WHO/EPI/LHIS/97.14
Original: English
Distribution: General

Equipment performance specifications and test procedures

Annexes

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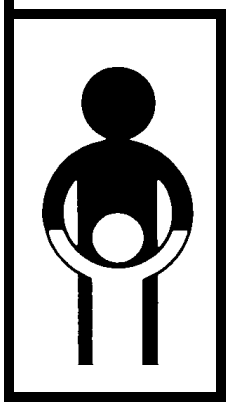

GLOBAL PROGRAMME FOR VACCINES AND IMMUNIZATION

EXPANDED PROGRAMME ON IMMUNIZATION

World Health Organization, Geneva, 1997

Date of last revision of this module: 1 January 1998

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 & E11:	Equipment performance specifications for insulated containers
E5:	Equipment performance specifications for icepacks
E6:	Equipment performance specifications for temperature monitoring devices
E7:	Equipment performance specifications for cold chain accessories
E8:	Equipment performance specifications for injection devices
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Annex 1: Testing institutions

Date of last revision: 1 January 1998

1. Criteria for qualifying test institutions

1.1 Procedures

Assessment and qualification of test institutions will involve the following procedures:

- application to WHO,
- assessment by WHO,
- qualification.

Application: A formal application should be submitted by the test institution to the WHO detailing the category of equipment for which qualification is sought. Such application will confirm compliance to the criteria for qualification (paragraph 1.2 below) and list the standard test equipment held by the laboratory.

Assessment: On receipt of the application WHO will:
examine the relevant control documents held in the laboratory,
assess the operation of the quality system on site,
assess the testing competence of the laboratory.

Qualification: Qualification will be awarded after examination of the normal application and assessment on site.

Maintenance of qualification: Following qualification laboratories will be subject to monitoring and reassessment visits. The purpose of periodic monitoring and reassessment is to determine whether a laboratory is continuing to comply with the WHO Qualifying Procedures. Such surveillance visits will usually be undertaken and completed within one day.

Withdrawal of qualification: If qualification is withdrawn the reason for this will be communicated to the laboratory by the WHO. It will be necessary to make formal application for reinstatement. This application must detail the corrective actions taken to warrant the laboratories re-qualification.

1.2 Criteria for qualification

Laboratories seeking to undertake testing of the specified equipment items should have the equipment identified in the following pages for each category of equipment, depending on the items being tested, and should in addition:

- Have a laboratory structure and management that is clearly defined and is organized in such a way that the integrity of its staff and operation can be judged.
- Employ suitably qualified laboratory staff experienced and technically competent for the work to be undertaken.
- Use laboratory equipment required for testing against the appropriate World Health Organization test protocol and which is properly installed,

maintained and calibrated. Adequate records of calibration and servicing must be maintained.

- Have a testing environment and laboratory suitable for the tests undertaken.
- Employ laboratory practices that are demonstrable and meet World Health Organization requirements, such as:

  - sample identification,

  - test methods and procedures,

  - supervision of staff,

  - checking of results and calculations.

- Operate a secure laboratory record system containing full details of all tests undertaken.
- Supply test reports and documents which are accurate, clear and unambiguous and contain all the relevant information.
- The above requirements are those identified as being the optimum requirement; nevertheless, failure to fully comply will not preclude consideration.

1.3 Standard test equipment for testing refrigerators and freezers

Test conditions:

Tests must be carried out in a room in which both temperature and humidity are controlled within an accuracy of +1 °C. Stable temperatures of +32°C and +43°C are required within the room. Humidity must be controlled in the range of 45% to 75% RH +5% RH.

The temperature within the room must also be capable of being reduced from an ambient temperature of +32°C to +15°C over a 2 hour period before being raised to +43 °C for 9 hours before being reduced to +15 °C over a further 3 hour period.

Conditions within the room should comply with ISO 5155.1983(E), Household Frozen Food Storage Cabinets and Food Freezers: Essential Characteristics and Test Methods, Section 8.1, General Test Conditions.

Test equipment:

Temperature within the appliance must be continuously recorded to within an accuracy of +0.5°C without the sensors influencing the tests in any way. Thermocouples which are sealed within the appliance are most commonly used. Up to 15 simultaneous temperature measurements may be required for a single appliance.

The energy consumption of an appliance also needs to be measured. For electrically operated appliances, a kilowatt hour meter is usual. For kerosene appliances, the volume is measured by volume or by weighing the tank for gas appliances, the weight is measured on a balance.

To carry out the various performance tests standard icepacks conforming to WHO Standard Performance Specifications E5/IP1 and E5/IP2 must be used. Approximately 50 kg per appliance being required.

To carry out the polluted kerosene test on a kerosene powered appliance low grade kerosene conforming to WHO Standard Specification (see Annex 3) must be used.

To measure the ice-loss test in icepack freezers a balance with a range of 0 to 10 kg is needed.

Basic black and white photographic equipment will be required to provide photographs for inclusion in the report.

Cardboard boxes 100 x 100 x 100 mm and 100 x 100 x 50 mm containing empty glass vials or bottles weighing 400 to 500 g per litre volume are used to simulate vaccine loads. Approximately 200 litres per appliance being required for most refrigerators.

1.5 Standard test equipment for testing photovoltaic solar refrigerators and freezers

Test conditions:

Tests must be carried out in a room in which both temperature and humidity are controlled within an accuracy of +1 C. Stable temperatures of +32°C and +43°C are required within the room. Humidity must be controlled in the range of 45% to 75% RH +5% RH.

The temperature within the room must also be capable of being reduced from an ambient temperature of +32°C to +15°C over a 2 hour period before being raised to +43°C over a 3 hour period, held at +43°C for 9 hours before being reduced to +15°C over a further 3 hour period.

Conditions within the room should comply with ISO 5155.1983(E), Household Frozen Food Storage Cabinets and Food Freezers: Essential Characteristics and Test Methods, Section 8.1, General Test Conditions.

Test equipment:

Temperature within the appliance must be capable of being continuously monitored to within an accuracy of +0.5°C without the sensors influencing the tests in any way. Thermocouples which are sealed within the appliance are most commonly used. Up to 15 simultaneous temperature measurements may be required for a single appliance.

The energy consumption of an appliance also needs to be measured. For electrically operated appliances, a kilowatt hour meter modified to allow for back electromotive force (back EMF) from Danfoss compressors is usual.

