health
Department:
Health
PROVINCE OF KWAZULU-NATAL

Quotation Advert

Opening Date:	2021 / 02 / 19
Closing Date:	2021 / 02 / 26
Closing Time:	11:00

INSTITUTION DETAILS

Institution Name:	RK Khan Hospital
Province:	KwaZulu-Natal
Department or Entity:	Department of Health
Division or Section:	Supply Chain Management
Place where goods / Services is required	R.K KHAN HOSPITAL
Date Submitted	2021 / 02 / 19

ITEM CATEGORY AND DETAILS

Quotation Number:	ZNQ: 677 / 20-21
Item Category:	Goods
Item Description:	**INSTALLATION OF A BULK WALK IN FRIDGE AT PHARMACY** **Suppliers to come with their own Mask & Hand Sanitiser.**
Quantity (if supplies)	AS PER SPEC.

COMPULSORY BRIEFING SESSION / SITE VISIT

Select Type:	**Briefing Session** (COMPULSORY)
Date :	**2021 / 02 / 23**
Time:	**11:00**
Venue:	**R.K KHAN HOSPITAL - MAINTENANCE**

QUOTES CAN BE COLLECTED FROM:

ON SITE MEETING DAY

FORMS MUST BE PRINTED ON-LINE/WEBSITE ONLY.

QUOTES SHOULD BE DELIVERED TO: COMPLETE QUOTATIONS CAN BE DROPPED OFF

IN THE TENDER BOX, R K KHAN HOSPITAL .

Name: Mrs M Khumalo

Email: maud.khumalo@kznhealth.gov.za

Contact Number: 031 459 6300

Finance Manager Name: MR IDMYEZA

Finance Manager Signature:

No late quotes will be considered

STANDARD QUOTE DOCUMENTATION SUPPLY CHAIN MANAGEMENT OVER R30 000.00

YOU ARE HEREBY INVITED TO QUOTE FOR REQUIREMENTS AT: R.K KHAN HOSPITAL

DATE ADVERTISED: 19 FEBRAURY 2021 CLOSING DATE: 26 FEBRUARY 2021 CLOSING TIME: 11:00

FACSIMILE NUMBER: 031 403 7333 E-MAIL ADDRESS: maud.khumalo@kznhealth.gov.za

PHYSICAL ADDRESS: 336 R.K KHAN CIRCLE,WESTCLIFF,CHATSWORTH - 4092

ZNQ NUMBER: 677 / 20-21

DESCRIPTION: INSTALLATION OF A BULK WALK IN FRIDGE AT PHARMACY

CONTRACT PERIOD: ONCE OFF *(if applicable)* VALIDITY PERIOD 60 Days SARS PIN:.....

CENTRAL SUPPLIER DATABASE REGISTRATION (CSD) NO.

UNIQUE REGISTRATION REFERENCE

DEPOSITED IN THE QUOTE BOX SITUATED AT *(STREET ADDRESS)*

336 R.K KHAN CIRCLE,WESTCLIFF,CHATSWORTH - 4092

Bidders should ensure that quotes are delivered timeously to the correct address. If the quote is late, it will not be accepted for consideration.

The quote box is open from 08:00 to 15:30.

ALL QUOTES MUST BE SUBMITTED ON THE OFFICIAL FORMS – (NOT TO BE RE-TYPED)

THIS QUOTE IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2011, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.

THE FOLLOWING PARTICULARS MUST BE FURNISHED
(FAILURE TO DO SO WILL RESULT IN YOUR QUOTE BEING DISQUALIFIED)

NAME OF BIDDER .....

POSTAL ADDRESS .....

STREET ADDRESS .....

TELEPHONE NUMBER CODE.....NUMBER..... FACSIMILE NUMBER CODE .....NUMBER.....

CELLPHONE NUMBER .....

E-MAIL ADDRESS .....

VAT REGISTRATION NUMBER (If VAT vendor) .....

HAS A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE BEEN SUBMITTED? (SBD 6.1) YES | NO

[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/SWORN AFFIDAVIT (FOR EMEs& QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]

OFFICIAL PRICE PAGE FOR QUOTATIONS ZNQ NUMBER: 677/20-21

DESCRIPTION: INSTALLATION OF BULK WALK IN FRIDGE AT PHARMACY

SIGNATURE OF BIDDER ..... DATE.....
[By signing this document I hereby agree to all terms and conditions]

CAPACITY UNDER WHICH THIS QUOTE IS SIGNED.....

Item No	Quantity	Description	Brand & model	Country of manufacture	Price R	Price c
1	01	INSTALLATION OF A WALK IN BULK WALK IN FRIDGE				
		WALK IN FRIDGE IN PHARMACY				
		SUPPLIER TO DO OWN MEASURMENT				
		OMPLUSORY SITE VISIT				
		DATE: 24 FEBRUARY 2021				
		N.B: DECLARATION FORMS,CSD NO.,UNIQUE REG.,				
		SUBMIT BBBEE VERIFICATION CERTIFICATE OR				
		SWORN AFFIDAVIT, THE CERTIFICATE MUST BE SANAS				
		APPROVED,MUST BE SUBMITTED WITH QUOTATION.				
VALUE ADDED TAX @ 15% (Only if VAT Vendor)						
TOTAL QUOTATION PRICE (VALIDITY PERIOD 60 Days)						

Does This Offer Comply With The Specification?		Does The Article Conform To The S.A.N.S. / S.A.B.S. Specification?	
Is The Price Firm?		State Delivery Period E.G. *E.G. 1day, 1week*	

Enquiries regarding the quote may be directed to:

Contact Person: MNP MTHETHW Tel: 0314596391

E-Mail Address: mngobi.mthethwa@kznhealth.go

Enquiries regarding technical information may be directed to:

Contact Person: K RAMSAMY Tel: 0314596310

DECLARATION OF INTEREST

1. Any legal person, including persons employed by the state[1], or persons having a kinship with persons employed by the state, including a blood relationship, may make an offer or offers in terms of this invitation to quote (includes a price quotation, advertised competitive quote, limited quote or proposal). In view of possible allegations of favouritism, should the resulting quote, or part thereof, be awarded to persons employed by the state, or to persons connected with or related to them, it is required that the bidder or his/her authorised representative declare his/her position in relation to the evaluating/adjudicating authority where-
   - the bidder is employed by the state; and/or
   - the legal person on whose behalf the bidding document is signed, has a relationship with persons/a person who are/is involved in the evaluation and or adjudication of the quote(s), or where it is known that such a relationship exists between the person or persons for or on whose behalf the declarant acts and persons who are involved with the evaluation and or adjudication of the quote.
2. In order to give effect to the above, the following questionnaire must be completed and submitted with the quote.

