WHO/V&B/02.33
ORIGINAL: ENGLISH

Equipment performance specifications and test procedures

E1: Cold rooms and freezer rooms

Vaccines and Biologicals

World Health Organization

WHO

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This module is part of the following series:

E1: Equipment performance specifications for cold rooms and freezer rooms
E2: Equipment performance specifications for motorcycles
E3: Equipment performance specifications for refrigerators and freezers
E4 and E11: Equipment performance specifications for insulated containers
E5: Equipment performance specifications for ice packs
E6: Equipment performance specifications for temperature-monitoring devices
E7: Equipment performance specifications for cold chain accessories
E8: Equipment performance specifications for injection devices
E9: Equipment performance specifications for steam sterilizers
E10: Equipment performance specifications for injection accessories

This module contains references to the following documents:

WHO/V&B/02.34: Guideline for establishing or improving primary and intermediate vaccine stores.
WHO/V&B/00.13: Product information sheets *(2000 edition).*

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Contents

Abbreviations

°C	degrees centigrade
CFC	chlorofluorocarbon
dB	decibels
EPI	Expanded Programme on Immunization (WHO)
hrs	hours
Hz	herz
Incoterms 2000	International Chamber of Commerce commercial delivery terms
ISO	International Standards Organisation
K	kelvin
kg	kilograms
kVA	kilovolt-ampere
kW	kilowatts
kWh	kilowatt-hours
m	metres
m^2	square metres
m^3	cubic metres
mm	millimetres
PC	personal computer
PIS	WHO/UNICEF product information sheets
ITS-90	International Temperature Scale of 1990
UNICEF	United Nations Children's Fund
W	watts
WHO	World Health Organization

1. Introduction

1.1 Cold rooms and freezer rooms

Cold rooms and freezer rooms are normally used to store vaccines at the national or subnational level for periods of several months. If a cold room or freezer room fails, the immunization services of an entire country may be placed at risk. Consequently, equipment must be specified, installed and maintained to the highest available standards.

This document outlines specifications for step-in and walk-in units with a capacity of up to about 40m^3. It should be modified to suit individual cases. Cold rooms and freezer rooms that are significantly larger should only be specified in consultation with a refrigeration specialist.

1.2 Equipment descriptions

The performance specifications given in this document apply to the following types of rooms suitable for storing vaccines:

E1/CR Cold rooms (+2°C to +8°C).

E1/FR Freezer rooms (-15°C to -25°C).

2. How to buy and maintain cold rooms and freezer rooms

Unlike other cold chain equipment, cold rooms and freezer rooms are purpose-made and have to be assembled and commissioned on site. The buyer is responsible for selecting a space for the room and for preparing the space so as to make it suitable for the installation. A building that houses a cold room should be accessible and in good condition, it should have suitable finishes and adequate ventilation, and it should have the correct electricity supply.

The stages involved in buying and commissioning a cold room are summarized below. For further details refer to WHO/V&B/02.34: *Guideline for establishing or improving primary and intermediate vaccine stores* and other relevant sources.

1. **Decide on location and capacity**: Decide on the location and the required capacity of the cold room(s) and freezer room(s). Select the space(s) in which the equipment is to be installed.
2. **Short-list suppliers**: Contact cold room suppliers and establish which are able to provide, install, commission and service cold rooms and freezer rooms conforming to the present specifications. Prepare a tender list of at least three companies. Although WHO does not endorse any particular manufacturers, a list of suppliers with relevant experience is given in document WHO/EPI/V&B/00.13: *Product information sheets* (2000 edition).
3. **Prepare and invite tenders**: Prepare tendering documentation with reference to the model specifications contained in the present document, and invite tenders. At the same time, tenders may be invited for stand-by generators if these are needed. Guidance on specifying and buying generators is given in document WHO/EPI/V&B/00.13: *Product information sheets* (2000 edition).
4. **Place order**: Receive and evaluate tenders, reach agreement on an installation programme and place an order with the winning supplier.
5. **Prepare the site**: Prepare the space for the cold room in accordance with the supplier's requirements and the guidance set out in document WHO/V&B/02.34: *Guideline for establishing or improving primary and intermediate vaccine stores.*
6. **Supervise**: Supervise the installation procedure and oversee commissioning and user training.
7. **Monitor**: Monitor the performance of the equipment in use and monitor the effectiveness of the maintenance agreement.
8. **Renew**: Ensure that the maintenance agreement is renewed after the expiry of the initial contract.

3. How to use this document

There are numerous cross-references between the standard clauses of the two specifications below. In order to avoid confusion, users should strike through any inapplicable clauses or options but should not change the clause numbers.

4. Cold rooms operating at +2°C to +8°C

CR.1 **Type of equipment**: Cold room(s) for storing bulk vaccine.

Location of installation: As in clause CR.6, and in accordance with the further details referred to in clause CR.7.

Number and size of units: As in clause CR.6.

Delivery terms: <*Term*> (Incoterms 2000) <*destination or port of entry*>.

