



TITLE: Cold rooms and freezer rooms

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1. Scope:

E01/CR-FR01 describes the performance requirements for a generic cold room or freezer room **installation**, with packaged cooling units, suitable for storing vaccine. It also specifies the installation and maintenance services that all manufacturers must offer in order to become pre-qualified. It applies to rooms up to a gross internal cubic capacity of 40m³.

The following documents are associated with this specification.

- **E01/CR-FR01-VP1** is a type-examination protocol which will be used for pre-qualification evaluations.
- **E01/CR-FR01-VP2** is completed by an **employer** or his **QA assessor** and sets out the requirements for a specific installation. The document also specifies the installation, commissioning and handover procedure. The completed protocol should be read in conjunction with **E01/CR-FR01**, to which it refers.

E01/CR-FR01 and a completed **E01/CR-FR01-VP2**, together with an **employer's** other documents, are intended to form the basis for a contractual agreement between the **legal manufacturer** or **reseller** and the **employer** for the supply, installation and commissioning of a specific **system**.

2. Normative references:

- EMAS: *European Union Eco-Management and Audit Scheme*.
- IEC 60335-1: 2006 - *Safety of household and similar electrical appliances, Part 1: General requirements*.
- IEC 60364-1: 2005 - *Low-voltage electrical installations - Part 1: Fundamental principles, assessment of general characteristics, definitions*.
- ISO 9001: 2000: *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*.
- WHO/PQS/E06/TH02.1: *Fixed gas or vapour pressure dial thermometer*.
- WHO/PQS/E06/TR03.1: *Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options*.
- WHO/PQS/E06/TR03-VP2.1: *Programmable electronic temperature and event logger systems with integral alarm and auto-dialer options – Quality Assurance protocol*.
- WHO/PQS/E06/TR04.1: *Wall-mounted pen recording thermometer*.
- WHO/PQS/E06/TR05.1: *User-programmable temperature data loggers*.
- WHO/PQS/E06/CR-FR01-VP1.1: *Cold rooms and freezer rooms – Type-examination protocol*.
- WHO/PQS/E06/CR-FR01-VP2.1: *Cold rooms and freezer rooms – Quality Assurance protocol*.

3. Terms and definitions:

Annual review: The 12-monthly review which all PQS pre-qualified manufacturers are required to pass in order to remain on the register of pre-qualified companies.

Approved Installer: A person or organization approved by the **legal manufacturer** or **Reseller** as a competent installer of the system components, and who has been appointed by the **employer** to carry out the installation of the **system**.

Cold climate freeze prevention: Any mechanism which prevents the temperature inside a cold room from dropping below +2°C, under low ambient temperature conditions, down to the temperature specified by the **employer**, at the time of procurement, subject to a minimum of -10°C.

Employer: The organization that contracts with the **legal manufacturer** or **reseller** to carry out the system installation and commissioning.

Holdover time: The time in hours during which:

- **Cold room:** All points remain between +2°C and +10°C after the power supply has been disconnected when the room is exposed to the maximum ambient temperature for which it is designed. In the case of a cold room with **cold climate freeze prevention**, holdover time is also measured at the minimum ambient temperature specified by the **employer**.
- **Freezer room:** All points remain below -10°C after the power supply has been disconnected when the room is exposed to the maximum ambient temperature for which it is designed.

Hot zone: Hot zone units must operate at a steady +43°C ambient temperature and over a +43°C/+25°C day/night cycling temperature range.

Installation: The complete cold room or freezer room installation specified in this document.

In writing: means communication by letter, fax or email.

Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Maintenance Contractor: A person or organization approved by the **legal manufacturer** or **reseller** as competent to maintain the **installation**.

Moderate zone: Moderate zone units 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.

QA Assessor: the person or organization appointed by the **employer** to assess the suitability of candidate **approved installers**, to evaluate their proposals and to monitor the assembly and commissioning of the installation on site.

QA: Quality Assurance.

Region: A contiguous geographical area within which the **legal manufacturer** or **Reseller** is able to provide the full range of services describe in this specification.

Reseller: A commercial entity, licensed to act on behalf of a **legal manufacturer**, and which carries product liability and warranty responsibilities no less onerous than those carried by the **legal manufacturer**.

Temperate zone: Temperate zone units must operate at a steady +32°C ambient temperature and over a +32°C/+15°C day/night cycling temperature range.

User: The person responsible for the day to day operation and temperature monitoring of the room.

