



Pharmaceutical Facility Drainage Systems

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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

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 “anions” because they migrate to the cathode and positive ions are called “cations” 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 (anion) and hydrogen (cation) 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 Fluoride (PVDF) 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.

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.

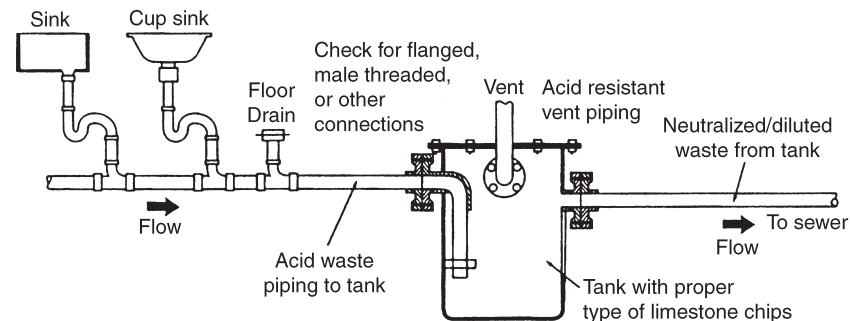


Figure 2-1 Large Acid-Neutralizing Basin

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		1/4 in./ft Slope		1/2 in./ft Slope	
	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps	Discharge, gpm	Velocity, fps
1 1/4							3.40	1.78
1 1/2					3.91	1.42	5.53	2.01
2					8.42	1.72	11.9	2.43
2 1/2			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 1/2-full pipe, n = 0.015. For 3/4-full pipe, multiply discharge by 0.274; multiply velocity by 0.701. For 5/8-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.	1 1/4	1 1/2	2	2 1/2	3	4	5	6	8
Capacity, gpm	6.5	10.5	22.6	41	67.2	143	261	423	915

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.

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.

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.

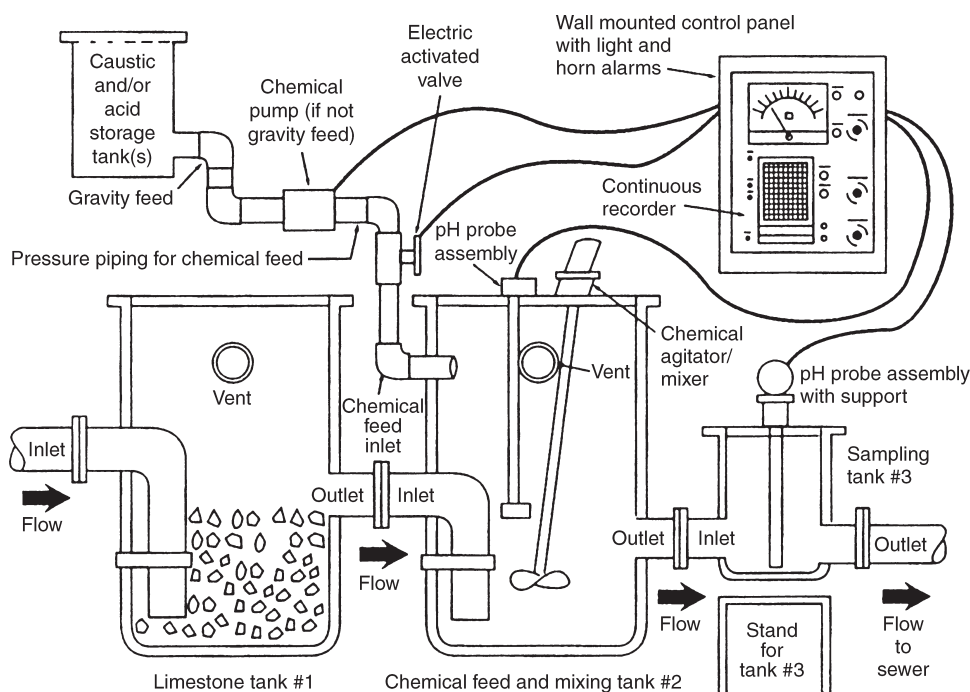


Figure 2-2 Continuous Acid-Neutralizing System

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

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 Fluoride (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 oleum 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

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:

- Imaging sciences.
- Diagnostic purposes.
- Treatment purposes.
- Industrial uses.
- 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:

- Iodine 131 (8-day half-life).
- Phosphorus 32.
- Technetium 99 (6-hour half-life).
- Calcium 45.
- Carbon 14.
- Strontium 90.
- 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

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.

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 dis-

charge 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.

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 stop-pages.
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).

