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DIVISION 11 - EQUIPMENT

SECTION 11 71 00

WARMING CABINETS, STERILIZERS, AND ASSOCIATED EQUIPMENT

02/09

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-- End of Section Table of Contents --
NOTE: This guide specification covers the requirements for warming cabinets, sterilizers, and associated equipment.

Adhere to UFC 1-300-02 Unified Facilities Guide Specifications (UFGS) Format Standard when editing this guide specification or preparing new project specification sections. Edit this guide specification for project specific requirements by adding, deleting, or revising text. For bracketed items, choose applicable item(s) or insert appropriate information.

Remove information and requirements not required in respective project, whether or not brackets are present.

Comments, suggestions and recommended changes for this guide specification are welcome and should be submitted as a Criteria Change Request (CCR).

PART 1 GENERAL

NOTE: Schedule equipment on the drawings and list required salient features on the schedule. These features include size of sterilizer, capacity of stills and storage tanks, manual, automatic or automatic microprocessor controls, sterilizer material handling accessories, and any optional exceptions to standards specified. Also include operating power requirements for each unit. Identify equipment on the schedule and in the drawings by Joint Schedule Numbers (JSN) from MIL-STD-1691, Construction and Material Schedule for Military Medical and Dental Facilities.

On the project drawings show exhaust ventilation (to keep gas away from person opening sterilizer door).
1.1 REFERENCES

NOTE: This paragraph is used to list the publications cited in the text of the guide specification. The publications are referred to in the text by basic designation only and listed in this paragraph by organization, designation, date, and title.

Use the Reference Wizard's Check Reference feature when you add a RID outside of the Section's Reference Article to automatically place the reference in the Reference Article. Also use the Reference Wizard's Check Reference feature to update the issue dates.

References not used in the text will automatically be deleted from this section of the project specification when you choose to reconcile references in the publish print process.

The publications listed below form a part of this specification to the extent referenced. The publications are referred to within the text by the basic designation only.

ASME INTERNATIONAL (ASME)

ASME B16.18 (2012) Cast Copper Alloy Solder Joint Pressure Fittings


ASME BPVC SEC VIII D1 (2010) BPVC Section VIII-Rules for Construction of Pressure Vessels Division 1

ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)

ANSI/AAMI ST8 (2013) Hospital Steam Sterilizers

ASTM INTERNATIONAL (ASTM)


and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications


and N06045)* and Nickel-Chromium-Cobalt-Molybdenum Alloy (UNS N06617) Rod, Bar, and Wire


INTERNATIONAL CODE COUNCIL (ICC)


U.S. GENERAL SERVICES ADMINISTRATION (GSA)

CID A-A-50879 (Rev A) Sterilization Test Strip Set, Bacterial Spore

UNDERWRITERS LABORATORIES (UL)


1.2 SUBMITTALS

**************************************************************************
NOTE: Review submittal description (SD) definitions in Section 01 33 00 SUBMITTAL PROCEDURES and edit the following list to reflect only the submittals required for the project.

The Guide Specification technical editors have designated those items that require Government
approval, due to their complexity or criticality, with a "G." Generally, other submittal items can be reviewed by the Contractor's Quality Control System. Only add a "G" to an item, if the submittal is sufficiently important or complex in context of the project.

For submittals requiring Government approval on Army projects, a code of up to three characters within the submittal tags may be used following the "G" designation to indicate the approving authority. Codes for Army projects using the Resident Management System (RMS) are: "AE" for Architect-Engineer; "DO" for District Office (Engineering Division or other organization in the District Office); "AO" for Area Office; "RO" for Resident Office; and "PO" for Project Office. Codes following the "G" typically are not used for Navy, Air Force, and NASA projects.

An "S" following a submittal item indicates that the submittal is required for the Sustainability Notebook to fulfill federally mandated sustainable requirements in accordance with Section 01 33 29 SUSTAINABILITY REPORTING.

Choose the first bracketed item for Navy, Air Force and NASA projects, or choose the second bracketed item for Army projects.

**************************************************************************

Government approval is required for submittals with a "G" designation; submittals not having a "G" designation are for [Contractor Quality Control approval.] [information only. When used, a designation following the "G" designation identifies the office that will review the submittal for the Government.] Submittals with an "S" are for inclusion in the Sustainability Notebook, in conformance to Section 01 33 29 SUSTAINABILITY REPORTING. Submit the following in accordance with Section 01 33 00 SUBMITTAL PROCEDURES:

SD-02 Shop Drawings
Approved Detail Drawings; G[, [_____]]

SD-03 Product Data
ASME Form U-1
Materials and Equipment
Spare Parts

SD-06 Test Reports
Factory Tests
Field Tests and Inspections

SD-10 Operation and Maintenance Data
Operations and Maintenance Instructions; G[, [_____]]
Training; G[, [_____]]
1.3 DELIVERY, STORAGE, AND HANDLING

Protect equipment delivered and placed in storage from the weather, humidity and temperature variation, dirt and dust, or other contaminants.

1.4 EXTRA MATERIALS

Submit spare parts data for each different item of material and equipment specified, not later than [_____] months before the date of beneficial occupancy. Include in the data a complete list of parts and supplies, with current unit prices and source of supply.

PART 2 PRODUCTS

2.1 MATERIALS AND EQUIPMENT

Provide materials and equipment which are the standard product of manufacturers regularly engaged in the manufacture of the products and that essentially duplicate items that have been in satisfactory use for at least 2 years prior to bid opening. With the exception of distillation equipment, all equipment described within this specification shall conform to UL 60601-1. The label or listing of the Underwriters Laboratories, will be accepted as evidence that the equipment conforms to the standard. In lieu of this label or listing, the manufacturer may submit a statement from a nationally recognized, equally equipped testing agency indicating that items have been tested in accordance with specification requirements. For Navy projects refer to 11 70 00 GENERAL REQUIREMENTS FOR MEDICAL AND DENTAL EQUIPMENT in lieu of this paragraph. Equipment shall be supported by a service organization that is, in the opinion of the Contracting Officer, reasonably convenient to the site. Submit a complete list of equipment and material, including manufacturer's descriptive data and technical literature, performance charts and curves, catalog cuts, and installation instructions.

a. Each major item of equipment shall have the manufacturer's name, address, and catalog or serial number permanently affixed to a plate securely attached to the equipment. In addition, each pressure vessel shall bear the ASME stamp and pressure rating, indicating compliance with applicable code requirements.

b. Belts, pulleys, chains, gears, couplings, projecting setscrews, keys, and other rotating parts exposed to personnel contact shall be fully enclosed or properly guarded.

c. Materials, unless otherwise specified, shall conform to the following:

2.1.1 Carbon Steel


2.1.2 Nickel

ASTM B39. Nickel-copper alloy or stainless steel or white metal.

