WHO/PQS/E003/FZ03.2
Original:

Distribution: General

PQS Performance Specification
English

TITLE: Water-pack freezer: Solar direct drive without battery storage

Specification reference:	E003/FZ03.2
Product verification protocol:	E003/FZ03-VP.2
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Contents

1. Scope

This specification defines the requirements for water-pack freezer appliances powered by a solar electric system with no battery. These appliances are not suitable for storing vaccine. Prequalification testing will establish a minimum solar radiation reference period below which the product should not be used. Testing will also establish the maximum autonomy that the product can achieve. Three temperature zone designations are described: moderate zone, temperate zone and hot zone. All appliances must fully meet the stated performance requirements for hot zone (+43°C) test temperatures.

PQS specification **E003/PV01** specifies a compatible **Type 2** solar power system to directly power the appliance.

Appliance design must account for performance degradation over the 10-year target life of the appliance in order to sustain acceptable water-pack freezing temperatures and other appliance features (if included).

The build quality of the appliance and all ancillary components must be consistent with the conditions under which these appliances are used, including, but not limited to, the following:

- Transport by air, sea and over rough, dusty road surfaces,
- High temperatures in transport, storage and operation,
- Low temperatures in transport, storage and operation,
- High humidity in transport, storage and operation,
- Operating locations with high wind and high density of dust particles,
- Operating locations near corrosive marine environments,
- Users with inconsistent training, and/or
- Users with no specific maintenance tools.

2. Normative references

(use most recent version of each reference)

EMAS: European Union Eco-Management and Audit Scheme.
EN ISO 6270-1 / ASTM D2247 / EN 13523-26: Determination of resistance to humidity – Part 1: Continuous condensation.
EN ISO 6270-2 / EN 13523-25: Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres.
GHS Rev 5. United Nations: Globally Harmonized System of Classification and Labelling of Chemicals.
IEC 60335-1: Amendment 1: Household and similar electrical appliances - Safety - Part 1: General requirements.
IEC 60335-2-24: 2007: Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers.
IEC 60364-1: 2005: Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions.
IEC 61000-6-1 edition 2.0: 2005: Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments.
IEC 61000-6-3 edition 2.1: 2011: Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.
IEC 62552: 2007: Household refrigerating appliances – Characteristics and test methods.
ISO 2409: 2013: Paints and varnishes – cross cut test (external cabinet).
ISO 6272 / EN 13523-5: Impact resistance - external cabinet.
ISO 9001: Quality Management Systems – Requirements.
ISO 14001: 2004: Environmental management systems - Requirements with guidance for use.
ISO 20282-1: 2006: Ease of operation of everyday products - Part 1: Context of use and user characteristics.
ISO/IEC 17025: 2005: General requirements for the competence of testing and calibration laboratories.
WHO/PQS/E005/IP01: Water-packs for use as ice-packs, cool-packs and warm-packs.
WHO/PQS/E006/TH02: Fixed gas or vapour pressure dial thermometer.

WHO/PQS/E006/TH06: Integrated electronic maximum-minimum thermometer, with factory programmed alarms, for vaccine refrigerators and freezers.
WHO/PQS/E003/FZ03 VP.1: Independent type testing protocol: Water-pack freezer: Solar direct drive without battery storage.
WHO/PQS/E003/PV01: Performance specification: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E003/PV01-VP1.2: Type-examination protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E003/PV01-VP2.2: Quality assurance protocol: Solar power system for compression-cycle vaccine refrigerator or combined refrigerator and water-pack freezer.
WHO/PQS/E005/IP01: Water-packs for use as ice-packs, cool-packs and warm-packs.

3. Terms and definitions

Autonomy (freezer): Time in hours that a solar direct drive water-pack freezer can maintain the minimum required capacity of fully frozen water-packs under low solar radiation conditions (e.g. rain). Autonomy is measured as described in **E003/RF05.4-VP.4.**
Gross volume: The measured volume of the air space inside the internal compartment with the door or lid shut. For combined appliances, the gross freezer volume and the gross refrigerator volume are reported separately.
Hot zone: Hot zone appliances must operate at a steady +43°C ambient temperature and over a+43°C/+25°C day/night cycling temperature range.
In writing: means communication by letter, fax or email.
Installation: The freezer specified in this document, connected to a solar power system complying with specification **E003/PV01**.
Legal manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of an appliance or device before it is placed on the market under the person's own name, regardless of whether these operations are carried out by that person or on their behalf by a third party.
Moderate zone: Moderate zone appliances must operate at a steady +27°C ambient temperature and over a+27°C/+10°C day/night cycling temperature range.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Reseller: A commercial entity, licensed to act on behalf of a legal manufacturer, and which carries appliance liability and warranty responsibilities no less onerous than those carried by the legal manufacturer.
Solar radiation reference period: The minimum average daily solar radiation on the plane of the solar array that is required to properly power the solar water-pack freezer, expressed in kWh/m²/day.
Temperate zone: Temperate zone appliances must operate at a steady +32°C ambient temperature and over a+32°C/+15°C day/night cycling temperature range.
Water-pack: A flat, leak proof, plastic container, filled with tap water, complying generally with specification **PQS/E005/IP01**.