Guidance note: *Specify the required Incoterms and point of delivery.*

CR.2 **Quality control standards**: Component manufacture and all installation and commissioning processes are to be in accordance with ISO 9001.

Guidance note: *The current version is ISO 9001:2000, but certification to ISO 9001:1994 should be acceptable.*

CR.3 **Information to be submitted with tender**: Submit the following supporting information with the tendering documents (ignore any clauses that have been deleted):

Technical details:

- Plans, elevations and sections at 1:50 scale showing each cold room, its refrigeration equipment and the shelving layout proposed.
- Method statement describing proposed shipment and assembly.
- Procedures (CR.25).
- Details of any building work to be carried out by the purchaser, including any requirements for permanent ventilation, heating or cooling in the space(s) housing the cold room(s).
- Programme for manufacture, delivery and erection.
- Evidence of ISO 9001 certification (CR.2).
- Full technical details of all incorporated components and equipment, including panel construction, shelving, refrigeration units, refrigerant, alarm system (including dB rating of sounder), temperature recorder, and proposed consumables and spare parts.
- Details of the voltage stabilizer, if required (CR.21).
- Evaporator area.
- Details of the oil separator (if condenser located outside).
- Power consumption data (CR.10).
- Electrical safety certifications for all components (CR.11).

- Details of the proposed spare parts and consumables inventory (CR.22 and CR.23).
- Details of the proposed training programme(s) (CR.26).
- Details of the proposed maintenance service and the local maintenance agent, together with specific proposals for routine and emergency maintenance (CR.27).
- Anticipated empty weight of the complete installation(s) in kilograms.

Tender details:

- Specify delivery time.
- Specify warranty terms.
- Specify shipping details, including packed weight and volume.
- Price for supplying the specified components to the site(s), including payment terms and currency.
- Price for installing and commissioning the components, including payment terms and currency.
- Price for supplying the spare parts, including payment terms and currency.
- Price for training users, including payment terms and currency.
- Price for training repair technician(s), including payment terms and currency.
- Estimated annual cost of consumables.
- Cost of five-year maintenance agreement, including payment terms and currency.

CR.4 **Temperature control**: The temperature of the cold room must remain between +2°C and +8°C when measured in any part of the room, under any loading condition between empty and full, and over the full ambient temperature range specified in CR.5.

CR.5 **Climatic conditions**: The temperature control set out in CR.4 is to be achieved under the following climatic conditions:

Hot zone: maximum continuous ambient summer temperature +43°C; minimum continuous ambient winter temperature 0°C.

Or

Temperate zone: maximum continuous ambient summer temperature +32°C; minimum continuous ambient winter temperature 0°C.

Or

Cold zone: maximum continuous ambient summer temperature +32°C; minimum continuous ambient winter temperature -5°C.

Guidance note: *Select one climate regime only and strike out the descriptions that do not apply. Alternatively, specify the actual temperature regime derived from national climate data. In cold climates, pay particular attention to the selection of the worst-case minimum winter temperature. For example, is the room in which the cold room is to be located permanently heated, and will this heating be 100% reliable? If not, low-temperature protection is essential.*

CR.6 **Capacity and location**: The cold room(s) and shelving layout(s) must be sized to accommodate the volume(s) of vaccine set out in the table below. Cross-refer to clause CR.16.

Unit ref.	Location	Maximum stored volume (litres)

Guidance note: *Calculate and insert the required net storage volume for each cold room. Make sure you know the type of packaging in which the vaccine is to be stored, e.g. intermediate packaging or insulated shipping containers. Choosing the latter will greatly increase the required size of the cold room. Include the volume of any other items that are to be stored in the cold room. Make a generous allowance for future needs, e.g. new vaccines in smaller presentations, integrated services.*

CR.7 **Location details**: Install cold room(s) in the locations(s) indicated on the worksheet(s) and drawing(s) attached to this specification. Details of the location(s) are shown on the drawing(s).

Guidance note: *For each location, complete the worksheet at the end of this document and provide a dimensioned drawing.*

CR.8 **Control by thermostat**: Cold room temperature must be controlled by a thermostat within the tolerances specified in clause CR.4. The thermostat must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

CR.9 **Holdover time**: In the event of power failure, the **c**old room temperature must remain above 0°C at the specified minimum ambient operating temperature, or below 10°C at the specified maximum ambient operating temperature, for at least 8 hours.

CR.10 **Power consumption**: Confirm the following for each cold room at the time of tendering:

- the maximum starting current per phase;
- the maximum running current per phase;
- the estimated annual energy consumption in kW/hrs.

Low power consumption is a factor in the selection of equipment.

CR.11 **Electrical safety rating**: At the time of tendering, confirm the national or international electrical safety standards to which each incorporated electrical and electronic component is manufactured and installed.

CR.12 **Panel insulation**: The thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m^2K or better. Foam insulation must be CFC-free.