2.1.3 Nickel and Nickel-Alloy Clad Steel

ASTM A265. Nickel or nickel-copper alloy and steel for pressure vessels,
mill-rolled under heat and pressure until integrally bonded over entire interface.

2.1.4 Nickel-Copper Alloy (Monel Metal)

2.1.5 Stainless Steel
ASTM A167, Type 301 or 316L; Class 304L for welded construction and Class 302 or 304 for construction formed without welding. Exposed surfaces of stainless steel to have satin finish.

2.1.6 Stainless Steel Bars and Rods
ASTM B166.

2.1.7 Stainless Steel for Pressure Vessels
ASTM A240/A240M.

2.1.8 Stainless Steel Clad
ASTM A264 for pressure vessels.

2.1.9 Tin
ASTM B339.

2.1.10 Titanium
For construction of products used in contact with distilled water, ASTM B348, Grade 2.

2.1.11 Fasteners
Use corrosion-resistant materials for all rivets, bolts, nuts, studs, spacers, and welding metal.

2.2 PIPING AND TUBING
Seamless, annealed, and ground smooth. Welded tubing to be thoroughly heat treated and properly quenched to eliminate carbide precipitation, drawn true to size and roundness. Piping and tubing shall conform to the following:

2.2.1 Steam Supply and Return Condensate Lines
Copper pipe shall conform to ASTM B42; brass pipe shall conform to ASTM B43; brass tube shall conform to ASTM B135M ASTM B135, Alloy 230. Include strainer, shut-off valve and pressure gage suitable for steam pressure up to 650 kPa 80 psig. In return line include steam trap, check valve, and hand shut-off valves.

2.2.2 Gaseous Sterilant Lines
Brass pipe shall conform to ASTM B43, Alloy 230; stainless steel tube shall conform to ASTM A269/A269M, ASTM A312/A312M, or ASTM B167 as applicable.
2.2.3 Water and Waste Lines

Copper tube shall conform to ASTM B88M ASTM B88 Type K, hard-drawn or annealed for bending; brass tube shall conform to ASTM B135M ASTM B135, Alloy 230 or C23000.

2.2.4 Pipe Fittings

Wrought copper or wrought bronze, brazing or solder joint type in accordance with ASME B16.18 and ASME B16.22. Use ASTM B32, Alloy Sb5 tin-antimony solder to make joints for copper tubing.

2.3 EQUIPMENT SUPPORTS

Furnish supports for stands, brackets, hangers, and similar equipment, and accessories including pipe, duct, and conduit. Floor stands shall be field adjustable for leveling.

2.4 ELECTRICAL WORK

Provide electric motor-driven equipment complete with motors, motor starters, and controls. Electrical equipment and wiring shall be in accordance with Section 26 20 00 INTERIOR DISTRIBUTION SYSTEM. Electrical characteristics shall be as specified herein or indicated. Provide motor starters complete with thermal overload protection and other appurtenances necessary for the motor control specified. Each motor shall be of sufficient size to drive the equipment at the specified capacity without exceeding the nameplate rating of the motor. Provide manual or automatic control, protective or signal devices required for the operation specified, and any control wiring required for controls and devices specified.

2.5 STERILIZER COMPONENTS

2.5.1 Pressure Vessels

Design, construction, materials, and testing of each pressure vessel, including doors, shall comply with applicable provisions of ASME BPVC SEC VIII D1. Submit a signed copy of ASME Form U-1 or U-1A, as shown in ASME BPVC SEC VIII D1 Appendix W, with each sterilizer, as applicable.

2.5.2 Welding Materials

Welding Materials shall comply with ASME BPVC SEC II-C. Welding equipment, electrodes, welding wire, and fluxes shall be capable of producing satisfactory welds when used by a qualified welder or welding operator using qualified welding procedures.

2.5.3 Doors

**************************************************************************
NOTE: Drawings must indicate swing option of sterilizer doors.
When vertical sliding doors are to be mandated, due to site conditions such as space limitations, the door requirement must be in the schedule or on the drawings as appropriate.
**************************************************************************
Sterilizer doors may be either hinge mounted or sliding type, manual or power operated, as required for the specific unit on drawing configuration. Doors shall be interlocked to prevent chambers from being charged until seal is established.

2.5.3.1 Hinge Mounted Doors

Hinge mounted doors shall conform to respective referenced specifications for the unit. Swing shall be as indicated.

2.5.3.2 Sliding Doors

Provide sliding doors where indicated and for sterilizers in lieu of hinge mounted doors, if necessary. Manual operation of sliding doors shall be by means of firmly attached handles. Temperature of handles, during operation, shall not exceed 50 degrees C 122 degrees F if metal, or 60 degrees C 140 degrees F if nonmetal. Doors shall require no more than a 22 N 5-pound force for opening.

2.5.4 Controls

Where a unit is scheduled or specified to have automatic microprocessor type controls, provide the controls consisting of a selectively programmable microcomputer that monitors and controls the system operations and functions. It shall be possible to energize the entire system by a single switch. If chamber temperature should fail to reach or fall 1 degree C 2 degrees F below the set value, timer will reset. Automatic controls shall include the following associated instrumentation:

2.5.4.1 Data Collection

Automatic data collection system, digital type, consisting of a printer-recorder, able to print at least 20 characters per line on a recording tape, and recording tape storage unit. During processing, printer-recorder shall document that all parameters of the cycle were met, or provide a record of the microcomputer's fault indicators and self diagnostics. The record shall be removable from the machine at the end of the cycle and shall provide space for the operator's signature and notation of sterilizer identification number. System shall include alarms and a programmable clock that displays time and date (day, month, year). The sterilizer shall be supplied with at least three rolls of printer paper and two ink supplies (either cartridges or ribbons, as appropriate).