To carry out the various performance tests standard icepacks conforming to WHO Standard Performance Specifications E5/IP1 and E5/IP2 should be available. Approximately 50 kg per appliance would normally be required.

Electrical test equipment required for testing power regulators will include:

- stabilized variable power supply and suitable 12 and 24 V battery system and charger,
- ammeter of appropriate rating,
- voltmeter of appropriate rating,
- rheostat of appropriate rating.

Programmable vibration table capable of undertaking vibration tests to IEC 68-2-6 part FC.

Cardboard boxes 100 x 100 x 100 mm and 100 x 100 x 50 mm containing empty glass vials or bottles are used to simulate vaccine loads. Approximately 200 litres per appliance being required for most refrigerators.

Basic black and white photographic equipment will be required to provide photographs for inclusion in the report.

1.6 Standard test equipment for testing insulated containers

Test conditions:

Tests must be carried out in a room in which both temperature and humidity are controlled within an accuracy of +1 C. Stable temperatures of +32°C and +43°C are required within the room. Humidity must be controlled in the range of 45% to 75% RH +5% RH.

Test equipment:

Temperature within the appliance must be capable of being continuously monitored to within an accuracy of +0.5°C without the sensors influencing the tests in any way. Thermocouples which are sealed within the appliance are most commonly used. Up to 15 simultaneous temperature measurements may be required for a single test.

To carry out the various performance tests standard icepacks conforming to WHO Standard Performance Specifications E5/IP1 and E5/IP2 should be used. Approximately 20 kg. per appliance being required.

Cardboard boxes 100 x 100 x 100 mm and 100 x 100 x 50 mm containing empty glass vials or bottles are used to simulate vaccine loads. Approximately 25 litres being required per cold box and 5 litres per carrier.

Basic black and white photographic equipment will be required to provide photographs for inclusion in the report.

Access to up to 11 kg of dry ice per container is required.

A suitable rig will also be required to undertake the drop test.

1.7 Standard test equipment for testing voltage control units

Test conditions:

Room temperature + 43°C and 95% RH humidity.

Test equipment:

Electrical test equipment required for testing automatic voltage control units will include:

- single phase capacitor start induction motors of appropriate capacity,
- dynamometer of appropriate capacity,
- variable voltage supply,
- voltmeter,
- thermocouples to measure temperature rise of motor windings,
- stopwatch,
- 1.5 KV voltage supply,
- insulation tester (Megger),
- resistive loads of appropriate KW ratings.
- programmable vibration table capable of undertaking vibration tests to IEC 68-2-6 part FC.

1.8 Standard test equipment for testing syringes and needles

Test conditions:

Room temperature and humidity.

Test equipment:

A steam autoclave is required to sterilize each syringe prior to commencement of either accuracy of leakage tests.

To measure the accuracy of the volume contained within the syringe an analytical balance giving readings of 0.1 mg is required.

To measure both the leakage and the friction an appropriate tensile test instrument capable of continuously recording the force, in both directions, is required.

The physical testing of needles requires the availability of relevant:

- plug and ring gauges,
- torque gauge,
- calipers,
- travelling microscope,
- microscope.

1.9 Standard test equipment for testing thermometers

Test conditions:

Room temperature of 18°C to 25°C and humidity less than 70% RH.

Test equipment:

To undertake performance testing for measurement accuracy standard reference thermometers with a temperature range from -30°C to +50°C and an accuracy of +0.1°C are required.

To undertake tests on the effect of high humidities a cabinet in which the temperature can be controlled at +43°C and the humidity from 90% RH and retained at these humidities for a period of up to one week.

A programmable vibrating table upon which a thermometer can be mounted and vibrated for 30 minutes at an amplitude of 10 mm (20 mm peak to peak), with the frequency varying between 2 Hz and 10 Hz at a rate of change (up and down) of 1 octave / minute.

Basic black and white photographic facilities will be required to take photographs for inclusion in WHO Product Information Sheets.

A chamber in which stable ambient air temperatures of nominally -10°C and +10°C are achievable. A cabinet which can be maintained at +43°C and an accuracy of +1°C. The cabinet must also have an exit port to allow a sensing probe of a remote sensing thermometer to pass.

A freezer capable of maintaining a temperature of -30°C and -2°C.

An oven capable of maintaining a temperature of +50°C and +2°C.

1.10 Standard test equipment for testing sterilizers

Test conditions:

Room temperature and humidity.

Test equipment:

A pressure gauge is required to measure the internal pressure variation during the sterilization cycle.

The temperature of the handles of the appliance must be capable of being monitored to within an accuracy of +or - 1°C without the sensor influencing the tests in any way. Thermocouples attached to the sterilizer handles are most commonly used.

Temperature within the room must also be capable of being continuously monitored within an accuracy of +or -0.5°C without the sensors influencing the tests in any way. Thermocouples which are sealed within the appliance are most commonly used. Up to 5 simultaneous temperature measurements may be required for a single test.

A timer is used to record the time of the sterilization cycle.

Basic black and white photographic equipment will be required to include in WHO Product Information Sheets.

- Equipment for testing operation of safety devices.
- Equipment to pressurize using compressed air.

2.0 Equipment testing laboratories and inspection agencies

Below is a list of testing laboratories and inspection agencies which have either conducted or inspected tests on equipment according to WHO specifications. As an indication of the type of assignment these institutions have performed for WHO in the past, the following are included below:

(a) the types of equipment tested by each laboratory, and
(b) the nature of surveillance carried out by each inspection agency.

It should be noted that, in order to avoid problems with customs and to ensure safe delivery of goods for testing, it is advisable to check shipping instructions in advance with the selected laboratory. Appendices 1 to 6 outline the procedures to be followed when sending equipment to be tested by The Association for Consumer Research / U.K., UNIVALLE / Colombia, TED / Singapore, MUERI / Australia, AIT / Bangkok and ERTL / India respectively.