2.1. Full Name of bidder/representative.....
2.2. Identity Number: .....
2.3. Position occupied in the Company (director, trustee, shareholder[2]):.....
2.4. Company Registration Number: .....
2.5. Tax Reference Number: .....
2.6. VAT Registration Number: .....

2.7. The names of all directors / trustees / shareholders / members, their individual identity numbers, tax reference numbers and, if applicable, employee / persal numbers must be indicated in paragraph 3 below.

[TICK APPLICABLE]

2.8. Are you or any person connected with the bidder presently employed by the state? YES ☐ NO ☐

2.8.1. If so, furnish the following particulars:
Name of person / director / trustee / shareholder/ member: .....
Name of state institution at which you or the person connected to the bidder is employed:.....
Position occupied in the state institution: .....Any other particulars:.....

2.8.2. If you are presently employed by the state, did you obtain the appropriate authority to undertake remunerative work outside employment in the public sector? YES ☐ NO ☐

2.8.2.1. If yes, did you attach proof of such authority to the quote document?

(Note: Failure to submit proof of such authority, where applicable, may result in the disqualification of the quote.)

2.8.2.2. If no, furnish reasons for non-submission of such proof: .....

2.9. Did you or your spouse, or any of the company's directors / trustees / shareholders / members or their spouses conduct business with the state in the previous twelve months? YES ☐ NO ☐

2.9.1. If so, furnish particulars:.....

2.10. Do you, or any person connected with the bidder, have any relationship (family, friend, other) with a person employed by the state and who may be involved with the evaluation and or adjudication of this quote? YES ☐ NO ☐

2.10.1. If so, furnish particulars:.....

2.11. Are you, or any person connected with the bidder, aware of any relationship (family, friend, other) between any other bidder and any person employed by the state who may be involved with the evaluation and or adjudication of this quote? YES ☐ NO ☐

2.11.1. If so, furnish particulars:.....

2.12. Do you or any of the directors / trustees / shareholders / members of the company have any interest in any other related companies whether or not they are bidding for this contract? YES ☐ NO ☐

2.12.1. If so, furnish particulars:.....

3. Full details of directors / trustees / members / shareholders.

NB: The Department Of Health will validate **details of directors / trustees / members / shareholders** on CSD. It is the suppliers' responsibility to ensure that their details are up-to-date and verified on CSD. If the Department cannot validate the **information** on CSD, the quote will not be considered and passed over as non-compliant according to National Treasury Instruction Note 4 (a) 2016/17.

4 DECLARATION

I, THE UNDERSIGNED (NAME).....CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 2.

I ACCEPT THAT THE STATE MAY REJECT THE QUOTE OR ACT AGAINST ME SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....	.....	.....	.....
Name of bidder	Signature	Position	Date

[1]"State" means –
a) any national or provincial department, national or provincial public entity or constitutional institution within the meaning of the Public Finance Management Act, 1999 (Act No. 1 of 1999);
b) any municipality or municipal entity;
c) provincial legislature;
d) national Assembly or the national Council of provinces; or
e) Parliament.

[2]"Shareholder" means a person who owns shares in the company and is actively involved in the management of the enterprise or business and exercises control over the enterprise.

SPECIAL CONTRACT CONDITIONS OF QUOTATIONS

1. AMENDMENT OF CONTRACT

1.1. Any amendment to or renunciation of the provisions of the contract shall at all times be done in writing and shall be signed by both parties.

2. CHANGE OF ADDRESS

2.1. Bidders must advise the Department of Health (institution where the offer was submitted) should their address (*domicilium citandi et executandi*) details change from the time of bidding to the expiry of the contract.

3. GENERAL CONDITIONS ATTACHED TO THIS QUOTATION

3.1. The institution is under no obligation to accept the lowest or any quote.
3.2. The price quoted must include VAT (if VAT vendor). However, it must be noted that the department reserves the right to evaluate all quotations excluding VAT as some bidders may not be VAT vendors.
3.3. The bidder must ensure the correctness & validity of quote:
(i) *that the price(s), rate(s) & preference quoted cover all for the work/item (s) & accept that any mistakes regarding the price (s) & calculations will be at the bidder's risk*
3.4. The bidder must accept full responsibility for the proper execution & fulfilment of all obligations conditions devolving on under this agreement, as the Principal (s) liable for the due fulfilment of this contract.
3.5. This quotation will be evaluated based on the 80/20 points system, specification & correctness of information. All required documentation must be completed in full and submitted.
3.6. Offers must comply strictly with the specification.
3.7. Only offers that meet or are greater than the specification will be considered.
3.8. Late quotes will not be considered.
3.9. Expired product/s will not be accepted. All products supplied must be valid for a minimum period of six months.
3.10. A bidder not registered on the Central Suppliers Database or verification has failed will not be considered.
3.11. All delivery costs must be included in the quote price, for delivery at the prescribed destination.
3.12. Only firm prices will be accepted. Such prices must remain firm for the contract period. Non-firm prices (including rates of exchange variations) will not be considered.
3.13. In cases where different delivery points influence the pricing, a separate pricing schedule must be submitted for each delivery point.
3.14. In the event of a bidder having multiple quotes, only the cheapest according to specification will be considered. Furthermore a verification will be done to identify if bidders have multiple companies and are quoting (cover-quoting) for this bid. In such instances only the cheapest bid according to specification will be considered.