4. Requirements

4.1 General:

4.1.1 *Initial pre-qualification*

A **legal manufacturer** or **reseller** seeking prequalification under the terms of this specification must satisfy WHO that he is able to supply, install and maintain a cold room or freezer room anywhere within the **region** for which pre-qualification is sought. He may provide this service in association with one or more named **approved installers** and one or more named **maintenance contractors** with whom he has a contractual relationship. Manufacturers may offer products suitable for one or more temperature zones.

4.1.2 *Extended region pre-qualification*

A pre-qualified manufacturer who wishes to extend the **region** for which he is already pre-qualified may do so at the time of the **annual review** by providing WHO with supplementary evidence **in writing** that he has a satisfactory contractual relationship with one or more named **approved installers** and one or more named **maintenance contractors** in the new area.

4.2 *Performance:*

4.2.1 *General requirements:*

All component parts and services offered by the [legal manufacturer](#) or [reseller](#) must satisfy the minimum requirements set out in this specification. It must be possible, using these components, to install and to maintain a wide range of different sized [installations](#) with a maximum individual room capacity of 40m³. Rooms larger than this may be required, but are not included in the scope of this specification and will be subject to special arrangement between the manufacturer and the [employer](#).

4.2.2 *Temperature zones:*

Provide [hot zone](#), [temperate zone](#) or [moderate zone](#) equipment as required for a specific installation. Where a cold room is required to have optional 'cold climate freeze prevention' it must maintain the vaccine compartment between +2°C and +8°C at ambient temperatures down to -10°C. In all cases the appropriate temperature zone rating sticker must be attached to the product before handover (see Annex 1).

4.2.3 *Temperature control:*

Room temperature must be controlled by a thermostat within the tolerances specified below. The thermostat must be calibrated to ITS-90 and be accurate to $\pm 0.5^{\circ}\text{C}$ or better.

- **Cold room:** Room temperature must remain between +2°C to +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 of the required temperature zone (see clause 4.2.2). Rooms specified to have [cold climate freeze prevention](#) must maintain the room temperature between +2°C and +8°C at ambient temperatures down to -10°C.
- **Freezer room:** Room temperature must remain between -25°C to -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 of the required temperature zone (see clause 4.2.2).

4.2.4 *Holdover time:*

In the event of a power failure at the maximum operating temperature for the specified temperature zone, all points in the room where vaccine is designed to be stored must remain within the limits stated below for a minimum period of eight hours when the room is empty.

- **Cold room:** Between +2°C and +10°C. In the case of a cold room with cold climate freeze prevention the minimum holdover time must also be achieved at the lowest ambient temperature at which the room is designed to operate.
- **Freezer room:** Below -10°C.

4.2.5 *Electrical safety rating:*

Electrical safety rating: Manufacturer to certify compliance of the supplied electrical and electro-mechanical components with IEC 60335-1. All on-site electrical installation work must comply with IEC 60364-1.

4.2.6 *Voltage, frequency and phasing:*

Depending on the size of the enclosure, the following options are to be offered:

- **Single -phase:** 220-240 volt 50/60 Hz and 100-127 volt 50/60 Hz single-phase.
 - **Three-phase:** 190-240 volt 50/60 Hz and 380-480 volt 50/60 Hz three-phase.
- 4.2.7 *Voltage stabilization and surge protection:*
Unless specifically excluded in a tender invitation, provide equipment to protect against high or low voltage, against cycle fluctuations and against lightning-induced power surges. The equipment must be compatible with the electricity supply installation at the site where the store is to be constructed. See clauses 4.5.1 and 4.5.2.
- 4.2.8 *Panel insulation:*
In **moderate zones** the thermal transmittance (U value) of the roof, wall and floor panels must be 0.25 W/m²K or better. In **temperate zones** the thermal transmittance (U value) of the roof, wall and floor panels must be 0.20 W/m²K or better. In **hot zones** the thermal transmittance (U value) of the roof, wall and floor panels must be 0.17 W/m²K or better. Foam insulation must comply with clause 4.7.2.
- 4.2.9 *Panel construction:*
Panels must be made from zinc coated 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 are to be resistant to damage from oil, fats, water and detergents. Floor panels must to have a hard-wearing non-slip finish. Wall and roof panels must have a white plastics coating.
- 4.2.10 *Shared walls in multi-room installations:*
In multi room installations with shared walls, the construction of the shared wall(s) between adjoining cold rooms and freezer rooms must be designed to ensure that there is no risk that vaccine stored on the cold room side of the wall will be exposed to temperatures below +2°C, or that vaccine stored on the freezer room side of the wall will be exposed to temperatures above -15°C.
- 4.2.11 *Door construction:*
Doors must be constructed and insulated to the same standard as clause 4.2.9. Doors must be lockable with 100% fail-safe provision for opening from inside. The clear opening width of the door must be 600mm minimum for rooms up to 10 cubic metres and at least 800mm minimum for larger rooms. Provide an internal clear plastic strip curtain.
- 4.2.12 *Door frame heating element:*
Provide a door frame heating element for all freezer rooms and for cold rooms in humid climates.
- 4.2.13 *Pressure relief valve (freezer rooms only):*
Provide a pressure relief valve in the roof of all freezer rooms.
- 4.2.14 *Heater mat (freezer rooms only):*
If required, provide an electric resistance heater mat, with thermostatic control, to prevent frost heave (ground floor location) or ceiling condensation (upper floor location) below freezer room floor panels.