2.1 List of testing laboratories

Asian Institute of Technology
PO Box 4
Klong Luang,
Pathumthani 12120
Thailand

Telephone: 66 (2) 524 5440
Facsimile: 66 (2) 524 5439
Telex:84276 AIT TH

BSI Testing
Contact: Mr. Gary Essam
Maylands Avenue
Hemel Hempstead
Hertfordshire HP2 4SQ
United Kingdom

Telephone: 44 (1442) 230 442
Direct dial: 44 (1442) 278 530
Facsimile: 44 (1442) 231 442
e-mail: Gary.Essam@bsi.bsi.co.uk

China Household Electric Appliances Research Institute
Contact: Ms. Sui Rong
9 Xie Xie Jie
Xuan Wu District
Beijing 100053
China

Telephone: 86 (10) 6301 3391
Facsimile: 86 (10) 6301 3391

Consumers' Association Research & Testing Centre

Contact: Mrs. Melanie Brookman
Davy Avenue
Knowhill
Milton Keynes
Bucks MK5 8NL
UK

Telephone: *44 (171) 830 7770*
Facsimile: *44 (171) 830 7830*
Telex: *826 619 CALAB G*

Force Institute

Mr Michael Svan
Head of Mechanical Dept
Park Alle 345
DK 2605 Broendby
Denmark

Telephone: *45 (43) 26 70 00 / 430*
Facsimile: *45 (43) 26 70 11*
e-mail: *mls@force.dk*

GET

Gesellschaft fur
Entwicklungstechnologie mbH
Dr Klaus Scharmer
Karl Heinz Beckurts Strasse 13
D-52428 Juelich
Germany

Telephone: *49 (2461) 690 760*
Facsimile: *49 (2461) 690 769*
e-mail: *getmbh@t-online.de*

Laboratory of Hospital Infection

Central Public Health Laboratory
Dr. Peter Hoffman
61 Colindale Avenue
London NW9 5HT
Royaume-Uni

Telephone: *44 (181) 200 44 00*
Facsimile: *44 (181) 200 74 49*

MUERI Murdoch University Energy Research Institute

Dr. Trevor Pryor
South Street
Murdoch WA 6150
Australia

Telephone: *61 (8) 9360 2868*
Facsimile: *61 (8) 9310 6094*
e-mail: *pryor@murdoch.edu.au*

SEMKO

Mr Bertyl Ringqvist
Torshamansgatan 43
P.O. Box 1103
Kista-SE 164 22
Sweden

Telephone: *46 (8) 750 00 00*
Facsimile: *46 (8) 750 60 30*
e-mail: *info@semko.se*

Singapore Productivity and Standards Board (PSB) Testing and Evaluation Division (TED)
1 Science Park Drive
Singapore 118 221
Republic of Singapore

Telephone: *65 772 96 20*
Facsimile: *65 775 97 25*
e-mail: *wkleong@psb.gov.sg*

Universidad del Valle (UNIVALLE)
Lab. de Ciencias Termicas
Apartado Aereo 25360
Cali, Colombia

Telephone: *57 (92) 339 6938*
Facsimile: *57 (92) 339 7264*
e-mail: camamb@mafalda.univalle.edi.co

Appendix 1 to Annex 1: Instructions for sending equipment for testing to the association for consumer research

The instructions below should be followed in sending equipment for testing to the Consumers' Association:

1. Shipping Address:

For equipment sent airfreight:-

Consumers' Association
Consumers' Association Research & Testing Centre
Attention: Mr. S. Roe
LEP International Special Services Department
Unit 8, Northumberland Close
STANWELL
Middlesex TW19 7LN
United Kingdom

Freight Couriers - DHL, TNT, Federal Express

Consumers' Association
Consumers' Association Research & Testing Centre
Attention: Mr. S. Roe
Davy Avenue
Knowlhill
MILTON KEYNES
Buckinghamshire MK5 8NL
United Kingdom

For equipment sent by road or sea:-

Consumers' Association
Consumers' Association Research & Testing Centre
Attention: Mr. S. Roe
Davy Avenue
Knowlhill
MILTON KEYNES
Buckinghamshire MK5 8NL
United Kingdom

2. Documentation:

The consignment should have a signed pro-forma invoice in duplicate, on which your VAT Number and our VAT Number, approximate value and weight of goods must be stated. One copy should be fixed firmly to the outside of the package and one copy should be in with the goods.
Our VAT mumber is GB 238 5341 58 000.

The following words must appear on the pro-forma:-

For consignments coming from outside the EEC: - *"Goods for examination and performance evaluation in the technical and standards testing notice 200 (CPC 53 00 06). Imported under general bond: SOLR 209/86".*

For consignments coming from inside the EEC:- *" Goods for examination and performance evaluation in the technical and standards testing notice 201 (CPC 53 00 28). Imported under general bond: SOLR 209/86".*

Copies of these documents, together with details of the airway-bill number should be sent by airmail / fax to:-

Mr. S. Roe
Consumers' Association Research & Testing Centre
Davy Avenue
Knowlhill
MILTON REYNES
Buckinghamshire MK5 8NL
United Kingdom
Telephone: 44 (171) 830 7799
Fax: 44 (171) 830 7830

An advance fax should always be sent to Mr. S. Roe, the contact person, when shipping information is known, before the product is due to arrive. The fax should give relevant information, such as the means of transport, number of packages, the total, weight, the estimated time of arrival and the freight document / airway-bill number.

Appendix 2 to Annex 1:
Instructions for sending equipment for testing to PAHO/WHO Test Facility, UNIVALLE, Cali

1. Shipping address:

Representante de la OPS/OMS en Colombia
Cra 13, No 32-76, Piso 5to. Edificio Urano
Apartado Aereo 253367
Santa Fé de Bogotá
Colombia
Telephone: 57 (1) 33 67 100
Facsimile: 57 (1) 33 67 306

Special markings: In addition to the address, all shipments must be clearly marked as follows:

"EXENTO DE LICENZIA DE IMPORTACION SEGUN DECRETO 363 DEL 10 DE MARZO DE 1972".

"DESPACHO DIPLOMATICO".

"PROGRAMA ENSAYOS OMS/OPS, UNIVERSIDAD DEL VALLE CALI COLOMBIA: ATENCION: CIENCIAS TERMICAS".

2. Documentation:

A proforma invoice should be sent to the above address, well in advance of shipment, with the following information:

- statement that the equipment is a donation for the purpose of testing,
- product description (such as cold box, refrigerator, etc.),
- brand name (such as Phillips, Polyfoam, etc.),
- model (such as TCW-1151, RC-65, etc.),
- serial number (if applicable),
- manufacturer's full name and address,
- number of items,
- number of packages,
- volume and weight of package(s),
- value of product(s) (in U.S. Dollars, if known),
- the statements given under "Special Markings" above.

