram of a multiple installation is illustrated in Figure 7-10.

Room-Waste Disposal

The rooms in which animals are kept must be designed to allow proper drainage practices and in accordance with the anticipated cleaning procedures of the facility. Floor drains, drainage trenches (or troughs) at room sides, adequate and

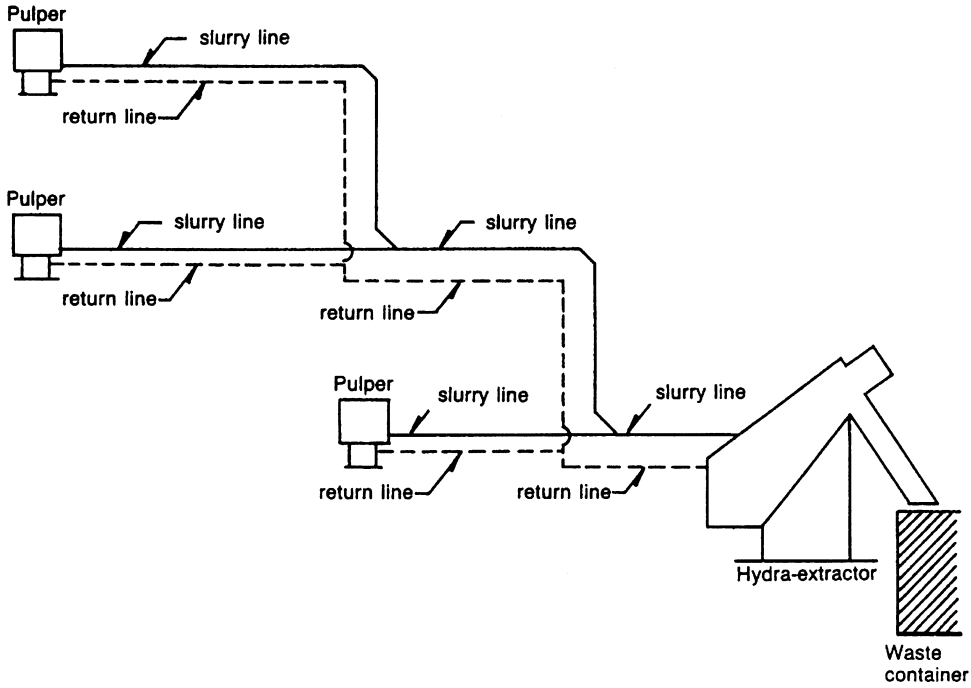


Figure 7-10 Typical Waste-Disposal System

consistent floor pitch to drains or troughs, and floor surfaces are all important considerations.

There are several considerations to be taken into account in locating floor drains. Experience has shown that placing drains in the center of a room is not acceptable because it is difficult to hose solids down a drain in this location. Another reason is that the floor must be pitched to the drain and if a cage rack is defective, it should roll to the side of the room. The best location is in a corner or at the side. Floor drains without troughs can be considered if the floors will only be squeegeed rather than hosed down. They should also be considered in contagious areas where contamination between rooms must be avoided. Gratings must have openings smaller than the wheels of racks or cages.

In rooms where washdown and cage-rack flushing are expected, the provision of a floor trough should be considered. Troughs are often provided at opposite ends of the room to minimize the amount of floor drop due to pitch. Accepted practice uses a minimum floor pitch of ⅛ in./ft of floor run. The floor is pitched to the troughs to facilitate cleaning and also to provide an easy method to dispose of waste generated from the rack-flush system. It is common practice to provide an automatic or manual trough-flushing system with nozzles or jets to wash down the trough sides and eliminate as much of the contamination remaining in the trough as possible. Wall troughs, similarly to roof gutters, are located at a higher elevation. This type of trough arrangement is sometimes provided in addition to or in lieu of floor troughs if the arrangement of elevated cages and racks make it an effective drainage method.

Experience has shown that prefabricated drain troughs in floors are preferred over those built on the wall as part of the architectural construction.

The floor troughs are drained by means of a floor drain placed in a low point at one end. The troughs are usually pitched at ¼ in./ft of run to the drain. The drain should be constructed of acid-resistant materials and have a grate that can be easily removed. For small animal rooms where bedding is not disposed of in the room, a 4-in. (100-mm) drain is considered adequate. In most other locations, it is recommended that a 6-in. (150-mm) drain be provided. A flushing-rim type drain should be considered to flush all types of waste into the drainage system.

Floor drains should have the capability of being sealed by the replacement of the grates with solid covers during periods when the room may not be in service.

Equipment Washing

Most facilities contain washing and sanitizing machines to wash cages, cage racks, and bottles, if used. There are two commonly used types of cage washer: the batch type and conveyer (tunnel) type. Batch washers require manual loading and unloading and are used where a small number of cages and racks are washed. The conveyer type is similar to a commercial dishwasher, where the cages and racks are loaded on a conveyer and automatically moved through the machine for the washing and sanitizing cycles.

Equipment Sanitizing

Maintaining drinking-water quality requires that the recoil hoses and rack manifolds be not merely washed but internally sanitized. This is most often done at the same time the cages are washed. Separate rack-manifold and recoil-hose flush stations are available for this purpose and are usually installed in the cage-wash area. Washing can be done manually or automatically. The hoses are flushed for 1 to 2 min with 4 gpm (16 L/min) of water. Chlorine is injected into the water by a chlorine-injection station (proportioner) set to deliver 10 to 20 ppm into the flush water. Ten scfm of oil-free compressed air at 60 psig is blown through the hoses to dry them. If chlorine is used as a disinfectant, a contact time of 30 min is recommended before evacuation and drying.

Periodic sanitizing of the room-distribution piping system is required for maintaining good water quality. Sanitizing is done prior to system flushing. To accomplish this, a portable sanitizer is used to manually inject a sanitizing solution directly into the piping system. In order to do this, an injection port is required at the inlet to the pressure-reducing station. The portable sanitizer usually consists of a 20-gal (90-L) polyethylene tank with a submersible pump inside and a flexible hose used to connect the tank to the injection port. The disinfecting solution is a mixture of chlorine and water with 20 ppm of chlorine. The mixture should maintain a contact time in the piping of 30 to 45 min.

Drainage-System Sizing

As mentioned previously, for individual animal rooms where bedding is not disposed of in the drainage system, a 4-in. drain is acceptable. In general, a 6-in. drain is considered good practice. The size of the drainage system piping should be a

minimum of 6 in., with a ¼-in. pitch when possible and the piping sized to flow ½ to ⅔ full in order to accommodate unexpected inflow.

MONITORING SYSTEMS

The monitoring of various animal-utility systems is critical to keep within a range of values consistent with the protocol of the experiments being conducted at the facility. This is accomplished by a central monitoring system that includes many measurements from HVAC and electrical systems. For the animal drinking-water system, parameters such as water pressure, flow rates, leakage, pH, and temperature in various areas of the facility are helpful for maintenance, monitoring, and alarms.

SYSTEMS DESIGN CONSIDERATIONS

The amount of exposed piping inside any animal room should be minimized. The exception is the animal drinking-water system, which is usually exposed on the walls of the room. This piping should be installed using standoffs to permit proper cleaning of the wall and around the pipe.

The piping material used for all systems should be selected with consideration given to the facility cleaning methods and type of disinfectant. Where sterilization is required and cleaning very frequent, stainless-steel pipe should be considered.

If insulation is used on piping, it should be protected with a stainless steel jacket to permit adequate cleaning.

Pipe penetrations should be sealed with a high-grade, impervious, and fire-resistant sealant. Escutcheons should not be used because they allow the accumulation of dirt and bacteria behind them.

8 Life-Safety Systems

INTRODUCTION

A threat to personnel safety often present in pharmaceutical facilities is accidental exposure and possible contact with toxic gases, liquids, and solids. This chapter describes water-based emergency drench equipment and systems commonly used as a first-aid measure to mitigate the effects of such an accident, Also described are the breathing-air systems that supply air to personnel for escape and protection when they are exposed to either a toxic environment resulting from an accident or normal working conditions that make breathing the ambient air hazardous.

EMERGENCY DRENCH-EQUIPMENT SYSTEMS

General

When toxic or corrosive chemicals come in contact with the eyes, face, and body, flushing with water for 15 min with the clothing removed is the most recommended first-aid action that can be taken by nonmedical personnel prior to medical treatment. Emergency drench equipment is intended to provide a sufficient volume of water to effectively reach any area of the body exposed to or has come into direct contact with any injurious material. Within facilities, specially designed emergency drench equipment, such as showers, drench hoses, and eye and face washes, are located adjacent to all such hazards. Although the need to protect personnel is the same for any facility, specific requirements differ widely because of architectural, aesthetic, location, and space constraints necessary for various industrial and laboratory installations.

System Classifications

Drench equipment is classified into two general types of system based on the source of water. These are plumbed systems, which are connected to a permanent water supply, and self-contained or portable equipment, which contains its own water supply. Self-contained systems can be either gravity feed or pressurized.

One type of self-contained eyewash unit is available that does not meet code requirements for storage or delivery flow rate. This is called the personnel eyewash station and is selected only to supplement, not replace, a standard eyewash unit. It consists of a solution-filled bottle(s) in a small cabinet. This cabinet is small enough to be installed immediately adjacent to a high hazard. If an accident occurs, the bottle containing the solution is removed and used without delay to flush the eyes while waiting for the arrival of trained personnel and during travel to a code-approved eyewash or first-aid station.

Codes and Standards

1. ANSI Z-358.1, *Emergency Shower and Eyewash Equipment.*

2. OSHA has various regulations for specific industries pertaining to the location and other criteria for emergency eyewashes and showers.
3. The Safety Equipment Institute (SEI) certifies that equipment meets ANSI standards.
4. Applicable plumbing codes.

For the purposes of the discussion in this section on drench equipment, the word "code" shall refer to ANSI Z-358.1.

Types of Drench Equipment

Emergency drench equipment consists of showers, eyewash units, face-wash units, and drench hoses, along with interconnecting piping and alarms if required. All of these units are available either singly or in combination with each other. Ancillary components include thermostatic mixing systems, freeze protection systems and enclosures. Each piece of equipment is designed to perform a specific function. One piece is not intended to be a substitute for another, but rather, to complement the others by providing additional availability of water to specific areas of the body as required.

Emergency Showers

Plumbed Showers Plumbed emergency showers are permanently connected to the potable water piping and designed to continuously supply enough water to drench the entire body. A unit consists of a large-diameter shower head intended to distribute water over a large area. The most commonly used type has a control valve with a handle extending down from the valve on a chain or rod that is used to turn the water on and off manually. Code requires the shower be capable of delivering a minimum of 30 gpm (113.6 L/min) of evenly dispersed water at a velocity low enough so as not to be injurious to the user. Where this flow rate is not available, 20 gpm (75.7 L/min) is acceptable if the shower-head manufacturer can show the same spray pattern required for 30 gpm can be achieved at the lower flow rate. The minimum spray pattern shall have a diameter of 20 in. (58.8 cm), measured at 60 in. (152.4 cm) above the surface on which the user stands. This requires a minimum pressure of approximately 30 psi (4.47 kPa). Emergency showers can be ceiling mounted, wall mounted or floor mounted on a pipe stand, with the center of the spray at least 16 in. (40.6 cm) from any obstruction. Showers should be chosen for the following reasons:

1. When large volumes of potentially dangerous materials are present.
2. Where a small volume of material could result in large affected areas, such as in laboratories and schools.

A typical emergency shower head mounted in a hung ceiling is illustrated in Figure 8-1.

Self-Contained Showers Self-contained emergency showers have a storage tank for water. Often this water is heated. The shower shall be capable of delivering a minimum of 20 gpm (75.5 L/min) for 15 min. The requirements for mounting height and spray pattern are the same as they are for plumbed showers.

Emergency Eyewash

Plumbed Eyewash Emergency eyewashes are specifically designed to irrigate and flush both eyes simultaneously with dual streams of water. The unit consists

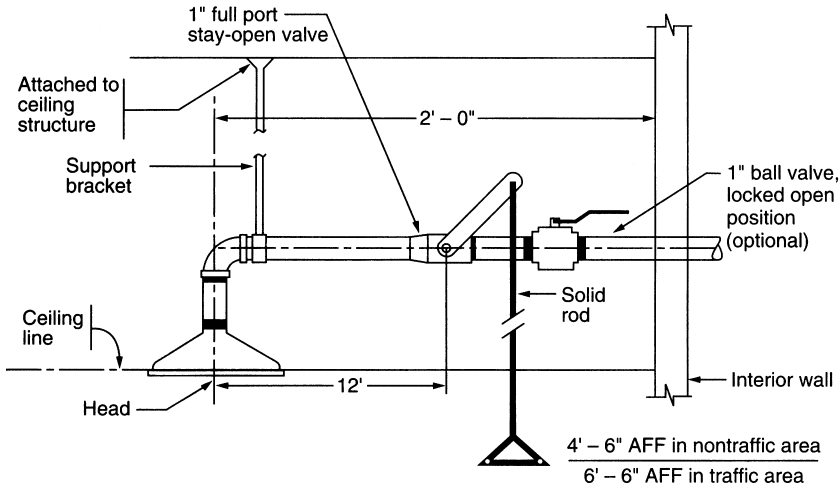


Figure 8-1 Typical Emergency Shower

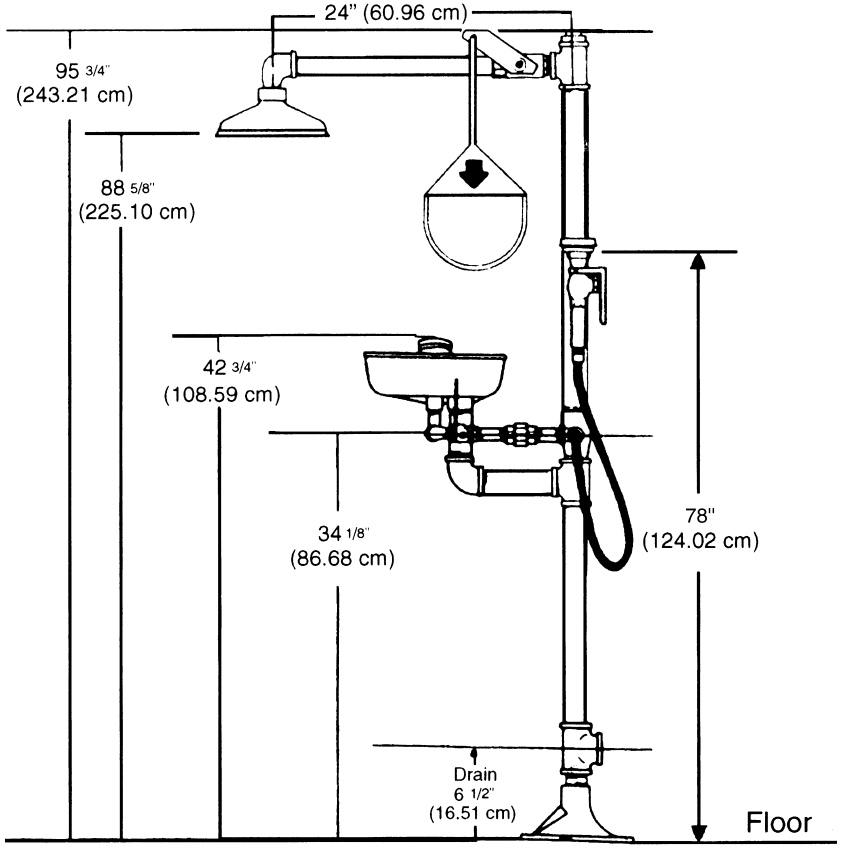
of dual heads in the shape of a "U," each specifically designed to deliver a narrow stream of water, and a valve usually controlled by a large push plate. Code requires the eyewash to be capable of delivering a minimum of 0.4 gpm (1.5 L/min). Many eyewashes of recent manufacture deliver approximately 3 gpm (11.4 L/min). Once started, the flow must be continuous and designed to operate without the use of the hands, which shall be free to hold open the eyelids. The flow of water must be soft to avoid additional injury to sensitive tissue. To protect against airborne contaminants, each dual stream head must be protected with a cover that is automatically discarded when the unit is activated. The head covers shall be attached to the heads by a chain to keep them from being lost. The eyewash can be mounted on a counter or wall, or as a free stranding unit attached to the floor. The eyewash could be provided with a bowl. The bowl does not increase the efficiency or usefulness of the unit but aids in identification by personnel. It is common practice to mount a swivel type eyewash on a laboratory sink faucet, installed so it can be swung out of the way during normal use of the sink but can be swung over the sink bowl in order to be operated in an emergency.