Guidance note: *There may be a case for increasing the thickness to 125 mm (U = 0.2) or 150 mm (U = 0.17) in very hot climates.*

CR.13 **Panel construction**: Panels must be of hot-dip galvanized steel sheet, fully insulated and without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed so as to minimize cold-bridging. Gaskets must be resistant to damage from oil, fats, water and detergents. Floor panels must have a hard- wearing non-slip finish. Wall and roof panels must have a white plastic coating.

CR.14 **Door construction**: Doors must be insulated to the same standard as in clause CR.12. Doors must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of door must be at least 600 mm for rooms of up to 10 cubic metres and at least 800 mm for larger rooms. Provide an internal clear plastic strip curtain.

Option: Provide a door frame heating element.

Guidance note: *A door frame heating element is recommended in humid climates.*

CR.15 **Shelving**: Provide wall-mounted or free-standing stove-enamelled steel, galvanized steel, stainless steel or aluminium slatted adjustable shelving units to carry vaccine in packages. Slatted shelves are preferred. Shelves must be not less than 450 mm deep and not more than 600 mm deep at approximately 450 mm vertical centres. The lowest shelf must be mounted 200 mm above the floor.

CR.16 **Refrigeration units**: Provide twin-packaged refrigeration units with single-phase or three-phase compressors, sized to give 100% stand-by capacity under worst-case conditions. There must be a timer-operated electric or hot-gas defrosting system and a condensate drip tray and drain connection. Provide an automatic duty-sharing circuit with seven-day changeover and manual override to be used in the event of mechanical failure. Provide protection against high or low voltage and against cycle fluctuations. There must be an automatic cut-out when conditions are outside the cold room manufacturer's defined safe limits and an automatic cut-in within 6 minutes of the restoration of safe conditions.

Units must be wall-mounted with the condenser unit discharging inside the building that houses the cold room.

Or

Option 1: The evaporator units must be wall-mounted with a weatherproof condenser unit mounted externally.

Or

Option 2: The units must be ceiling-mounted with a condenser unit discharging inside the building that houses the cold room.

Or

Option 3: The evaporator units must be ceiling-mounted with a weatherproof condenser unit mounted externally.

Guidance note: *Strike out options that do not apply.*

Some vaccines are damaged by exposure to a temperature of -0.5°C. Size the evaporator units so that the plume of discharged air at a temperature below 0°C is clear of shelving units. If necessary, provide a removable mesh cage around the evaporator so as to maintain a safe storage zone.

Option: Provide a low-temperature protection system to prevent the temperature of the cold room dropping below +2°C under worst-case winter conditions.

Guidance note: *Strike out this option only if there is NO risk of the ambient temperature outside the cold room falling below the + 2°C internal minimum specified in CR.4 for periods of more than a few hours. For example, even a hot zone location COULD require low-temperature protection during the winter months.*

CR.17 **Refrigerant**: CFC-free to comply with the requirements of the Montreal Protocol. Flammable refrigerants are not acceptable. The casing of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10 mm high. The casing of each refrigeration unit must be permanently marked with the WHO/EPI CFC-free symbol, as shown in Annex 1. The symbol must be not less than 100 mm in diameter.

CR.18 **Lighting**: Provide an internal ceiling-mounted tungsten-filament light fitting with an external switch and pilot light. The external light and light switch must be fixed to the wall of the cold room enclosure near the entrance door. **Note**: Fluorescent lighting damages certain vaccines and must not be used.

CR.19 **Alarm system**: Provide a mains-operated audible alarm with battery backup and automatic recharge, which is triggered in the event of mains failure or when cold room temperatures are outside the set limits.

Option: Alarm sounder repeater located in.....

Guidance note: *The alarm sounder must be located where it can be heard. This may not be in the building where the cold room is housed.*

CR.20 **Temperature recording**: Provide PC-based temperature- and event-logging equipment, including temperature sensor(s), a door-open sensor and program diskettes. Provide a dial thermometer or digital thermometer mounted on the wall of the cold room in an accessible position. Temperature loggers and thermometers must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Or

Option 1: Provide a digital electronic recorder with continuous digital temperature read-out mounted on the wall of the cold room in an accessible position. The recorder must have a memory of at least 7 days, temperature sensor(s), a door-open sensor and a printing device allowing a hard copy of the temperature records to be retained. The device must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Or

Option 2: Provide a 7-day wall-mounted pen recording thermometer with a temperature sensor and a door-open sensor. The device must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Guidance note: *PC-based system is now considered essential for national stores and is preferred for all cold rooms. However, a digital recorder with a print-out facility or a pen recorder may be acceptable for small subnational stores. If no suitable PC is available to run the temperature-logging software, ensure that one is obtained as part of the installation contract. Door-open sensors are desirable but not essential.*

CR.21 **Voltage stabilizer**: Provide protection against high or low voltage and against cycle fluctuations. The cold room manufacturer must offer a voltage stabilizer appropriate to the electricity supply conditions where the store is to be constructed.