4.2.15 *Shelving:*

Wall-mounted or free-standing stove enameled 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 450mm and not more than 600mm deep at approximately 450mm vertical centres. The top face of the lowest shelf must be mounted 200mm above the floor. Each shelf must be rated to support at least 2 kg/cm². The span between supports must be 1.0 metres or less.

4.2.16 *Refrigeration units:*

Packaged refrigeration units with single-phase or three-phase compressors, sized to give 100% stand-by capacity under worst-case conditions. Refrigerants must comply with clause 4.7.1. 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 in 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. Depending upon the internal room layout and the room location, units may be arranged in the following ways:

- **Either:** Units may be wall-mounted with the condenser unit discharging inside the building that houses the cold room.
- **Or:** Evaporator units may be wall-mounted with a weatherproof condenser unit mounted externally (split unit).
- **Or:** Units may be ceiling-mounted with a condenser unit discharging inside the building that houses the cold room.
- **Or:** Evaporator units may be ceiling-mounted with a weatherproof condenser unit mounted externally (split unit).

4.2.17 *Evaporator plume guard (cold rooms only):*

Size and position the evaporator units so that the plume of discharged air at a temperature below +2°C is clear of shelving units. If necessary provide a removable mesh cage or deflector shield around the evaporator so as to maintain the safe storage zone.

4.2.18 *Cold climate freeze prevention (cold rooms only):*

Where [cold climate freeze prevention](#) is specified provide a low-temperature protection system to prevent the temperature of the cold room dropping below +2°C under low ambient temperature conditions, down to the temperature specified by the [employer](#), at the time of procurement, subject to a minimum of -10°C.

4.2.19 *Lighting:*

Provide internal ceiling-mounted tungsten filament lighting 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 to the entrance door. The minimum illumination level on the vertical face of the lowest shelves must be 150 lux.

Note: Fluorescent lighting damages certain vaccines and must not be used.

4.2.20 *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 set limits. The alarm must comply with PQS specification **E06/AL01**, or with **E06/TR03** if a component part of an event logger system. Alarm sounder repeaters are to be located adjacent to the cold room/freezer room and at one remote location.

4.2.21 *Temperature recording:*

As required for the specific installation, provide:

- **Either:** A 7-day wall-mounted pen recording thermometer complying with **PQS E06/TR04** fitted with alarm contacts and door-open sensor and linked to the alarm system specified in clause 4.2.19.
- **Or:** A programmable electronic temperature and event logger system with auto-dialer complying with **PQS E06/TR03** linked to the alarm system specified in clause 4.2.19.

In both cases, provide a backup gas or vapour pressure dial thermometer complying with **PQS E06/TH02**, mounted on the wall of the cold room in an accessible position.

4.2.22 *Consumables:*

Provide consumables sufficient for two years of normal operation at the specified location(s).

4.2.23 *Spare parts:*

Provide spare parts sufficient for five years of normal operation at the specified location(s).

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport and storage:*

-30°C to +55°C when components are in transit.

4.3.2 *Ambient humidity range during transport, storage and use:*

5% to 95% RH.

4.4 *Physical characteristics:*

4.4.1 *Room capacity:*

Individual rooms, not exceeding 40m³ each, and which may form part of a multi-room assembly.

4.4.2 *Overall dimensions:*

Individual components must generally be able to fit through an 800mm wide door opening (with the door leaf removed if necessary).

4.4.3 *Weight:*

Component elements of the room enclosure and component elements of the refrigeration unit(s) must be capable of being safely manhandled into their final positions. Mechanical lifting equipment will typically not be available at the installation sites.

4.5 Interface requirements:

4.5.1 Voltage stabilizer compatibility:

Voltage stabilization and surge protection will generally be required for cold rooms and freezer room installations. All electrical components must be compatible with voltage stabilizers that use servo-mechanical or tap-changing technology. The preferred option is that this equipment should be supplied as part of the cold room/freezer room installation package.