2.5.4.2 Status

Status indicator to indicate each cycle phase. Indicator shall visually alert if door is unlocked and shall visually and/or audibly alert if sterilizer does not reach set temperature or drops below set temperature during sterilizing phase. On two-door-model sterilizers, the remote door end shall include phase indicators, information for previous cycle parameters and cycle start/stop control.

2.5.4.3 Processing Time

Processing time indicator in the form of a digital display that shows sterilizing time.
2.5.4.4 Cycle Selector

Cycle selector to program and actuate each cycle individually. Selected cycle shall be visually displayed and all others shall be locked out.

2.5.4.5 Time Setting

Time setting switches to accurately set individual cycle times. Once cycle has started, times cannot be changed unless reset/abort switches are actuated and completed, or regular cycle is completed. Provide visual display of time setting.

2.5.4.6 Cycle Monitor

Cycle monitor device, nonresetable, to count each cycle.

2.5.4.7 Main Switch

Main power and control switch to energize and de-energize main power and controls.

2.5.4.8 Reset/Abort

Reset/abort switch to stop cycle.

2.5.4.9 Battery Backup

Battery backup or battery backup system to hold cycle parameters for a minimum of 60 seconds in event of power failure.

2.5.5 Chamber Evacuation System

Sterilizers may utilize a vacuum system consisting of a condenser water ejector in lieu of a vacuum pump.

2.5.6 Connections to Equipment

****************************************************************************************************
NOTE: Specifications, covering supply to units specified herein, must provide cutoff of supply in vicinity of equipment so that unit may be removed for servicing. Make provisions for allowing steam lines to be blown down, prior to equipment connection, to prevent preservations and cleansers in piping and boiler from being blown into chamber.
****************************************************************************************************

Prewire and prepipe each unit of equipment complete with trim and fittings. Equipment shall include fittings to prevent backflow of polluted water or waste into water supply system or equipment in accordance with ICC IPC. Provide reduced pressure or atmospheric type backflow preventer.

2.6 GRAVITY AIR STEAM STERILIZERS

****************************************************************************************************
NOTE: Do not return condensate from units located so far from steam boiler that it is uneconomical. Only jacket steam condensate is reusable.
****************************************************************************************************
Gravity air steam sterilizers shall be suitable for sterilization of heat and moisture stable instruments, supplies, flaked liquids, and utensils, utilizing steam saturation as the sterilizing agent. Unless otherwise scheduled, gravity air steam sterilizers shall conform to the applicable provisions of ANSI/AAMI ST8. The following shall be included:

a. [Automatic controls] [Microcomputer controls, with cycle documentation via strip recorder for each cycle. Microcomputer controls shall allow for programming chamber aeration cycle at same temperature as sterilizing cycle, adjustable from 1 to 59 minutes, 59 seconds. Controls should be designed to facilitate mounting at location up to 15,000 mm 50 feet from sterilizer].

b. [Sterilizer condensate assembly for condensate to waste] [Steam supply line on unit fitted with provisions for condensate return line].

c. Electrical characteristics: 120 volt, 60 Hz, single phase.

d. Materials handling accessories, including two loading cars and two transfer carriages for each car.

2.7 PREVACUUM/STEAM FLUSH STEAM STERILIZERS

**************************************************************************
NOTE: Do not return condensate from units located so far from steam boiler that it is uneconomical. Only jacket steam condensate is reusable.
**************************************************************************

Steam sterilizers shall be suitable for sterilization of heat and moisture stable instruments, supplies, flaked liquids, and utensils, utilizing steam saturation as the sterilizing agent. Chamber evacuation of prevacuum sterilizers shall be by mechanical means or steam flush. Steam sterilizers shall conform to the applicable provisions of ANSI/AAMI ST8, except as otherwise specified. Testing for floor loading type sterilizers shall conform to applicable provisions of ANSI/AAMI ST8, as they apply to a size 5 unit with the exceptions listed in the following 3 subparagraphs. Include the following items:

a. [Automatic controls] [Microcomputer controls with cycle documentation via strip recorder, for each cycle. Microcomputer controls shall allow for programming chamber aeration cycle at same temperature as sterilizing cycle, adjustable from 1 to 59 minutes, 59 seconds. Controls designed to facilitate mounting at location up to 15,000 mm 50 feet from sterilizer].

b. [Jacket condensate to return] [Condensate to waste].

c. Manual or power operating door.

d. Electrical characteristics:
   (1) Vacuum pump: [120] [200] [230] [460] volt, 60 Hz, [single] [three] phase.
   (2) Controls and similar equipment: 120 volt, 60 Hz, single phase.
2.7.1 Pack Sterilization

**************************************************************************
NOTE: Do not return condensate from units located so far from steam boiler that it is uneconomical.
Only jacket steam condensate is reusable.
**************************************************************************

Sterilizer shall be electrically heated, gravity air removal type, single door unit, recess mounted through one wall, with manually operating door, either hinged or sliding. Unit suitable for sterilization of packs, utilizing saturated steam or sterilizing agent. Challenge packs shall conform to ANSI/AAMI ST8. The following shall be included:

a. [Automatic controls] [Microcomputer controls with cycle documentation via strip recorder, for each cycle. Microcomputer controls shall allow for programming chamber aeration cycle at same temperature as sterilizing cycle, adjustable from one to 59 minutes, 59 seconds. Controls should be designed to facilitate mounting at location up to 15,000 mm 50 feet from sterilizer].

b. Condenser assembly for condensate to waste.

c. Electrical characteristics:
   (1) Heating system: [120] [200] [230] [460] volt, 60 Hz [single] [three] phase.

c. Controls: 120 volt, 60 Hz, single phase.

d. [Materials handling accessories, including removable rack with three full-length removable shelves] [Materials handling accessories, including loading car and transfer carriage].

2.7.2 Solution Sterilization

Solution performance test shall conform to ANSI/AAMI ST8.

2.7.3 Allowable Cycle Times

Performance test shall conform to ANSI/AAMI ST8.

2.8 GAS AERATORS

A gas aerator is an apparatus that effectively removes residual ethylene oxide from gas sterilized medical and surgical supplies.