4. SPECIAL INSTRUCTIONS AND NOTICES TO BIDDERS REGARDING THE COMPLETION OF THIS QUOTATION.

4.1. Unless inconsistent with or expressly indicated otherwise by the context, the singular shall include the plural and vice versa and with words importing the masculine gender shall include the feminine and the neuter.
4.2. Under no circumstances whatsoever may the quotation/bid forms be retyped or redrafted. Photocopies of the original bid documentation may be used, but an original signature must appear on such photocopies.
4.3. The bidder is advised to check the number of pages and to satisfy himself that none are missing or duplicated.
4.4. Quotation submitted must be complete in all respects.
4.5. Any alteration made by the bidder must be initialled.
4.6. Use of correcting fluid is prohibited
4.7. Quotation will be opened in public as soon as practicable after the closing time of quotation.
4.8. Where practical, prices are made public at the time of opening quotations.
4.9. If it is desired to make more than one offer against any individual item, such offers should be given on a photocopy of the page in question. Clear indication thereof must be stated on the schedules attached.

5. SPECIAL INSTRUCTIONS REGARDING HAND DELIVERED QUOTATIONS

5.1. Quotation shall be lodged at the address indicated not later than the closing time specified for their receipt, and in accordance with the directives in the quotation documents.
5.2. Each quotation shall be addressed in accordance with the directives in the quotation documents and shall be lodged in a separate sealed envelope, with the name and address of the bidder, the quotation number and closing date indicated on the envelope. The envelope shall not contain documents relating to any quotation other than that shown on the envelope. If this provision is not complied with, such quotations/bids may be rejected as being invalid.
5.3. All quotations received in sealed envelopes with the relevant quotation numbers on the envelopes are kept unopened in safe custody until the closing time of the quotation/bids. Where, however, a quotation is received open, it shall be sealed. If it is received without a quotation/bid number on the envelope, it shall be opened, the quotation number ascertained, the envelope sealed and the quotation number written on the envelope.
5.4. A specific box is provided for the receipt of quotations, and no quotation found in any other box or elsewhere subsequent to the closing date and time of quotation will be considered.

5.5. No quotation/bid sent through the post will be considered if it is received after the closing date and time stipulated in the quotation documentation, and proof of posting will not be accepted as proof of delivery.

5.6. Quotation documents must not be included in packages containing samples. Such quotations may be rejected as being invalid.

6. SAMPLES

6.1. In the case of the quote document stipulating that samples are required, the supplier will be informed in due course when samples should be provided to the institution. (This decreases the time of safety and storage risk that may be incurred by the respective institution). The bidders sample will be retained if such bidder wins the contract.

(i) If a company/s who has not won the quote requires their samples, they must advise the institution in writing of such.

(ii) If samples are not collected within three months of close of quote the institution reserves the right to dispose of them at their discretion.

6.2. **Samples must be made available when requested in writing or if stipulated on the document.**

(i) If a Bidder fails to provide a sample of their product on offer for scrutiny against the set specification when requested, their offer will be rejected. All testing will be for the account of the bidder.

7. COMPULSORY SITE INSPECTION / BRIEFING SESSION

7.1. Bidders who fail to attend the compulsory meeting will be disqualified from the evaluation process.

(i) The institution has determined that a compulsory site meeting ✓ take place

(ii) Date 23/02/2021 Time 11:00 Place _____

R.K. KHAN HOSPITAL

Institution Stamp: SUPPLY CHAIN MANAGEMENT 23 FEB 2021 PRIVATE BAG X004 CHATSWORTH 4030	Institution Site Inspection / briefing session Official Full Name: ..... Signature: ..... Date: .....

8. STATEMENT OF SUPPLIES AND SERVICES

8.1. The contractor shall, when requested to do so, furnish particulars of supplies delivered or services executed. If he/she fails to do so, the Department may, without prejudice to any other rights which it may have, institute inquiries at the expense of the contractor to obtain the required particulars.

9. SUBMISSION AND COMPLETION OF SBD 6.1

9.1. Should a bidder wish to qualify for preference points they must complete a SBD 6.1 document. Failure by a bidder to provide all relevant information required, will result in such a bidder not being considered for preference point's allocation. The preferences applicable on the closing date will be utilized. Any changes after the closing date will not be considered for that particular quote.

10. TAX COMPLIANCE REQUIREMENTS

10.1. In the event that the tax compliance status has failed on CSD, ***it is the suppliers' responsibility to provide a SARS pin in order for the institution to validate the tax compliance status of the supplier.***

10.2. In the event that the institution cannot validate the suppliers' tax clearance on SARS as well as the Central Suppliers Database, ***the quote will not be considered and passed over as non-compliant according to National Treasury Instruction Note 4 (a) 2016/17.***

11. TAX INVOICE

11.1. A tax invoice shall be in the currency of the Republic of South Africa and shall contain the following particulars:

(i) the name, address and registration number of the supplier;
(ii) the name and address of the recipient;
(iii) an individual serialized number and the date upon which the tax invoice is issued;
(iv) a description and quantity or volume of the goods or services supplied;
(v) the official department order number issued to the supplier;
(vi) the value of the supply, the amount of tax charged;
(vii) the words tax invoice in a prominent place.

12. PATENT RIGHTS

The supplier shall indemnify the **KZN Department of Health** (hear after known as the purchaser) against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

13. PENALTIES

13.1. If at any time during the contract period, the service provider is unable to perform in a timely manner, the service provider must notify the institution in writing/email of the cause of and the duration of the delay. Upon receipt of the notification, the institution should evaluate the circumstances and, if deemed necessary, the institution may extend the service provider's time for performance.

13.2. In the event of delayed performance that extends beyond the delivery period, the institution is entitled to purchase commodities of a similar quantity and quality as a substitution for the outstanding commodities, without terminating the contract, as well as return commodities delivered at a later stage at the service provider's expense.

13.3. Alternatively, the institution may elect to terminate the contract and procure the necessary commodities in order to complete the contract. In the event that the contract is terminated the institution may claim damages from the service provider in the form of a penalty. The service provider's performance should be captured on the service provider database in order to determine whether or not the service provider should be awarded any contracts in the future.

13.4. If the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance.

14. TERMINATION FOR DEFAULT

14.1. The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

(i) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract,

(ii) if the supplier fails to perform any other obligation(s) under the contract; or

(iii) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

14.2. In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services.

14.3. Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

15. FAILURE TO COMPLY WITH ABOVE WILL RESULT IN YOUR QUOTE BEING PASSED OVER.

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2017

This preference form must form part of all quotes invited. It contains general information and serves as a claim form for preference points for Broad-Based Black Economic Empowerment (B-BBEE) Status Level of Contribution

NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF B-BBEE, AS PRESCRIBED IN THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017.