The code recommends (but does not require) the use of a buffered saline solution to wash the eyes. This could be accomplished with a separate dispenser filled with concentrate that will introduce the proper solution into the water supply prior to reaching the device head. A commonly used device is a wall-mounted, 5 to 6-gal (20 to 24-L) capacity solution tank connected to the water inlet dispenses a measured amount of solution when flow to the eyewash is activated. A backflow device shall be installed on the water supply.

Self-Contained Eyewash A typical self-contained eyewash has a storage tank with a minimum 15-min water supply. The mounting height and spray pattern requirements are the same as those for a plumbed eyewash.

Emergency Face Wash

The face wash is an enhanced version of the eyewash. It has the same design requirements and configuration, except the spray heads are specifically designed to deliver a larger water pattern and volume will flush the whole face and not just the eyes. The face wash should deliver approximately 8 gpm (55 L/min). The stream configuration is illustrated in Figure 8-2. Very often, the face wash is chosen for combination units. In general, the face wash is more desirable than the eyewash because it is very likely an accident will affect more than just the eyes. All dimensions and requirements of the free-standing face wash are similar to those for the eyewash.



(Drawing not to scale)

Figure 8-2 Combination Emergency Shower, Eye/Face Wash, and Drench Hose Unit

Drench Hoses

A drench hose is a single-head unit connected to a water supply with a flexible hose. The head is generally the same size as a single head found on an eye/face wash. Code requires the drench hose be capable of delivering a minimum of 0.4

gpm (1.5 L/min). It is controlled either by a squeeze handle near the head or a push-plate ball valve located at the connection to the water source. It is used as a supplement to showers and eye/face washes to irrigate specific areas of the body. Drench hoses are selected for the following reasons:

1. To spot drench a specific area of the body when the large volume of water delivered by a shower is not called for.
2. To allow irrigation of an unconscious person or a victim who is unable to stand.
3. To irrigate under clothing prior to the clothing's removal.

Combination Equipment

Combination equipment consists of multiple-use units with a common water supply and supporting frame. Combinations are available that consist of a shower, eye/face wash, and drench hose in any configuration. The reason for the use of combination equipment is usually economy, but the selection should be made considering the type of irrigation appropriate for the potential injuries at a specific location. For combination units, the water supply must be larger, capable of delivering the flow rate of water required to satisfy two devices concurrently rather than only a single device.

The most often-used combination is the drench shower and face wash. Figure 8-2 illustrates a combination shower, eye/face wash and drench hose complete with mounting heights.

Drench Equipment Components

Controls

Often referred to as "activation devices," controls cause water to flow at an individual device. Stay-open valves are required by code in order to leave the hands free for the removal of clothing or for holding eyelids open. The valves most often used are ball valves with handles modified to provide for the attachment of chains, rods, and push plates. In very limited situations, such as in schools, valves that automatically close (quick-closing) are permitted if they are acceptable to the facility and authorities having jurisdiction.

Valves are operated by different means to suit the specific hazard, location, durability, and visibility requirements. The operators on valves are handles attached to pull rods, push plates, foot-operated treadle plates and triangles. A solid pull rod is often installed on concealed showers in order to push the valve closed after operation. Another method is to have two handles attached to chains that extend below the hung ceiling, one to turn on the valve and another handle to turn it off. Chains are used if the handle might be accidentally struck, they enable the handle to move freely and not injure the individual who might accidentally strike the hanging operator.

Operating handles for the physically challenged are mounted lower than those for a standard unit. In many cases, this requires that operating handles be placed near walls to keep them out of traffic patterns where they would be an obstruction to able-bodied people passing under them. A free-standing combination shower and eyewash that is handicapped accessible using handles hung from the ceiling is illustrated in

Figure 8-3. The handle must be located close enough to the center of the shower to be easily reached, which is about 2 ft 0 in. from the center of the shower.

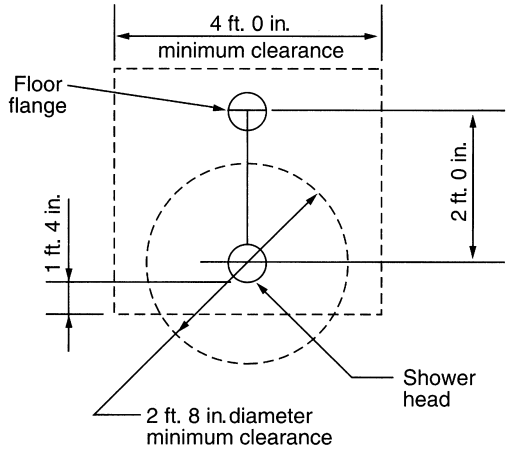


Figure 8-3 Clearance Dimensions Around Shower and Eye/Face Wash

Alarms

Alarms are often installed to alert security or other rescue personnel that emergency drench equipment has been operated and to guide them rapidly to the scene of the accident. Commonly used alarms are audible and visual devices—such as flashing or rotating lights on top of, or adjacent to, a shower or eyewash—and electronic alarms wired to a remote security panel. Remote areas of a plant are particularly at risk if personnel often work alone. Alarms are most often operated by a flow switch activated by the flow of water when a piece of equipment is used.

When tempered water systems are used to supply drench equipment, a low water temperature of 60°F shall cause an alarm annunciation.

Flow-Control Device

Where water pressure exceeds 80 psig (550 kPa) or if the difference in water pressure between the first and last shower head is more than 20 psig (140 kPa), it is recommended that a self-adjusting flow-control device be installed in the water-supply pipe. Its purpose is to limit the flow to just above the minimum required by the specific manufacturer for proper functioning of equipment. Such devices are considered important because a shower installed at the beginning of a long run has a much greater flow than the device at the end. During operation, the higher pressure could cause the flow rate to be as much as 50 gpm (L/min). If no floor drain is provided, the higher flow for 15 min at the higher pressure could produce a much greater amount of water that must be cleaned up and disposed of afterwards. Drench hoses and eye and face washes are not affected because of their lower flow rates and their flow head designs.

Where pressure-reducing devices are required for an entire system, they should be set to provide approximately 50 psig (345 kPa).

System Design

General

It is a requirement that a plumbed system be connected to a potable water supply as the sole source of water. This system is therefore subject to filing with a plumbing or other code official for approval and inspection of the completed facility, as are standard plumbing systems.

An adequately sized pipe with sufficient pressure must be provided from the water supply to meet system and device operating-pressure requirements for satisfactory functioning. One maintenance requirement is that the water in the piping system be flushed to avoid bacterial growth.

It is common practice to add antibacterial and saline products to a self-contained eyewash unit and an antibacterial additive to an emergency shower. Water is also commonly used if it can be changed every week. It is well established that no preservative will inhibit bacterial growth for an extended period of time. Self-contained equipment must be checked regularly to determine if the quality of the stored water has deteriorated to a point where it is not effective or safe to use.

If valves are placed in the piping network for maintenance purposes, they should be made for unauthorized shut-off.

Water-Supply Pressure and Flow Rates

Emergency showers require between 20 and 30 gpm (76 to 111 L/min), with 30 gpm recommended. The minimum pressure required is 30 psig (4.5 kPa) at the farthest unit, with a generally accepted maximum pressure of 70 psi (485 kPa). Code mentions a high pressure of 90 psig (612 kPa), which is generally considered to be excessive. Most plumbing codes do not permit water pressures as high as 90 psig. Generally accepted practice limits the high water pressure to between 70 and 80 psig (480 and 620 kPa).

Most eyewash units require a minimum operating pressure of 15 psig (105 kPa) with a flow rate minimum of 3 gpm (12 L/min) at the farthest unit. Maximum pressure is similar to that for showers. Face washes and drench hoses require a minimum operating pressure of 15 psig (105 kPa) with a minimum flow rate of 8 gpm (30 L/min) at the farthest unit.

System Selection

Plumbed System

The advantages of a plumbed system include:

1. Permanent connection to a fresh supply of water, requiring no maintenance and only minimum testing of the devices to ensure proper operation.
2. It provides an unlimited supply of water often at larger volumes than self-contained units.

Disadvantages include:

1. Higher first cost than a self-contained system.
2. Maintenance is intensive. Such systems require weekly flushing, often into a bucket, to remove stagnant water in the piping system and replace it with fresh water.

Self-Contained System

Advantages of the self-contained system include:

1. Lower first cost compared to a plumbed system.
2. Can be filled with a buffered, saline solution, which is recommended for washing eyes.
3. Available with a container to catch waste water.
4. Portable units can be moved to areas of greatest hazard with little difficulty.
5. A gravity eyewash is more reliable. The water supply can be installed where there is room above the unit. If not, a pressurized unit mounted remotely should be selected.

Disadvantages include:

1. Only a limited supply of water at a lesser flow rate is available.
2. The stored liquid must be changed on a regular basis to maintain purity.

The plumbed system is the type of system selected most often because of the unlimited water supply.

Pipe Sizing and Material

In order to supply the required flow rate to a shower, a minimum pipe size of 1 in. (25 mm) is required by code, with 1¼ in. (30 mm) recommended. If the device is a combination unit, a 1¼-in. size should be considered as minimum. An emergency eye/face wash requires a minimum ½ in. (13 mm) pipe size.

Except in rare cases where multiple units are intended to be used at once, the piping system size should be based on only one unit operating. The entire piping system is usually a single size pipe based on the requirements of the most remote fixture. Appropriate pressure loss calculations should be made to ensure the hydraulically most remote unit is supplied with adequate pressure with the size selected. Adjust sizes accordingly to meet friction loss requirements.

The pipe material should be copper to minimize clogging the heads of the units in time with the inevitable corrosion products released by steel pipe. Plastic pipe (PVC) should be considered where excessive heat and the use of closely located supports will not permit the pipe to creep in time.

Emergency drench equipment shall be sized based on the single highest flow rate, usually 30 gpm (115 L/min) for an emergency shower. Piping is usually a 1¼-in. header of copper pipe for the entire length of a plumbed system.

Flushing Water Disposal

Water from emergency drench equipment is mainly discharged onto the floor. Individual eye/face washes mounted on sinks discharge most of the water into the adjacent sink. Combination units have an attached eye/face wash also discharge water on the floor. There are different methods of disposing of the water resulting from an emergency device depending on the facility. The basic consideration is whether to provide a floor drain adjacent to a device to route that water from the floor to a drainage system.

It is accepted practice not to provide a floor drain at an emergency shower. Experience has shown in most cases, particularly in schools and laboratories, it is easier to mop up water from the floor in the rare instances emergency devices are used

rather than add the extra cost of a floor drain, piping and a trap primer. Considerations include:

1. If the drain is not in an area where frequent cleaning is done, the trap may dry out, allowing odors to be emitted.
2. Is there an available drainage line in the area of the device?
3. Can the chemical, even in a diluted state, be released into the sanitary sewer system or must it be routed to a chemical waste system for treatment?
4. Must purification equipment be specially purchased for this purpose?

Installation Requirements for Drench Equipment

The need to provide emergency drench equipment is determined by an analysis of the hazard by design professionals or health or safety personnel and by the use of common sense in conformance with OSHA, CFR, and other regulations for specific occupations. Judgment is necessary in the selection and location of equipment. Very often, facility owners have specific regulations for its need and location.

Dimensional Requirements

The mounting height of all equipment, as illustrated in ANSI Z-358.1, is shown in Figure 8-2. If the shower head is free-standing, the generally accepted dimension for the mounting height is 7 ft 0 in. (2.17 m) above the floor. Generally accepted clearance around showers and eye/face washes is illustrated in Figure 8-3. A wheelchair-accessible, free-standing, combination unit is illustrated in Figure 8-4.

Equipment Location

The location of the emergency drench equipment is crucial to the immediate and successful first-aid treatment of an accident victim. It should be located as close to the potential hazard as is practical without being affected by the hazard itself or potential accidental conditions, such as a large release or spray of chemicals resulting from an explosion or a pipe and tank rupture. Another location problem is placement adjacent to electrical equipment. Location on normal access and egress paths in the work area will reinforce the location to personnel, who will see it each time they pass.

There are no requirements in any code pertaining to the location of any drench equipment in terms of specific, definitive dimensions. ANSI code Z-358.1 requires emergency showers be located a maximum distance of either 10 seconds travel time by an individual or no more than 75 ft (22.5 m) from the potential protected hazard, whichever is shorter. If strong acid or caustic is used, the equipment should be located within 10 ft (3 m) of the potential source of the hazard. The path to the unit from the hazard shall be clear and unobstructed, so impaired sight or panic will not prevent clear identification and access. There is no regulation as to what distance could be covered by an individual in 10 seconds. There are also no specific provisions for the physically challenged.