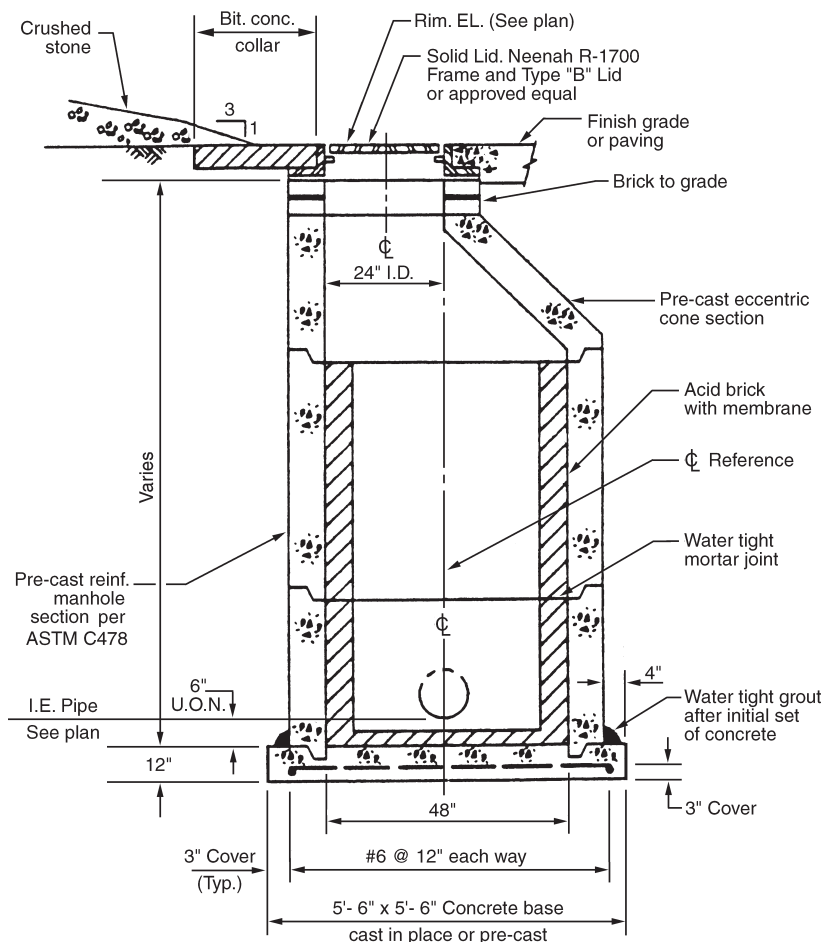


Figure 2-3 Lined Manhole

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.

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CE Questions — "Pharmaceutical Facility Drainage Systems" (CEU 219)

1. Which of the following plastic piping materials is the most resistant to the widest variety of chemicals?
 - a. PYDF
 - b. CPVC
 - c. PTFE
 - d. PP
2. What is the discharge capacity of a 5-inch-diameter horizontal drainage pipe at $\frac{1}{4}$ inch-per-foot slope?
 - a. 3.16 fps
 - b. 96.6 gpm
 - c. 68.3 gpm
 - d. 2.23 fps
3. Which of the following is a component of a continuous acid-neutralizing system?
 - a. pH probe assembly
 - b. sampling tank
 - c. chemical agitator
 - d. all of the above
4. Which of the following materials is generally unsuitable for acid-waste drainage piping?
 - a. stainless steel
 - b. FRP
 - c. HDPE
 - d. duriron
5. _____ radiation carries the most energy and therefore is the most dangerous to humans.
 - a. alpha
 - b. beta
 - c. gamma
 - d. x-ray
6. Which of the following materials is commonly used for shielding radiation?
 - a. glass
 - b. concrete
 - c. sheet lead
 - d. both b and c
7. The radiological safety officer is responsible for _____.
 - a. monitoring personnel exposure limits
 - b. assisting engineers in the design of mechanical systems
 - c. controlling any release of radio nuclides to the sewer system
 - d. all of the above
8. If a floor drain must be installed in a laboratory handling radioactive materials, of which material should it be manufactured?
 - a. concrete
 - b. stainless steel
 - c. copper
 - d. cast iron
9. An ideal radwaste drainage pipe should be _____.
 - a. easy to clean
 - b. acid resistant
 - c. nonoxidizing
 - d. all of the above
10. In a laboratory handling biological waste, the traps on all floor drains should have a seal _____ deeper than the negative difference in air pressure.
 - a. 1 inch
 - b. 1.5 inches
 - c. 2 inches
 - d. 2.5 inches
11. Which of the following is an often-used material in chemical waste drainage systems?
 - a. cast iron
 - b. vitrified clay
 - c. stainless steel
 - d. PTFE
12. For chemical waste drainage systems, the minimum size drain line under an isolated slab or underground should be _____.
 - a. 1 inch
 - b. 2 inches
 - c. 4 inches
 - d. 6 inches