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to all quotes:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and

1.2 The value of this quote is estimated to not exceed R50 000 000 (all applicable taxes included) and therefore the 80/20 preference point system shall be applicable.

1.3 Points for this quote shall be awarded for:
(a) Price; and
(b) B-BBEE Status Level of Contributor.

1.4 The maximum points for this quote is allocated as follows:

	POINTS
PRICE	80
B-BBEE STATUS LEVEL OF CONTRIBUTOR	20
Total points for Price and B-BBEE must not exceed	100

1.5 Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor together with the quote, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.

1.6 The purchaser reserves the right to require of a bidder, either before a quote is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the purchaser.

2. DEFINITIONS

(a) **"B-BBEE"** means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;

(b) **"B-BBEE status level of contributor"** means the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act;

(c) **"bid"** means a written offer in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of goods or services, through price quotations, advertised competitive bidding processes or proposals;

(d) **"Broad-Based Black Economic Empowerment Act"** means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

(e) **"EME"** means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;

(f) **"functionality"** means the ability of a tenderer to provide goods or services in accordance with specifications as set out in the tender documents.

(g) **"prices"** includes all applicable taxes less all unconditional discounts;

(h) **"proof of B-BBEE status level of contributor"** means:

1) B-BBEE Status level certificate issued by an authorized body or person;

2) A sworn affidavit as prescribed by the B-BBEE Codes of Good Practice;

3) Any other requirement prescribed in terms of the B-BBEE Act;

(i) **"QSE"** means a qualifying small business enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;

(j) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

3. POINTS AWARDED FOR PRICE

3.1 THE 80/20 PREFERENCE POINT SYSTEMS

A maximum of 80 points is allocated for price on the following basis:

$$Ps = 80\left(1 - \frac{Pt - P\min}{P\min}\right)$$ Where

Ps	=	Points scored for price of bid under consideration
Pt	=	Price of bid under consideration
Pmin	=	Price of lowest acceptable bid

4. POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

4.1 In terms of Regulation 6 (2) and 7 (2) of the Preferential Procurement Regulations, preference points must be awarded to a bidder for attaining the B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of points (80/20 system)
1	20
2	18
3	14
4	12
5	8
6	6
7	4
8	2
Non-compliant contributor	0

5. BID DECLARATION

5.1 Bidders who claim points in respect of B-BBEE Status Level of Contribution must complete the following:

6. B-BBEE STATUS LEVEL OF CONTRIBUTOR CLAIMED IN TERMS OF PARAGRAPHS 1.4 AND 4.1

6.1 B-BBEE Status Level of Contributor: = ...(maximum of 20 points)

(Points claimed in respect of paragraph 7.1 must be in accordance with the table reflected in paragraph 4.1 and must be substantiated by relevant proof of B-BBEE status level of contributor.

7. SUB-CONTRACTING

(Tick applicable box)

7.1 Will any portion of the contract be sub-contracted?

YES		NO	

7.1.1 If yes, indicate:

i) What percentage of the contract will be subcontracted.....%
ii) The name of the sub-contractor.....
iii) The B-BBEE status level of the sub-contractor.....

8. Whether the sub-contractor is an EME or QSE (Tick applicable box)

iv) Specify, by ticking the appropriate box, if subcontracting with an enterprise in terms of Preferential Procurement Regulations,2017:

YES		NO	

Designated Group: An EME or QSE which is at last 51% owned by:	EME √	QSE √
Black people		
Black people who are youth		
Black people who are women		
Black people with disabilities		
Black people living in rural or underdeveloped areas or townships		
Cooperative owned by black people		
Black people who are military veterans		
OR		
Any EME		
Any QSE		

9. **DECLARATION WITH REGARD TO COMPANY/FIRM**

9.1 Name of company/firm:.....

9.2 VAT registration number:.....

9.3 Company registration number:.....

9.4 TYPE OF COMPANY/ FIRM [TICK APPLICABLE BOX]

- ☐ Partnership/Joint Venture / Consortium
- ☐ One person business/sole propriety
- ☐ Close corporation
- ☐ Company
- ☐ (Pty) Limited

9.5 DESCRIBE PRINCIPAL BUSINESS ACTIVITIES

.....

.....

9.6 COMPANY CLASSIFICATION [TICK APPLICABLE BOX]

- ☐ Manufacturer
- ☐ Supplier
- ☐ Professional service provider
- ☐ Other service providers, e.g. transporter, etc.

9.7 Total number of years the company/firm has been in business:.....

9.8 I/we, the undersigned, who is / are duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the B-BBE status level of contributor indicated in paragraphs 1.4 and 6.1 of the foregoing certificate, qualifies the company/ firm for the preference(s) shown and I / we acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 6.1, the contractor may be required to furnish documentary proof to the satisfaction of the purchaser that the claims are correct;

iv) If the B-BBEE status level of contributor has been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the purchaser may, in addition to any other remedy it may have –

(a) disqualify the person from the bidding process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

(d) recommend that the bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted by the National Treasury from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution.

WITNESSES 1. ..... 2.	..... SIGNATURE(S) OF BIDDERS(S) DATE: ..... ADDRESS..... ....

QAS/14.598
Supplement 6

Temperature and humidity monitoring systems for fixed storage areas

Technical supplement to WHO Technical Report Series, No. 961, 2011

Annex 9: Model guidance for the storage and transport of time and temperature–sensitive pharmaceutical products

August 2014

Health Organization be liable for damages arising from its use. The named authors alone are responsible for the views expressed in this publication.

Acknowledgments

The authors of this document are Jean Bedard, MBA , Infitrak Inc and Ryan Sanders, Infitrak Inc.

Contents

Abbreviations

30DTR	30-day temperature recorder
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practice
GSP	Good Storage Practice
IQ	Installation Qualification
IT	Information Technology
LAN	Local Area Network
MKT	Mean Kinetic Temperature
OQ	Operational Qualification
PDA	Personal Digital Assistant
PDA	Parenteral Drug Association
PQ	Performance Qualification
RFID	Radio Frequency Identification Device
SaaS	Solution as a Service
SMS	Short Message Service
TCP/IP	Transmission Control Protocol (TCP) and Internet Protocol (IP)
SOP	Standard Operating Procedure
TTSPP	Time and Temperature-Sensitive Pharmaceutical Product
URS	User Requirements Specification
USB	Universal Serial Bus

Glossary

Component: Any major piece, part or assembly of the main equipment or sub-equipment that does not have its own power supply and could not operate as a standalone unit (valves, switches, etc.).