Since there are no specific code requirements for locating drench equipment, good judgment is required. Accepted practice is to have the equipment accessible from three sides. Anything less generally creates a "tunnel" effect that makes it more difficult for the victim to reach the equipment. It should be located on the same level as the potential hazard when possible. Traveling through rooms that may have locked doors to reach equipment shall be avoided, except placing emergency

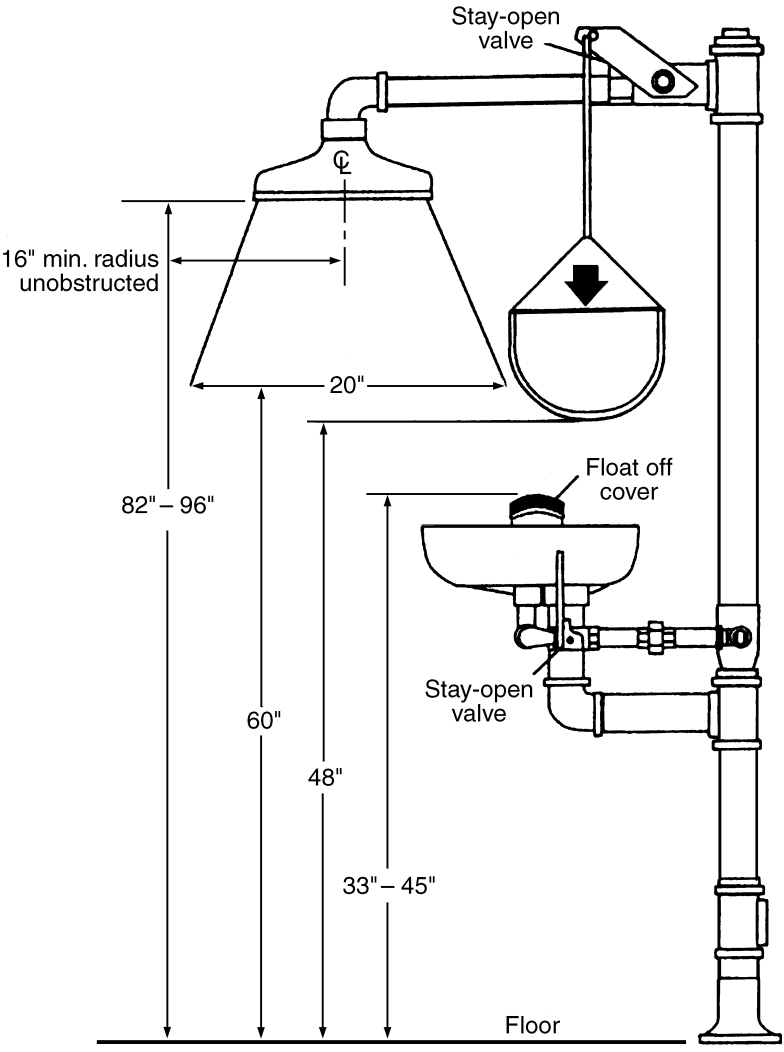


Figure 8-4 Wheelchair-Accessible Shower and Eyewash Equipment

showers in a common corridor, such as outside individual laboratory rooms, is accepted practice. Care should be taken to avoid locating the shower in the path of the swinging door to the protected room to prevent personnel coming to the aid of the victims from knocking them over.

Emergency eye/face washes should be located close to the potential source of hazard. In laboratories, accepted practice is to have 1 sink in a room fitted with an eyewash on the counter adjacent to the sink. The sink cold-water supply provides water to the unit. The eyewash could be designed to swing out of the way of the sink if desired.

Visibility of Devices

High visibility must be considered in the selection of any device. The recognition methods usually selected are high-visibility signs mounted at or on the device; having the surrounding floors and walls painted a contrasting, bright color; and having the device in a bright, well lit area on the plant floor to help a victim identify the area and help in first-aid activities.

Number of Stations

The number of drench-equipment devices provided in a facility is a function of the number of people in rooms and areas with potential exposure to any particular hazard at any one time, based on a worst-case scenario. It is rare for more than one combination unit to be installed. It is important to consider if a group of individuals has potential exposure to a specific hazard, more than one drench unit may be required. Consulting with the end user and the safety officer will provide a good basis for the selection of the type and number of equipment.

Generally, one shower can be provided between an adjacent pair of laboratories, with emergency eye/face washes located inside each individual laboratory. In open areas, it is common practice to locate emergency equipment adjacent to columns for support.

Water Temperature

Code now requires tempered water of approximately 85°F be supplied to equipment. A comfortable range of 60 to 95°F (15 to 35°C) is mentioned in the code. For most indoor applications, this temperature range is achieved because the interior of a facility is heated in the winter and cooled in the summer to approximately 70°F (20° C). Since the water in the emergency drench system is stagnant, it assumes the temperature of the ambient air. A generally accepted temperature of between 80 and 85°F (27 and 30°C) has been established as a "comfort zone" and is now the recommended water temperature.

The body will attempt to generate body heat lost if the drenching fluid is at a temperature below the comfort zone. The common effect is shivering and increased heart rate. In fact, most individuals are uncomfortable taking a shower with water at about 60°F (15°C). With the trauma induced by an accident, the effect is escalated.

Another consideration is the potential chemical reaction and/or acceleration of reaction with flushing water or water at a particular temperature. Where the hazard is a solid, such as radioactive particles, that can enter the body through the pores, a cold-water shower shall be used in spite of its being uncomfortable. It is necessary to obtain the opinions of medical and hygiene personnel where any doubt exists about the correct use of water or water temperature in specific facilities.

Where showers are installed outdoors, or indoors where heating is not provided, the water supplying the showers must be tempered if the air temperature is low. Manufacturers offer a variety of tempering methods, including water-temperature maintenance cable similar to that used for domestic hot-water systems for this purpose and mixing valves with hot and cold-water connections. In remote locations, complete self-contained units are available with storage tanks holding and maintaining heated water.

Protection Against Temperature Extremes

In areas where freezing is possible and water drench equipment is connected to an above-ground, plumbed water supply, freeze protection is required. This is most often accomplished by using electric heating cable and providing insulation around the entire water-supply pipe and the unit itself. It is recommended the water temperature be maintained at 85°F (20°C).

For exterior showers located where freezing is possible, the water supply shall be installed below the frost line and a freeze-proof shower shall be installed. This type of shower has a method of draining the water above the frost line when the water to the drench equipment is turned off.

When a number of drench-equipment devices are located where low temperature is common, a circulating tempered-water supply should be considered. This uses a water heater and a circulating pump to supply the drench equipment. The heater shall be capable of generating water from 40 to 80°F at a rate of 30 gpm (or more if more than one shower could operate simultaneously).

In areas where the temperature may get too high, it is accepted practice to insulate the water-supply piping.

BREATHING-AIR SYSTEMS

General

Breathing-air systems supply air of a specific minimum purity to personnel for purposes of escape and protection after exposure to a toxic environment resulting from an accident or during normal work where conditions make breathing the ambient air dangerous. As defined by 30 CFR 10, a toxic environment has air that "may produce physical discomfort immediately, chronic poisoning after repeated exposure, or acute adverse physiological symptoms after prolonged exposure."

This section discusses the production, purification, and distribution of a low-pressure breathing air and individual breathing devices used to provide personnel protection only when used with supplied air systems. Low pressure for breathing air refers to compressed air pressures up to 250 psig (1725 kPa) delivered to the respirator. The most common operating range for systems is between 90 and 110 psig (620 and 760 kPa).

Much of the equipment used in the generation, treatment, and distribution of compressed air for breathing-air systems is common to that for medical/surgical air discussed in the "Compressed-Gas Systems" chapter.

Codes and Standards

1. OSHA: 29 CFR 1910.
2. CGA: commodity specifications G-7 and G-7.1.
3. Canadian Standards Association (CSA).
4. National Institute of Occupational Safety and Health (NIOSH).
5. Mine Safety and Health Act (MSHA).
6. NFPA: NFPA-99, *Medical Compressed Air*.
7. DOD (Department of Defense): Where applicable.
8. ANSI: Z-88.2, *Standard for Respiratory Protection*.

9. *Code of Federal Regulations* (CFR).

Breathing-Air Purity

Air for breathing purposes supplied from a compressor or a pressurized tank must comply, as a minimum, with quality verification level grade D in CGA G-7.1 (ANSI Z-86.1). Table 8-1, from ANSI/CGA G-7.1, lists the maximum contaminant levels for various grades of air.

For grade D quality air, individual limits exist for condensed hydrocarbons, carbon monoxide, and carbon dioxide. Particulates and water vapor, whose allowable

Table 8-1 Maximum Contaminant Levels for Various Grades of Air (in ppm [mole/mole] unless shown otherwise)

Limiting Characteristics	A	K	L	D	E	G	J	M	N
Percent O_2 balance predominantly N_2 [a]	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5	atm/ 20 - 22	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5	atm/ 19.5 - 23.5
Water, ppm (v/v)[b]		200	50				1	3	
Dew point, °F [b]		-33	-54				-104	-92	
Oil (condensed) (mg/m^3 at NTP)				5[c]	5[c]				None[d]
Carbon monoxid				10[e,f]	10	5	1	1	10
Odor									None
Carbon dioxide				1000[f]	500	500	0.5	1	500
Total hydrocarbon content (as methane)		25			25	15	0.5	1	
Nitrogen dioxide Nitric oxide						2.5	0.1	0.5	2.5
Sulfur dioxide						2.5	0.1		5
Halogenated Solvents						10	0.1		
Acetylene							0.05		
Nitrous oxide							0.1		
USP									Yes

Source: ANSI/CGA G-7.1.ANSI 2-86.1, Table 1.

Note: The 1973 edition of CGA G-7.1 listed nine quality verification levels of gaseous air, lettered A to J, and two quality verification levels of liquid air, lettered A and B. Some of those letter designations were dropped from the 1989 edition, since they no longer represent major volume usage by industry. Four new letter designations, K, L, M, and N, have been added to reflect current specifications. To get a listing of quality verification levels dropped, see CGA-7-1-1973 or contact the Compressed Gas Association.

a The term atmospheric (atm) denotes the oxygen content normally present in atmospheric air; the numerical values denote the oxygen limits for synthesized air.

b The water content of compressed air required for any particular quality verification level may vary with the intended use from saturated to very dry. For breathing air used in conjunction with a self-contained breathing apparatus in extreme cold where moisture can condense and freeze, causing the breathing apparatus to malfunction, a dew point not to exceen -50°F (63 ppm v/v), or 10° lower than the coldest temperature expected in the area, is required. If a specific water limit is required, it should be specified as a limiting concentration in ppm (v/v) or dew point. Dew point is expressed in °F at 1 atmosphere pressure absolute, 101 kPa abs. (760 mm Hg).

c Not required for synthesized air whose oxygen and nitrogen components are produced by air liquefaction.

d Includes water.

e Not required for synthesized air when the nitrogen component was previously analyzed and meets National Formulary (NF) specification.

f Not required for synthesized air when the oxygen component was produced by air liquefaction and meets United States Pharmacopeia (USP) specification.

quantities have not been established, must also be controlled because of the effects they may have on different devices of the purification system, on the piping system, and on the end user of the equipment.

Contaminants

Condensed Hydrocarbons Oil is a major contaminant in breathing air. It causes breathing discomfort, nausea, and, in extreme cases, pneumonia. It can also create an unpleasant taste and odor and interfere with an individual's desire to work. In addition, the oxidation of oil in overheated compressors can produce carbon monoxide. A limit of 5 ppm has been established.

Some types of reciprocating and rotary-screw compressors put oil into the airstream as a result of their operating characteristics. Accepted practice is to use only oil-free air compressors in order to eliminate the possibility of introducing oil into the airstream.

Carbon Monoxide Carbon monoxide is the most toxic of the common contaminants. It enters the breathing-air system through the compressor intake or is produced by the oxidation of heated oil in the compressor. Carbon monoxide easily combines with the hemoglobin in red blood cells, replacing oxygen. The lack of oxygen causes dizziness, loss of motor control, and loss of consciousness. A limit of 10 ppm in the airstream has been established based on NIOSH standards.

Carbon Dioxide Carbon dioxide is not considered one of the more dangerous contaminants. Although the lungs have a concentration of approximately 50,000 ppm, a limit of 1,000 ppm has been established for the breathing airstream.

Water and Water Vapor Water vapor enters the piping system through the air compressor intake. Since no upper or lower limits have been established by code, the allowable concentration is governed by specific operating requirements of the most demanding device in the system, which is usually the CO converter, or the requirement of being 10°F lower than the lowest possible temperature the piping may experience.

After compression, water vapor is detrimental to the media used to remove CO. The dew point of the airstream must be greatly lowered at this point in order to provide the highest efficiency possible for this device. Water vapor is removed to such a low level that breathing air with this level of humidity will prove uncomfortable to users.

After purification, too much humidity will fog the faceplate of a full face mask. It will also cause freeze-up in the pipeline if the moisture content of the airstream in the pipe has a dew point that is higher than the ambient temperature of the area where the compressed-air line is installed.

Solid Particles Solid particles known as "particulates" can enter the system through the intake. They are released from non-lubricated compressors as a result of friction from carbon and Teflon material used in place of lube oils. No limits on particulates have been established by code.

Odor There is no standard for odor measurement. A generally accepted requirement is that there be no detectable odor in the breathing air delivered to the user. This requirement is subjective and will vary with individual users.

Types of System

There are three basic types of breathing-air system: constant flow, demand flow, and pressure demand.

Constant-Flow System

Also known as a "continuous-flow system," the constant-flow system provides a continuous flow of purified air through personnel respirators to minimize the leakage of contaminants into the respirator and to ventilate the respirator with cool or warm air depending on conditions.

This system could be used in a wide variety of areas, ranging from least harmful to most toxic, depending on the type of respirator selected.

Demand-Flow System

The demand-flow system delivers purified air to personnel respirators only as the individual inhales. Upon exhalation, the flow of air is shut off until the next breath. Demand-flow systems automatically adjust to an individual's breathing rate.

This system requires tight-fitting respirators. Its application is generally limited to less harmful areas because the negative pressure in the respirator during inhalation may permit leakage of external contaminants. This system is designed for economy of air use during relatively short-duration tasks and is usually supplied from cylinders.

Pressure-Demand System

A pressure-demand system delivers purified air continuously through personnel respirators with increased air flow during inhalation. By continuously providing a flow of air above atmospheric pressure, leakage of external contaminants is minimized.

This system also uses tight-fitting respirators, but the positive pressure aspect allows them to be used in more toxic applications.

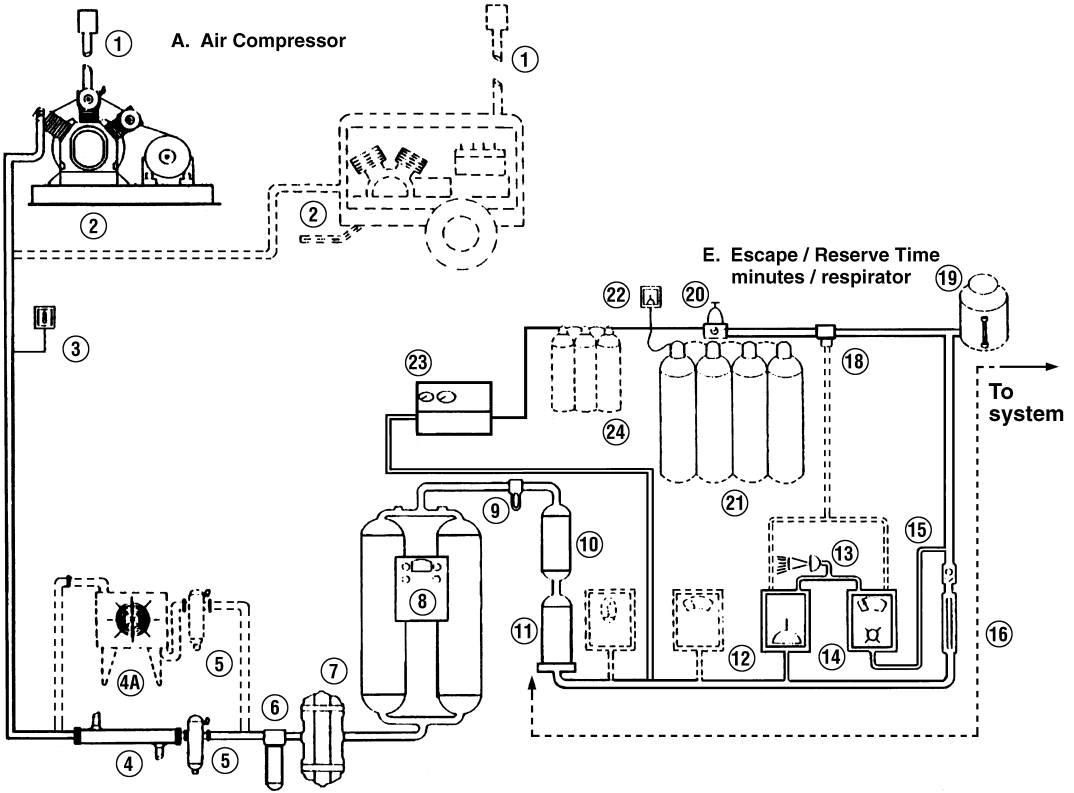
System Components

The breathing-air system consists of a compressed-air source, purification devices and filters to remove unwanted contaminants from the source airstream, humidifiers to introduce water vapor into the breathing air, the piping distribution network, respirator outlet manifolds, respirator hose, and the individual respirators used by personnel. Alarms are needed to monitor the quantity of contaminants and other parameters of the system as a whole and to notify personnel if necessary.