4.5.2 Standby generator:

Cold rooms and freezer rooms are typically connected to a standby generator. This will either be installed already, or it will be supplied by others. The design of each specific [system](#) must be coordinated with the standby generator installer.

4.6 Human factors:

4.6.1 Generally:

The product, its controls and temperature monitoring equipment must be useable by the widest practicable range of active health workers, regardless of age, gender, size or minor disability, including long-sighted people without glasses, in accordance with the general principles laid out in ISO 20282-1: 2006.

4.7 Materials:

4.7.1 Refrigerant:

CFC-free to comply with the requirements of the Montreal [Protocol](#). Flammable refrigerants are not acceptable. The casing and/or the compressor body of each refrigeration unit must carry a permanent label clearly identifying the refrigerant used in letters not less than 10mm high.

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

4.8 Warranty:

[Installations](#) are to be covered by a three year on-site replacement warranty in the event of any component failure arising from defective design, materials or workmanship. All warranty rights are to pass from the [approved installer](#) to the [employer](#) after the [installation](#) has been commissioned and has been formally accepted by the [employer](#). Where the [employer](#) is a UN agency, the warranty rights are to pass to the host government¹.

¹ Some installations will initially be purchased by one of the UN procurement agencies. In this situation, warranty rights must pass to the host government.

- 4.9 Servicing provision:
Installations are to be designed to achieve a service life of not less than 20 years apart from routine cleaning and programmed maintenance.
- 4.10 Disposal and recycling:
The manufacturer is to provide information to the buyer on the hazardous materials contained within the installation and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union **WEEE** compliance in accordance with European Union Directive 2002/96/EC is mandatory.
- 4.11 Instructions:
For each cold room provide a user's manual, a workshop manual and an installation guide in the language most appropriate to the installation site - Arabic, English, French, Mandarin Chinese, Russian or Spanish.
- 4.12 Training:
- **For all installations:** Provide a **user'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.
 - **If specifically required:** Provide a training course designed for qualified refrigeration technicians, covering the maintenance and repair of the installed equipment.
- All training course material must be presented in Microsoft PowerPoint in a language understood by all those attending the course. A CD copy of the material must be handed over.
- 4.13 Verification:
Pre-qualification evaluation of the system components and the offered installation and maintenance services will be carried out in accordance with PQS Verification Protocol **E01/CR-FR01-VP1**. Post-tender assessment and field commissioning of **installations** incorporating pre-qualified components will be carried out in accordance with PQS Verification Protocol **E01/CR-FR01-VP2**.
5. **Packaging:**
Materials used for packaging the **installation** components are to be free of ozone-depleting compounds as defined in the **Montreal Protocol**. The general specification of shipping containers will be subject to agreement with the individual procurement agencies and/or the **employer**.
6. **On-site installation:**
Installation components are to be installed on site, and the **installation** is to be commissioned, by personnel who have been trained to carry out these tasks.

7. **Product dossier:**

The [legal manufacturer](#) or [reseller](#) is to provide WHO with a pre-qualification dossier containing the following:

General information:

- Dossier examination fee in US dollars.
- General information about the [legal manufacturer](#), including name and address.
- General information about the reseller, including name and address (where applicable).
- Details of the [region\(s\)](#) for which pre-qualification is sought.
- Details of the [approved installers](#) and named [maintenance contractors](#) in each country in the [region\(s\)](#), with whom the [legal manufacturer](#) or [reseller](#) has a contractual relationship.
- A list of completed installations in each of the countries in the [region](#) for which pre-qualification is sought. If no installations have been completed in one or more of these countries, explain why these countries should be considered for pre-qualification.
- A minimum of five references from separate clients in at least three of the countries in the [region](#). References must be no more than three years old.

Technical details:

- Confirm the cold room sizes that are being offered.
- Confirm the freezer room sizes that are being offered.
- Full specifications, photographs and technical details of the individual components (excluding temperature monitoring systems) sufficient to demonstrate compliance with all the requirements set out in this document, including details of product marking and traceability.
- List of the temperature monitoring systems, already pre-qualified under PQS section E06, which will be offered as part of the package.

Norms and standards:

- Certified photocopies of all type-approvals obtained for the individual components, including CE marking and the like.
- Certified photocopies of the [legal manufacturer](#) or [reseller's](#) ISO 9001: 2000 quality system certification.
- Where relevant, certified photocopies of the [legal manufacturer](#) or [reseller'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 product specifications

Installation documentation:

- A sample of the pre-installation documentation supplied to current customers.
- A copy of the company's standard warranty agreement (clause 4.8).
- A copy of the company's standard on-site maintenance agreement (clause 8).