Electronic temperature monitoring and event logger system: System for recording and reporting air and/or product temperatures, with optional facilities for recording and reporting specific events such as door-opening or defrost cycles, and for issuing alarms. Such systems may be user-programmable and may also be remotely monitored via a satellite link.

Mapping: Documented measurement of the temperature and/or relative humidity distribution within a storage area, including identification of hot and cold spots.

Operational qualification (OQ): The process of obtaining and documenting evidence, under controlled conditions, that the premises, equipment and supporting systems operate in accordance with their design specifications.

Performance qualification (PQ): The process of obtaining and documenting evidence that the premises, equipment and supporting systems, as connected together, will consistently perform in accordance with the approved process method and specifications.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included[1].

Qualification: Action of proving that any premises, equipment and supporting systems work correctly and actually lead to the expected results. The meaning of the word *validation* is sometimes extended to incorporate the concept of qualification.

Refrigeration equipment: The term 'refrigeration' or 'refrigeration equipment' means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

Standard Operating Procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Storage temperature: The temperature range listed on the TTSPP label, and within the regulatory filings, for long-term storage.

[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments.*

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise pre-defined limits.

Temperature excursion: An event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

Time and temperature sensitive pharmaceutical product (TTSPP): Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Validation: Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting pre-determined acceptance criteria.[2]

[2] PDA Technical Report No. 39: *Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment*, 2007.

1. Introduction

This technical supplement has been written to amplify the recommendations given in Section 4.5.2 and 4.5.4 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*[3]. It covers the selection, installation and initial commissioning of temperature and humidity monitoring systems in fixed storage locations. It does not cover the routine operation of these systems. Related topics are covered in the following Technical Supplements:

- *Checking the accuracy of temperature control and monitoring devices.*
- *Qualification of temperature-controlled storage areas.*
- *Temperature and humidity monitoring systems for transport operations.*
- *Temperature mapping of storage areas.*

1.1 Requirements

The Model Guidance document defines minimum standards for temperature and humidity monitoring and alarm systems and components, and for the operational management of these systems.

1.1.1 Temperature monitoring systems

Air temperature monitoring systems and devices should be installed in all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers used to store TTSPPs. Electronic sensors should be accurate to ± 0.5°C or better[4]. Sensors should be located in areas where the greatest variability in temperature is expected to occur within the qualified storage volume and they should be positioned so as to be minimally affected by transient events such as door opening.

1.1.2 Humidity monitoring systems

Humidity monitoring systems and devices should be used in temperature-controlled rooms that are used to store TTSPPs that require a humidity-controlled environment. Monitoring sensors should be accurate to ± 5% RH and located to monitor worst-case humidity levels within the qualified storage volume and they should be positioned so as to be minimally affected by transient events such as door opening.

1.1.3 Alarm systems

Temperature, and where necessary, humidity alarm systems should be linked to the monitoring system(s) with high and low alarm set points. There should be a visual alarm and also preferably an audible alarm, together with automatic telephone dial-up or SMS text warnings to key personnel.

[3] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

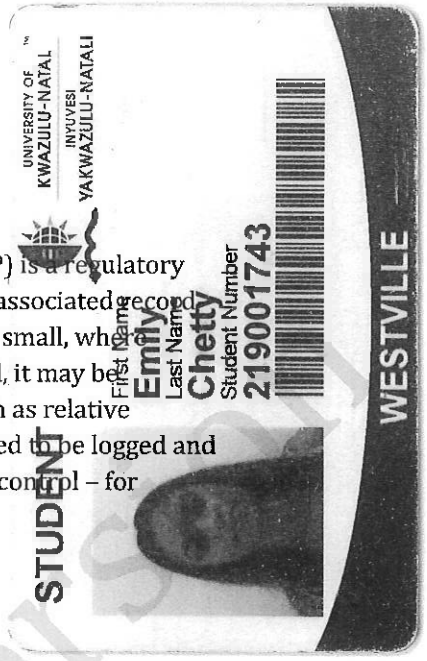
[4] Alcohol, bi-metal, gas or vapour pressure thermometers are also covered, but the focus of this Supplement is on electronic systems.

1.2 Objectives

The objective of the Technical Supplement is to provide guidance on how to protect TTSPPs from damage by the correct use of electronic temperature monitoring systems. It describes how to establish requirements and define specifications for these systems and how to assure traceability of the data that is generated.

1.3 Target readership

This document is relevant to wholesalers, warehouse operators, distributors, dispatchers and 3PLs who store TTSPPs. The specific target audience within these organizations includes those who have direct responsibility for quality management, for example, Quality Assurance (QA) Managers and Operations Managers.



2. Guidance

The ability to demonstrate compliance with Good Storage Practice (GSP) is a regulatory requirement in most countries. Effective temperature monitoring and associated record keeping is critically important component of GSP in all stores, however small, where TTSPPs are stored. In addition, depending on the products being stored, it may be necessary to monitor and record other environmental parameters, such as relative humidity (RH). Finally, there are operational events which may also need to be logged and recorded because they can have a significant impact on environmental control – for example door opening in freezer rooms and cold rooms.

2.1 Associated materials and equipment

None

2.2 Related activities

In order that this guidance can be fully applied, the following steps also have to be completed:

a. Identify the storage areas and equipment which will be used for storing TTSPPs and their relevant temperature regimes – ambient, controlled ambient, refrigerated and frozen.

b. Map these storage areas and equipment and determine hot and cold points. For areas that can be impacted by seasonal changes, mapping should cover both cold and hot seasons. See Technical Supplement: *Temperature mapping of storage areas.*

c. Qualify the storage areas and storage equipment (IQ, OQ and PQ). See Technical Supplement: *Qualification of temperature-controlled storage areas.*

d. Ensure that all storage areas and equipment complies with applicable regulations and guidelines on the storage of TTSPPs before these products are brought into the store.

2.3 Choosing a monitoring system

In this context, a monitoring system generally refers to an automated system that simultaneously and continuously records and documents one or more physical parameters (such as temperature and relative humidity) at one or more predefined points. A monitoring system is used to record and document the conditions in various storage areas whilst minimizing the need for manual measuring and recording. Such a monitoring system is increasingly required in facilities storing TTSPPs. This section outlines the steps that need to be taken to choose a suitable system or systems.