Compressed-Air Source

The source of air for the breathing-air system is an air compressor and/or high-pressure air stored in cylinders. Cylinders use ambient air, which is purified to reduce or eliminate impurities to the required level, and compress it to the desired pressure. A typical schematic detail is shown in Figure 8-5.

Air Compressor The standard for air compressors used to supply breathing air shall comply with the requirement for oil-free medical gas discussed in the



AIR SOURCE
1. Air Compressor: Locate Air Intake in *Contamination Free* Area.
2. Electric Air Compressor (Air Source)

PURIFICATION SYSTEM
3. High Temperature Alarm & Cutout
4. Aftercooler Water Cooled (Heat Removal)

4A. Aftercooler Air Cooled (Alernate Heat Removal)

5. Air / Moisture Separator (Condensed Water & Oil Removal)
6. Coalescer (Water & Oil Slug Removal)
7. Color Change filter (Oil Vapor & Dirt Removal)
8. Regenerative Adsorbent, Purging Dryer (Final Water Vapor Removal)
9. Blue Moisture Indicator (Monitors Dryer Performance)
10. Carbon Monoxide Catalytic Convertor (CO Catalyst)
11. Odor Filter (Odor Removal)
12. Air Compressor Pressure Monitor (Switch over to High Pressure Air Reserve)
13. Alarm Horn (CO, Low Pressure, Failure of Power)
14. Carbon Monoxide Monitor (Monitors Low and High Pressure Air Quality)
15. Outlet Check Valve (Switch over to High Pressure Air Reserve)
16. Breathing Air Flow Meter (Optional)
17. Respirator Outlet Manifold with Pressure Regulator and Gage
18. High Pressure air Reserve Valve
19. Breathing Air Moisturizer (Optional)

STANDBY HIGH PRESSURE BREATHING AIR RESERVE
20. High Pressure Regulator (3000 psig Inlet / 100 psig Outlet)
21. Standby High Pressure Breathing Air Reserve
22. Breathing Air Reserve Pressure Monitor (for Air Reserve Fill)
23. High Pressure Booster (Alternate High Pressure Breathing Air Source)
24. Short term Breathing Air Reserve — Supervisory & Inspection

Figure 8-5 System with Standby High-Pressure Breathing Air Reserve

Source: Courtesy of Nomonox.

"Compressed-Gas Systems" chapter. Medical-gas type compressors are used because these systems as a whole generate far fewer contaminants than other types of system. When a liquid-ring compressor is used, it has the advantage of keeping the temperature of the air leaving the unit low. It is also possible to use any type of compressor for this service, provided the purification system is capable of producing air meeting all the requirements of code.

The air-compressor assembly consists of the intake assembly (including the inlet filter), the compressor and receiver, the aftercooler, and the interconnecting water-seal supply and the other ancillary piping. All of these components are discussed in the "Specialty Gases for Laboratories" section.

Air compressors have a high first cost and are selected if the use of air for breathing is constant and continuous, making the use of cylinders either too costly or too maintenance intensive because of the frequent changing of cylinders.

Storage Cylinder When high-pressure cylinders are used either as a source or as an emergency supply of breathing air, they shall be filled with air conforming to breathing-air standards. The regulator should be set to about 50 psi (340 kPa) depending on the pressure required to meet system demands and losses.

The cylinders have a low initial cost and are not practical to use if there is continuous demand. Cylinders are best suited to intermittent use for short periods of time or as an emergency escape backup for a compressor.

Aftercooler

Some components of the purification system require a specific temperature in order to function properly. Depending on the type of compressor selected and the type of purification necessary, the temperature of the air leaving the compressor may have to be reduced. This is done with an aftercooler.

Aftercoolers can be supplied with cooling water or use air as the cooling medium. Water, if recirculated, is the preferred method. The manufacturer of both the compressor and purification system should be consulted as to the criteria used and the recommended size of the unit.

Purification Devices

The contaminants that are problematic for breathing-air systems must be removed. This can be done with separate devices used to remove individual contaminants or with a prepiped assembly of all the necessary purification devices, commonly referred to as a "purification system," which requires only an inlet and outlet air connection. For breathing-air systems it is commonly done with a purification system.

The individual purification methods used to remove specific contaminants are the same as those discussed in the "Compressed-Gas Systems" chapter. For breathing air, oil and particulates are removed by coalescing and other filters, water is removed by desiccant or refrigerated dryers, and carbon monoxide is removed by chemical conversion to carbon dioxide using a catalytic converter.

Carbon Monoxide Converter The purpose of the converter is to oxidize carbon monoxide and convert it into carbon dioxide, which is tolerable in much greater quantities. This is typically accomplished by the use of a catalyst usually

consisting of manganese dioxide, copper oxide, cobalt, and silver oxide in various combinations and placed inside a single cartridge. The material is not consumed but does become contaminated. The conversion rate greatly decreases if any oil or moisture is present in the airstream. Therefore, moisture must be removed before air enters the converter. Catalyst replacement is recommended generally once a year since it is not possible to completely control all contaminants that contribute to decreased conversion.

Moisture Separator Water and water vapor are removed by two methods, desiccant and refrigerated dryers. The most common desiccant drying medium is activated alumina. For a discussion of air-drying methods, refer to the "Compressed-Gas Systems" systems.

Odor Remover Activated, granular charcoal in cartridges is used for the removal of odors.

Particulates Remover Particulates are removed by means of in-line filters. Generally accepted practice eliminates particulates 1 μ and larger from the piping system .

Humidifier

When water is removed from the compressed airstream prior to catalytic conversion, the dryer produces very dry air. If the breathing-air system is intended to be used for long periods of time, very low humidity will dry the mucous membranes of the eyes and mouth. Therefore, moisture must be added to the airstream to maintain recommended levels. Humidifiers, often called "moisturizers," are devices that inject the proper level of water vapor into an airstream. Some require a water connection.

A recommended level of moisture is 50% relative humidity in the compressed airstream. Care must be taken not to route the air-distribution piping through areas capable of having temperatures low enough to cause condensation. If the routing is impossible to change, a worker will have shorter periods of time on the respirator.

Combination Respirator Manifold and Pressure Reducer

This is a single component with multiple quick-disconnect outlets providing a convenient place both to reduce the pressure of the distribution network and to serve as a connection point for several hoses. A pressure gauge should be installed on the manifold to ensure the outlet pressure is within the limits required by the respirator.

Respirator Hose

The respirator hose is flexible and is used to connect the respirator worn by an individual to the central-distribution piping system. Code allows a maximum hose length of 300 ft (93 m)

Personnel Respirators

There are two general categories of respirator used for individual protection: air purifying and supplied air.

The air-purifying type of respirator is portable and has self-contained filters that purify the ambient air on a demand basis. The advantages to its use are that it is

less restrictive to movements and is light in weight. Disadvantages are that it must not be used where gas or vapor contamination cannot be detected by odor or taste and in an oxygen-deficient atmosphere. This type of respirator is outside the scope of this book, it is mentioned only because of its availability.

The type of respirator selected depends on the expected breathing hazards. In the choice of a respirator, the highest expected degree of hazard, applicable codes and standards, manufacturer recommendations, suitability for the intended task and the comfort of the user are all important considerations.

The EPA Office of Emergency and Remedial Response has identified four levels of hazard at cleanup sites involving hazardous materials and lists guidelines for the selection of protective equipment for each:

1. Level A calls for maximum available protection, requiring a positive-pressure, self-contained suit, generally with a self-contained breathing apparatus worn inside the protective suit.
2. Level B protection is required when the highest level of respiratory protection is needed but a lower level of skin protection is acceptable.
3. Level C protection uses a full face piece and air-purifying respiratory protection with chemical resistant, disposal garments. This is required when the contaminant is known and the level is relatively constant. Typical of its uses is for asbestos removal.
4. Level D protection is used where special respiratory or skin protection is not required but a rapid increase of contaminant level or degradation of ambient oxygen content is possible.

If the hazard cannot be identified, it must be considered an immediate danger to life and health (IDLH). This is a condition that exists when the oxygen content falls below 12.5% (95 ppm O_2) or where the air pressure is less than 8.6 psi (450 mm/Hg), which is the equivalent of 14,000 ft (4270 m).

There are five general types of respirator available, as follows:

Mouthpiece Respirators Used only with demand type systems, mouthpiece respirators are designed only to deliver breathable air. They offer no protection to the skin, eyes, or face. Their use is limited to areas where there is insufficient oxygen and no other contaminants could affect the eyes and skin.

Half-Face-Piece Respirators Half-face-piece respirators cover the nose and mouth and are designed primarily for demand and pressure type systems. They are usually tightfitting and provide protection for extended periods of time in atmospheres that are not harmful to the eyes and skin. Often worn with goggles, these respirators are limited to areas of relatively low toxicity.

Full-Face-Piece Respirators Full-face-piece respirators cover the entire face and are designed for use with constant-flow and pressure-demand systems. They are tightfitting and suitable for atmospheres of moderate and high toxicity. They are usually used in conjunction with full protective clothing for such tasks as chemical-tank cleaning where corrosive and toxic gas, mist, and liquids may be present. Since the face masks provide protection to the face and eyes, they are also suitable

for other tasks, such as welding and the inspection of tanks and vessels where there is an oxygen-deficient atmosphere.

Hood-and-Helmet Respirators Hood-and-helmet respirators cover the entire head and are normally used with a constant-flow system. They are loose fitting and suitable only for protection against contaminants such as dust, sand, powders, and grit. Constant flow is necessary to ventilate the headpiece and to provide sufficient air pressure to prevent contaminants from entering the headpiece.

Full-Pressure Suits Full-pressure suits range in design from loose-fitting, body-protective clothing to completely sealed, astronaut-like suits that provide total environmental life support. They are designed to be used only with constant-flow systems and are suitable for the most toxic and dangerous environments and atmospheres.

Component Selection and Sizing

Breathing-Air Source

Air Compressor The air-compressor size is based on the highest flow rate, in cfm (L/min), required by the number and type of respirators intended to be used simultaneously and the minimum pressure required by the purification system.

The following general flow rates are provided as a preliminary estimate for various types of respirator. Since there is a wide variation in the pressure and flow rates required for various types of respirator, the actual figures used to size the system must be based on the manufacturer's recommendations for the specific respirators selected.

1. 4 scfm (113 L/min) for pressure-demand respirators.
2. 6 scfm (170 L/min) for constant-flow respirators.
3. Up to 16 scfm (453 L/min) for flooded-hood respirators.
4. Up to 35 scfm (990 L/min) for flooded suits.
5. Add 15 scfm (425 L/min) of air for suit cooling if used.

High-Pressure Storage Cylinder High pressure cylinders are used either to supply air for normal operation to a limited number of personnel for short periods of time or as an emergency supply to provide a means of escape from a hazardous area if the air compressor fails. The main advantage to using cylinders is the air in the cylinders is prepurified, and no further purification of the air is necessary.

The number of cylinders is based on the simultaneous use of respirators, the cfm (L/min) of each and the duration, in min, the respirators are expected to be used, plus a 10% safety factor. The total amount of compressed air in the cylinders should not be allowed to decrease too low. A low-pressure alarm should sound when pressure falls to 500 psig (3450 kPa) in a cylinder normally pressurized to 2400 psig (16 500 kPa) when filled to capacity.

Example 9-1
Establish the number of cylinders required for an emergency supply of air for 8 people using constant-flow respirators require 15 min to escape the area.

1. $8 \times 6 \times 15 = 720$ scfm + 72 (10%) = 792 scfm total required

2. Next, find the actual capacity of a single cylinder at the selected high pressure, generally 2400 psi (16 500 kPa), and divide the capacity of each cylinder into the total scfm required to find the number of cylinders required.
3. If 1 cylinder has 225 scf, 792 ÷ 225 = 3.5. Use 4 cylinders.

PURIFICATION COMPONENTS

The air used to fill breathing-air cylinders is purified before being compressed. Breathing air produced by air compressors requires purification to meet minimum code standards for breathing air.

Prior to the selection of the purification equipment, several samples of the air where the compressor intake is to be located should be taken so specific contaminants and their amounts can be identified. The ideal situation is to have the tests taken at different times of the year and different times of the day. These tests quantify the type and amount of contaminants present at the intake. With this information known, the purification systems needed to meet code criteria can be chosen. The other requirement is the highest flow rate that can be expected. With these criteria, the appropriate size and types of purifier can be selected.

The most commonly used method of purification is an assembly of devices called a "purification system" specifically chosen and based on the previously selected criteria. Manufacturers' recommendations are commonly followed in the selection and sizing of the assembly.

Carbon-Monoxide Converter The requirement for installation of a carbon-monoxide converter is rare. The need for a converter is based on tests of the air at the proposed location of the compressor intake. Another source of information is the EPA, which has conducted tests in many urban areas throughout the country. Another indication that installation may be necessary is the use of a non-oil-free compressor. Good practice requires the installation of a converter if there is an outside chance the level of carbon monoxide may rise above the 10 ppm limit set by code.

The converter is sized based on the flow rate of the system.

Coalescing Filter/Separator The coalescing filter/separator is a single unit that removes large oil and water drops and particulates from the airstream before the air enters the rest of the system. It is selected on the basis of maximum system pressure, flow rate, and the expected level of contaminants leaving the air compressor, using manufacturer's recommendations. If an oil-free compressor is used, a simple particulate filter could be substituted for the coalescing filter.

Dryers (Moisture Separators)

Desiccant Dryers— The two types of desiccant media dryer most commonly used are the single-bed dryer, which is a disposable cartridge, and the continuous-duty, two-bed dryer.

When two-bed dryers are used, a portion of the air from the compressor is used for drying one bed while the other is in service. The compressor must be capable of producing enough air for both the system and dryer use.

The single-bed dryer has a lower first cost but a higher operating cost. The disposable cartridge often is combined with other purification devices into a single,

prepiped unit. An indicator is often added to the media so the need for replacement is indicated by a color change.

Disposable units are best suited for short durations or occasional use, such as for replacement of a main unit during periods of routine service. Because of their generally small size, only a limited number of respirators can be supplied from a single unit. Other considerations are that these disposable units have a limited capacity, in total cfh, they can process. Manufacturers' recommendations must be used in the selection of the size and number of replacement cartridges required for any application.

The two-bed unit, commonly called a "heatless dryer," is similar in principle to that discussed in the "Compressed-Gas Systems" chapter. Such units are used for continuous duty.