Water-pack freezing capacity: The daily maximum weight and number of water-packs which can be fully frozen, in one batch, during a 24-hour freezing cycle.
Water-pack storage capacity: The maximum number of fully frozen water-packs that can remain fully frozen at the end of water-pack storage compartment testing over a multi-day period.

4. Requirements

4.1 General

Solar powered water-pack freezers are used primarily in areas without any electricity or where there is less than eight hours of reliable electricity over a typical day. Reliability, durability and effective maintenance is essential for a successful installation. The associated power system must be designed to match both the freezer power consumption and local climate conditions (i.e. ambient temperatures and solar radiation resource). All appliances must fully meet the stated performance requirements with a minimum solar radiation reference period of 3.5 kWh/m²/day and hot zone (+43°C) test temperatures. In addition, manufacturers may offer appliances suitable for hot zone and a lower temperature zone and/or lower solar radiation reference period.

4.2 Performance

4.2.1 Operating temperature range

The operating temperature range is indicated on the temperature zone symbol attached to the appliance (see Annex 1). All appliances must be suitable for hot zone (+43°C). Solar Direct Drive (SDD) water-pack freezers are not required to indicate a minimum rated ambient temperature.

4.2.2 Refrigeration

Electrically powered compression-cycle unit or thermoelectric freezers operating with input of direct current (DC) electricity.

4.2.3 Voltage

Solar power system input voltage up to 45 Voc is acceptable.

4.2.4 Water-pack freezing

Minimum 24-hour water-pack freezing capacity is based on gross freezer volume. For gross freezer volume less than 50 litres a minimum of 1.6 kg. For gross freezer volume equal to or greater than 50 litres a minimum of 2.4 kg per each 50 litres of gross storage volume. Some overnight ice loss is acceptable – see Clause 4.2.7.

4.2.5 Water-pack storage compartment capacity

The freezer compartment to hold a minimum of 3.2 kg of water-packs and at least twice the daily water-pack freezing capacity determined by **E003/FZ03 VP.1**. The water-packs must comply with **E005/IP01**. These may be frozen gradually over several days. Some overnight ice loss is acceptable – see Clause 4.2.7.

4.2.6 Vaccine storage warning

These units are not suitable for storing vaccine. All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the words: '*Do not store vaccine in this freezer'* in letters a minimum of 20 mm high in the languages specified in Clause 4.11. The label should be fixed to the lid of chest freezers and near the top of the door on upright freezers.

4.2.7 Temperature control

The compartment must be capable of producing fully frozen water-packs for use by health workers at the beginning of each working day. Under the water-pack freezing tests, the temperature of the water-pack freezing compartment is permitted to exceed 0°C during the 12-hour night phase of the test and the first three hours of the 12-hour solar phase. The net amount of fully frozen water-packs remaining under worst-case overnight test conditions and day/night cycling per **E003/FZ03 VP.2** will be visually estimated and reported. The net amount of fully frozen water-packs remaining under worst-case overnight test conditions will be visually estimated and reported.

4.2.8 Thermostat

A thermostat must be provided that is effective throughout the ambient operating temperature range. It must be designed so that it cannot be adjusted by the user. A means for adjustment by a technician is acceptable provided the device is protected from user interference (e.g. by location within the appliance cabinet). Alternatively, programmable thermostats may be password-protected. Bulb and capillary tube thermostats are not acceptable.

4.2.9 Thermometer

- **Option A:** Externally readable cabinet-mounted gas or vapour pressure dial thermometer.
- **Option B:** Externally readable cabinet-mounted electronic thermometer. Dry cell batteries must not be used.
- **Option C:** Electronic thermometer powered by a photovoltaic cell which forms part of the device. This type draws no power from the appliance in which it is installed.

4.2.10 Indicator light:

A minimum of one green LED indicator light is required to be located on the front or top of the appliance to alert users that the cooling system is actively operating. A constant green LED light is required to indicate that the compressor or cooling system is active and the light is to go off when the compressor or cooling system is off.

Optionally, additional indicator lights may be added to indicate other operating conditions including temperature and faults.