All equipment sent for testing must be accompanied by full manufacturer's instructions and technical data. A copy of these instructions should also be sent to WHO, Attention: Mr. Michel Zaffran, GPV/EPI, 1211 Geneva 27, Switzerland; Telex: 415416 MS, fax: 41-22-791 4193

An advance telex or cable with shipping information should always be sent to the contact person at least 48 hours before the product is due to arrive. Shipments should not arrive in Bogota on weekends or national holiday dates. The telex should give relevant information such as the name of the airline, the estimated time of arrival and freight document number (airway bill number). A sample telex might read as follows:

"041310 FOR REPRESENTATIVE OPS/OMS ONE CARTON CONTAINING: REFRIGERATOR BY NATIONAL PANASONIC SENT FROM MANILA FOR WHO TESTS ON 26 NOVEMBER AIRWAYBILL 213 1215 1234 FLIGHT BRANIFF 623 ETA BOGOTA 27 NOVEMBER 13.20 HOURS".

This telex should be copied to either: Mr. Michel Zaffran, WHO, Geneva, attention EPI (for shipments requested by WHO Geneva), or to Mr. Peter Carrasco, WHO/Regional Office for the Americas/ Pan American Sanitary Bureau, Attention: EPI, 525 23rd Street NW, Washington DC 20037, USA; Telex 248338 (for shipments requested by PAHO).

Appendix 3 to Annex 1: Instructions for sending equipment for testing to BSI Testing in the United Kingdom

1. Shipping address:

Unless agreed otherwise, all sample must be consigned to BSI at the address below, and should, if known, have a BSI contact identified on the outer packaging. If test sample are only consigned to the point of entry into the UK, there may be a considerable delay and extra costs before BSI receives them.

BSI Testing
Contact: Mr. Gary Essam
Maylands Avenue
Hemel Hempstead
Hertfordshire HP2 4SQ
United Kingdom
Telephone: 44 (1442) 230 442
Direct dial: 44 (1442) 278 530
Facsimile: 44 (1442) 231 442
E-mail: Gary.Essam@bsi.bsi.co.uk

A local freight handler, LEP, assists BSI with clearance of test samples. Whichever freight handling agents customers use, it is recommended that all items are clearly marked with whichever of the following is appropriate:

Samples for testing to destruction in UK

Free domicile

Samples for testing and return to origin

Free domicile

For advice on UK clearance contact:

LEP International
London Luton Airport
Telephone: 44 (1582) 27 550
Facsimile: 44 (1582) 30 077

2. Documentation:

All test samples must be accompanied by documentation showing their commercial value (even if this is zero).

For test items sent by sea freight, customers must send all associated documentation (bills of lading, etc.) to their UK freight agent to ensure that HM Customs and Excise clearance can be obtained at the port of entry.

Appendix 4 to Annex 1: Instructions for sending equipment for testing to WPRO/WHO Test Facility, Mueri, Perth, Australia

1. Shipping address:

Equipment should sent by airfreight or sea to the following address:

MUERI Murdoch University Energy Research Institute
Dr. Trevor Pryor
South Street
Murdoch WA 6150
Australia
Telephone: *61 (8) 9360 2868*
Facsimile: *61 (8) 9310 6094*
E-mail: *pryor@murdoch.edu.au*

Confirmation should first be obtained of the availability of the test facility before dispatch of any equipment.

2. Documentation

Before dispatching the equipment, a Carnet Form must be completed in the country of origin by the owner of the equipment to be tested. The duration of the Carnet Form should be at least for six months.

Advance notice by fax or airmail letter should always be sent to the above address prior to dispatch of the equipment. Relevant pre-alert information such as the means of transport, number of packages, total weight, estimated time of arrival and Carnet Form No should be included. MUERI will acknowledge receipt of this advance notice.

Appendix 5 to Annex 1: Instructions for sending equipment for testing to WPRO/WHO Test Facility, PSB, Singapore

1. Shipping address

For equipment and goods sent by Air Freight or Sea:

Singapore Productivity and Standards Board (PSB)

Testing and Evaluation Division (TED)

1 Science Park Drive
Singapore 118 221
Republic of Singapore
Telephone: 65 772 96 20
Facsimile: 65 775 97 25
E-mail: wkleong@psb.gov.sg

2. Documentation

The following documents should be followed in sending equipment / goods to the TED for testing:

i) Operation instruction / Manual of equipment or products
ii) Authorization letter
iii) The following additional information
   a) equipment / goods description
   b) brand name
   c) Model or type
   d) Serial number if applicable
   e) Value and weight of equipment and products (for customs purposes)
   f) Name of Manufacturer
   g) Manufacturer's instructions and technical data sheets

A message of advice should always be sent to the TED by fax or electronic mail before shipment of equipment / goods. The e-mail / fax should give relevant information such as the means of transport, number of packages, the total weight, the estimated time of arrival and freight document / airway bill number.

Appendix 6 to Annex 1: Instructions for sending equipment for testing to SEARO/WHO Test Facility, AIT, Bangkok, Thailand

1. Mailing address:

The coordinator
Energy program
Asian Institute of Technology
PO Box 4
Klong Luang, Pathumthani 12120
Thailand
Telephone: 66 (2) 524 5440
Facsimile: 66 (2) 524 5439
Telex: 84276 AIT TH

2. Shipping address:

The coordinator
Energy program
Asian Institute of Technology
No. 58 Moo 9, Km 42, Phaholyothin Highway
Klong Luang, Pathumthani 12120
Thailand
Telephone: 66 (2) 524 5440
Facsimile: 66 (2) 524 5439
Telex: 84276 AIT TH

3. Documentation:

The consignment should have a signed proforma invoice in duplicated; one copy should be fixed firmly to the outside of the package and one copy should be in with the equipment.

The proforma invoice should contain the following information:

- Statement that the equipment is sent for testing and evaluation purposes,
- Equipment description, brand name, model, serial number, manufacturer's name and address,
- Number of items, volume and weight of package,
- Value of equipment (if known or no commercial value)

Copies of the documents, together with details of the airway bill number should be sent to the above address at the time of the shipment.

All equipment sent for testing must be accompanied by full manufacturer's instructions and technical data.

An advance telex or fax with shipping information should always be sent to the contact person before the equipment is due to arrive. The telex or fax should give relevant information such as the means of transports, number of packages, the estimated time of arrival, freight document / airway bill number.

Appendix 7 to Annex 1:
Instructions for sending equipment for testing to China Household Electric Appliances Research Institute, Beijing, China

1. Mailing address

China Household Electric Appliances Research Institute
Contact: Ms. Sui Rong
9 Xie Xie Jie
Xuan Wu District
Beijing 100053
China

Telephone: 86 (10) 6301 3391
Facsimile: 86 (10) 6301 3391
Air freight should be sent through Beijing Airport.