The two factors contributing to the breakdown of media are fast-drying cycles and high air velocity. If a desiccant dryer is selected, the velocity of air through the unit shall conform to manufacturer's recommendations. Velocity should be as low as is practical to avoid fluidizing the bed. High velocity requires more cycles for drying, which means wasting more air. If the size of the dryer is a concern, more drying cycles means smaller dryer beds. Longer drying cycles reduce component wear.

Refrigerated Dryers—Refrigerated dryers are used if there is no requirement for a nitrous oxide converter and if the 35–39°F dew point produced is 10°F below the lowest ambient air temperature where any pipe will be installed. The refrigerated dryer is less efficient than the desiccant dryer. Its advantages are that all the air produced by the compressor is available to the system and it has a lower pressure loss.

When refrigerated dryers are preferred, several purification devices are often combined into a single unit, including the refrigeration unit, filter/separator for oil and water, and a charcoal filter for odor removal. This unit produces air that is lower in temperature than the inlet air.

If the breathing-air distribution piping is to be routed through an area of lower temperature, the pressure dew point of the air must be reduced to 10°F lower than the lowest temperature expected.

Odor Remover Odors are not usually a problem, but their removal is provided for as a safeguard. The activated charcoal cartridges remove odors are selected using manufacturers' recommendations based on the maximum calculated flow rate of the breathing-air system. The cartridges must be replaced periodically.

Humidifiers

Often called a "moisturizer," a humidifier is required to increase the relative humidity of the breathing air to approximately 50% if required. The unit is selected using the increase in moisture required for the airstream and the flow rate of air. Caution must be used so as not to increase the dew point of the compressed air above a temperature 10°F lower than the lowest temperature in any part of the facility the pipe is routed through.

Respirator Hose

The respirator hose most often used to connect the respirator worn by an individual to the central-distribution piping system is ⅜ in. (10 mm) in size. Code allows a

maximum hose length of 300 ft (93 m). The most common lengths are between 25 and 50 ft (7.75 and 15.5 m).

System Sizing Criteria

System Pressure The outlet pressure of the compressor shall be within the range required by the purification system. Typically, the pressure is approximately 100 psi (70.3 kg/cm2). The precise range of pressure and flow rate shall be obtained from the purification system manufacturer selected for the project.

The pressure in the distribution system should be as high as possible to reduce the size of the distribution-piping network. Code requires the pressure be kept below 125 psi (88 kg/cm2). The distribution-piping pressure range is usually 90 to 110 psig (620 to 760 kPa) available in the system after the purifier.

The pressure required at the respirator ranges from approximately 15 psig for pressure-demand respirators to 80 psig for full-flooded suits that require cooling. The actual requirements can be obtained only from the manufacturer of the proposed equipment because of the wide variations possible. Pressure-regulating valves shall be installed to reduce the pressure to the range acceptable to the respirator used. Often, this reduction is done at the respirator manifold, if one is used, or, if a single respirator type with a single pressure is used throughout the facility, a single regulator can be installed to reduce the pressure centrally.

Pipe Sizing and Materials The most commonly used pipe is type L copper tubing, with wrought copper fittings and brazed joints.

For pipe sizing, follow the sizing procedure discussed in the "Compressed-Gas Systems" chapter. The number of simultaneous users must be obtained from the facility. No diversity factor should be used.

Alarms and Monitors

The following alarms and monitors are often provided:

CO Monitor Usually included as a built-in component, this monitor measures the CO content of the airstream and sounds an alarm when the level reaches a predetermined high set point.

Oxygen-Deficiency Monitor Used as a precautionary measure in an area where respirators are not normally required, the oxygen monitor measures the oxygen content of the air in a room or other enclosed area and sounds an alarm to alert personnel when the level falls below a predetermined level. Usually, several alarm points are annunciated prior to reaching a level low enough to require the use of respirators.

Low-Air-Pressure Monitor The low-air-pressure monitor must sound an alarm when the pressure in the system reaches a predetermined low point. This set point allows the users of the breathing-air system to leave the area immediately while still being able to breathe from the system. For cylinder storage, this set point is about 500 psig in the cylinders. For a compressor system, the alarm should sound when the pressure falls to a point 10 psig below the pressure set to start the compressor. This should also switch over to the emergency backup supply if one is used. If no backup is used, the pressure set point shall be 5 psig higher than the minimum required by the respirators being used.

Dew-Point Monitor A dew-point monitor is used to measure the dew point and sound an alarm if it falls to a low point, set by a health officer, that might prove harmful to the users. It is required to alarm if the dew point reaches a point high enough to freeze in some parts of the system.

High-Temperature Air Monitor Some purifiers or purifier components will not function properly if the inlet air temperature is too high. The set point is commonly 120° F but will vary among different manufacturers and components.

Failure-to-Shift Monitor This monitor is placed on desiccant dryers to initiate an alarm if the unit fails to shift from the saturated dryer bed to the dry bed when regeneration is required.

9 Facility Environments

INTRODUCTION

The facility environment provides protection for the production and regulation of pharmaceuticals, diagnostic products, and medical devices through the control of potential contamination by microorganisms, particulates, and other contaminants. Contaminants also include other products that may be manufactured in the same facility. At issue is the safety of the user as well as the safety of manufacturing, laboratory, and medical personnel. Environments for radiopharmaceuticals, microbiologicals, aseptic products, and blood products must meet the unique requirements of each product.

At one time, the industry relied on final product testing to ensure quality. As the industry progressed, the importance of manufacturing systems and environments became evident. Most notable in this evolution was the wide-scale, septic contamination of large-volume parenterals in the early 1970s. This contamination was attributable to package design, water, compressed air, and environmental problems. The industry learned quality can not be tested into a product. Quality must be designed and built into the manufacturing environment and systems from the beginning.

The issue of controlled environments is complex in terms of both regulation and application. Regulation has become more complicated in the increasing globalization of manufacturing and sales. This has created an international industry that must meet a multiplicity of national and local requirements. Common to all regulations is the general requirement the environment be both reliable and consistent. Further, verification must be made that the environment performs within predetermined acceptance criteria.

"Controlled environments" are defined areas where the processing of drugs and medical devices is conducted. Within these areas the quality and quantity of measurable attributes are controlled and monitored to ensure product quality. The measurable attributes are compared to standards that control or relate to the quality of the final product.

"Clean rooms" are critical controlled environments where the microbiological and particulate levels are reduced and maintained to high levels of cleanliness and purity. Clean-room classification is dependent on the quality of air, services, surfaces, and personnel attire.

In addition to the design and construction focus, which ensures quality conditions, the industry and regulators have adopted the concept of validation. Validation uses statistical methods to verify the functionality and reliability of key systems

from design through installation to qualification before product is qualified. The validation effort is meant to identify potential problems prior to manufacturing to optimize product quality and consistency. Section 211.110 of the federal regulations defines the intent of validation as follows:

"Control procedures shall be established to monitor the output and *validate* the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product."

Validation of environmental conditions normally follows three distinct levels of qualification:

- **Installation qualification** A method to verify and document that equipment meets its specifications. This includes verification that all utilities and services meet the design intent and support equipment performance. Checks normally be made in this phase include materials of construction, motor sizing, etc. related to the equipment specification against which the equipment was purchased or manufactured.
- **Operational qualification** A method to verify the equipment or system meets its operational and performance requirements. Checks made during this phase include proper rotation, interlock functions, instrument performance, etc. related to the function of equipment in operation.
- **Product or process qualification** A method of conducting product runs to show the product and all intermediate product steps meet all purity and performance requirements. Normally three consecutive runs are required to establish a process or product system is performing.

For more information on the process of validation, see the "Validation" chapter.

CLEAN ROOMS

Clean room requirements are dependent not only on manufacturing systems, but also on the final product. The requirements for an oral drug are not the same as those for a parenteral or a medical diagnostic reagent. A parenteral product must be sterile as it is injected into the bloodstream and bypasses a patient's natural defenses. Conversely, a diagnostic reagent may be unaffected by variations unrelated to its chemical indication reaction.

For years the American guidelines for controlled environments were the most stringent in the world. Generally, products manufactured in accordance with the United States Food and Drug Administration (FDA) requirements could be sold globally. In 1992, however, the European Economic Community (EEC) published *Good Manufacturing Practice for Medicinal Products in the European Community*. These EEC guidelines, which were revised in 1997, continue to establish more stringent requirements for the international industry than those of the US FDA.

The requirements for pharmaceutical controlled areas are classified by the air quality as measured primarily by the presence of particulates and organisms. The intent of this classification is best illustrated, in Table 9-1 by the applications intended for each class.

The critical-zone design is dependent on many factors that may affect the environmental requirements established by international criteria. It is possible to meet

both EEC and US FDA requirements through proper design and installation. For example, the background classification of Class 10,000 of the American standard is for operational conditions while the EEC Grade B requirement is for static, nonoperational conditions. This difference allows the same installation to meet both requirements with proper design. The parameters for critical areas or zones are presented in Table 9-2.

Table 9-1 Air Quality Classification

US Class	EEC Class	Typical Application
100	Grade A	Sterilized product critical zones
100	Grade B	Surrounding critical areas
10,000	Grade C	Controlled area, such as sterile-product component processing
100,000	Grade D	Controlled non-sterile-product processing

Note: United States = US, EEC = European Econimic Class

Table 9-2 Parameters for Critical Areas

Parameters	US Criteria	EEC Criteria
Critical area clean room	Class 100 zone	Grade A zone
Maximum particulates: 0.5μ or larger	100/ft^3 (3531/m^3)	3500/m^3 (99/ft^3)
Max. viable organisms	0.1/ft^3 (3.53/m^3)	1/m^3 (0.03/ft^3)
Air flow rate	Vertical: 90 fpm (0.457 m/s) at 1 ft upstream of work are Horizontal: 114 fpm (0.58 m/s) at 1 ft upstream of work area	Vertical: 0.3 m/s (59 fpm) at 1 ft upstream of work area Horizontal: 0.45 m/s (88.6 fpm) at 1 ft upstream of work area
Zone pressurization	Positive 0.05 in. water	Positive 10-15 Pa
Background	Class 10,000	Grade B

Note: United States = US, EEC = European Econimic Class

To achieve the above parameters required by critical-zone applications, or those required by any lesser clean environment, the area design must be specified to support the environmental class. The area finishes, support utilities, and equipment must be developed to support the environmental control, particulate count, and microbiological levels required. General design factors, which must be incorporated, include:

- Hard surfaces that are easily cleaned and sanitized
- Clean water, air, and steam supplies that do not vent in the area and are concealed within chases.
- When exposed piping is required it must be constructed and installed away from walls so as to be completely cleanable. It shall have no horizontal surfaces that will catch dirt or other contaminants.
- Piping insulation must be covered with a material that can be wet cleaned and will not generate particulates.
- Exposed piping shall be identified as to purpose.

- No sinks or open drains are permitted in critical areas unless absolutely necessary. If drains are installed, they shall be capable of being closed with a smooth-top, stainless-steel cover.
- Drains shall be of proper design and prevent backflow.
- Effluent must be treated to eliminate contamination.

MEDICAL DEVICE AND DIAGNOSTIC PRODUCT ENVIRONMENTS

This section pertains to environmental design for product that is not invasive during patient treatment. Invasive critical devices, such as hypodermic needles, are manufactured in environments similar to those for drugs. In contrast, the facility design for standard devices and diagnostics should provide a clean environment that supports the efficacy, use, processing, and packaging of the device or diagnostics. The area may be conditioned for personnel and humidity controlled for the product or packaging equipment. In general, exposure of the product to the environment is not a major concern. Room cleanliness is controlled to eliminate potential contamination and to ensure product integrity.

LABORATORY ENVIRONMENTS

The usual laboratory related to pharmaceuticals, medical devices, and diagnostic products is for chemical, analytical, or microbiological testing. Such laboratories may be used for research and development but may provide quality-control functions directly related to manufacturing control. The complexity and variety of normal laboratory operations may well dictate the environmental considerations critical to design. For example, a microbiological laboratory used for the verification of manufacturing contamination must meet the critical, aseptic requirements of the most critical manufacturing area. For general-purpose areas, the use of solvents and cylinder gases within these environments requires safety to take precedence in area design and installation.

ANIMAL-CARE ENVIRONMENT

Both the pharmaceutical and medical device industries maintain animal facilities to test and qualify products. Animal testing is often necessary to establish product safety. Testing is performed both to verify product attributes and to prequalify product for approval. An animal-housing facility must be divided into areas suitable for:

- Quarantine of animals on receipt to ensure animals are healthy.
- Housing and care of separated species of animals.
- Laboratory testing or experiment.
- Cleaning and sanitation of all systems and animal equipment.

The design must support the animals' health and comfort and must not adversely affect the test integrity.

The environmental design must be designed to provide for continuous operation and to eliminate cross-contamination between functions. Generally, animal-facility air-conditioning systems are dedicated to the facility. The facility shall be designed to have positive air pressure with regard to the outside environment to eliminate

potential contamination. Test laboratories within the facility are usually positive with regard to the animal care and housing areas.

The design should allow for an efficient and hygienic operation. Monolithic and durable materials are preferred to allow repetitive cleaning and disinfecting. Floors should be pitched to eliminate standing water and to permit easy cleaning. Design should accommodate the use of high-pressure water and steam in the cleaning protocols.

CURRENT GOOD MANUFACTURING PRACTICES

Current good manufacturing practice requires conformity with the following standards:

- *NASA Standards for Clean Rooms and Work Stations for the Microbially Controlled Environment* (NASA, 1967).
- Federal Standard 209, *Airborne Particulate Cleanliness Classes in Clean Rooms and Clean Zones*.

10 Validation

INTRODUCTION

This chapter explains validation and how this process affects the plumbing engineer. Disciplines other than the plumbing design group will likely originate and perform the actual validation process, but it is important for the plumbing engineer to understand the process in order to make informed decisions about documents that are produced and the method in which they are created and filed.

The FDA defines "validation" as follows: "Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product, meeting its predetermined specifications and quality attributes."

The objective is to demonstrate the process is as specified and under control. Validation is the responsibility of the end user and it must be an approved protocol. All data and adjustments must be recorded and reviewed. Written reports are essential. Validation must be controlled by quality assurance and there must be a scientific need to challenge and prove equipment functions. The facility equipment is owned and operated by the user throughout the validation process.

CODES AND STANDARDS

1. *Code of Federal Regulations*, CFR 21.
2. FDA rules and regulations.

VALIDATION REQUIREMENTS

Validation Process Requirements

The process of validation should ensure that the given utility, system, process, or piece of equipment:

1. Meets or exceeds the specifications of its design.
2. Is properly built, shipped, received, stored, installed, and maintained.
3. Is suitable for its intended application.
4. Is in accordance with principles established and generally accepted by the scientific community.
5. Conforms to basic cGMP design criteria.
6. Is likely to satisfy the concerns of regulatory agencies.
7. Is capable of consistently producing a product fit to use.
8. Will meet the goals established for productivity, safety, and quality.

Validation File Requirements

A typical validation file should contain the following documents, as a minimum:

1. Engineering drawings.

2. Engineering specifications.
3. Validation documents.
4. Vendor drawings and manuals.
5. Calibration documents and certifications.
6. Construction documents.

Required Validation Documents

Documentation is the key to the successful validation of a facility. Key validation documents include, but are not limited to:

1. Validation master plan.
2. Validation protocols, including installation qualification (IQ), operation qualification (OQ), performance qualification (PQ), computer validation, cleaning validation, process validation.
3. Standard operating procedures (SOPs), including operation, preventive maintenance, calibration, and cleaning.