Guidance note: *Strike out this clause only if the power supply is sufficiently reliable. If the supply is not reliable, provide tenderers with the information listed in Annex 2, clause 15.*

CR.22 **Consumables**: Provide consumables sufficient for two years of normal operation at the specified location(s).

CR.23 **Spare parts**: Provide spare parts sufficient for two years of normal operation at the specified location(s).

Guidance note: *Spare parts may not be necessary if there is a service contract with a local agent. Consider purchasing spare refrigeration unit(s) so as to ensure the maintenance of the integrity of the system in the event of a unit failure. Try to standardize room sizes so that the spares inventory has universal application. Refer to CR.27.*

CR.24 **Instructions**: For each cold room provide a user's manual, a workshop manual and an installation guide in the ..... language.

Guidance note: *Specify the international language most used in the country.*

CR.25 **Installation and commissioning**: Installation and commissioning must be carried out by the manufacturer, the supplier or the supplier's appointed agent. Details of the commissioning tests must be recorded and a copy of the test report must be handed over with the instruction manuals.

Guidance note: *The following protocol is an indication of the tests that may be carried out:*

- Cool-down time: The refrigeration unit is started when the room is empty and when the temperature is the same inside and outside the room. During the test the cold room door must be kept closed. The time needed for the internal temperature to drop below +8°C is recorded. The test period is at least 48 hours.
- Running test: The number of hours for which the compressor runs is recorded with the door closed and the room empty. The internal and external temperatures, the evaporator and condenser temperatures, and the pressures of the system are monitored. The maximum temperature difference in the cold room is measured and the location of any warm or cold spots is recorded.
- Temperature rise test: The electricity supply to the room is cut off and the period required for the internal temperature to rise by 5°C from the normal operating temperature is measured.
- Control and monitoring equipment tests: The operation of automatic duty-sharing, temperature control, temperature-monitoring and alarm equipment is tested. If computerized temperature-monitoring is used the software is loaded, configured and tested.
- Stand-by generator operation test: The power output of the stand-by generator is checked, together with the operation of the automatic mains failure control system. The generator is run continuously for 48 hours.

CR.26 **Training**: Provide an operator's training course lasting not less than four hours and covering all aspects of safe operation and routine non-specialist maintenance of the cold room.

Option: Provide a course to train qualified refrigeration technicians in the maintenance and repair of the installed equipment.

Guidance note: *Strike out the option if not required. See guidance note to CR.27.*

CR.27 ***Option***: **Maintenance**: Provide proposals for a routine and emergency maintenance service for an assured period of not less than five years after commissioning. The emergency service must guarantee the following:

- If one refrigeration unit fails the defective unit or component must be repaired or replaced within seven days after the failure is reported.
- If both refrigeration units fail, at least one must be repaired or replaced within 24 hours after the failure is reported. The second unit must be repaired or replaced within seven more days.
- Ancillary components such as alarms and thermometers must be replaced within seven days after reported failure.

Guidance note: *Managers of immunization services MUST ensure that the best available maintenance arrangements are in place for the cold room. Either local refrigeration technicians should be trained as indicated in clause CR.26 or the cold room installer should be contracted to provide a maintenance service similar to that described in clause CR.27. In some countries it is not possible to achieve the response times given in CR.27. In such cases the clause should be modified in consultation with the installer.*

5. Freezer rooms operating at -15°C to -25°C

FR.1 **Type of equipment**: Freezer room(s) for storing bulk vaccine.

Location of installation: As in clause FR.6 and in accordance with the further details referred to in clause FR.7.

Delivery terms: <*Term*> (Incoterms 2000) <*destination or port of entry*>.

Guidance note: *Specify the required Incoterms and point of delivery.*

FR.2 **Quality control standards**: Component manufacture and all installation and commissioning processes must be in accordance with ISO 9001.

Guidance note: *The current version is ISO 9001:2000, but certification to ISO 9001:1994 should be acceptable.*

FR.3 **Details to be submitted with tender**: Submit the following supporting information with the tendering documents (ignore any clauses that have been deleted):

Technical details:

- Plans, elevations and sections at 1:50 scale showing each freezer room, including its equipment and the shelving layout proposed.
- Method statement describing proposed shipment and assembly procedures (FR.27).
- Programme for manufacture, delivery and erection.
- Details of any building work to be carried out by the purchaser, including any requirements for permanent ventilation, heating or cooling in the space(s) housing the freezer room(s).
- Evidence of ISO 9001 certification (FR.2).
- Full technical details of all incorporated components and equipment, including panel construction, shelving, refrigeration units and refrigerant, alarm system (including dB rating of sounder), temperature recorder, and proposed consumables and spare parts.
- Details of the voltage stabilizer, if required (FR.23).
- Evaporator area.
- Details of the oil separator (if condenser located outside).
- Power consumption data (FR.10).
- Electrical safety certifications for all components (FR.11).
- Details of the proposed training programme(s) (CR.26).