2.8.1 Cabinet

Individual aerator units shall have a welded or riveted cabinet, supported by a channel steel base provided with leveling shims or feet. Cabinet and base shall have a factory finish.

2.8.2 Processing Chamber

Chamber shall be welded or riveted stainless steel, or electroplated aluminum, with stainless steel shelves and stainless steel shelf supports with stops. The exterior of the chamber shall be insulated with an R-value of 0.62 (square m) K/W (R 3.5) R 3.5. The insulation shall be secured in
place with thermosetting tape or corrosion and heat resistant straps and clips. Chamber shall have a perforated panel to facilitate air circulation.

2.8.3 Processing Chamber Door

Door shall be welded or riveted stainless steel, or electroplated aluminum. The door shall be tightly secured against the chamber's gasket with a safety interlock. Each door shall have steel, brass, or chromium-plated metal hinges located to permit swing as indicated. Doors shall be reversible without any additional welding or use of any special tools. A silicone rubber gasket shall ensure a tight seal between the door and the processing chamber.

2.8.4 Automatic Control Unit

On setting of timer and actuating power switch, the aerator shall automatically heat the load to the operator selected temperature and aerate the load with heated and filtered air, and time the cycle.

2.8.5 Control and Instrument Panel

Controls and instruments shall be installed in a control panel in a readily accessible location. Panel shall include:


b. Cycle phase indicators that operate when the heaters are actuated and when chamber temperatures are within operating range.

c. Timer, adjustable, having a range of 16 hours, minimum.

d. Unit on/off indicating light.

e. Chart recorder, 24 hour.

f. Temperature selector.

2.8.6 Aerating System

System shall be concealed, accessible, and in a suitable location. System shall include thermostatically controlled heaters, bacteria retaining filter for incoming air, and circulating blower fan. Blower fan shall produce not less than one air change in the processing chamber every minute. The blower motor shall have overload protection. Heaters shall be protected by a high temperature thermostat with reset. With automatic reset, an indicator shall be provided that high temperature thermostat has activated.

2.8.7 Vent Stack

**************************************************************************
NOTE: Indicate on the drawings vent connections or discharge points with details of discharge ducts.
**************************************************************************

Effluent air shall be conducted through a vent stack on the aerator. The openings shall be designed for connection to a building vent line discharging the effluent air outside the building.
2.9 WASHER/STERILIZER

Washer/sterilizer shall be a steam heated device suitable for the pre-washing and sterilizing of heat and moisture stable surgical instruments and utensils so that the products may be safe for handling and further preparation as may be necessary. Units shall be ETL listed. Include the following:

a. Automatic controls and electric characteristics: 120 volts, 60 Hz, single phase.

b. Material handling accessories: Rack and either 2 or 3 shelves.

c. Instrument trays: 2

2.10 AUTOMATIC [WASHER-STERILIZER] [WASHER-DECONTAMINATOR]

Automatic [washer-sterilizer] [washer-decontaminator] shall automatically accept, thoroughly wash, rinse, sterilize, and dispatch basket/racks containing heat and moisture stable hard goods, such as surgical instruments and utensils, utilizing saturated steam as the sterilizing agent. System shall be suitable for on-line, continuous operation throughout a work day and include necessary components to provide complete working entity, conforming to function, productivity and performance requirements specified.

2.10.1 Chamber

The chamber shall be single-shell welded construction of 316L stainless steel, nickel clad, monel clad, or 304L stainless steel clad steel, with cladding on surface exposed to sterilant. Chamber shall comply with ASME BPVC SEC VIII D1 code for unfired pressure vessel of at least 450 kPa 50 psig and shall have an ASME stamp. Interior shall be fitted with guides or tracks for material handling containers. Guides or tracks shall be constructed of material consistent with the chamber. Fittings shall be affixed on clad or bonded surfaces so that the steel will not be exposed to the sterilant. Provide automatically controlled means for wash and rinse water with steam injectors or coils. Chamber shall be equipped with removable screen, overflow and water level control.

2.10.2 Doors

Doors shall be automatic, power operated, sliding type, located on each end of each unit. Doors shall have manufacturer's standard exterior finish and shall be constructed of material consistent with the chamber. Door gaskets shall be renewable, heat resistant resilient sealing type with material consistent with the chamber. Load and unload doors shall not open when water pressure is in excess of 13.8 kPa 2 psig or vacuum in chamber, and never during a washing-sterilizing cycle.

2.10.3 Washing System

Water spray arms, nozzles and related piping shall be stainless steel, bronze or brass. Motor driven centrifugal pump, of appropriate size and rating, shall be provided to force wash and rinse water through nozzles. Arms and nozzles shall be arranged to fully spray entire load at high pressure. Include provisions to heat wash and rinse water from ambient to between 60 and 71 degrees C 140 and 160 degrees F and thermostatically maintain temperature within this range.
2.10.4 Sterilizing System

Unit shall be provided with necessary valves, traps, and regulators for operation on building steam supply. A steam strainer shall also be provided for assembly. Sterilize phase shall not progress if chamber temperature should fall to reach or fall 1 degree C 2 degrees F below set value. Following sterilizing period, steam and condensate shall automatically be discharged to waste.

2.10.5 Safety Valve

Safety valve shall be provided that is ASME approved, preset for chamber maximum working pressure and sealed to prevent changing setting.

2.10.6 Insulation

Exterior surfaces of chamber (except doors) shall be covered with nominal 25 mm 1 inch thick aluminum foil-backed glass fiber insulation, secured with thermosetting tape or corrosion and heat resistant straps and clips. Recyclable materials shall conform to EPA requirements in accordance with Section 01 33 29 SUSTAINABILITY REPORTING.

2.10.7 Detergent Dispensing

Detergent dispensing system shall automatically dispense proper amount of detergent, at appropriate times, to sterilizer chamber. Dispenser shall be built-in type and may include integral storage or be the type that draws directly from supplier's containers. Built-in storage shall hold at least 12 cycles of detergent. Include at least [one] [_____] full 12-cycle [supply] [supplies] of detergent for the unit.