Validation Master Plan

A validation master plan answers the questions, what is to be validated, why (which authority, which products), how (validation methodology), who (validation team responsibilities) and when (validation programs). The master plan also identifies all systems and equipment to be commissioned/validated.

The validation master plan serves as a document that may be presented to regulatory bodies to convey the level of understanding of company responsibilities concerning the validation program. It also serves as a guide to those administering and performing validation activities, a management tool for tracking validation performance and progress, a mechanism for establishing responsibilities and accountabilities, and a plan to ensure all products manufactured meet all product specifications and cGMP values.

The major items included in a validation master plan are:

1. Glossary of terms.
2. Facility description (drawings, room specification sheets, flows).
3. Process description (equipment utilities, automation).
4. Scope of validation activities.
5. Acceptance criteria.
6. List of SOPs.
7. Validation schedule.
8. Validation supplies.
9. Validation personnel and responsibilities.
10. Protocol examples.
11. Environmental monitoring program.
12. Training program.
13. Analytical testing procedures.
14. Calibration program.

Some of the systems requiring validation include, but are not limited to:

1. Water systems, including water for injection, purified water and chilled water.

2. Compressed gases, including compressed air, process air, and nitrogen.
3. Clean steam and plant steam.
4. Process vacuum.
5. CIP/SIP systems (clean-in-place and sterilize-in-place).
6. Solvent storage and recovery.
7. Warehouse and packaging systems.
8. Process automation systems.
9. HVAC.
10. Process equipment, including reactors and agitators, centrifuges, freeze dryers, and autoclaves.

Validation Protocols

Validation protocols are plans for a specific system or piece of equipment that, when executed, provides evidence the design and manufacturing intentions are met. The protocols are written to incorporate the following factors:

1. They should be user-friendly, i.e., capable of being executed with minimal supervision.
2. They should be non-generic, i.e., the user should be led through the required steps rather than rely on prior knowledge or experience.
3. They should be consistent with existing customer specifications and applications.
4. They should incorporate a modular format to provide ease of writing, presenting, modifying, and executing.
5. They should be plans such that equipment specifications are validated in the context in which they are utilized.
6. They should be tailored to the client facility and equipment.

Installation Qualification (IQ) An IQ verifies the system or equipment is installed according to design and specification and ensures instrumentation is properly calibrated. The IQ can be performed as construction proceeds, bearing in mind certain systems must be used as they are constructed. Drainage systems are an example of this type of system.

The documents required for an IQ include, but are not limited to:

- Process flow diagrams (PFDs).
- Piping and instrument diagrams (P&IDs).
- Layout.
- Isometric piping drawings.
- Equipment list.
- Instrument list.
- Purchase orders.
- Design specifications.
- Vendor specifications.
- Vendor drawings.
- Vendor cut sheets.
- Construction certifications.
- Vendor certifications.

- Operating manuals.
- System descriptions.
- Equipment descriptions.
- Factory acceptance tests.
- Site acceptance tests.
- Piping certifications (pressure tests, weld certifications, passivation certifications).
- Spare parts list.

Some examples of IQ checks are:

- P&IDs.
- Calibration.
- Installation.
- Certifications (HEPA filters, etc.).
- Construction documentation.
- Specifications.
- As-builts.
- Utility reviews.

Operational Qualification (OQ) An OQ verifies the system or equipment operates according to design and specifications. OQs are performed after installation qualifications. OQs can be performed as part of start-up operations (which requires training and schedule coordination).

Some examples of OQ checks are:

- Training.
- SOPs.
- Maintenance logs.
- Alarms and interlocks.
- Operating conditions.
- Set points.
- Capacity checks.

Performance Qualification (PQ) A PQ verifies the system or equipment performs as intended and specified. A PQ is generally executed with product and verifies the same conditions are maintained as in actual operation. The conditions must be repeated three consecutive times in order to be valid.

Some examples of PQ checks are:

- Consistency of operation and function over time.
- Repeatability.
- Verification that under the same conditions, product quality and specifications are realized.

Mechanical Completion (MC) The completion of the scope of all the contractors' construction-site activities in full accordance with the contract design documents, drawings, specifications and applicable codes.

GENERAL VALIDATION CONSIDERATIONS

Given all the above descriptions and explanations, and from a design standpoint, the primary emphasis is on documentation and procedure. The kind of questions that should be asked include:

1. Is there a procedure for maintaining documentation within the firm?
2. Can retrieval of vendor information or data when specifically requested be accomplished in a timely manner?
3. Have the documents listed above been requested in the specifications?
4. Verification of who will be responsible for validation to ensure a procedure is in place within the organization should that person be called upon to provide such services.

COMMISSIONING

Although outside the scope of this manual, commissioning is an important ancillary to validation. Validation requires the criteria and theory of the process work. The purpose of commissioning is to identify and rectify actual problems that may occur during initial start-up and operation of systems and equipment. Commissioning is considered a supplier responsibility. It may not be to an approved protocol but should conform to accepted good engineering practice. Not all data and adjustments are necessarily recorded and reviewed and no written report is made unless specified. The engineering project team usually controls commissioning. The facility equipment is owned and operated by the supplier until commissioning is completed.

11 Clean-in-Place and Steam-in-Place Systems

CLEAN-IN-PLACE SYSTEMS

Clean-in-place (CIP) is a method for cleaning process equipment and systems without opening or dismantling them. CIP was originated by the dairy industry decades ago but has been applied with increasing regularity in the pharmaceutical and biotechnology industries during the past few years. Although commonly used for process tanks, granulators, and similar equipment, some complex systems such as tablet presses and fillers have been adapted for CIP.

CIP systems have several advantages over manual cleaning. They include validatability, improved product quality, reduced costs, and greater operator safety.

Safety involves the exposure of the operators either to hazardous cleaning compounds needed for removing particularly difficult materials or to hazardous or toxic products themselves. With closed CIP systems, the possibilities of exposure are greatly reduced.

The CIP system improves product quality by providing a cleaner environment for processing operations than manual cleaning procedures, with lower levels of both residual products and cleaning agents. Along with the improvement in quality, there is a major advance over manual operations in reproducibility of the cleaning processes. An automated CIP system can be designed to provide the same quantity, flow rate, pressure, and distribution of cleaning agents to the equipment in every cycle. This is impossible with manual cleaning. Cleaning validation acceptance criteria can be met with a far greater degree of assurance, and in less time.

Cost savings are achieved by a reduction in the time spent and the labor costs involved in cleaning the equipment and an increase in the production time available. Equipment or system disassembly is eliminated with CIP.

System cleaning is affected by several variables. The most important are the time the equipment is exposed to cleaning solutions, the temperature of the solutions, the degree of turbulence at the point of contact with the surfaces, the type and concentration of the cleaning agents, and the characteristics of the surfaces to be cleaned. The CIP system must be designed to optimize these factors, with a view to providing a system that operates cost efficiently. In most cases, the more severe the cleaning conditions, the better the degree of cleaning, but this must be tempered by operating-cost concerns. For example, 200°C water will be more effective in cleaning than 150°C water in most cases, but maintaining a 200°C system is substantially more costly.

Flow rates are critical to efficient cleaning. The quantity of solution is dependent upon the size and type of surface to be cleaned and the degree of difficulty of remov-

ing the material. There are some rules of thumb used to determine the amount of solution needed, ranging from 0.1 to 0.5 gpm/ft2 of area to be cleaned.

Spray heads are used inside vessels to provide the cleaning motive force. Static spray balls with either upper-hemisphere spray or full spray are common in tank cleaning, with most of the spray directed upward to the head and to the upper walls. They use flow rates ranging from 20 to 60 gpm at 15 to 20 psig. Dynamic spray heads are either mechanically or hydraulically driven. Mechanically driven spray heads can be used in vessels or in equipment with more complex configurations. As an average, they require about 10 gpm, but at about 60 psig. Hydraulically driven heads use about 20 gpm at up to 150 psig.

CIP systems contain one to three solution vessels, a heat exchanger, one or more circulation pumps and usually some method for returning the cleaning solution to the tanks. This can be done by gravity, by pump, or by an eductor system. There are once-through systems, which can be portable or can be used for biocontainment. Once-through systems are more expensive to operate than other types of system, because of the higher cost of cleaning chemicals. Water is heated using either a shell-and-tube or plate heat exchanger to heat the cleaning solution to the correct temperature. The hot solution is distributed to the equipment to be cleaned.

Gravity-return systems are obviously the least expensive to operate but their use is restricted to certain configurations within buildings. Return pumps are commonly used to bring the fluids from the discharge of the vessel or other equipment back to the CIP system. Only two or three vessels can be connected to a single return pump, so multiple pumps may be required. A portable return pump can be used, if the size of the system to be cleaned and the cleaning schedule can be adapted to its use. An eductor eliminates the need for return pumps. A separate motive pump recirculates water in a line containing an eductor. This creates a vacuum at the restriction to pull the cleaning fluids back to the CIP tanks. One potential drawback is the possibility of vapor lock in the motive pump when hot fluids are used.

Types of CIP System

A single-tank CIP system is designed to deliver cleaning solutions to the equipment and to divert them to the drain after the wash is complete. Fresh water can then be added to the CIP tank and circulated through the system to rinse out chemical residues. A sanitizer can also be added to the rinse water via a supply nozzle in the pump-suction line, if it is needed for the process. Obviously, cleaning solutions and rinses can not be recirculated and reused in a single-tank system. It is the method with the lowest capital cost, but it has higher operating costs. A single-tank configuration is illustrated in Figure 11-1.

A two-tank CIP system allows cleaning solution to be stored in one tank for use in subsequent cleaning operations. The second tank contains fresh water for system rinses. The tank can be filled for the first rinse and then refilled for a second, or the same rinse water can be used for more than one rinse. If a detergent is used on a once-through basis, the rinse water supplied to the system from the second tank can be collected in the detergent tank and used to make up detergent solution for the next cleaning cycle. A dual-tank configuration is illustrated in Figure 11-2.

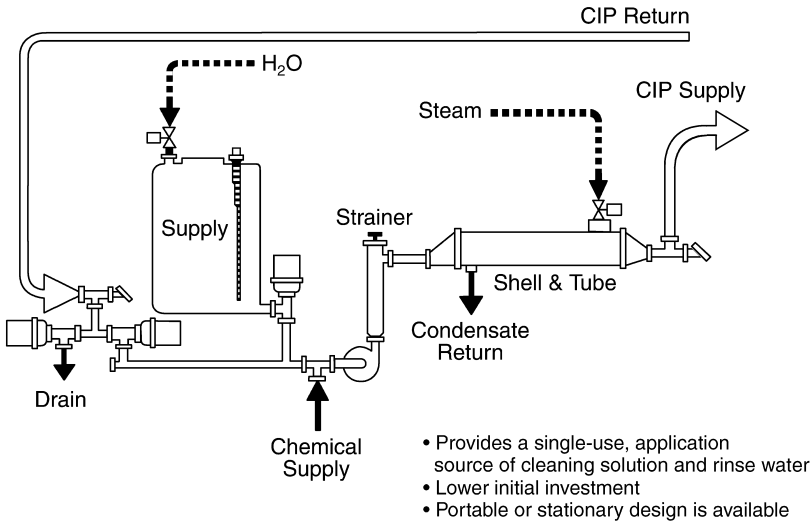


Figure 11-1 Clean-in-Place System — Single-Tank Configuration

Source: Courtesy of Sani-Matic Systems.

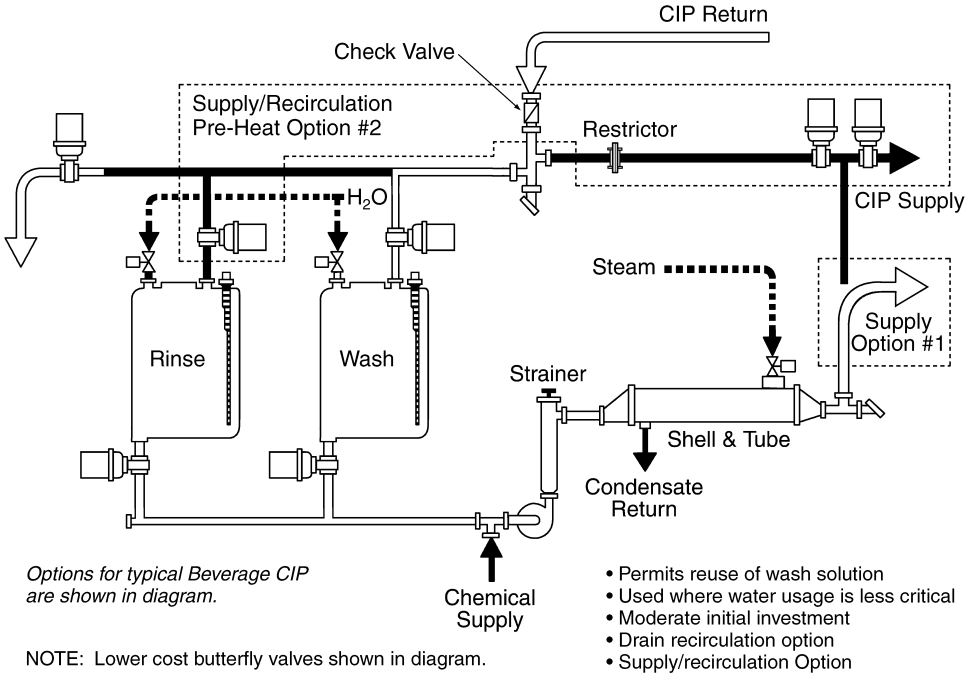


Figure 11-2 Clean-in-Place System — Dual-Tank Configuration

Source: Courtesy of Sani-Matic Systems.

A three-tank CIP system operates similarly to a two-tank system. It provides an additional storage tank to collect spent rinse water, which can be used either as a prerinse or for detergent makeup for the next cycle. In both two and three-tank systems, chemicals can also be added to the wash liquid via an injection port on

the circulating-pump suction line. A three-tank configuration is illustrated in Figure 11-3.

Two and three-tank systems have higher capital costs than a single tank, but provide operating savings by allowing for recycling and reusing of cleaning agents.

Dual CIP systems contain either two or three tanks but have two circulation pumps and two heat exchangers and separate supply and return piping loops. This setup allows for the cleaning of two separate systems at the same time, provided the same cleaning agent is used in each. The controls and piping are more complex than they are for a single loop, but there is an advantage in cycle time that could compensate for the capital cost differential. This type of system is useful in cases where cleaning time must be minimized to maintain production. A dual system is illustrated in Figure 11-4.

CIP systems are usually constructed of polished type 316 stainless-steel tubing. Lines are welded using automatic welding machines or are connected using sanitary clamp-type fittings. The piping should be pharmaceutical quality if it is being used to clean pharmaceutical manufacturing systems. Centrifugal pumps and system valves are of sanitary design. The flow in the circulating system should be designed for a minimum of 5 fps.

STEAM-IN-PLACE SYSTEMS

Sanitize or steam-in-place (SIP) is a method of sanitizing or sterilizing large or complex equipment by heating it with pure steam to at least 121°C for a minimum of 15 min. It is critical the entire system be heated and maintained at that temperature for the requisite time. Smaller vessels can also be steamed in place rather than moved to an autoclave for sterilization. A rule of thumb is about 30 kg of steam are needed per cubic meter of equipment volume to be sterilized.