4.2.11 Autonomy

All solar direct drive freezers must prequalify with a minimum autonomy of overnight (0.5 days) at the minimum solar radiation reference period and when tested for the hot zone. Autonomy is determined by testing in accordance with **E003/FZ03-VP.1**.

4.2.12 Power system requirements

PQS specification **E003/PV01** specifies a compatible **Type 2** solar power system to directly power the appliance.

A battery powered/assisted cooling system for freezer operation will not be accepted.

Ancillary power storage systems (e.g. capacitor) may be included provided these have a minimum guaranteed design life of 10 years under the environmental conditions for which the freezer is prequalified.

Solar module voltage up to 45 volts open circuit (Voc at Standard Test Condition of solar radiation 1000 W/m², cell temperature +25°C, air mass 1.5) is acceptable provided all electrically powered system components are integrated in such a way that performance and component life is not reduced by voltage input from the solar array.

4.2.13 Humidity control and defrosting

Legal manufacturers are to propose water-pack placement instructions, racks and/or structure to prevent frozen water-packs from adhering to other water-packs or adhering to freezer walls and/or other surfaces. Defrost drainage must be supplied.

If used, the defrost switch (or switches) must be accessible to the user without tools but must be protected from accidental changes in position.

4.2.14 Lock

The door or lid must be fitted with a lock or a means of locking (e.g. with a padlock). Two keys are to be supplied with every unit.

4.2.15 Corrosion resistance

The legal manufacturer must certify compliance that internal and external cabinet, lid and frame are protected against corrosion as appropriate to **EN ISO 6270-1 / ASTM D2247 / EN 13523-26**, **EN ISO 6270-2 / EN 13523-25**, **ISO 6272 / EN 13523-5** and **ISO 2409: 2013.**

4.2.16 Electrical safety rating

The legal manufacturer must certify compliance with **IEC 60335-1**, **IEC 60335-2-24** and **IEC 60364-1**.

4.2.17 Markings

If used, compressors must be marked with the blue identifying symbol shown in Annex 2. In addition, the cabinet must be permanently marked, near the compressor position, with the chemical name of the refrigerant, or with the refrigerant number, formula or proportion (for blended refrigerants).

Appliances not utilizing compressor-based cooling methods must be marked identifying any refrigerant and/or heat transfer fluids used including, but not limited to, the chemical name, formula or proportion (for blended refrigerants).

All appliances to label hazardous materials and include a Safety Data Sheet. Label and Safety Data Sheet must comply with the Globally Harmonized System for the Classification and Labelling of Chemicals **GHS Rev.5**.

4.2.18 Labelling

All units must carry a factory-fitted non-removable label, designed to last the lifetime of the appliance, carrying the following information: '*Do not store vaccine in this freezer*', water-pack freezing instructions, key maintenance requirements and the appropriate temperature zone symbol as provided in Annex 1.

All key information should be summarized on a single sheet fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the appliance.

The instructions should be fixed to the lid of chest freezers and near the top of the door on upright freezers. Labelling is to be available in the languages as specified in Clause 4.11

The appliance must carry the following additional information fixed to the front of the cabinet: manufacturer and model number (unless already located on the front of the unit), serial number, date of manufacture, PQS identification number, applicable service phone number and website URL.

4.2.19 Electromagnetic compatibility

The legal manufacturer must certify compliance with the requirements of the latest edition of **IEC 61000-6-1** and **IEC 61000-6-3**.

4.3 Environmental requirements

4.3.1 Ambient temperature range during transport and storage

The ambient temperature range during transport and storage is -30°C to +70°C when the appliance is inactivated.

4.3.2 Ambient humidity range during transport, storage and use

The ambient humidity range during transport, storage and use is 5% to 95% RH, non-condensing.

4.4 Physical characteristics

4.4.1 Overall dimensions

To allow for manoeuvring through corners, corridors and doorways, the minimum dimension of the appliance (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension must not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm.

4.4.2 Weight

Mechanical lifting equipment will typically not be available at the installation sites. It is recommended that the freezer and any associated components should be designed for lifting in such a way that no single worker is required to carry more than 25 kg whilst working on their own, or in a group.

4.5 Interface requirements

4.5.1 Electrical components

All electrical components must be compatible with a **Type 2** solar power system as specified in specification **E003/PV01**.

4.5.2 Power switch

Each appliance to provide an on and off power switch that is readily accessible to the user either on the outside of the appliance cabinet or in a wall-mounted switch within one meter of the appliance. Plug and play solar array cable connectors (i.e. locking female and male coupler system) are not acceptable for on and off switching of the solar power system or appliance.