2.10.8 Controls

Furnish either single console designed to control all functions of system, or decentralized panel providing individual controls for each automated washer-sterilizer with system. Regardless of control style, it shall be possible to energize entire washer-sterilizing system by single switch. Provide control to stop cycle of washer-sterilizer if chamber temperature falls 1 degree C 2 degrees F below set value or if power to unit fails, or both. Controls shall be automatic microprocessor type providing for the following cycles:

a. Wash and sterilize.
b. Flash sterilize only.
c. Wash only.
d. Pressure and temperature indicators.

2.10.9 Loader

Loader shall be capable of receiving at least one load of racked utensils at a time and, on demand by unit, automatically introduce load into processing chamber. Components of loader in contact with basket or racks shall be stainless steel or PVC.
2.10.10  Unloader/Storage Unit

Unloader/storage unit shall automatically remove at least one full load of
racked utensils at a time from processing chamber and move rack(s) onto
storage component which shall have capacity for at least two such full
loads. When fully loaded with racks, unit shall cease to discharge
additional loads. Parts of unit in contact with utensil racks shall be
stainless steel or PVC. Design rollers on storage unit with noise reducing
PVC finish.

2.10.11  Horizontal Conveyor

**************************************************************************
NOTE: Drawings must indicate layout of the rack conveyor system and interface with feed and holding
tables on automatic sterilizers.
**************************************************************************

The horizontal conveyor shall receive, transport, and transfer loaded
basket/racks to and from the processing unit and shall be capable of
accumulating the basket/racks until a processing unit becomes available.
Conveyor shall be power driven roller, accumulating type, designed to
automatically hold basket/racks of utensils until they can be removed. At
loader, conveyor shall automatically release each basket/rack onto loader.
Conveyor shall be size appropriate for material handling basket/racks,
entirely suitable for the intended purpose, and complying with ASME B20.1.

2.10.12  Wash and Sterilize Performance Requirements

When tested in the following manner, system shall render test utensils and
surgical instruments sterile and visually free of soil.

2.10.12.1  Test Load Preparation

Test load shall be prepared by coating surfaces, both inside and out, of
test utensils listed below with standard test soil, and utensils allowed to
drain for 10 minutes. Then test load shall be baked at 38 degrees C 100
degrees C for 5 minutes in chamber of preheated sterilizer with steam in
jacket only.

2.10.12.2  Spore Strip

Place a test spore strip in tray with instruments, protected from water. A
control and the test spore strip shall be inoculated with a mixture of
Bacillus stearothermophilus spores with a population adjusted to survive
132 degrees C 270 degrees F for 20 seconds and be killed when exposed to
132 degrees C 270 degrees F for 2 minutes.

2.10.12.3  Processing and Evaluation

Load shall be processed through one complete wash-rinse-sterilize cycle,
load removed and articles examined for visible soil in 1076 Lx 100
foot-candles of light. Presence of any soil is cause for rejection. Spore
strips shall be removed and incubated together with control strips
according to manufacturer's directions. Test strips shall show no growth
while control strips shall. Failure of growth in control strip shall be
cause for rejection of test, and complete test shall be rerun.
2.10.12.4 Test Utensils and Instruments

One full chamber load shall be composed to include one rack and a mixture of the following items:

a. Basin, solution, stainless steel, nominally 350 mm 14-inch diameter.
b. Bedpan, stainless steel.
c. Bottle, one liter, sterile fluid storage.

2.10.12.5 Standard Test Soil

Test soil shall be a homogeneous mixture of the following:

<table>
<thead>
<tr>
<th>Test Soil</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut Butter</td>
<td>100 grams</td>
</tr>
<tr>
<td>Butter</td>
<td>100 grams</td>
</tr>
<tr>
<td>Flour</td>
<td>100 grams</td>
</tr>
<tr>
<td>Lard</td>
<td>100 grams</td>
</tr>
<tr>
<td>Dehydrated egg yolk</td>
<td>100 grams</td>
</tr>
<tr>
<td>Evaporated milk</td>
<td>150 ml</td>
</tr>
<tr>
<td>Distilled water</td>
<td>500 ml</td>
</tr>
<tr>
<td>India ink</td>
<td>40 ml</td>
</tr>
<tr>
<td>Printing ink, diluted 1:1 with boiled linseed oil</td>
<td>100 drops</td>
</tr>
<tr>
<td>Blood agar base (dehydrated)</td>
<td>10 grams</td>
</tr>
<tr>
<td>1 Normal Solution Sodium Hydroxide</td>
<td>30 ml</td>
</tr>
</tbody>
</table>

2.10.13 Service Characteristics

**************************************************************************
NOTE: Rinse water below can be either tap or pretreated water, such as demineralized, distilled, or soft water.
**************************************************************************

[Include electrical power indicator-recorder that will, throughout each process cycle, indicate chamber temperature and indicate and record chamber temperature, together with chamber vacuum and pressure. Locate temperature sensor in condensate drain line from chamber. Locate vacuum and pressure sensors inside chamber. Recorder to be 24 hour type with capillary-style pens. Other instrumentation to include chamber pressure-vacuum gage and process-cycle-phase indicating lights]. [Include printer/controller to control, monitor and print all cycle functions. Printout to include]
temperature and pressure/vacuum readings at key cycle transition points. Use pressure transducer and resistance thermal detector for sensing chamber conditions.] The following shall be included:

a. Motor(s): [115] [120] [200] [230] [460] volt, [single] [three] phase, 60 Hz

b. Automatic controls: 120 volt, 60 Hz, single phase.

c. Steam: 450 to 750 kPa 50 to 80 psig (dynamic) at maximum rate of 190 kg 400 pounds per hour.

d. Hot and cold water: 375 to 750 kPa 40 to 80 psig.

e. Rinse water: [Tap] [_____] water, 150 Lpm 40 gpm.

2.11 MATERIAL HANDLING EQUIPMENT FOR STERILIZERS

**************************************************************************

NOTE: Equipment for the automated washer/sterilizers is specified in this specification. On small projects, quantities and assemblies for the remaining sterilizers may be specified herein. However, on large or complex projects, these accessories should be scheduled with the specific unit. The following is a guide for selection:

a. Gravity Air Sterilizers; General Purpose:

(1) 400 by 400 mm (16 by 16 inch): 3 instrument trays and 2 shelves.