- Details of the proposed spare parts and consumables inventory (FR.24 and FR.25).
- Details of the proposed training programme(s) (FR.28).
- Details of the proposed maintenance service and of the local maintenance agent, together with specific proposals for routine and emergency maintenance and details of the proposed spares inventory (FR.29).
- Anticipated empty weight of the complete installation in kilograms.

Tender details:

- Specify delivery time.
- Specify warranty terms
- Specify shipping details, including packed weight and volume.
- Price for supplying the specified components to the site(s), including payment terms and currency.
- Price for installing and commissioning the components, including payment terms and currency.
- Price for supplying the spare parts, including payment terms and currency.
- Price for training users, including payment terms and currency.
- Price for training repair technician(s), including payment terms and currency.
- Estimated annual cost of consumables.
- Cost of five-year maintenance agreement, including payment terms and currency.

FR.4 **Temperature control**: Freezer room temperature must remain between -25°C and -15°C when measured in any part of the room, under any loading condition between empty and full, and over the full ambient temperature range specified in FR.5

FR.5 **Climatic conditions**: The temperature control set out in FR.3 must be achieved under the following climatic conditions:

Hot zone: maximum continuous ambient summer temperature +43°C and minimum continuous ambient winter temperature 0°C.

Or

Temperate zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature 0°C.

Or

Cold zone: maximum continuous ambient summer temperature +32°C and minimum continuous ambient winter temperature -5°C.

Guidance note: *Select one climate regime only and strike out the descriptions that do not apply. Alternatively, specify the actual temperature regime derived from national climate data.*

FR.6 **Capacity and location**: The freezer room(s) and shelving layout(s) must be sized to accommodate the volume(s) of vaccine set out in the table below. Cross-refer to clause FR.17.

Unit ref.	Location	Maximum stored volume (litres)

Guidance note: *Calculate and insert the required net storage volume for each freezer room. Make sure you know the type of packaging in which the vaccine is to be stored, e.g. intermediate packaging or insulated shipping containers. Choosing the latter will greatly increase the required size of the freezer room. Include the volume of any other items that are to be stored in the freezer room. Make a generous allowance for future needs, e.g. new vaccines in smaller presentations, integrated services.*

FR.7 **Location details**: Install freezer room(s) in the locations(s) indicated on the worksheet(s) and drawing(s) attached to this specification. Details of the location(s) are shown on the drawing(s).

Guidance note: *For each location, complete the worksheet at the end of this document and provide a dimensioned drawing.*

FR.8 **Control by thermostat**: Freezer room temperature must be controlled by a thermostat within the tolerances specified in clause FR.4. The thermostat must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

FR.9 **Holdover time**: In the event of power failure the freezer room temperature must remain below 10°C for a minimum period of 8 hours at the specified maximum ambient operating temperature.

FR.10 **Power consumption**: Confirm the following for each freezer room at the time of tendering:

- the maximum starting current per phase;
- the maximum running current per phase;
- the estimated annual energy consumption in kW/hrs.

Low power consumption is a factor in the selection of equipment.

FR.11 **Electrical safety rating**: At the time of tendering, confirm the national or international electrical safety standards to which each incorporated electrical and electronic component is manufactured and installed. Provide written evidence of compliance.

FR.12 **Panel insulation**: The thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m^2K or better. Foam insulation must be CFC-free.

FR.13 **Panel construction**: Panels must be made from hot-dip galvanized steel sheet, fully insulated, without internal structural members or stiffeners between the skins. Tongued and grooved joints between panels must be designed to minimize cold-bridging. Gaskets must be resistant to damage from oil, fats, water and detergents. Floor panels must have a hard-wearing non-slip finish. Wall and roof panels must have a white plastic coating.

FR.14 **Pressure relief valve**: Provide a pressure relief valve in the roof.

FR.15 **Door construction**: Doors must be insulated to same standard as in clause FR.12. They must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of the door must be at least 600 mm for rooms of up to 10 cubic metres and at least 800 mm for larger rooms. Provide an internal clear plastic strip curtain. Provide a door frame heating element.

Guidance note: *A door frame heating element is essential for freezer rooms.*

FR.16 **Heater mat**: Provide an electric resistance heater mat below the floor of the freezer room with thermostatic control.

Guidance note: *Under certain circumstances, a freezer room can freeze the soil under the room floor. Freezing causes the ground to expand and this can crack a concrete floor slab. Laying an electric heater mat under the freezer room floor panels eliminates this risk.*

A heater mat is also necessary if a freezer room is located on an upper floor, in order to prevent excessive cooling of the structural floor slab and consequent damage from moisture condensation on the ceiling below.

Whether a heater mat is required ultimately depends on the location of the store, the climatic regime and the size of the freezer room: seek the manufacturer's advice.

FR.17 **Shelving**: Provide wall-mounted or free-standing stove-enamelled steel, galvanized steel, stainless steel or aluminium slatted adjustable shelving units to carry vaccine in packages. Slatted shelves are preferred. Shelves must be not less than 450 mm and not more than 600 mm deep at approximately 450 mm vertical centres. The lowest shelf must be mounted 200 mm above the floor.