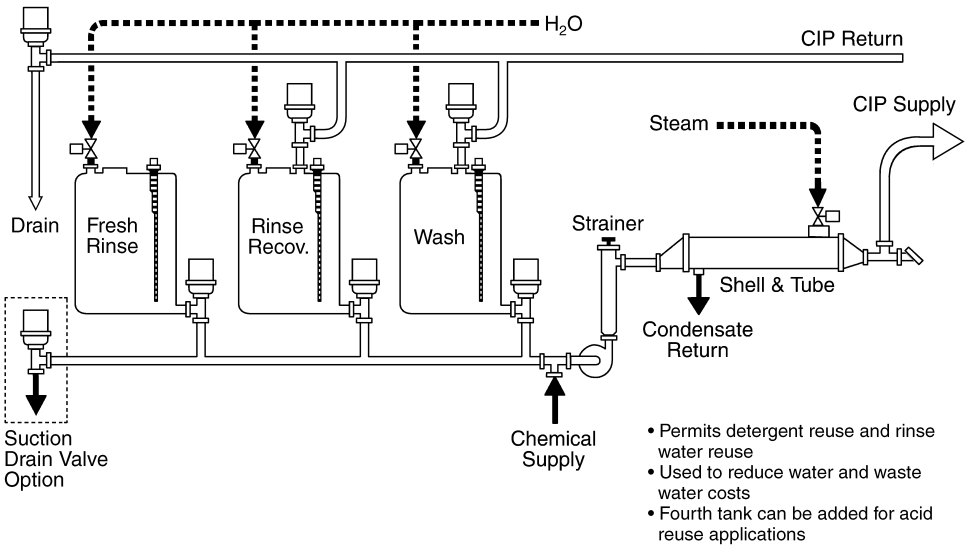


Figure 11-3 Clean-in-Place System — Typical Three-Tank Configuration

Note: Courtesy of Sani-Matic Systems.

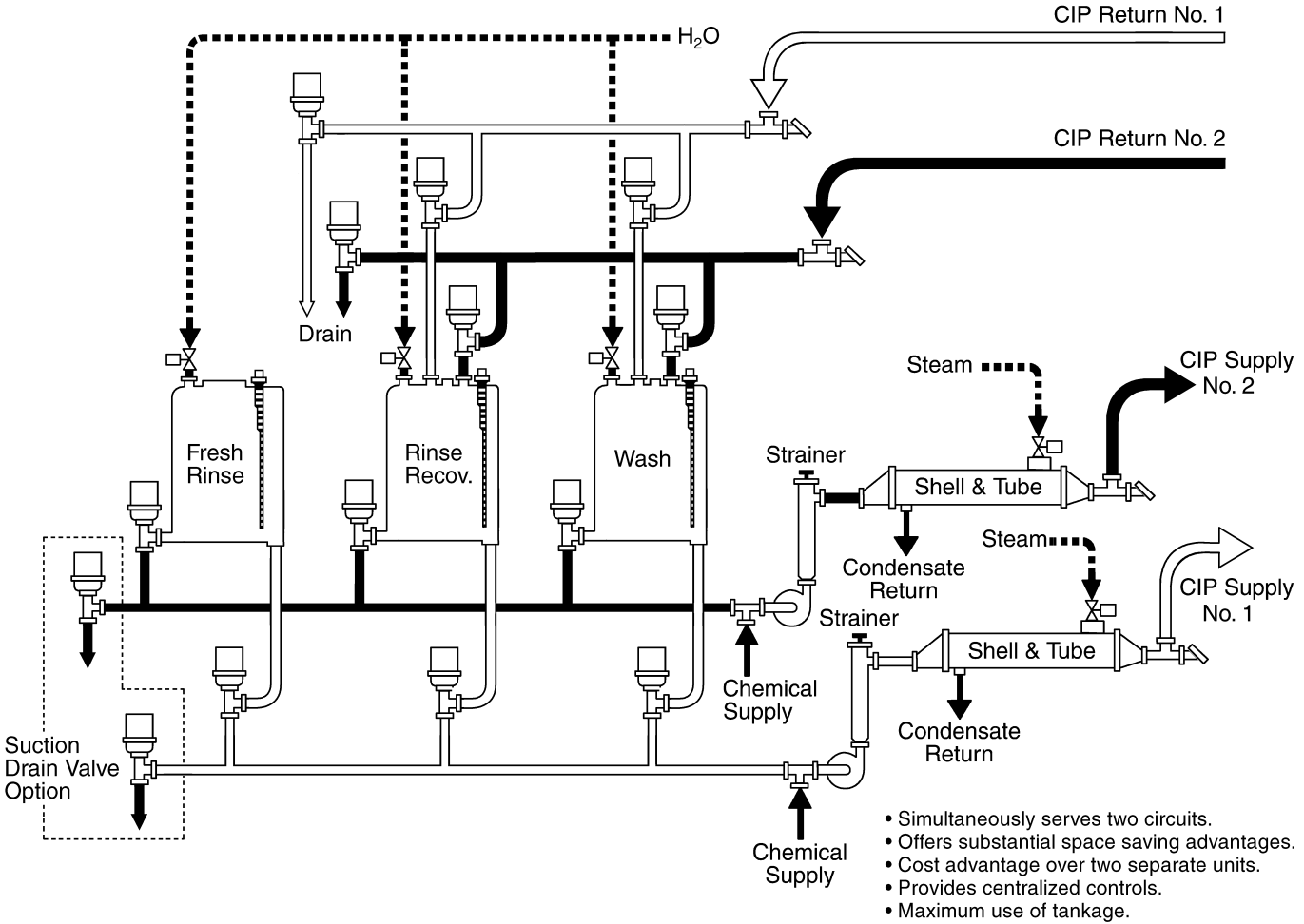


Figure 11-4 Dual Clean-in-Place System

Source: Courtesy of Sani-Matic Systems.

SIP piping can be the same system as the CIP distribution, with pure steam being introduced upstream of the equipment, or the steam can be added directly to the vessels from the pure steam line. Pure steam lines are usually double valved, first with a ball valve at the steam line and then with a sanitary diaphragm valve at the equipment. The diaphragm valve is susceptible to damage from the steam if it is used as a block valve in the main steam line.

Process transfer lines are steamed either by filling the process vessel with steam or by adding steam directly to the transfer lines. At times both methods are used. Sanitary steam traps should be installed at low points in lines and at vessel drains to remove the condensate from the SIP process. Great care must be taken with non-pressure rated vessels during cooling to be sure the walls do not collapse when a vacuum forms from the condensing steam. Filtered air or nitrogen should be used to break the vacuum after steaming.

12 Utilities for Pharmaceutical Process Equipment

INTRODUCTION

In this chapter we discuss the types of equipment the plumbing engineer may encounter in the design of pharmaceutical facilities. For a typical aseptically processed pharmaceutical product, several process stages are involved in its formulation. These include, but are not limited to:

1. Dispensing.
2. Compounding.
3. Fermentation.
4. Sterile Filtration.
5. Container Preparation.
6. Stopper Preparation
7. Granulation.
8. Filling and Stoppering.
9. Tableting and Coating.
10. Capsuling.
11. Lyophilization.
12. Capping and Crimping.
13. Terminal Sterilization.
14. Inspection.
15. Packing.

Associated with these processes, there are several types of equipment with which the design engineer should become familiar. We do not endeavor, in this chapter, to describe every piece used or every pharmaceutical process, but give a general overview of those most likely to be encountered in the most common operations. These include such items as pressure tanks, vessels, autoclaves, washers, filters, lyopholizers, dryers, compression machines, coating machines, pumps, filling machines, and packaging machines. The discussion of other types of equipment, such as chillers, compressors, and the like, required for process-support systems is provided elsewhere in this manual, such equipment may be mentioned here as it applies to the types of equipment described herein.

In the design of a pharmaceutical facility, it is typically the responsibility of the architect to develop the equipment arrangements and layouts during the programming and schematic phases of the project. The plumbing engineer is rarely invited to participate during this phase of the project and is usually handed a set of the near-completed arrangements and asked to provide the utilities required. It is the opinion of this writer, however, this practice is not necessarily in the best interests of the project. Input from the plumbing engineer at these phases can actually pre-

clude having to relocate or rearrange equipment due to the need for clearance or an access constraint an architect or scientist may overlook. If the plumbing engineer has the opportunity to be a part of the programming procedure or review the arrangements, the information listed here will help in his or her assessment of the layout. All parties involved should understand, however, that most of the equipment is arranged using the best available vendor information, usually nothing more than a catalog cut. Refinements to the arrangement most likely take place upon receipt of certified vendor information. With this in mind, it is probably a good idea to keep the plumbing design flexible enough to allow for these refinements, either as a design revision or field modification by the contractor.

That being said, let us proceed to the definition and discussion of some pharmaceutical equipment and processes.

PHARMACEUTICAL PROCESS EQUIPMENT

Tanks and Pressure Vessels

General

Most plumbing engineers have had some experience providing utility or process piping to tanks and vessels at some point in their careers. Their application within a pharmaceutical facility is not very different than other applications. It is important to have a drawing of the tank or vessel on hand before beginning to lay out the piping. The most important part of this process is the setting of the tank or vessel nozzle orientation. Since a tank or vessel is not typically an "off-the-shelf" piece of equipment, the fabricator relies on the end user for information regarding quantity, size, rating, and orientation of the nozzles attached. Verify with the architect or owner who is responsible for setting the orientation and confirm through a thorough study the orientation is appropriate given the location of the equipment and its proximity to adjacent equipment or other obstructions. The layout should allow for sufficient access to manholes, handholes (a small opening in the tank to put hands through), instruments, gauges, and any valves in the piping for proper operation of the vessel. Be aware of any agitators that may be necessary for product activation and allow sufficient clearance for removal and maintenance. (See Figure 12-1.)

Bioreactors and fermenters must be a vertical shell design to accommodate cGMP dead-leg minimization, cleaning, and drainage. The vessel usually requires a single spray ball for cleaning and wetting of the internal vessel surface. If a horizontal design is necessitated by building construction or other constraints, then additional spray balls are required to wet the large horizontal interior surfaces. At times, two vertical tanks may be a cleaner alternative to a single, large horizontal vessel. Smaller vessels may be required to be portable in order to transfer batch processes. Make the necessary piping connections by way of hoses as required to minimize piping hard connections that could limit the movement of the vessels. Vessel nozzles are constructed of sanitary ferrules in most applications. Nozzle projections should be kept to 1½ diameters for cleanability. Nozzles attached to the vessel walls should be attached with a minimum 15° downward slope for internal drainage and cleaning. Threaded connections are not allowed on sanitary vessels. (See Figure 12-2.)

Identify whether the equipment requires clean-in-place or steam-in-place cleaning and sterilization and, if so, make sure the piping design contains the necessary

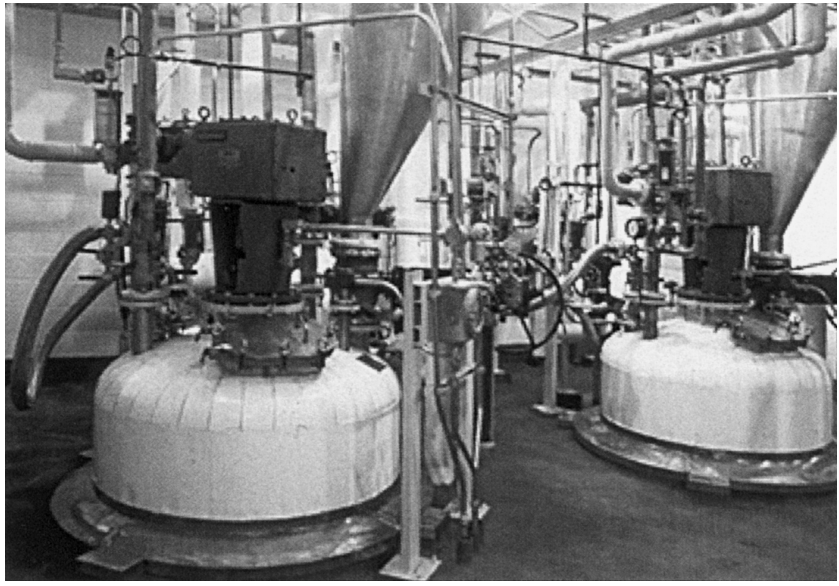


Figure 12-1 Tanks Layout Providing Access to Equipment

Figure 12-2 Vessels

slopes. Provide traps and drains at low points and connections for the cleaning medium or steam and condensate to be adequately and completely removed. Provide typical details for such connections. For sterile piping fabricated with orbital butt welds, ensure sanitary clamps are used at the appropriate connections to pumps or vessels.

Autoclaves

An "autoclave" is an apparatus used for sterilization of either process equipment, apparatus, or product in which special conditions (such as high or low pressure or temperature) can be established for a variety of applications. Wet heat is the most dependable method of sterilization. Autoclaving (saturated steam under pressure of approximately 15 psi to achieve a chamber temperature of at least 250°F for a prescribed time) is the most convenient method of rapidly achieving destruction of all forms of microbial life. In addition to proper temperature and time, prevention of entrapment of air is critical to achieving sterility. Material to be sterilized must come in contact with steam and heat. An airtight seal is required between the aseptic side of the autoclave and its mechanical space to prevent contamination potential.

Autoclaves can vary in size from bench-top to room size. The size depends on the application for which it is utilized. The simplest autoclaves are similar to those found in almost every doctor and dentist's office, where the sterilization of utensils is of primary concern. Larger autoclaves are the focus of this discussion due, in part, to the complexity of their arrangement and their utility requirements. That is not to say, however, the smaller types are not used in a pharmaceutical facility. It is the job of the plumbing engineer to ascertain all types used on a project and furnish the utilities necessary for their proper operation.

An autoclave is basically a pressure vessel with a large door or doors. (See Figure 12-3.) The equipment may have an "in-and-out" arrangement, with the items to be sterilized entering and exiting the autoclave from the same portal, or be a once-through device, with a dirty side and a clean side. The openings of the autoclave must be large enough to allow equipment—such as vessels, tanks, or carts with product or smaller vessels stacked on them—to be wheeled in and out of the chamber. The door can be a swinging door or a sliding door. In either case, the door should be dogged, or latched, to sustain the internal pressure. The chamber usually has a mechanical space placed adjacent to it in which the vacuum pump and utility piping and controls reside. This space must be accessible and is usually arranged by the autoclave vendor. The chamber, vacuum pump, and all interconnecting piping are provided by the autoclave vendor and installed by a contractor under the direction of the autoclave vendor.

Because items to be sterilized may be rolled into the chamber of the autoclave, there are chamber drain points, of necessity, below the floor level. For this reason, some autoclaves are built with a depression or pit in the floor around the chamber and mechanical space. Adequate drainage for the equipment and the pit must be provided. A general-duty floor drain is usually adequate. In addition, the vacuum pump may be of the liquid-ring type and a drain with a funnel or similar type receptor must be provided and connected to a pipe of adequate size to receive the once-through water required for vacuum formation. The drainage system to which these drains are connected must be determined because there may be some contaminants in the waste stream that require special handling or treatment. All equipment drain connections should be made by indirect means.