(2) 500 by 500 mm (20 by 20 inch): 2 shelves.

(3) All others, 3 cart and carriages each.

b. Gravity Air, Laboratory:

(1) 400 by 400 mm (16 by 16 inch): 3 instrument trays and 2 shelves.

(2) 500 by 500 mm (20 by 20 inch) through 500 by 900 by 1200 mm (24 by 36 by 48 inch): 2 shelves.

(3) All others, 2 carts and carriages each.

c. Prevacuum Sterilizers, General: 3 loading-cars and carriages each or 3 loading carts for floor loading models.

d. Gas Sterilizers: Same as gravity air and/or floor loading models.

**************************************************************************

Material handling equipment for sterilizers are scheduled with the individual units. Accessories shall conform to the following:
2.11.1 Instrument Trays

Each instrument tray shall be made of welded nickel-copper-alloy, or Type 304 stainless steel.

2.11.2 Bottom Shelf

Each bottom shelf where scheduled shall be of nickel-copper-alloy, or Type 304 stainless steel. Supports shall conform to the same material requirements as the shelf.

2.11.3 Shelves

Where scheduled, shelves and related supports shall be nickel-copper-alloy, or Type 304 stainless steel.

2.11.4 Loading-Car and Carriage

Loading-car and carriage shall accommodate the transferring and loading of goods in sterilizers and aerators. Loading-cars and carriages as scheduled for each unit shall be furnished. Loading-car shall be welded nickel-copper-alloy or Type 304 stainless steel with two or more adjustable shelves. Wheels shall be stainless steel or brass. Carriage shall be welded tubular steel with chip-resistant finish. Loading-car tracks shall be height adjustable to align with tracks in processing chamber.

2.11.5 Loading Cart

Loading cart shall accommodate the transferring and loading of goods in floor loading style sterilizers and aerators. Cart shall be polished stainless steel tubular stock with each corner upright fitted with a rubber bumper. Shelves shall be Type 304 stainless steel. Cart and shelves shall be welded. A fixed bottom shelf and two shelves height-adjustable to at least five positions shall be provided. Shelf mounts shall be noise suppressing. Cart shall be mounted on two fixed and two swivel casters fitted with nonmarking treads and suitable for repeated exposure to steam at 135 degrees C 275 degrees F without flat spotting or other deterioration.

2.11.6 Automatic Materials Handling Accessories

[Washer-Sterilizer] [Washer-Decontaminator]: Metal parts shall be nickel-copper-alloy or Type 304 stainless steel. In addition to 6 general purpose racks per unit, each unit shall be provided with the necessary racks, trays, inserts and load covers to suitably hold the following quantity of items for processing.

a. Bedpans, 6 each.

b. Basins, wash, nominally 350 mm 14 inch diameter, 16 each.

c. Basins, 175 mm 7 inch diameter, 10 each.

d. Flasks, 2000 mL., 24 each.

e. Surgical Instruments, at least 15 kg 32 pounds, including retractors, forceps, and hemostats.
2.12 WATER DISTILLATION EQUIPMENT

2.12.1 Laboratory Distilling Apparatus

Laboratory distilling apparatus shall produce distillate free of pyrogen and containing not more than 1.0 ppm total solids, with a pH value of 5.4 to 7.2, an electrical resistance of not less than 300,000 ohms per centimeter (ohms/cm) at 25 degrees C 77 degrees F. Distilling apparatus shall be passivated stainless steel, tin-coated copper or tin-coated copper alloy, or titanium. Parts of copper or copper alloy in contact with water vapor and distillate shall be coated with tin 0.025 mm 0.001 inch thick, minimum. Valves, tubing, and fittings shall be passivated stainless steel, tin-lined copper, or tin-lined copper alloy. Exterior surfaces of copper shall be polished nickel or chromium plate. Tin lining in piping, tubing, valves, or fittings shall be 1.6 mm 1/16 inch thick, minimum. Distillate collector, still body, and condenser shall be stainless steel. Metallic surfaces in contact with distillate shall not contaminate the distillate.

2.12.1.1 Recording Conductivity Meter

A meter shall monitor water quality and include an automatic diverter device to discharge effluent to waste if the effluent is not of acceptable purity. The meter shall be the electronic indicating and recording type operating on 120-volt, single-phase, 60 Hz current. Meter shall be suitable for wall mounting. Solid-state electronic circuitry will be acceptable. Indicator shall be a horizontal scale approximately 150 mm 6 inch long with easily read graduations and a prominent mark at the point of minimum quality. Recorder shall be 30-day strip chart type which prints by a stylus against pressure-sensitive paper. Conductivity cell electrodes and automatic temperature compensating thermistor shall be contained within a glass or titanium body secured between the adapter and draw-off cock to register and record the quality of the distillate at the outlet of the still at all times. Meter shall have a cam switch to actuate a solenoid valve which will divert water with less than 300,000 ohms/cm resistance to waste automatically. An alarm shall sound when water is discharged to waste. The alarm shall be provided with a manual shut-off. One year's supply of pressure-sensitive strip chart paper shall be provided.

2.12.1.2 Additional Equipment

Additional equipment shall include thermostatic steam trap, check valve, automatic steam pressure regulating valve, pressure gauge, steam supply valve, water supply valves, and water pressure regulator.

2.12.1.3 Disassembly

Major components of the still, including the condenser, shall be easily disassembled and reassembled for cleaning and maintenance.

2.12.1.4 Mounting Devices

All parts of mounting bracket devices, including bolts and screws for securing brackets to wall, shall be stainless steel or welded steel with a corrosive resistant finish.

2.12.1.5 Finish

The exterior finish on exposed pipe, pipe fittings, valves, gauge cases, and trim shall be polished nickel or chromium plating, except on stainless
steel. The finish of other components not fabricated of stainless steel may be manufacturer's standard finish.