2.3.1 Prepare a user requirements specification

The first step in the process of commissioning and installing a monitoring system is to draw up a user requirements specification (URS). This document sets out the relevant compliance requirements, the operational, technical and business needs, and also outlines

the intended implementation programme. The document should be drafted by a suitably qualified person and then reviewed, revised and finalised in collaboration with all key departments: quality management, warehousing, transport operations, information technology, etc. Once the URS has been drafted, the implementation programme must be carefully planned.

2.3.2 *Select the basic system type*

There are two fundamentally different design options for a centralised monitoring system. The first is a hosted system and the second is the Solution as a Service (SaaS) approach.

- *Hosted system:* The monitoring system is fully installed and hosted by the commissioning organization. The server and database are stored, managed and maintained by the organization, which is also responsible for maintaining the system and ensuring its qualification.

  For small scale facilities with limited cold chain equipment, such as primary health care facilities and small pharmacies, the most appropriate hosted system will often be a standalone device; typically a simple portable electronic recorder which can be directly read by the person responsible for the cold chain equipment.

- *Solution as a Service (SaaS):* The monitoring system hardware (sensors and readers) is installed at the organization's site, but the software, server and database are hosted by the system supplier. The data are collected, stored and managed by the supplier whilst the organization has access to the data through a secure web interface. In this scenario, the system supplier ensures the system maintenance and qualification.

Choosing between these options is a key decision, with long-term operational and financial implications.

2.3.3 *Match the system to the needs*

Monitoring systems should be carefully chosen to match the specific needs of the application; this could be a small pharmaceutical store, a single large-scale warehouse, or an operation with multiple warehousing sites. In addition, the type of organization is relevant; for example whether it is a 3PL, a wholesaler or a distributor. Each combination of operator and operation will have different monitoring and reporting requirements. The following sections outline a few of these.

Large pharmaceutical warehouses: Large pharmaceutical warehouses typically have complex infrastructure with a mix of storage areas. These may include primary warehousing, mezzanine floors, vaults and cages, cold rooms, walk-in coolers and refrigerators and freezers. These organizations require reliable and adaptable monitoring systems with hardware that is designed for use on industrial sites. Wireless (RF) sensor networks are a suitable technology for these types of facility. Alternatively, hard-wired sensor systems may be used. Regardless of the chosen system, it is essential that it is compatible with the storage environment and can be altered and extended as necessary to suit changing needs. A web-based system, centrally hosted and monitored by the organization, is typically used by these types of facility.

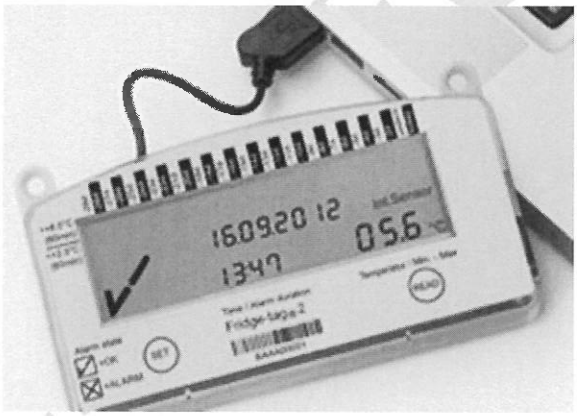
Hospitals: Pharmacies, laboratories, blood and tissue banks are typical of the hospital storage areas that need to be equipped with a monitoring system. These institutions have specific communication and technical requirements and system compatibility challenges (e.g. wireless communication) that may limit system choice.

Small-scale pharmacies and laboratories: Pharmacies and laboratories may find it cheaper and more convenient to use an externally hosted SaaS system because of the cost and complexity of the IT and operational requirements needed to support an in-house hosted system. Hardware is installed in the storage areas but the supplier hosts the software and the database, making the data accessible on-demand. This type of system generally uses wireless sensors (RF or WiFi), as they are easier to install in smaller facilities than wired systems. The size and location of the facility will determine the final choice; at the smaller end of the scale there is an overlap with small storage facilities.

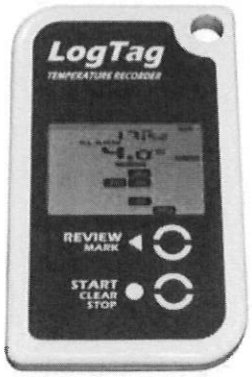
Small storage facilities: These facilities also require reliable and adaptable monitoring systems. Small storage facilities typically have limited equipment for storing TTSPPs such as a small walk-in cold room and/or refrigerator(s) and freezer(s). In stores with several pieces of equipment, a small-scale version of a system suitable for large pharmaceutical warehouses may be appropriate. In peripheral stores such as health facilities or retail pharmacies a 30-day temperature recorder (30DTR)[5] may be all that is needed – see Figure 1. An SMS-enabled device can offer out-of-hours assurance because staff can receive alarm alerts on their mobile phones. A USB-enabled device allows temperature records to be downloaded and these records can then be reported to supervisory staff.

Figure 2 – 30-day temperature recorders

FridgeTag2™ with USB



LogTag® temperature recorder



2.3.4 *Automated continuous monitoring*

The monitoring system should preferably be automated and continuous. Installing a real-time or nearly real-time data recording system is clearly an advantage, except in the

[5] Typically these devices have an operating life of two or three years, after which they need to be replaced.

smallest facilities. Automated data monitoring provides reliability advantages compared to manual measurements, which rely on human intervention. Because data needs to be recorded accurately and continuously, a cost effective and efficient monitoring platform is also required.

Automated monitoring systems provide an array of analytical and reporting functions that can be accessed easily from any connected device (computer, phone, or PDA). Reports based on time, date, activity, input, event type or multiple criteria can then be generated. Data can also be compiled and analysed over longer periods of time so that trending and risk analysis exercises can be conducted.