FR.18 **Refrigeration units**: Provide twin-packaged refrigeration units with single-phase or three-phase compressors sized to give 100% stand-by capacity under worst-case conditions. There must be a timer-operated electric or hot gas defrosting system and an electrically heated condensate drip tray and drain connection. Provide an automatic duty-sharing circuit with seven-day changeover and a manual override to be used in the event of mechanical failure. Position the evaporator units so that the plume of discharged air cannot be blocked by stored vaccine. Provide protection against high or low voltage and against cycle fluctuations. There must be an automatic cut-out when conditions are outside the freezer room manufacturer's defined safe limits, and an automatic cut-in within six minutes of the restoration of safe conditions.

Units must be wall-mounted with the condenser unit discharging inside the building that houses the freezer room.

Or

Option 1: The evaporator units must be wall-mounted with a weatherproof condenser unit mounted externally.

Or

Option 2: The units must be ceiling-mounted with the condenser unit discharging inside the building that houses the freezer room.

Or

Option 3: The evaporator units must be ceiling-mounted with a weatherproof condenser unit mounted externally.

Guidance note: *Strike out options that do not apply.*

FR.19 **Refrigerant**: CFC-free, complying with the requirements of the Montreal Protocol. Flammable refrigerants are not acceptable. The casing of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10 mm high. The casing of each refrigeration unit must be permanently marked with the WHO/EPI CFC-free symbol (see Annex 1). The symbol must be not less than 100 mm in diameter.

FR.20 **Lighting**: Provide an internal ceiling-mounted tungsten filament light fitting with an external switch and a pilot light. An external light and light switch must be fixed to the wall of the freezer room enclosure, near the entrance door. **Note**: Fluorescent lighting damages certain vaccines and must not be used.

FR.21 **Alarm system**: Provide a mains-operated audible alarm with battery backup and automatic recharge, which is triggered in the event of mains failure or when freezer room temperatures are outside the set limits.

Option: Alarm sounder repeater located in .....

Guidance note: *The alarm sounder must be located where it can be heard. This may not be in the building where the freezer room is housed.*

FR.22 **Temperature recording**: Provide PC-based temperature- and event-logging equipment, including temperature sensor(s), a door-open sensor and program diskettes. Provide a dial thermometer or digital thermometer mounted on the wall of the freezer room in an accessible position. Temperature loggers and thermometers must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Or

Option 1: Provide a digital electronic recorder with continuous digital temperature read-out mounted on the wall of the freezer room in an accessible position. The recorder must have a memory of at least 7 days, temperature sensor(s), a door-open sensor and a printing device so that a hard copy of temperature records can be retained. The device must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Or

Option 2: Provide a 7-day wall-mounted pen recording thermometer with a temperature sensor and a door-open sensor. The device must be calibrated to ITS-90 and accurate to ± 0.5°C or better.

Guidance note: *A PC-based system is now considered essential for national stores and is preferred in all cold rooms. However, a digital recorder with a print-out facility or a pen recorder may be acceptable for small subnational stores. If no suitable PC is available to run the temperature-logging software, ensure that one is obtained as part of the installation contract. Door-open sensors are desirable but not essential.*

FR.23 **Voltage stabilizer**: Provide protection against high or low voltage and against cycle fluctuations. The cold room manufacturer must offer a voltage stabilizer appropriate to the electricity supply conditions where the store is to be constructed.

Guidance note: *Strike out this clause only if the power supply is sufficiently reliable. If the supply is not reliable, provide tenderers with the information listed in Annex 2, clause 15.*

FR.24 **Consumables**: Provide consumables sufficient for two years of normal operation at the specified location(s).

FR.25 **Spare parts**: Provide spare parts sufficient for two years of normal operation at the specified location(s).

Guidance note: *Spare parts may not be necessary if a service contract is taken out with a local agent. Consider purchasing spare refrigeration unit(s) so as to ensure the maintenance of the integrity of the system in the event of a unit failure. Try to standardize room sizes so that the spares inventory has universal application. Refer to FR.29.*

FR.26 **Instructions**: For each freezer room provide a user's manual, a workshop manual and an installation guide in the ..... language.

Guidance note: *Specify the international language most used in the country.*

FR.27 **Installation and commissioning**: Installation and commissioning must be carried out by the manufacturer, the supplier or the supplier's appointed agent. Details of the commissioning tests must be recorded and a copy of the test report must be handed over with the instruction manuals.

