(September 2021)

PERFORMANCE CRITERIA
FOR

SECTION 11 53 23

LABORATORY REFRIGERATORS & FREEZERS
09/21

TABLE OF CONTENTS

GENERAL
This Performance Criteria specifies the requirements for laboratory refrigerators & freezers.

1.1 REFERENCE

1.1.1 Unified Facilities Criteria (UFC)
Contractor must comply with the following:
- **A.** UFC 1-200-01 General Building Requirements
- **B.** UFC 1-200-02 High Performance and Sustainable Building Requirements
- **C.** UFC 3-120-10 Interior Design
- **D.** UFC 4-510-01 Military Medical Facilities

1.1.2 Military Standard
- **A.** MIL-STD 1691 Construction and Material Schedule for Medical, Dental, Veterinary and Medical Research Laboratories

1.1.3 National Fire Protection Association (NFPA)
- **A.** NFPA 99 Healthcare Facilities Code
- **B.** NFPA 101 Life Safety Code

1.1.4 Military Health Services Standards
- **A.** Reserved for future

1.1.5 Underwriters Laboratories (UL)
- **A.** UL 471 Standard for Commercial Refrigerators and Freezers
- **A.** UL 60601-1 Medical and Electrical Equipment, Part 1: General Requirements for Safety
- **B.** UL 60601-2-040 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used To Treat Medical Materials

1.1.6 International Electrotechnical Commission (IEC)
- **A.** IEC 60601 Medical Electrical Equipment and Systems

1.1.7 Food and Drug Administration (FDA)

A. CFR Title 21, Chapter I

1.1.8 Division of AIDS (DAIDS)

A. DAIDS Guidelines for Good Clinical Laboratory Practice Standards

1.1.9 Defense Health Agency (DHA)

A. DHA Immunization Healthcare Vaccine Storage and Handling Guidelines

1.1.10 Other Standards

A. Reserved for future

2.1 DESCRIPTION & MATERIALS

All requirements within the MIL-STD 1691 JSN descriptions must be met as well as the performance guidelines listed in the following descriptions.

2.1.1 All JSN'S

A. Paints, fabrics, and finishes must be selected from the manufacturer's standard options for the specified model unless noted otherwise.

B. All product finishes must be capable of maintaining sheen and color through warranty period when using industry standard cleaning and disinfection solutions.

C. All display panel surfaces must maintain clarity through warranty period when using industry standard cleaning and disinfection solutions.

D. All equipment that have components that are meant for reuse must be autoclavable or able to withstand industry standard cleaning and disinfection processes.

E. Electrified equipment must be 115 Volt 15 amp maximum unless noted otherwise.

F. Casters provided must be designed for use on the installed floor finish.

G. All products that have interoperability capable hardware (i.e. internal storage, data transmission via wireless, Ethernet, LAN, or USB to PC or server connectivity) must meet Cybersecurity requirements in accordance with DoDI 8510.01 Risk Management Framework.

H. DoDI 8510.01 applies to all DoD IT (medical devices included) that receive, process, store, display, or transmit DoD information. These technologies are broadly grouped as DoD IS, platform IT (PIT), IT services, and IT products. This includes IT supporting research, development, test and evaluation (T&E), and DoD-controlled IT operated by a contractor or other entity on behalf of the DoD.

2.1.2 Dry Ice Equipment

R4790 – Icemaker, Dry Ice

A. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.

2.1.3 Freezers

A. Biological Freezers

R1700 – Freezer, 2 Section, CRS
R1705 – Freezer, Drawer, Undercounter
R5100 – Freezer, Biological, -85, 19-25 Cubic Feet, Upright
R5135 – Freezer, Undercounter, 5 Cubic Feet
R5200 – Freezer, Counter High, -70 C, 5 CUFT
R6050 – Freezer, Biological, Chest, -70c, 12 Cubic Feet
R6111 – Freezer, Cryogenic, Chest

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Undercounter freezers must be [-15°] [-25°] [-30°] [-40°] Celsius].
4. [Temperature chart recorder must be included.]
5. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for

continuous monitoring of temperature.]
6. [Freezers must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
7. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
8. [Provide ability to lock doors when closed.]