2. Documentation

The consignment should be accompanied by the airway bill and the invoice. The latter should mention the unit price and the following text must be clearly visible:

"Value for customs purpose only, no commercial value."

Annex 2: Electrical safety ratings

Date of last revision: 1 January 1998

Rating	Condition
1. Dangerous	There is a huge risk of electrical shock or injury when the product is used normally.
2. Potentially dangerous	There is a risk of serious shock or injury when the product is used after the development of one fault or following accidental misuse, foolish action or breakage.
3. Unsatisfactory	There is a risk of serious shock or injury after two related faults have developed or after the occurrence of a number of unrelated faults.
4. Satisfactory	Within the limits of the tests carried out the product has no faults or only minor ones which do not present a hazard; or, shock or injury could result only from bizarre action from the user; or, hazard is not serious.
5. Completely satisfactory	No fault was found in full tests conducted on an appropriate standard model.

Annex 3: Robustness rating

Date of last revision: 1 January 1998

Robustness rating for insulated containers is based on a drop test. The container is fully loaded with icepacks then dropped 26 times from a height of 1 meter onto a smooth concrete floor. For a detailed description of the test, see EPI Equipment Test Procedures, E4/PROC/1. The resulting damage to the box is rated on the basis of the following scale:

Rating	Damage to container	Damage to fittings
1.	Heavy damage or pulled off	Hinges and /or catches broken
2.	Easily repairable damage	Hinges and/or catches become undone
3.	Superficial damage; satisfactorily	Hinges and catches work
4.	Slightly marked	
5.	Unmarked	

Annex 4: Classification of vaccine packaging

Date of last revision: 1 January 1998

Vaccine packaging for international transport of vaccines falls into the following three categories, as defined in document EPI/CCIS/81.4/Rev.1:

Class A:

Freeze-dried measles and liquid oral poliomyelitis vaccine shall be packed to ensure that the warmest storage temperature of the vaccine does not rise above +8°C in continuous outside temperatures of +43°C for a period of at least 48 hours. Cold chain monitor cards should be packed with each 3000 doses of vaccine.

The diluent for freeze-dried measles vaccine need not be subject to the same packaging, but should travel with the vaccine consignment whenever feasible.

Class B:

BCG and adsorbed DTP vaccine shall be packed to assure that the storage temperature of the vaccine does not rise above +30°C in continuous outside temperatures of +43°C for a period of at least 48 hours. Cold chain monitor cards should be packed with each 3000 doses of vaccine.

The diluent for BCG need not be cooled, but should travel with the vaccine whenever feasible.

Class C:

DT and tetanus vaccine need not be packed in insulated cartons with icepacks for international air transport. However, chemical temperature threshold indicators should be packed with each 3,000 doses of vaccine.

Annex 5: Standard opalescence rating

Date of last revision: 1 January 1998

The opalescence rating of syringes is based on a test which compares syringes filled with an aqueous suspension of formazine with a syringe filled with distilled water. For a full description of the test, see EPI Equipment Test Procedures, E4/PROC/1. The observed opalescence is rated according to the following scale:

Rating	Opalescence
0	No transparency / opalescence not perceptible
1	Fair transparency / opalescence noticeable
2	Good transparency / opalescence evident
3	Excellent transparency / opalescence clearly visible

Annex 6: Kerosene quality

Date of last revision: 1 January 1998

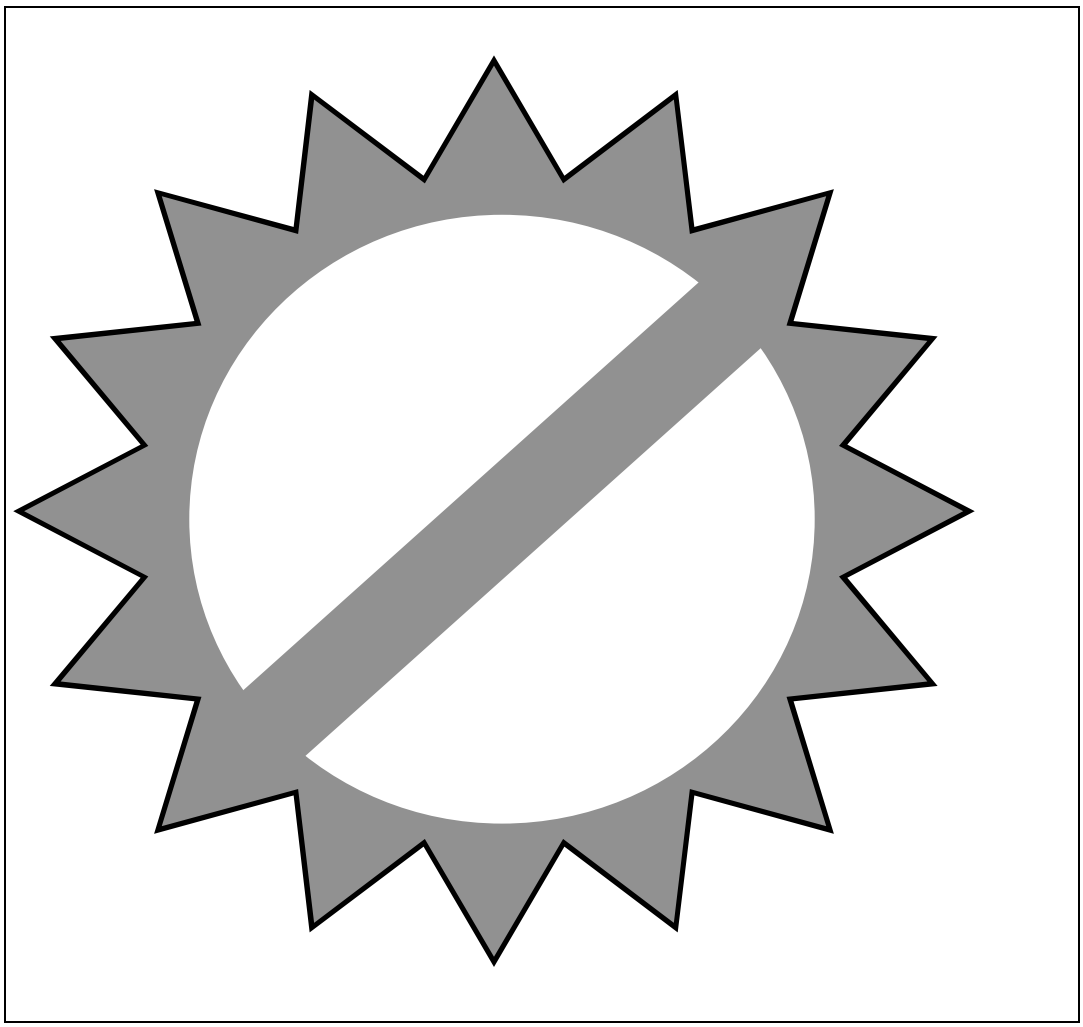
The quality of kerosene (BS 2869 Class C1) recommended for wick burning stoves and refrigerators has the following characteristics:

Minimum smoke point	35 mm
Maximum char value	10 mg/kg
Distillation: maximum % recovery at 200°C	60%
Flock test	Negative
Maximum sulphur content	0.04%

Annex 7: CFC free symbol

Date of last revision: *1 January 1998*

Standard WHO/EPI Symbol for CFC-Free Equipment in the Vaccine Cold Chain



Annex 8: Test procedures drawn from IEC 335-1 (1991) and Amendment 1 (1994-11), 'Safety of household and similar electrical appliances'

Date of last revision: 1 January 1998

Clause:

(8)	Protection against access to live parts.
(13)	Leakage current and electric strength at operating temperature - measures effectiveness of insulation under high humidity conditions.
(15,16)	Moisture resistance / leakage current and electric strength - measures effectiveness of insulation under conditions of high temperature (+43°C ± 1°C) and high humidity (RH 93% ± 2%).
(22,23)	Construction / internal wiring - internal examination and assessment of components assembly, internal wiring, security of wiring.
(25,27)	Supply connection and external flexible cords / provision for earthing - examination and assessment of supply connections, cord and earthing arrangements.
(29)	Creapage distances, clearances and distances through insulation - assesses probability of contact between live parts of different polarity and live parts and earth.

Annex 9: Performance and design specifications for batteries used in solar-powered vaccine refrigerators

Date of last revision: 1 January 1998

1. Type

The battery bank should comprise 2, 6 or 12-v, lead / acid flooded-electrolyte modules of either tubular- or flat-plate design. Sealed batteries (VRBs) will not be considered.

2. Battery-shipment

The batteries must be shipped in the dry-charged state and be air tight to enable long storage times. They should be delivered in sturdily constructed, wooden crates with acid-resistant internal packaging. This is to minimize any vibration and movement within the containers during transportation.

3. Positive-plate thickness

For flat-plate batteries, the minimum thickness of the positive-plate should be 6 mm (pasted and formed).

4. Grid antimony content

The antimony content of both the positive and negative grids should be between 1.5 and 2 wt. & % for flat-plate batteries and 1.5 to 2.5 wt % for tubular-plate units.

5. Separation mode

As a minimum requirement, the positive plates should be wrapped with glass-mat, both vertically and horizontally. A separator envelope is preferred.

6. Sediment space

Flat-plate batteries should have sufficient sediment space to allow the build up of shed material without the formation of short-circuits. The height of the sediment space should be at least 10% of the plate height.

7. Battery container

The battery container should be constructed from transparent material.

8. Water maintenance

The minimum water replacement period should not be less that 6 months without recombination devices.

9. Protection of plate edges

The negative and positive plates should have suitable edge protection to decrease the likelihood of internal short-circuits (top, bottom and sides).

10. Cycle life

The battery must be able to deliver at least 1000 cycles to 80% DOD at 25°C. The discharges are to be performed at the $C_5/5$ rate. The battery will be deemed to have failed when the C/5 capacity has dropped to 80% of the nominal value.

11. Self-discharge

The self-discharge of the battery should not exceed 3% of the rated C/10 capacity per month at 25°C.

12. Specific construction

The battery should be designed to accumulate relatively large amounts/levels of grid growth in both the vertical and horizontal planes.

13. Specific gravity

The specific gravity of the electrolyte should be in the range 1.220 to 1.250.

Supporting information

The following information should be provided by solar refrigerator system suppliers who wish to supply new battery types with their solar systems:

1. General description of battery

1.1 Name of manufacturer _____

1.2 Country of manufacture _____

1.3 Brand name / Model No. _____

1.4 Warranty period

{Describe in detail both the full warranty and pro-rata warranty components} _____

1.5 Nominal voltage of battery (V) {e.g., 2-, 6- or 12-V} _____

1.6 Configuration of battery bank for the proposed refrigerator system {e.g., 6, 2-V units in series}. _____

1.7 Positive plate type {i.e., flat / tubular} _____

1.8 Cell / module* container material used for construction _____

handles? _____

1.9 Cell / module* packing

during transport _____

at site _____

1.10 Recommended operating temperature range (°C)

_____

1.11 Safety features _____

_____

1.12 Drawings / photographs of the following shall be supplied for scrutiny

* cell / module 2 design

*complete arrangement in battery box showing all camping / packing pieces, position and a size of cables, ventilation, drainage.

1.3 Complete operating and maintenance instructions shall be supplied.

2. Physical parameters of unit cell/module

2.1 Weight

dry charged (kg) _____

acid filled (kg) _____

2.2 Container dimensions

length (mm) _____

height (mm) _____

width (mm) _____

2.3 Sediment space distance between bottom of container and bottom of plates (mm) _____

expressed as a percentage of the overall plate height _____

2.4 Outer plate support (e.g., do the supports for the outer plates offer full or partial support?) _____

3. Unit cell/module 1 connection system

3.1 No. terminal posts per cell / module * per polarity _____

3.2 Shape and dimensions (mm) of

positive terminal post(s) _____

negative terminal post (s) {supply diagrams if possible} _____

3.3 Method of main cable connection _____

3.4 Method of inter-unit connection _____

3.5 Connecting cable cross-sectional area _____

main (mm^2) _____

inter-unit (mm^2) _____

3.6 Connecting cable current-carrying capability _____

main (A) _____

inter-unit (A) _____

3.7 Method used to protect connections against corrosion _____

* Delete as appropriate

4. Plate parameters

4.1	Positive plate dimensions	
	length (mm)	_____
	height (mm)	_____
	thickness (pasted) (mm)	_____
4.2	Negative plate dimensions	
	length (mm)	_____
	height (mm)	_____
	thickness (pasted) (mm)	_____
4.3	No. plates per cell	
	positive	_____
	negative	_____
4.4	Plate support	
	positive	_____
	negative	_____
4.5	Is cell positive- or negative-plate limited?	_____
4.6	Grid alloy composition	
	positive grid / spine) wt. %)	_____
	negative (wt. %)	_____
4.7	Grid thickness	
	positive (grid / spine) (mm)	_____
	negative (mm)	_____
4.8	Grid design (rectangular, radial, etc.)	_____
4.9	Grid fabrication method (i.e., cast expanded, wrought expanded)	_____
4.10	Top-lead alloy composition	
	positive (wt. %)	_____
	negative (wt. %)	_____