4.6 Human factors

4.6.1 General design

The appliance must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including colour blind users and long-sighted (hyperopia) people without glasses, in accordance with the general principles laid out in **ISO 20282-1: 2006**.

4.6.2 Control panel, indicator light and thermometer

Controls panel, indicator light, thermometer and other visual displays may be positioned on the front of the unit preferably as close to eye level as possible. Alternatively, they may be mounted on top of the unit at a height not exceeding 1.3 metres. If a low-level position is essential, the display should be aligned so that it can easily be read without the user having to squat or kneel down. The on and off switch and/or defrost switch, if present, should be recessed or otherwise protected from accidental change in position so that it is not possible to inadvertently activate it.

4.7 Materials

4.7.1 Refrigerant

Hydrocarbon (HC) refrigerants such as R600a or other gases with global warming potential (GWP) $\leq$ 11 and zero ozone depletion potential (ODP) must be used.

Existing appliances with HCFC refrigerants including R134a will be phased out over a transition period of two years from the issue date of this specification.

The suitability of alternative refrigerant gases will continue to be assessed and preference will be given to appliances that use gases with low global warming potential (GWP).

4.7.2 Thermal insulation foaming agents

Any gas complying with the limitations and deadlines set by the Montreal Protocol on the elimination of ozone-depleting chemicals.

4.7.3 Other restricted materials

The appliance and its constituent components, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 Warranty

The appliance is to be covered by a two-year replacement warranty in the event of any component failure arising from defective design, materials or workmanship. Ancillary power storage (e.g. capacitors) to be covered by a 10-year warranty.

4.9 Servicing provision

The appliance and solar power system is to be designed to achieve a low-maintenance life of not less than 10 years (with the exception of routine defrosting, cleaning and solar array cleaning and shading prevention).

4.9.1 Essential spare parts and user maintenance tools/supplies

Based on product design and requirements the type and quantity of spare parts, basic installation tools/supplies, user and technician maintenance manuals (see Clause 4.11), must be determined and agreed upon in advance of order placement. As a minimum, each appliance to be supplied with 10 spare fuses of all fuse size and type used in the appliance. The spares fuses are to be attached within or on the appliance.

Legal manufacturers are to publish a list of spare parts recommended for purchases of 10 and 50 appliances. The legal manufacturer must ensure supply of spare parts for a minimum of five years from the time of cessation of the last production of equipment. Spare parts are to be provided in kit form for storage in appropriate quantities at National or Sub-national level in the purchasing country, as agreed with the purchasing agency.

4.10 Disposal and recycling

The legal manufacturer must provide information to the buyer on proper disposal, including child-proofing the cabinet, the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For legal manufacturers from the European Union WEEE compliance in accordance with European Union Directive 2002/96/EC is mandatory.

4.11 Instructions

Each freezer to include a separate user manual and technician installation manual in Arabic, English, French, Mandarin Chinese, Russian and Spanish. An English version of all instructions and manuals are required to be supplied at time of laboratory testing. Instructions to include easy to understand visuals whenever possible to avoid reliance on text.

The user manual must include the following information:

- Health and safety guidance;
- Basic operations description; or
- Preventive maintenance tasks (e.g. daily, weekly, and monthly).

The technician installation manual must include the following information:

- Health and safety guidance;

- Detailed operations description;
- Correct handling to avoid appliance damage and for the safety of handling persons;
- Installation procedures;
- Compatible solar power system voltage;
- Technical maintenance tasks (e.g. daily, weekly and monthly);
- Periodic preventive maintenance procedures;
- Corrective maintenance, diagnostic and repair procedures;
- Itemized list of spare parts including part numbers;
- End-of-life resource recovery and recycling procedures; and
- User training guidance.

Printed user operations and routine maintenance instructions specifically directed at the health centre or store staff must be pictorial. All key information should be summarized on a single sheet pictogram fixed onto the appliance cabinet; the sheet should be sufficiently durable to last the life of the appliance.

Installation, repair and servicing instructions must be supplied in printed format, and optionally on DVD and/or on-line to instruct the installation teams in installation standards and practices specific to the appliance and its power system. In addition, supporting video material supplied on DVD and/or on-line can be supplied to assist the instructor when delivering on-site user training.

4.12 Training

If requested, all legal manufacturers are required to have the capability of providing in-person training in the countries where their product is deployed. Training may be delivered by the legal manufacturer, manufacturer's representative or reseller. The legal manufacturer must provide user training guidance to enable installation technicians to present user training. In addition, supporting video material supplied on DVD and/or online can be supplied to assist the instructor when delivering on-site user training.