B. Blood Bank Freezers

R5110 – Freezer, Rapid, Blood/Plasma, 4 Cubic Feet
R5115 – Freezer, Blood, Chest, Double Compartment
R5120 – Freezer, Blood/Platelet, Upright, -85, 20-30 Cu Ft
R5130 – Freezer, Plasma, Upright, -35c, 20 Cubic Feet

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Freezers must meet American Association of Blood Banks (AABB) and FDA guidelines for storage of whole blood and blood components.]
4. [Blast freezers storing plasma must meet American Association of Blood Banks (AABB) guidelines for rapidly freezing plasma prior to long-term storage.]
5. [Temperature chart recorder must be included.]
6. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for continuous monitoring of temperature.]
7. [Freezers must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
8. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
9. [Provide ability to lock doors when closed.]

2.1.4 Refrigerators

A. Blood Bank Refrigerators

R6010 – Refrigerator, Blood Bank, Glass Do, Dr, 25 Cu Ft
R6030 – Refrigerator, Blood Bank, Undercounter, Drawer
R6040 – Refrigerator, Blood Bank, 2 Glass Do, Dr, 48 Cu Ft

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Refrigerators must meet American Association of Blood Banks (AABB) and FDA guidelines for storage of whole blood and blood components.
4. [Temperature chart recorder must be included.]
5. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for continuous monitoring of temperature.]
6. [Refrigerators must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
7. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
8. [Provide ability to lock doors when closed.]

B. Biological Refrigerators

R6060 – Refrigerator, Biological, SS, 2 Door, 40 Cu Ft
R6065 – Refrigerator, Biological, 3 Door, 78 CUFT
R6280 – Refrigerator, Lab, SS, 2 Door, 6 Shelves
R6900 – Refrigerator, Bio, Radio/Pharm, Approx. 5 CuFt

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Temperature chart recorder must be included.]
4. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for continuous monitoring of temperature.]

5. [Refrigerators must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
6. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
7. [Provide ability to lock doors when closed.]

2.1.5 Refrigerator/Freezer Equipment

A. Biological Storage

R6070 – Refrigerator/Freezer, Biological, Upright, 18 Cu Ft
R6080 – Refrigerator/Freezer, Biological, SS, 2 Door
R6090 – Refrigerator/Freezer, Biological, 1 Door

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. [Temperature chart recorder must be included.]
4. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for continuous monitoring of temperature.]
5. [Refrigerator/Freezers must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
6. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
7. [Provide ability to lock doors when closed.]

B. Hazardous Material Storage

R6180 – Refrigerator/Freezer, Explosion Proof, 13 Cu Ft

1. Display must be LCD/LED high contrast with continuous display of measured parameters. Display text must be readable in any ambient light level.
2. Construction must be free of sharp edges, impervious to fluids, and corrosion resistant. Parts must allow for thorough cleaning and disinfection.
3. Refrigerator/Freezer must meet NFPA and OSHA guidelines for Hazardous Locations, Class 1, Division II, Group C & D.
4. [Temperature chart recorder must be included.]
5. [Provide an access port to allow an internal probe connected to an external device mounted to the unit for continuous monitoring of temperature.]
6. [Refrigerator/Freezers must have an external data connection for the monitoring of temperature from a remote location and the signaling of alarms.]
7. [Hardware must include wireless, Ethernet, or USB to PC connectivity for data transmission.]
8. [Provide ability to lock doors when closed.]