Guidance note: *The following protocol is an indication of the tests that may be carried out:*

- Cool-down time: The refrigeration unit is started when the room is empty and when the temperature is the same inside and outside the room. During the test the freezer room door must be kept closed. The time needed for the internal temperature to drop below -15°C is recorded. The test period is at least 48 hours.
- Running test: The number of hours the compressor runs should be recorded with the door closed and the room empty. The internal and external temperatures, the evaporator and condenser temperatures and the pressures of the system are monitored. The maximum temperature difference in the freezer room is measured and the locations of any warm or cold spots are recorded.
- Temperature rise test: The electricity supply to the room is cut off and the period for the internal temperature to rise from the normal operating temperature by 5°C is measured.
- Control and monitoring equipment tests: The operation of automatic duty-sharing, temperature control and temperature monitoring and alarm equipment is tested. If computerized temperature monitoring is used, the software is loaded, configured and tested.
- Stand-by generator operation test: The power output of the stand-by generator is checked, together with the operation of the automatic mains failure control system. The generator is run continuously for 48 hours.

FR.28 **Training**: Provide an operator's training course that lasts at least four hours, covering all aspects of safe operation and routine non-specialist maintenance of the freezer room.

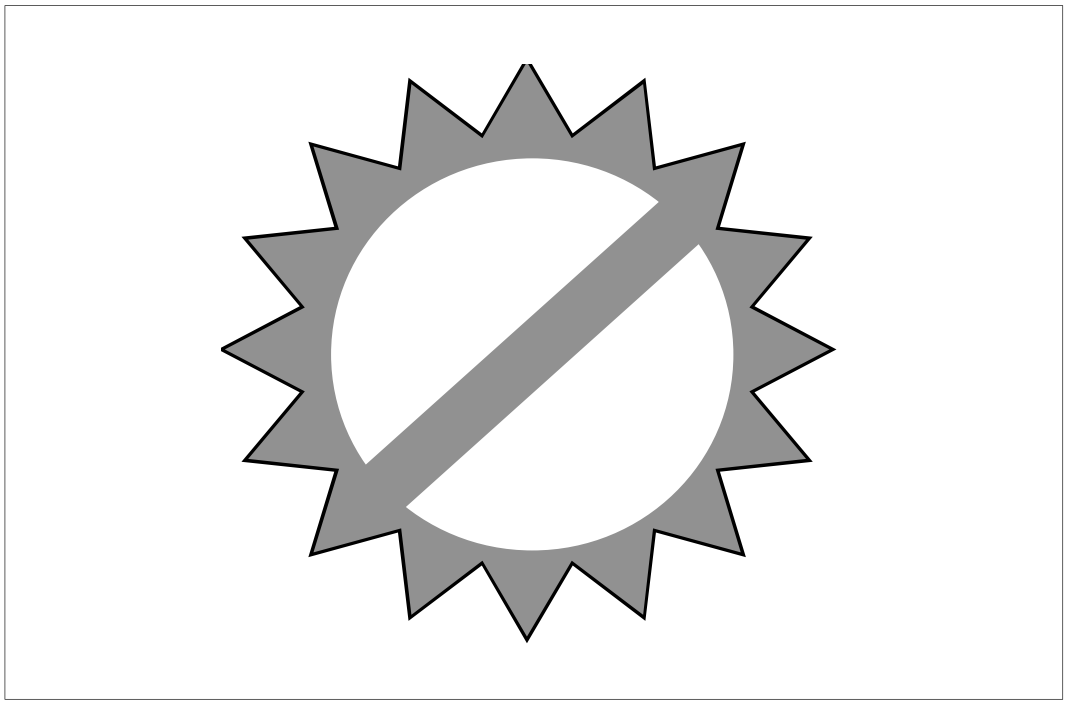
Option: Provide a course for qualified refrigeration technicians in the maintenance and repair of the installed equipment.

FR.29 ***Option***: **Maintenance**: Provide proposals for a routine and emergency maintenance service for an assured period of not less than five years after commissioning. The emergency service must guarantee the following:

- If one refrigeration unit fails the defective unit or component must be repaired or replaced within seven days after the failure is reported.
- If both refrigeration units fail, at least one must be repaired or replaced within 24 hours after the failure is reported. The second unit must be repaired or replaced within seven more days.
- Ancillary components such as alarms and thermometers must be replaced within seven days after reported failure.

Guidance note: *Managers of immunization services MUST ensure that the best available maintenance arrangements are in place for the freezer room. Either local refrigeration technicians should be trained as indicated in clause FR.28 or the freezer room installer should be contracted to provide a maintenance service similar to that described in clause FR.29. In some countries it is not possible to achieve the response times given in FR.29. In such cases the clause should be modified in consultation with the installer.*

Annex 1:
CFC-free symbol



Annex 2:

Location details for cold room or freezer room

Note: Complete one worksheet for each cold room or freezer room location

Unit reference:		
1 **Location of cold room** (*Describe location, e.g. "in medical store attached to central hospital".*)	.....	
	.....	
	.....	
	.....	
	.....	
	Insert tick or number where appropriate:	
2 **Number of storeys in building**	(including basement[s])	.....
3 **Location of space**	Basement	.....
(*Note: cold rooms are heavy. Floor loading should be checked by a structural engineer.)*	Ground floor (lowest floor in building)	.....
	Ground floor above a basement or crawl space	.....
	Upper floor	.....
4 **Floor structure**	Solid concrete laid directly on the ground	.....
(*Note: floors must be damp-proof and strong enough to support weight of cold room.*)	Raised concrete floor spanning between supports	.....
	Timber joists/beams spanning between supports	.....
	Other (describe)	.....
	.....	