2.12.2 Cabinet-Type Water Distillation Unit

**************************************************************************
NOTE: A condensate feedback assembly can be an excellent source of purified supplemental feed water to improve distillate quality and reduce the frequency of cleaning (descaling) a water still; however, a condensate feedback assembly should never be specified if corrosion-inhibiting compounds are used, or contemplated for use in the central steam generating plant, or if the distillate will be used for production of surgical fluids. Distillation of the condensate would not remove compounds such as filming amines (octadecylamines) and/or soluble amines (morphine) which could be harmful to patients.
**************************************************************************

Cabinet-type water distillation unit shall be designed to produce its rated capacity at 276 kPa 40 psig steam pressure and 207 kPa 30 psig water pressure. The still with [condensate feedback purifier and] distillate cooler shall produce pyrogen-free water with a pH value of 6.5 to 7.2, total solids of 0.05 to 0.2 ppm, and with an electrical resistance of 1,000,000 to 3,000,000 ohms/cm at 25 degrees C 77 degrees F.

2.12.2.1 Storage Tank

Storage tank shall be made of stainless steel or tin-coated copper or copper alloy sheets. The storage tank shall be supplied with an immersion type ultraviolet lamp replaceable without exposing the tank interior to atmospheric contamination. Tank shall have a water level sight gauge and a tin-coated, self-closing draw-off faucet.

2.12.2.2 Controls

Automatic controls and accessories shall start the still when distilled water in the storage tank falls to a preset level and shall stop the still when the storage tank is full. The controls shall include a tank level control, automatic water and steam valves, and a manually-operated drain valve. A steam trap pressure gauge, automatic cooling water temperature regulator, steam and water pressure reducing valves, and effluent purity meter shall be provided. The purity meter shall be a direct-reading continuous-measurement type having a range of 0-18 megohms. Meter may have multiple scales and shall have an accuracy of not less than 2 percent of full scale. All gauges, switches, and signal lights shall be mounted on an instrument panel in the cabinet. All interconnecting piping shall be provided.

2.12.2.3 Condensate Feedback Purifier

The feedback device shall prepurify steam condensate before distillation to eliminate scale build-up inside the still's evaporator. Prepurification equipment shall include condensate cooler with demineralizing and organic-material removing cartridges. A light shall indicate when cartridges are spent. Each unit shall be provided with [5] [_____] spare cartridges.
2.12.2.4 Cabinet

Cabinet shall be stainless steel with removable front access panels. Ten gpm unit shall have a stainless steel work counter with drain.

2.12.3 Self-Contained Water Distillation Unit

Self-contained water distillation unit shall produce distillate containing not more than 1.0 ppm total solids with a pH value of 5.4 to 7.2 and electrical resistance not less than 300,000 ohms/cm at 25 degrees C 77 degrees F.

2.12.3.1 Storage Tank

Storage tank and still shall be tin-coated copper or tin-coated copper alloy sheets.

2.12.3.2 Floor Stand

Floor stand shall be welded steel tubing and shall have adjustable floor flanges for leveling the stand.

2.12.4 Individual Distilled Water Storage Tanks

Distilled water storage tanks shall be borosilicate glass carboy, tin-coated copper or tin-coated copper alloy, stainless steel, or titanium. Tin coating of 0.025 mm 0.001 inch minimum thickness shall be applied on copper or copper alloy where the metal surfaces are in contact with water, water vapor or distillate. The tank shall be fitted with distilled water inlet, air vent with filter, self-closing overflow draw-off cock, sight gauge, [ultraviolet lamp,] and seamless tin-lined copper or stainless steel fittings for connection of tank to still. Air tube and block fitting for draw off cock on carboy may be inert polyvinyl chloride.

2.12.4.1 Air Vent Filter

Filter shall remove particulate matter greater than 0.2 micron in diameter, bacteria, organic solvent vapors, and acid gases.

2.12.4.2 Ultraviolet Lamp

Lamp shall be replaceable without contaminating the stored water.

2.12.4.3 Mounting Device

A corrosion-resisting steel bracket shall be furnished for wall mounting. Glass carboys shall be mounted on the bracket, inverted on a rubber protected ring that is an integral part of the bracket. Through bolts and stud plate shall be stainless steel.

2.13 SOLUTION WARMING CABINETS

Solution warming cabinets shall essentially consist of a heated cupboard-like device suitable for the warm storage of solutions used in surgical procedures. Double compartment units shall additionally be suitable for the warm storage of blankets in the second compartment.
2.13.1 Fabrication

Cabinet shall be welded or riveted, with a stainless steel interior and manufacturer's standard factory finished exterior.

2.13.2 Heated Compartment

Each heated compartment shall be capable of selectively maintaining the solutions environment in a range of 37 to 72 degrees C 97 to 160 degrees F plus or minus 5 degrees C 10 degrees F of set temperature. Heated compartment shall be fully insulated with an R-value of 3.5 or greater. Air circulation system shall be included in compartment to maintain temperature uniformity.

2.13.3 Controls

Controls shall include indicator lights to signify various phases of operation. An over temperature control shall be incorporated that will shut off heat source, actuate an audible alarm and a visual signal when temperature inside the cabinet exceeds set point by 8 degrees C 15 degrees F. Electric unit shall be: 120/208/240 volt, single phase, 2000 watts.

2.13.4 Two Compartment Units

Where two compartment units are scheduled, both compartments shall be heated, have independent controls, and include adjustable corrosion resistant shelves.

2.14 BEDPAN WASHER-SANITIZER

Bedpan washer-sanitizer shall be a built-in device for the hands-free rinsing and sanitizing of heat-resistant hospital bedpans and urinals, utilizing water and steam from building source. Unit shall be type as scheduled, and be able to sanitize a standard adult size bedpan or a male urinal each cycle.

2.14.1 Cycles

Automatic control shall provide for a cold water flush and rinse, followed by a steam sanitizing phase with a signal light to indicate cycle is in progress.

2.14.2 Door

Door shall incorporate an air intake slot and be flanged to prevent leakage of water or excess steam. When foot pedal control is depressed, door shall open while simultaneously releasing utensil holding members, and door shall close automatically when foot pedal control is released.

2.15 EQUIPMENT FINISHES

Exposed carbon steel surfaces of equipment shall be protected by manufacturer's standard finish. Unless otherwise specified, exposed stainless steel surfaces of all equipment shall have satin No. 3 or No. 4 finish unless otherwise approved.