3.1 SUBMITTALS

3.1.1 Submittals required for government review

A. Submittal requirements are outlined in [Division 01] [PWS SOW] [___]
B. [Product Information must include manufacturer's installation instructions, sizing (including required clearance for access and maintenance), utility requirements, isometric drawings, tagged floorplans showing placement for count accountability and accessories/options/consumables lists.]
C. All submittals require Government approval prior to procurement. Submit all listed items herein, with information sufficient to show full compliance with the criteria. Submit all product selections for review and approval, including but not limited to: materials, finishes, colors, options, accessories, and complimentary products. Provide for review all warranties and service contracts and any available extended warranty or service options.
D. Samples: Furnish material samples and full range of color selection options for all items that offer material and color selections.
E. Submit and highlight all applicable options for Government review for all items which optional accessories are provided.
F. [Joint Interoperability Test Command (JTIC) Approval Documentation.]

3.2 QUALITY ASSURANCE

3.2.1 Materials and Equipment

A. Materials and equipment must be standard products of a manufacturer regularly engaged in the manufacture of products which are of a similar material, design, and workmanship and are offered for sale on the commercial market through advertisements, manufacturer's catalogs, or sales brochures. The products must have been in commercial or industrial use under similar circumstances and of similar size for 2 years prior to selection for approval/procurement. Products must be supportable for at least three years after government acceptance.

3.2.2 Alternative Service Record

A. Products having less than a 2-year field service record will be acceptable if a certified record of the manufacturer's factory or laboratory tests demonstrating performance compliance is provided to the Contracting Officer.

3.2.3 Service Support

A. Equipment items must be supported by service organizations located near the equipment installation, able to service the equipment on a regular basis and respond to emergency calls throughout the warranty period.

3.2.4 Manufacturer's Nameplate

A. Each item of equipment must have an attached nameplate that is securely affixed in a conspicuous space. A nameplate listing only the name of the distributing agent is not acceptable. The nameplate must contain the following fields in English:

1. Manufacturer’s name and address
2. Model and Serial Number
3. Item’s utility ranges and/or capacities
4. Voltage, amperage, and applicable Underwriters Laboratory (UL) or Conformitè Europëenne (CE) rating if electrically powered
5. Date of manufacture

3.2.5 Factory Inspection

A. Arrange and perform all quality control and quality assurance inspections required by the technical sections of the criteria, unless otherwise specified. Report these inspections in the daily report to the Government inspector.

3.2.6 Product Qualifications

A. The products specified in the technical sections of this criteria establish standards for each item.

3.2.7 Design Parameters

A. It is not the intention of this Criteria to limit consideration to products of specific manufacturers. The product standards establish the characteristics for which submitted items of equipment will be reviewed and approved by the Government. Equipment furnished must meet each of the following parameters specified in the technical sections:

1. Size of equipment
2. Function of equipment
3. Standard and listed accessories and options
4. Equipment controls and performance of equipment
5. Construction of equipment
6. Finish

3.3 STANDARDS DEVIATIONS

3.3.1 Reporting and Submission for Approval

A. Submit for approval a record of deviations from the standards listed in section (3.2.7.A.) established for each specified product, before ordering equipment.

3.4 DELIVERY, STORAGE AND PROTECTION

3.4.1 Packaging and Transporting

A. Each unit of equipment must be placed in a substantial shipping container or crate for safe transportation to final destination. The shipping container or crate for heavy equipment must be on skid construction to facilitate handling by lift equipment.

3.4.2 Packing List

A. Clearly and legibly indicate on exterior of each container or crate the shipping address and a brief description of contents. Fasten to outside of container a packing list and complete instructions for uncrating equipment and setting it in place. Protect such information in a weatherproof envelope.

3.4.3 Protection

A. Properly protect all materials and equipment from injury and damage during storage, installation, and acceptance.

3.5 INSTALLATION, VERIFICATION AND ACCEPTANCE TESTING

3.5.1 Qualifications of Installers and Inspectors

A. If required by product warranty, use installers that are approved and licensed by the manufacturer. When required to complete installation, all electricians and plumbers used must be bonded and licensed in the project's jurisdiction.

B. [Company specializing in installing the products specified in this section must have a minimum 5 years of documented experience.]

C. [Company specializing in installing the products specified in this section must be within 200 miles or 4 hours travel time.]