2.3.5 *Data collection: wireless* versus *wired data transmission*

A typical monitoring system consists of a network of sensors which are linked together to form an integrated electronic temperature and event logger system. Data transmission through this network may be done through wireless communication modes (Bluetooth, Wi-Fi, Radio-Frequency (RF) 418/433 MHz, 900 MHz, etc) or through a wired network (e.g.. Ethernet). Both system options can be either installed as a stand alone system or as a SaaS. The advantages of using a SaaS solution is to outsource the management of the system as well as upgrades and validation/qualification. Figure 2 illustrates some typical arrangements.

Figure 2 – Monitoring system options

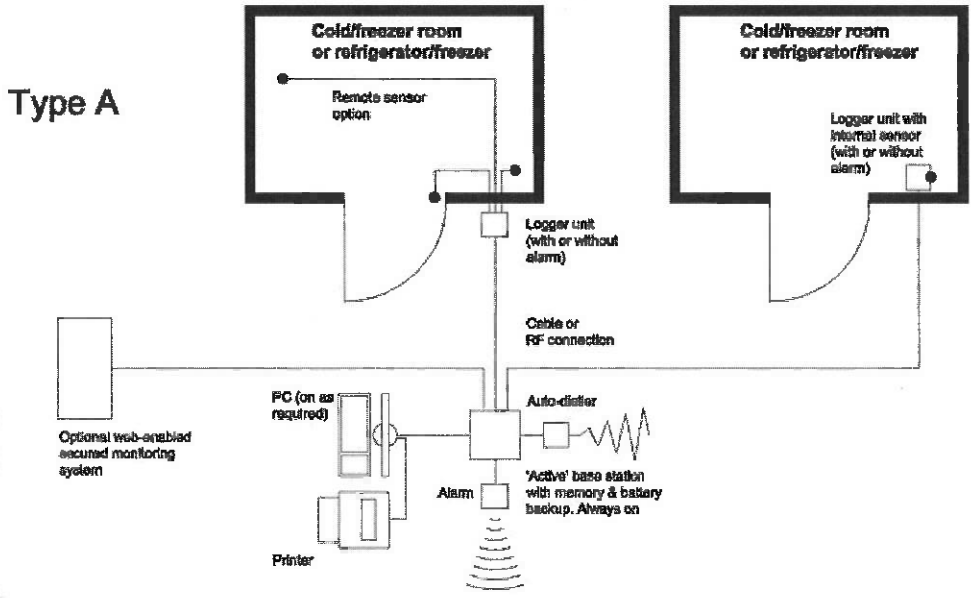
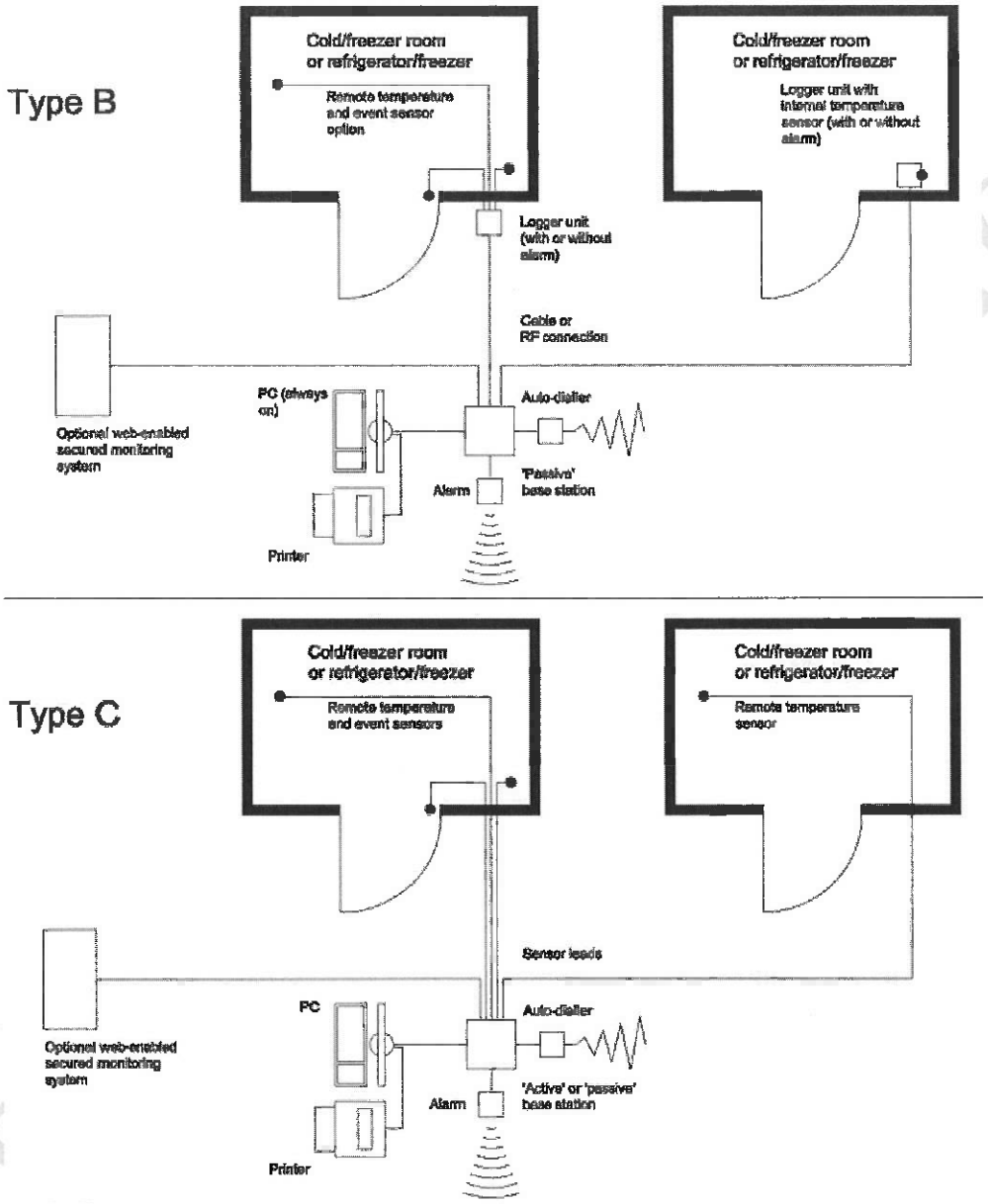


Figure 2 – Monitoring system options (continued)



Source: WHO/PQS

Wired sensors provide reliable data recording; however they can also require complex and costly installation and this technology inhibits simple changes to the network configuration. Monitoring networks with wired sensors are also limited in the adaptability of the monitoring architecture. This complicates matters when equipment needs to be moved, or a warehouse needs to be reconfigured, potentially incurring additional costs.