2.16 FACTORY TESTS

The factory test shall be conducted with the ambient temperature maintained
between 21 and 29 degrees C 70 and 85 degrees F, at atmospheric pressure. The test load material shall be at ambient temperature. Testing apparatus and instruments shall not interfere with accurate operation measurements. Spore strips shall conform to CID A-A-50879, Type A or B. The performance tests specified may be waived for equipment of the same model or similar model which has been previously tested and installed and for which the manufacturer has filed certified test records not more than 24 months previously.

PART 3 EXECUTION

3.1 EXAMINATION

After becoming familiar with all details of the work, verify all dimensions in the field, and advise the Contracting Officer of any discrepancy before performing the work.

3.2 INSTALLATION

Install equipment at locations indicated in accordance with manufacturer's printed installation instructions, Section 11 70 00 GENERAL REQUIREMENTS FOR MEDICAL AND DENTAL EQUIPMENT, and approved detail drawings. Submit detail drawings containing complete wiring and schematic diagrams and any other details required to demonstrate that cabinets and sterilizer systems have been coordinated and will function as a unit. Drawings shall show proposed layouts and anchorage of equipment and appurtenances, and equipment relationship to other work including clearances for maintenance and operation. Drawings shall include installation details and settings, drain piping connections, and complete electrical wiring and control diagrams. Necessary items such as framing, mounting hardware and trim shall be furnished and installed as required for the type of equipment furnished.

3.3 ADJUSTING

Following installation, flows, timers, levelers, and similar components and operation devices shall be adjusted as appropriate. After testing, and before acceptance, equipment shall be examined to ensure that adjustments are correct and that any additional adjustments deemed necessary during product testing or because of timing, have been incorporated.

3.4 UTILITIES

3.4.1 Service Runs

Connect service runs from equipment to building services as indicated.

3.4.2 Dissimilar Metal Connectors

Connections between ferrous and nonferrous metallic pipe shall be made with dielectric waterways and flanges. Dielectric waterways shall have temperature and pressure rating equal to or greater than that specified for the connecting piping. Waterways shall have metal connections on both ends suited to match connecting piping. Dielectric waterways shall be internally lined with an insulator specifically designed to prevent current flow between dissimilar metals. Dielectric flanges shall meet the performance requirements described herein for dielectric waterways.
3.4.3 Steam Connections to Building Source

********************************************************************************
NOTE: Mechanical drawings should indicate individual cut-off for each equipment unit to permit maintenance and removal of the equipment. Steam lines should be provided with blow-down valve or other suitable means of protection to steam powered equipment for use when steam power and distribution system is cleaned.
********************************************************************************

Steam lines on equipment for connection to building source shall be connected only after building steam lines have been cleaned of preservatives and materials that may be harmful to the equipment.

3.4.4 Waste Steam

Distillate coolers or other protective devices shall be installed as necessary to protect high temperature discharge to waste.

3.5 MANUFACTURER'S FIELD SERVICES

********************************************************************************
NOTE: Delete this paragraph when an economical analysis of the project deems this requirement unnecessary.
********************************************************************************

Provide the services of a manufacturer's representative who is experienced in the installation, adjustment, and operation of the equipment specified shall be provided. The representative shall supervise the installation, adjustment, and testing of the equipment.

3.6 FIELD TESTS AND INSPECTIONS

3.6.1 Before Testing

Pipes, equipment and components shall be cleaned of grease, dirt, stains, and other foreign materials.

3.6.2 Testing

Testing shall be performed in accordance with referenced specifications and/or requirements specified. One item or similar model, as necessary or appropriate, shall be tested to ensure that it is operational and installation conforms to specification requirements. Hydrostatically test piping system at pressure of 1.5 times system operating pressure with water at temperature not exceeding 38 degrees C 100 degrees F. Before test, remove or isolate gage traps and apparatus that may be damaged by that pressure. Install calibrated test gage in system to observe any loss of pressure. Close off system and maintain test pressure not less the one hour. Inspect joints and equipment connections for leaks. Retest and make repair until no further leaks are observed. Manufacturer's standard equipment warranty shall not begin until the manufacturer certifies equipment conformance to all required testing specified and until beneficial occupancy of the portion of the facility where the equipment is installed. Submit certified copies of results of factory tests of equipment tested. Test reports in booklet form showing field tests.
performed to adjust each component and all field tests performed to prove compliance with the specified performance criteria, upon completion and testing of the installed equipment. Each test report shall indicate the final position of controls.

3.6.3 Inspection

Each item shall be examined for visual defects and conformance to specifications.

3.7 CLEANING

3.7.1 For Final Acceptance

Remove labels, fingerprints, and clean all surfaces both inside and out. Tightly cover and protect fixtures and equipment against rust, dirt, water, and chemical or mechanical injury. Marred surfaces shall be repaired, patched, and touched-up as suitable for conditions.

3.7.2 Marred Surfaces Exposed-to-View

Marred exposed surfaces that affect appearance, such as both interior and exterior cabinet finishes, shall be finished to match the adjacent finishes, like new. Parts that cannot be refinished in this manner shall be replaced.

3.7.3 Concealed Marred Surfaces

Marred surfaces exposed to atmosphere, where such surfaces do not affect product's appearance but do affect resistance to elements, such as galvanized pipes and insulation shall be finished to equal resistance performance as the unmarred surfaces.

3.8 TRAINING

3.8.1 Training Course

Conduct training course for operation staff as designated by the Contracting Officer. The training period, for a total of [_____] hours of normal working time, shall start after systems are functionally complete but prior to final acceptance. The field instructions shall cover all of the items contained in the operations and maintenance instructions, as well as demonstrations of routine maintenance operations. Notify Contracting Officer at least 14 days prior to date of proposed conduction of training course. The manuals shall be approved prior to the training course.

3.8.2 Operating Manual

Submit [six] [_____] complete copies of operation manual outlining the step-by-step procedures required for system startup, operation, and shutdown. The manuals shall include the manufacturer's name, model number, service manual, parts list, and brief description of all equipment and their basic operating features.

3.8.3 Maintenance Manual

Submit [six] [_____] complete copies of maintenance manual listing routine maintenance procedures, possible breakdowns and repairs, and trouble shooting guide. The manuals shall include simplified schematic diagrams.
for the equipment as installed. Submit operation and maintenance data in accordance with Section 01 78 23 OPERATION AND MAINTENANCE DATA.

-- End of Section --