3.5.2 Installation, Operation, Testing and Certification

A. Products must be delivered in manufacturer's original packaging with manufacturer's installation instructions. Include clearly marked project reference.

B. Prior to installation, thoroughly examine the equipment, materials, and components for both visual defects and conformance with criteria.

C. Install all equipment in compliance with manufacturer's written instructions and installation procedures.

D. After installation, the equipment must be inspected and tested under operating conditions. If the equipment fails an inspection or test, such defects/failures must be corrected. Upon correction of defects/failures, inspect and retest all affected functions related directly and indirectly to the defect or failure. Corrections, replacement, and retesting must be made at no additional expense to the Government.

E. Provide all items necessary to make equipment fully functional.

F. Provide appropriately trained personnel to energize, commission, inspect, electrical safety check, calibrate, certify, and provide all required technical testing for equipment and systems. Contractor must provide documentation, test reports and certification documentation attesting that the equipment is properly installed, functional, safe, calibrated, and ready for its intended use.

G. An equipment item will be considered defective if it cannot be made to meet all established criteria consistent with the activities listed in section (F).

H. Provide two sets of special tools, software, and any other item/s for each equipment [item] [item type] if required for maintenance and/or future reconfiguration of the item.

I. Contractor to supply all start-up supplies for medical equipment for a fully operational installation. Contractor must supply to the Government a listing of all needed supplies for ongoing equipment operation for each item of equipment requiring additional supplies for operation.

J. Engage a factory-authorized service representative to train Government's staff and maintenance personnel to adjust, operate, and maintain medical equipment.

K. [Confirm functionality of required interfaces to other systems and networks.]

3.6 WARRANTY

3.6.1 Minimum Requirements

A. Warranty requirements are outlined in [Division 01] [PWS SOW] [___].

B. [Provide manufacturer's written warranty for all items listed. Provide warranty for a minimum of (1) year against defects in materials and workmanship. Warranty must provide for material, labor and all associated replacement and/or repair costs required to provide for a fully operational equipment replacement or repair. Submit manufacturers and installers standard service contract beyond the warranty period for Government review. Warranty

must be transferrable to the final owner without risk of being voided. All warranty certification and documentation must be provided to the final owner after date of acceptance.]

C. Provide routine warranty service in accordance with manufacturer's warranty requirements, for a period of [12 months (minimum)] [___] after the open for business date. Perform work during regular working hours. Perform service only by factory trained personnel. Maintain a maintenance log of all service orders performed during the warranty period.

3.7 OPERATIONS AND MAINTENANCE (O & M)

3.7.1 Provide the following to the final owner

A. Provide O & M data for all FFE-LVS as outlined in [Division 01] [PWS SOW] [___].

B. Upon completion of equipment installation, furnish [two (2)] copies of operators/service/maintenance manuals for each type of equipment which will require service or maintenance

C. Each manual must contain operating instructions and information required for performing periodic maintenance on the equipment. Each service manual must include an illustrated parts breakdown which identifies each part of the unit with manufacturer's part number, wiring diagrams, and a list of necessary service parts, tools, and equipment needed to support maintenance requirements.

D. Accessory Catalogs: Upon completion of the Project, furnish two copies of the manufacturer's catalogs containing optional accessory items available for all equipment relative to the procured equipment/system delivered herein.

E. Provide instruction video for cleaning and maintenance, when available.

F. Provide cleaning requirements for all items to prevent void of warranty.

G. [Provide contact information for Repair Technician or Emergency Repair Company]

H. Provide contact information to [Logistics, Pharmacy, Laboratory, and Biomedical Equipment Services.]

I. Train designated staff in the operation and maintenance of the provided equipment/system. Provide two training sessions for equipment/system users and two training sessions for maintenance personnel scheduled to accommodate shift work. [Provide training certificates that can be executed up to eleven months after the system is installed, in order to provide a refresher course for each group of trainees.] Provide DVD copy of the training with the O & M data.

--End of Section--