8. On-site maintenance:

Unless specifically excluded in the tender invitation, on-site maintenance of the [installation](#) will be required and the [legal manufacturer](#) or [reseller](#) must provide evidence of the ability to provide a routine and emergency maintenance service for a period of not less than five years after commissioning. Following a reported failure, the emergency service must guarantee the following response rate:

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

9. Change notification:

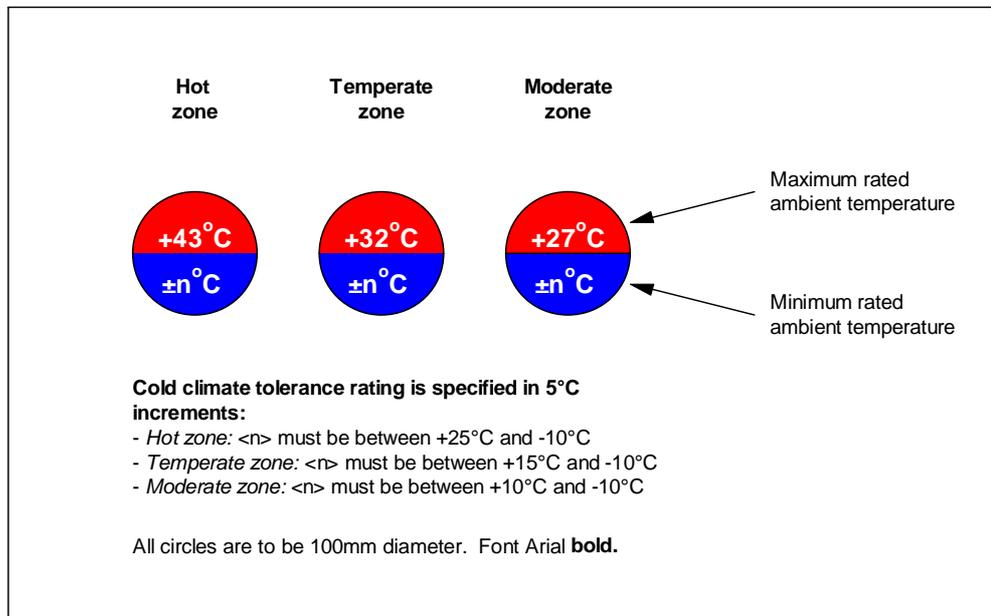
The [legal manufacturer](#) or [reseller](#) is to advise WHO [in writing](#) of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

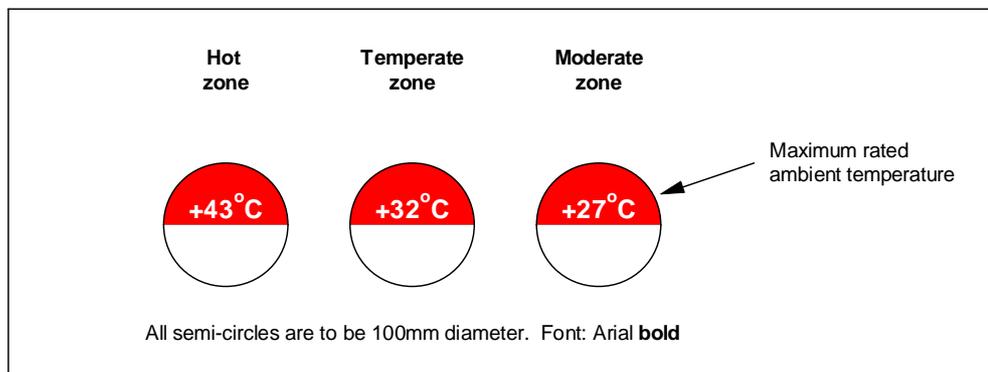
The [legal manufacturer](#) or [reseller](#) is to advise WHO and the UN purchasing agencies [in writing](#) in the event of safety-related product recalls, component defects and other similar events.

Annex 1 - Temperature zone symbols

Cold room symbols



Freezer room symbols



Revision history:			
Date	Change summary	Reason for change	Approved
20.03.2007	Updated and re-drafted in PQS format	Compatibility with PQS.	UK
09.05.2007	Revised to SMC comments & teleconference UK, SMC, AG 26.04.07		UK
16.05.2007	Final review version		UK
02.08.2007	Final version – no changes.		UK