4.13 Verification

In accordance with PQS Verification Protocol **E003/FZ03-VP.1.**

5. Packaging

Materials used for packaging the finished appliance are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

The packaging is to be a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions and high humidity. The packaging is to be not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of +70°C (tropical conditions).

To avoid destructive unpacking prior to installation, legal manufacturers are encouraged to add a re-sealable observation opening in their packaging to aid inspectors in finding labelling and/or placing additional markings prior to

installation. Instructions on the packaging alerting inspectors to use of the opening and what information will be revealed are also advised.

The general specification of shipping containers will be subject to agreement with the individual procurement agencies.

6. On-site installation

Not required.

7. Product dossier

The legal manufacturer or reseller must provide WHO with a prequalification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the appliance type.
- Brand name of the appliance.
- Full specifications of the appliance being offered, covering all the requirements set out in this document, including details of appliance marking and traceability.
- Full details of the recommended compatible **Type 2** solar power system (see specification **E003/PV01**).
- A comprehensive set of photographs including a three-quarter view of the appliance with the door open. Take additional photographs showing all external surfaces of the unit, the interior layout, the compressor or cooling system and a close-up of the thermometer, indicator light(s), the control(s), control panel and any special features.
- Certified photocopies of all type-approvals obtained for the appliance, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however, preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the appliance specifications.
- Indicative cost of the appliance per unit, per 10 units and per 100 units, EXW (Incoterms 2010) including appliance and solar power system.

8. On-site maintenance

Maintenance will be carried out by the end-user and/or their agents.

9. Change notification

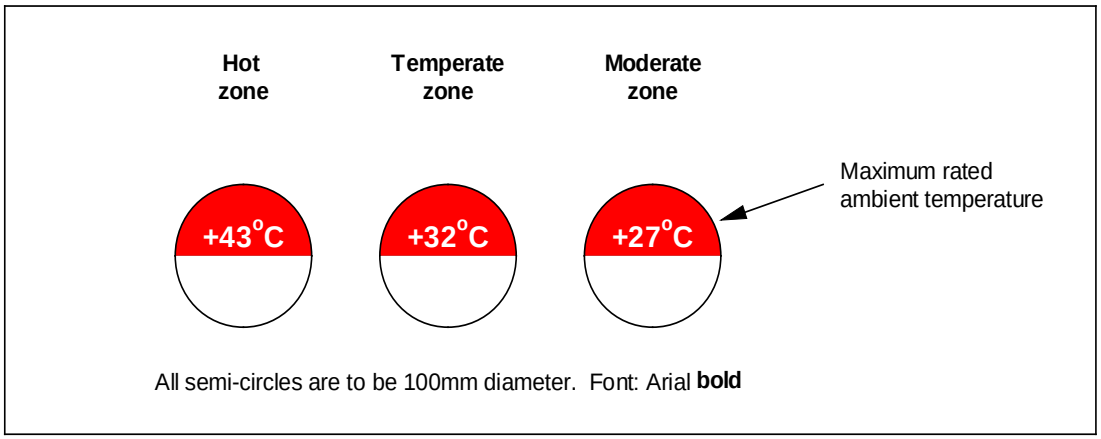
The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the appliance after PQS

prequalification has taken place. Any change that WHO considers would alter the test results obtained against the PQS verification protocol **E003/ FZ03-VP.1** will result in a request for the appliance to be retested.

10. Defect reporting

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related appliance and/or solar power system recalls, defects and other similar events. If requested to do so by WHO/UNICEF, the manufacturer is to submit a report to WHO/UNICEF stating the number of affected systems and the number of component repairs/replacements provided, together with copies of any associated field reports.

Annex 1: Temperature zone symbol for water-pack freezers



Annex 2: Refrigerant symbols

Revision history			
Date	**Change summary**	**Reason for change**	**Approved**
18/01/2018	Normative references (new): WHO/PQS/E006/TH02 WHO/PQS/E006/TH06.	References required per all E003 specifications.	
18/01/2018	Definition changes include: Gross volume, Hot zone, Moderate zone, Temperate zone, Water-pack freezing capacity and Water-pack storage capacity	Minor wording changes to harmonize definitions with the same definitions used throughout the PQS E003 category.	
18/01/2018	4.2.7 Temperature control: clarification	Minor wording changes to harmonize specification with the same specification used with solar direct drive refrigerator/freezers per RF05.4	
18/01/2018	4.10 Disposal and recycling: child proofing instructions now required	Added safety requirement is customary and merited.	
18/01/2018	4.12 Training: video and other forms of training aides suggested, not required.	Minor clarification to improve training.	