Flat-plate positive batteries only

4.11	Paste density	
	positive (g cm^{-3})	_____
	negative (g cm^{-3})	_____

Tubular-plate positive batteries only

4.12 No. tubes per positive _____

4.13 Gauntlet material _____

5. Method of plate separation

5.1 Describe the total separation / retainer method for both the positive and negative plats {e.g., positive - wrapped in glass-mat and enclosed in complete, ribbed polyethylene separator envelope that is sealed on all edges except for the top; negative - no wrapping ; general - ribbed polyethylene sheets are located between the enveloped positive and the negative plates}

positive _____

negative _____

general _____

5.2 Separator geometry_

length (mm) _____

height (mm) _____

thickness (mm) _____

6. Electrolyte specifications

6.1 Specific gravity, fully charged (25°C)

at maximum electrolyte level _____

at maximum electrolyte level _____

6.2 Specific gravity after C / 10 discharge to (80% DOD (25°C9

at maximum electrolyte level _____

at minimum electrolyte level _____

6.3 Electrolyte reserve

distance between top of plate group and maximum electrolyte level _____

expressed as a percentage of the total plate height _____

6.4 Volume of electrolyte / cell (to max. level) (cm^3) _____

6.5 Minimum water replacement interval (months) _____

6.6 Filler cap / vent design _____

7. Battery Performance

7.1 Capacity at (25°C)

°C/5 _____O__ Ah °C/10 _____ Ah

°C/20 _____ Ah °C/100 _____ Ah

Cut - off voltage (V) _____

temperature coefficient (Ah/°C) _____

Note, please supply voltage/time curves for each discharge rate.

7.2 Cycle life {cut-off is at 80% of the rated capacity}

80% DOD at C_5/5 rate _____

100% DOD at C_5/5 rate _____

7.3 Self-discharge rate (% C/10 capacity / month at25° C _____

45°C _____

7.4 Internal resistance {when fully charges} (m0) _____

7.5 Predicted shelf life in dry-charged state (years) _____

8. Charging characteristics

8.1 Detailed description of recommended normal charging regime {e.g., 20 A until 2.55 V is reached, followed by a 2.55 V constant voltage charge for a further 8 h}

_____

_____

_____

8.2 Recommended float-charging voltage (V) _____

8.3 Boost charging

current (A) _____

voltage limit (V) {if applicable} _____

time (h) _____

frequency (weeks) _____

8.4 Max. AC. ripple allowed {charger} _____

8.5 Temperature compensation for charging voltage (mVs / °C / cell) _____

Please supply charging-voltage / current characteristics at 0, 15, 25 and 45 °C.

8.6 Please Supply charge-efficiency / state-of-charge curves for various charge rates

at 25 and 40°C.

9. Special features

Please list any additional features that are considered to make the battery particularly suitable for solar-based refrigeration system, for example:

- Protection against active-material / pillar shedding and place shorting
- method(s) for minimizing electrolyte stratification
- electrolyte level indicator
- built-in specific gravity indicator
- transparent container
- thermal management system.

Annex 10: Battery charge controller specifications

Date of last revision: 1 January 1998

WHO/EPI/PV Powered vaccine refrigeration system

1. General information

Warranty period of 5 years required for no-cost replacement of defective units.

2. Regulation characteristics

Voltage regulation algorithm must be a series-linear type (constant-voltage) or a pulse-width-modulated (PWM) design (>15 pulse per second during regulation) simulating a constant-voltage algorithm.

2.1 Regulation performance at 25°C

Voltage Regulation Set Point: 14.5 ± 0.1 (V)
Load discount voltage (low voltage disconnect):11.3 ± 0.1 (V)
Load reconnect hysteresis (load reconnect voltage): 12.75± 0.25 (V)

2.2 Battery temperature compensation

Voltage Regulation: Set point must be compensated for battery temperature.

Temperature Sensor: Located on the controller circuit board or external battery probe.

Temperature Compensation Coefficient: - 5 ± 1mV / °C / cell.

Probe or sensor must be matched to calibration of controller for temperature compensation and must be linear (± 10%) over range of temperatures. Loss of probe or other temperature compensation failure should cause regulator to default to regulation value at 25°C.

2.3 Set point adjustability

Voltage regulation set points must not be user adjustable. If designer / installer adjustments are provided, they must not be readily accessible to users. Adjustments can be made by DIP switches, jumpers (to select lead-antimony or lead-calcium batteries) or 10-20 turn trim pots.

Load disconnect set points must not be readily accessible to users, if adjustable.

2.4 Control design

PV array control element will be solid-state and must use MOSFETs or bi-polar transistors. Steady-state DC rating must be 150% of maximum PV array short-circuit current- Peak / surge DC current rating must be 200 % of maximum PV array short-circuit current.

Load control element must be an electronic-mechanical relay. Contact materials must be gold-plated or hermetically sealed. Contacts must be rated for a minimum of 1000 cycles. Steady-state DC current rating must be of 150% of

maximum load current. Peak / surge DC current rating must be 200% of maximum load current.

2.5 Surge protection and grounding

Surge protection must be provided on PV array input. Surge protection devices used must be either varistors or spark gaps. Controller must handle surge load for inductive load starting (compressor). System grounding must be provided through a separate terminal on charge controller.

3. Environmental specifications

Maximum / minimum ambient temperature limits: -20 to 45°C
Maximum / minimum battery temperature limits: - 20 to 45°C
Maximum / minimum relative humidity limits: - 0 to 100%

4. Mechanical characteristics

Terminations:

Temperature must be binding post or compression - type and accept wire sizes from # 8 to # 12 AWG (4 to 11 mm^2). Terminal materials must be manufactured from stainless steel or other non-corrosive metal. Any wire splices or connections to system must be soldered and electrically insulated. Circuit board must be encapsulated, conformally coated or potted.