5	**Floor finish**	Cement/concrete	.....
	(*Note: a level dust-free washable surface in good condition is required.*)	Timber boards	.....
		Ceramic or terrazzo tiles	.....
		Plastic tiles	.....
		Other (describe)	.....
		.....	
6	**External wall construction**	Masonry (brick, block or stone)	.....
		Steel frame with cladding	.....
		Timber frame with cladding	.....
		Other (describe)	.....
		.....	
7	**External wall insulation**	None	.....
		Fibreglass or mineral fibre	.....
		Plastic foam	.....
		Other (describe)	.....
		.....	
8	**External wall insulation thickness**	Approximate thickness (mm)	.....
9	**Internal finish to walls**	Exposed masonry	.....
	(*Note: a dust-free non-combustible surface is required.*)	Plaster or render	.....
		Plasterboard/drywall	.....
		Timber boarding	.....
		Other (describe)	.....
		.....	

10 **Roof construction**	Concrete	.....
(*Note: a sound roof free of leaks is required.*)	Timber- or steel-framed pitched roof	.....
	Timber- or steel-framed flat roof	.....
	Other (describe)	.....
	.....	
11 **Ceiling finish**	None (room open to roof space)	.....
(*Note: a dust-free non-combustible surface is required.*)	Concrete	.....
	Fibreboard lining	.....
	Plasterboard/drywall lining	.....
	Other (describe)	.....
	.....	
12 **Roof insulation**	None	.....
	Fibreglass or mineral fibre	.....
	Plastic foam	.....
	Other (describe)	.....
	.....	
13 **Roof insulation thickness**	Approximate thickness (mm)	.....
14 **Heating/air-conditioning**	Permanent heating system installed	.....
	Mechanical air extraction system installed	.....
	Air-conditioning system installed	.....
15 **Electricity supply**	volts	.....
(*Note: consult the electricity supply company and/or ask an electrical engineer to check the supply.*)	amps	.....
	cycles (Hz)	.....
	Is three-phase supply possible? Yes/no	.....
	Voltage range: ..... to V	
	Cycle range: ..... to ..... Hz	

16 **Expected hours of supply**		24 hours per day	.....
(*See clauses CR.9 and FR.9. Increase holdover time for supply of less than 16 hrs.)*		18-24 hours per day	.....
		12-18 hours per day	.....
		8-12 hrs per day	.....
17 **Unexpected loss of supply**		Once or more a month	.....
(*Failure frequency during expected supply hrs.*)		Once or more a week	.....
		Once or more a day	.....
18 **Stand-by generator installed**		No	.....
(*Note: to calculate "adjusted kVA", reduce the rated kVA by 1% for each 100 m the site is above sea level and by 1% for each 5.5°C that the maximum ambient temperature is above 20°C. Thus for a site at 500 m altitude and 32°C, de-rate kVA by –5% (for altitude) and by -2% (for temperature), i.e. by -7%*).		Yes (give details below)	.....
		• Manufacturer and model:	
		.....	
		.....	
		• Petrol	.....
		• Diesel	.....
		• Rated output kVA	.....
		• Adjusted for altitude and temperature kVA	.....
		• Hand start	.....
		• Automatic start on mains failure	.....

Sketch plan of site

Draw a sketch plan of each cold room site giving room dimensions, positions and sizes of doorways, positions and sizes of windows, height of room at lowest point, position of fixed equipment (radiators, air-conditioners, etc.). Provide supporting photographs if possible.

The Department of Vaccines and Biologicals was established by the World Health Organization in 1998 to operate within the Cluster of Health Technologies and Pharmaceuticals. The Department's major goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases.

Five groups implement its strategy, which starts with the establishment and maintenance of norms and standards, focusing on major vaccine and technology issues, and ends with implementation and guidance for immunization services. The work of the groups is outlined below.

The *Quality Assurance and Safety of Biologicals team* team ensures the quality and safety of vaccines and other biological medicines through the development and establishment of global norms and standards.

The *Initiative for Vaccine Research* and its three teams involved in viral, bacterial and parasitic diseases coordinate and facilitate research and development of new vaccines and immunization-related technologies.

The *Vaccine Assessment and Monitoring team* assesses strategies and activities for reducing morbidity and mortality caused by vaccine-preventable diseases.

The *Access to Technologies team* endeavours to reduce financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies.

The *Expanded Programme on Immunization* develops policies and strategies for maximizing the use of vaccines of public health importance and their delivery. It supports the WHO regions and countries in acquiring the skills, competence and infrastructure needed for implementing these policies and strategies and for achieving disease control and/or elimination and eradication objectives.

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