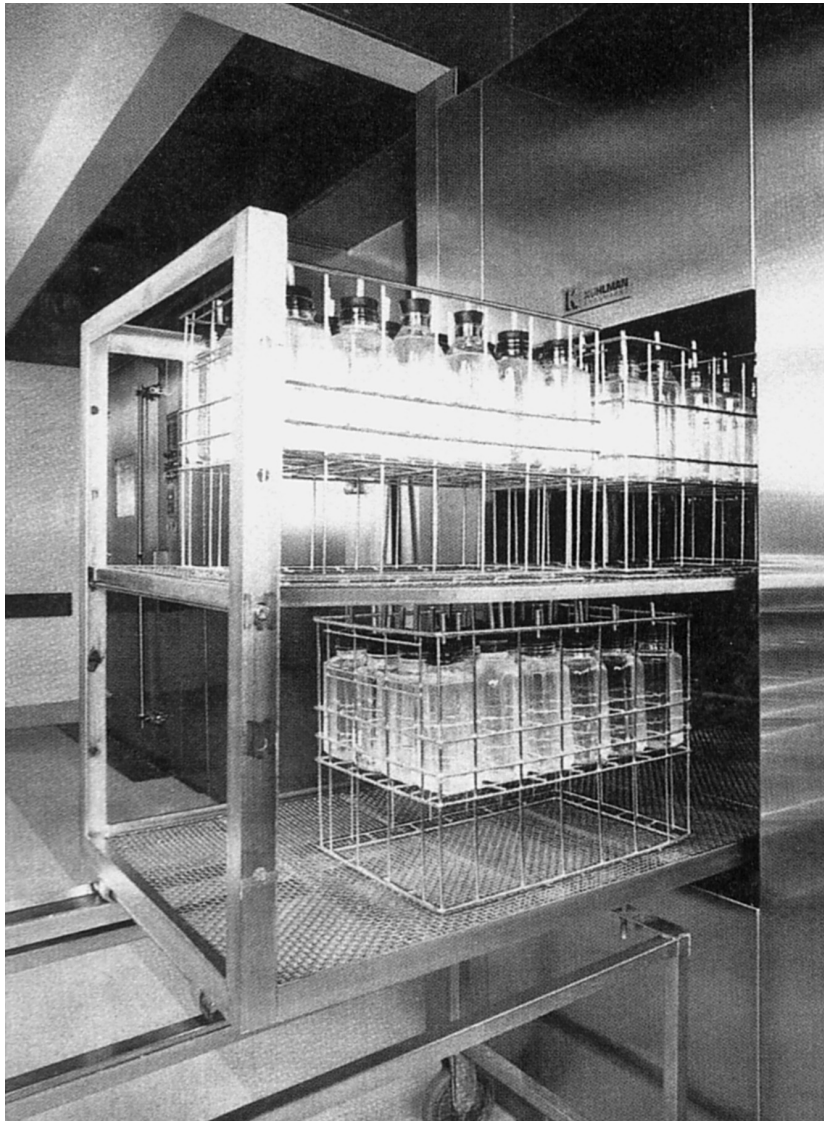


Figure 12-3 Autoclave

Hard-piped utilities required for proper autoclave operation can include compressed air for air ballasting, purified water and clean steam for sterilization, condensate returns, vacuum as well as power and data I/O ports. The plumbing engineer should review the vendor cuts and/or equipment drawings for the utilities required, the capacity and size of such utilities, the location and type of each of the connections, and any special conditions for the connections. It should be established who is responsible for providing any shutoff valves or regulators, steam traps, strainers, backflow preventers, vacuum breakers, or other such devices necessary for proper operation of the apparatus and for code compliance. The design

engineer should pay particular attention to any cross-connection hazard that may exist when water lines are directly connected to the equipment. Location of floor drains in the chamber pit should not interfere with the placement of the vendor's vacuum pump or piping. Utility piping run to the unit should terminate at or near the point indicated by the vendor and all piping not utilized specifically for the equipment should be kept clear of the area. In cases where vendor drawings are not available, the utility piping should be run to within 5 ft of the unit and adequate notes placed on the plans for the mechanical contractor to make all final connections. Air-conditioning and exhaust requirements for the proper operation of the equipment and its appurtenant spaces would indicate the need for ductwork in the area as well. Be sure to coordinate the location of piping and ductwork with the appropriate engineering discipline.

Sterile Filtration

Sterile filtration provides a defined reduction in the microbiological concentration of product feed solutions and is intended to render the product stream sterile. Sterile filtration is conventionally achieved by airtight pressure filtration from feed to recipient pressure vessels, with the sterile filter fitted in line between the two. In small-scale, sealed operations, use of sealed, nonpressure vessels and peristaltic pumps is an alternative approach. In large-scale operations, the vessels and associated systems may be cleaned and sterilized in place. In smaller-scale operations the vessels and components may be cleaned and rinsed manually, autoclaved, or sterilized in place.

The integrity of the sterile filter membrane and its installation within the housing must be checked by means of a proven filter-integrity test method. This should be done prior to filtration but must be done following filtration. Filter-integrity testing is preferably done in situ. Expect to provide nitrogen piping for over-pressuring.

Lyophilizers

In the simplest of terms, a "lyophilizer" is essentially a freeze-dryer. Drying of a material or product always causes some loss of activity or other damage. Lyophilization, also called "freeze-drying," is a method of drying that significantly reduces such damage. Lyophilization consists of three separate, unique, but independent processes: freezing, sublimation, and desorption. Because lyophilization is the most complex and expensive form of drying, its use is usually restricted to delicate, heat-sensitive materials of high value. An industrial lyophilizer would normally consist of a vacuum chamber, a means of removing water vapor, and refrigeration equipment. It is important to ascertain the type and number of doors involved. It may have one or two doors for a pass-through version. Clear space in front of the doors is required for loading and unloading the product. Product loading may be done manually or by automatic means. Special care must be taken to provide adequate product protection from filling to freeze-drying. The most critical step is usually lyophilizer loading, where product containers pass from the outlet of the filling line to the shelves inside the lyophilizer, under Class 100 conditions. Lyophilizers usually employ some door-closing system. Pneumatic and/or vacuum means are generally utilized for closing and sealing the doors.

Mechanical space is required around the machinery, adjacent to the vacuum chamber and condenser. Access for removal of tube bundles, condenser heads, and such should be maintained when running utility piping. Refrigeration equipment required may be incorporated into the lyophilizer design or provided as separate skid-mounted packages requiring several pieces of interconnecting piping. It should be determined who is responsible for the design and fabrication of this piping. If the lyophilizer vendor furnishes this piping, allow sufficient space for the installation and fit up of these spools.

The utilities required for the proper operation of the lyophilizer include cooling water, which may be either once-through plant water or closed-loop cooling-tower water, for refrigeration condensers; potable or plant water for vacuum pumps; and nitrogen and compressed air for pre and final aeration, respectively. If the unit requires clean in place or sterilization, a cleaning medium and/or clean steam will also be required. In some cases, some form of ultra-pure water may be required for a sterile final rinse of the chamber after cleaning. Provide adequate drainage for the chamber and all of the lyophilizer's ancillary equipment where it is required by the vendor.

Washers

In the pharmaceutical facility, cleaning is an extremely important issue, particularly in a sterile facility. As parts and containers are used, it is necessary to ensure no contaminants are passed from one batch process to the next. Washing procedures must be demonstrated to be effective in rendering the apparatus suitable for use on a new batch. Several kinds of washer are produced to wash items such as bottles, vials, trays, pallets, containers, and totes. It is not possible to list each particular variety because vendor capabilities allow machines to be developed to meet almost any need encountered in the pharmaceutical industry.

Manual cleaning is a cost-effective way to accomplish process-equipment washing and depyrogenation rinsing. Sinks are used specifically for rinsing apparatus and parts. They should be of stainless-steel construction and meet all cGMP requirements. At sinks, always verify the need for hot and/or cold potable water. Sometimes such supplies are not desirable or necessary. Where a final sterile rinse of parts may be required, some form of purified water or Water for Injection (WFI) may be required. Ascertain the final use-point purity from the owner and determine whether such purity is available from the central system. Provide use-point polishing equipment if required. For an in-depth discussion of purified water systems, refer to the "Water Systems" chapter.

Semi-automated washing systems are desirable if manual cleaning becomes a bottleneck or cost prohibitive. Such systems include recirculation, ultrasonic, and cabinet washers. These devices are useful for components and equipment that can be disassembled and moved from the process area to the preparation area and must be cleaned on a routine basis. Check the project programming requirements for such equipment.

Washers range in size and arrangement from those of a domestic, under-the-counter dishwasher to a massive, large-capacity tunnel washer. Automatic washing equipment must be arranged for ease of loading and unloading as well as for

maximum access to the mechanical parts. It is important for the plumbing engineer to gather information from the owner and vendor concerning the consumption of utilities and the duration and length of wash cycles, as this information is vital in determining the peak demands on the applicable utilities as well as the sizing of the piping.

The utilities required for the proper operation of washing equipment vary with the type and size of the equipment served. Expect to see requirements for potable cold water, potable hot water at 140°F (60°C), purified water, either DI or WFI, plant or clean steam and condensate and compressed air. Be sure to ascertain the drainage requirements for washers also. Some of these machines may discharge large quantities of water in a short period of time. Check the size of the drain serving the washer and ensure it can handle such flow rates. The effluent from some washers may not be suitable for discharge into a house (sanitary) sewer. It may be necessary to run branches of process or other sewer into the space.

Finishing Machinery

There are several configurations of this type of machinery, and it is beyond the scope of this manual to describe them all. Some of the operations related to finishing pharmaceutical products include spray drying, fluid-bed processing, extrusion spheronization, high-sheer granulation, encapsulation, pelletization, tableting, and tablet coating. Suffice it to say they all have essentially the same purpose, to prepare solid products in their final form prior to packaging. Dosage of pharmaceutiacals is available in either solid or liquid, oral or injectible form. Pharmaceuticals administered as a suppository or intravenously are included in the aforementioned types. A specific piece of equipment is needed to perform the necessary operation based on the type of dosage required. We cover the overall function of the equipment, the pertinent items of arrangement, and the utility requirements the plumbing engineer should keep in mind if he or she encounters these types of equipment in a project.

Tablet pressing and encapsulation are generally open processes. Product transfer is usually open. The process creates dust, which may be partly controlled by the equipment. The product, a tablet or capsule, has a degree of containment that lessens the need for a total enclosure to keep the dust from spreading or what the industry calls a "closed-out feed condition."

Coating machinery, as the name implies, is used for the coating of tablets after the compounds have been compressed into tablet form. At the beginning of the coating operation, there is limited dust generation. The coating operation involves the spraying of a coating onto the tablets to a determined thickness and then to maintain a consistent motion while the tablets dry.

As implied in these definitions, there must be some degree of dust control involved with these operations. Dust-collection terminals and compressed-air stations are the most often required utilities for tableting and coating operations.

Packaging and Conveying Machinery

Number, type, and complexity of packaging lines vary according to a wide range of manufacturing needs, beginning with very simple, manual or semi-automatic lines,

equipped with integrated loading and delivery systems. The packaging operation for sterile products is a secondary operation for already sealed primary containers. The packaging operation may include inspection and labeling, if such operations are performed on line. The main issues of concern, from the cGMP point of view, are the following:

- Mix-up risk for primary containers.
- Identification of each and every component, before assembly of the final pack.
- Correct and complete assembling of each final package.

In order to achieve such a high level of control, automatic control systems and reject stations are sometimes employed. Such systems utilize conveyers and diverters that are usually actuated with compressed air. The plumbing engineer should provide ample outlets for each connection on the packaging line, ensuring the proper quality of air as required by the equipment vendor.

UTILITIES SYSTEMS

The utilities mentioned here, which are used in sterile facility operations, may be categorized as either process systems or process-support systems. The owner should review the various systems within the facility and determine the category or categories into which each falls. This will provide the basis for determining the design, construction, commissioning, and documentation (validation) requirements for the system.

Process systems are "direct-impact systems" and/or:

- Contact the product.
- Contact materials that ultimately will become part of the product.
- Could otherwise directly impact product quality.

Process-support systems are "indirect impact systems" and/or:

- Do not contact the product or materials that ultimately will become part of the product.
- Are generally site or building systems not tailored to sterile manufacturing facilities.
- Deal with a side effect of the manufacturing process.

Examples:

- Purified water and clean steam normally are categorized as process systems because they are used in the manufacturing process itself.
- Heating/cooling systems for depyrogenation tunnel, filling line, etc. generally would be categorized as process-support systems.
- Breathing air, chilled water, instrument air, potable water systems for general-purpose use, and floor drains normally are categorized as process-support systems.

The following paragraphs give some general guidance for each category. Table 12-1 summarizes the most common services and gives the recommended classification of each.

Process Systems

Process systems are considered "direct-impact systems" and should be designed, constructed, and commissioned to provide a service to meet a defined specification (considering product-quality requirements) and prevent product contamination accordingly.

Selection of materials for storage and distribution systems should take into account the nature of the fluid or gas being conveyed. For noncorrosive fluids and gases, such as nitrogen, typical materials include copper, plastics, and galvanized and stainless steel. The sterile product manufacturer should consider what type of cleaning and sterilants (if required) will be used. For example, if the nitrogen is a sterile feed to a vessel for blanketing, stainless steel would be used at least from the point of filtration downward to permit steam sterilization. If, however, the nitrogen manifold in the room requires merely a surface sanitization, chemical-resistant plastics, which do not absorb, react to, or add to the material being conveyed, are acceptable.

Care should be taken to locate as large an amount of service components and piping outside the aseptic area as possible. Any protrusion into the clean room will need to be sanitized or sterilized.

The plumbing engineer should consider the environmental conditions in which process conditions can be located. For example, in the design of a hydrophobic vent filter for a water-for-injection storage tank, the method of maintaining or ensuring the vessel's microbiological integrity during maintenance should be considered.

Process-Support Systems

Process-support systems generally are considered "indirect-impact systems" and should be designed and constructed in compliance with good engineering practice, and applicable codes and standards. Such systems typically are not located within a clean room, therefore, the materials of construction depend upon service requirements. If a service is required in an aseptic processing area, care must be taken to provide materials of construction that can be sanitized and/or sterilized. Care also must be taken to prevent accidental spills and possible contaminant release into the area (e.g., by providing point-of-use filters for an instrument air-supply line).

Process-support services should be located outside the aseptic area. If these services, or their points of use must be located inside the aseptic area, the materials of construction should be nonadditive, nonreactive, nonabsorptive, and able to withstand repeated sanitation with harsh chemicals.

Table 12-1 gives general guidance on typical system classifications, although these may vary for particular facilities.

Multiple Categorization

In the design of systems that can be multi-categorized consideration should be given to the cost/benefit derived from installing separate utility systems or distribution networks versus special treatment at points of use. For example, a compressed-air system may be used as both a process and process-support system. If there are many manufacturing uses, there may be economical justification for running separate system throughout the facility. If there are only a few manufacturing uses, utilizing

a process-support system with point-of-use filters and stainless-steel piping after the filter, at the manufacturing use points, may be the more economical design. However, due consideration must be given to the upstream piping materials to ensure air quality is not compromised (e.g., by the use of low arsenic copper).

For example, if compressed air is used to operate a vial filler, and the pressure of the air dictates the line speed, independent of fill volume, then due consideration must be given to a substantive qualification regime and high and low-pressure alarms for the service. These systems should be designed and constructed in compliance with good engineering practice and applicable codes and standards.

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