5. Other characteristics

Light/alarms:

Indicator lights or alarms must be included with the system or charge controller per WHO / EPI performance specification WHO / EPI / LHIS / 91.1 - ER / RF.4. The following three conditions must be indicated: 1) load disconnect - red, 2) PV array charging - green, and 3) low battery SOC (no ice-making) - yellow.

Blocking diode:

Blocking diode or night-time PV array disconnect may be included if desired. If desired. If blocking diode included it must be either germanium or Schotky type.

Failure modes:

If controller fails, PV and load must remain connected to battery. If battery voltage drops below load disconnect point, load must disconnect and PV must remain connected. If temperature compensation becomes disabled, controller must regulate specified at specified VR set point at 25°C.

Installation, operation and troubleshooting guidelines for controller must be provided with system manuals. Colour-coded electrical diagram/drawing/photograph of controller must be provided also.

WHO/EPI PV POWERED REFRIGERATION SYSTEMS: BATTERY CHARGE CONTROLLER CHARACTERISTICS AND SPECIFICATIONS

QUESTIONNAIRE

General information

Model: _____

Manufacturer: _____

Address _____

_____

Contact: _____

Telephone: _____ Facsimile: _____

Warranty period: _____ (years)

Replacement cost: _____ $ US

Electrical specifications

Nominal ratings

Nominal system / battery voltage : _____ / _____(V)

Nominal / maximum PV array current: _____ / _____(A)

Nominal / maximum load current: _____ / _____(A)

Maximum PV open-circuit voltage: _____ / _____(V)

Regulation characteristics

Voltage regulation algorithm:	Series	YES	NO
	Shunt	YES	NO
	Series linear	YES	NO
	PWM	YES	NO
	Other_____		
Load disconnect algorithm:	Series	YES	NO
	Shunt	YES	NO
	Series linear	YES	NO
	PWM	YES	NO
	Other_____		

Load voltage regulation YES NO

If yes, voltage: :_____

Load timing or control YES NO

If yes, explain:_____

Regulation performance at 25°C

Voltage regulation (PV array disconnect voltage): _____ (V)

Voltage regulation hysteresis (PV array reconnect voltage): _____ (V)

Is voltage regulation dependent on PV current YES NO

Is voltage regulation dependent an load current YES NO

If answer yes to previous two questions, please explain:

_____

_____

Load disconnect voltage (low voltage disconnect):_____ (V)

Load reconnect hysteresis (load reconnect voltage): _____ (V)

Is load disconnect set point dependent on PV current? YES NO

Is load disconnect set point dependent on load current? YES NO

If answer is yes to two previous questions,
please explain: _____

_____

Battery temperature compensation:

Voltage regulation set point compensated YES NO

Location of sensor: Circuit board YES NO

External probe YES NO

Probe type: Thermistor YES NO

RTD YES NO

Other:_____

Probe length _____ (m)

Coefficient _____ (mV / °c / cell)

Linear compensation ? YES NO

Set point adjustability:

Voltage regulation set points adjustable ?		YES NO
Adjustments / settings performed by:		
	Designer	YES NO
	Installer	YES NO
	User	YES NO
Adjustments method / type:		
	trim pot	YES NO
	dip switch	YES NO
	Fixed resistor	YES NO
Interdependent load disconnect and hysteresis adjustments:		YES NO

Switching design

PV array switching:

	Positive leg	YES NO
	Negative leg	YES NO
Switching elements used	Solid state	YES NO
	Electro-mechanical	YES NO
Contact materials	gold plated	YES NO
	Plated steel	YES NO
	Copper plated	YES NO
Relay hermetically sealed		YES NO
Switch rated for how many cycles:	_____	

Load switching:

	Positive leg	YES NO
	Negative leg	YES NO
Switching elements used	Solid state	YES NO
	Electro-mechanical	YES NO
Contact materials	Gold plated	YES NO
	Plated steel	YES NO
	Copper plated	YES NO
Relay hermetically sealed		YES NO
Switch rated for how many cycles:	_____	

Surge protection:

Surge devices used:	Varistors	YES NO
	Transorbs	YES NO
	Spark gaps	YES NO
	Fuses	YES NO
	None	YES NO
	Other: _____	
Does controller handle surge load for compressor start?		YES NO

Grounding:

System grounding:	Required	YES NO
	Recommended	YES NO
	Not recommended	YES NO
Ground connected to:	Positive leg	YES NO
	Negative leg	YES NO

Ground location _____

Environmental specifications

Maximum / minimum ambient temperature limits _____ / _____ (°C)

Maximum / minimum battery temperature limits _____ / _____ (°C)

Maximum / minimum relative humidity limits _____ / _____ (°C)

Heat sinking required YES NO

Mechanical characteristics

Physical:

Size:

length _____ (cm) width _____ (cm)

depth _____ (cm) weight _____ (cm)

Casing material: _____

Terminal wire gages accepted (range): _____(mm^2)

Circuit board encapsulation:

	Potted	YES	NO
	Conformal coat	YES	NO
	None	YES	NO

Other characteristics

Voltmeters included ?	PV	YES	NO
	Battery	YES	NO
	load	YES	NO
Ammeters included ?	PV	YES	NO
	Battery	YES	NO
	Load	YES	NO
	None	YES	NO
Indicator lights ?	Load disconnect	YES	NO
	PV Charging	YES	NO
	PV Disconnect	YES	NO
Alarms / bells ?	Low battery volts	YES	NO
	High fridge temperature	YES	NO
Battery voltage sense leads included ?		YES	NO
Blocking diodes included ?		YES	NO
Blocking diode type	Silicon	YES	NO
	Germanium	YES	NO
	Other	YES	NO
Is installation / connection of charge controller required with system ?		YES	NO
Controller operation and troubleshooting guidelines provided in system manuals ?		YES	NO
Electrical diagram of controller provided ?		YES	NO

Photograph of controller provided ? YES NO

Failure mode / mechanism (describe):

_____

_____

_____

Has controller passed file safety or other
test protocol (IEC, UL, NEMA ?) YES NO

If yes please describe: _____

_____

Battery considerations:

(Please fill in the information below even if you have already provided it when the battery questionnaire was sent to you).

Battery type:

Manufacturer: _____

Model: _____

Type: _____

Capacity: _____

Cut off voltage _____ (V)

End of
charge voltage: _____