Wireless monitoring systems are now widely available, with different wireless transmission modes that can be adapted to suit the needs of the organization.

Wireless systems are supported on a local area network and are easier to install and use; this reduces costs and the time required for installation and maintenance.

2.3.6 *Specific requirements for wireless networks*

Wireless sensor networks should have the following technical characteristics:

- Sensors should continuously collect and buffer data, even during network outages and power cuts. The buffered data should then be sent to the host server when the connection is re-established. Ideally, sensors should have a built in data storage capability so that they can also act as data loggers.
- Sensors should be chosen to suit the different monitoring functions required in the network. This may include: temperature sensors for ambient and refrigerated stores, sensors with remote probes for low temperatures, temperature and relative humidity sensors and sensors for logging events such as door opening.
- Sensor accuracy: ± 5% maximum accuracy. Generally speaking, a sensor accuracy of ± 0.5 °C or better should be expected.
- Sensors should be calibrated annually. An annual calibration plan for the system sensors should be planned and designed so that it can be carried out without major disruption to the monitoring process.
- The wireless sensor network should be self-adaptable, and self-healing: sensors should also act as data transmitters within the network.
- The wireless sensor network should automatically detect and incorporate newly installed sensors.

For a wireless system, the sensor-reader subsystem should also be evaluated in terms of transmission capability, efficacy (e.g. ability to transmit through walls or doors) and power consumption. In a complex or extended monitoring scenario, wireless configurations should be tested to avoid dead zones or wireless transmission concerns.

2.3.7 *Web-based systems*

Web-based systems should be user-friendly, even if they are required to perform complex operations. This minimizes training requirements, reduces the time taken to deploy the system and enables the user organization to obtain maximum performance.

Monitoring systems typically operate over existing local area networks (LAN) and wide area networks (WAN), using TCP/IP, and should provide the ability to manage multiple users, buildings and sites.

Web-based systems generally emphasize ease of use, with system dashboards enabling the user to trace operations and activities, to see and follow-up all alarms, and to compile data into preformatted reports. Web-based systems also allow the data to be stored in the internet 'cloud' rather than at a specific facility. Authorized users have access to an online database via secure access arrangements. When systems of this type are adopted they should be subject to system validation/qualification before any use.

Monitoring solutions should incorporate a complete management system that includes the following features:

- User management;
- Sensor inventory management;
- Site calibration management;
- A system for reading the sensors, installed at every site;
- All sensors or tags clearly assigned to a specified location;
- Management of alarm set points;
- A system for directing alarm messages to specific individuals.
- The system that allows rapid tracking of system activities; tracking could be by combinations of location, sensor, tag, document (e.g. way bill), user or date.

2.3.8 *Alarm system*

The monitoring system should include an integrated alarm function that reports out-of-range events. Alarms should be managed automatically. Alarm limits should only be set by authorized users and should automatically alert responsible staff via email, SMS text message or other communication medium in case of out-of-range events or incidents.

Available equipment includes combinations of audible and visual alarms and electronic messaging systems; the latter allow authorized users to be alerted via e-mail, phone or text (SMS) message. A fully integrated system should allow the user to set an alarm schedule for different alert levels – for example work days, weekends and holidays.

2.3.9 *User controls*

Data needs to be recorded accurately and in real-time, and should be provided in the form of reports, charts, and graphs, which users are able to customize.

The system should allow all sensor and alarm parameters to be configured and customized by users. For instance, it should be possible to configure the sensor recording (sampling) rate or set a variety of parameters for the alarm settings. These could include:

- Low and high alarm threshold settings, triggered *before* temperature goes out of range;
- Low and high alarm settings, triggered *after* temperature goes out of range;
- Event alarms such as mains power failure or door open.

Reports should be customizable by users: format (text, pdf, graph...), time period and content (high and low temperature events, MKT analysis).

2.3.10 *Adaptability and expandability*

Unless the user requirement is very simple, it is wise to choose an adaptable and scalable system. A fully flexible system should support the following features:

- Ease of configuration for small-scale or large-scale facilities;

- Central monitoring of multiple remote sites;
- On-site hosting or vendor-hosting (SaaS);
- Open architecture, allowing future expansion and upgradeability. Such systems can include enhanced features such as:
  - Monitoring other parameters (airflow, pressure, flooding, movement, etc.).
  - Integrated monitoring of transport systems (refrigerated and temperature-controlled vehicles or containers)[6].
  - Automatically detecting and monitoring mobile sensors and tags (e.g. RFID)

It is important to determine both short-term and long-term needs. Making the correct initial choice makes it possible to scale appropriately if needed. Scaling possibilities can range from monitoring a specific storage area all the way up to installing a national cold chain monitoring system.

2.3.11 Security and compliance

There are specific security and compliance requirements which apply to monitoring systems and they should be installed and managed in accordance with relevant standards and regulations such as 21CFR part 11, and GAMP. Specifically:

- Audit trails should be included in the system;
- The database and the data that it holds should be secured;
- There should be a comprehensive set of Standard Operating Procedures (SOPs) covering installation, use, backup and decommissioning operations. For training purposes, a tutorial should be also available to users.
- Installed systems should be fully qualified by following the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) sequence;
- The system should provide different 'user levels'; each of these levels should have clearly defined authorization and access privileges.

2.4 Maintenance and support

Monitoring systems are a crucial to compliance with industry regulations and any system failures have to be resolved as rapidly as possible. Whether the system is hosted or SaaS, this means that a 24/7 technical support plan should be part of the contract package. This package should include a requirement for the installer or service provider to cover maintenance, support and warranties for both hardware and software. The support period and the renewal arrangements need to be defined in the URS.

[6] See Technical Supplement: *Temperature and humidity monitoring systems for transport operations.*

2.5 System extent

A comprehensive monitoring system for TTSPPs should be designed to record temperature and relative humidity for all storage areas where these products are stored or temporarily held. The system should extend to include the following areas:

- *General warehouse areas:* All warehousing areas, including distinct zones such as mezzanines and controlled ambient stores.
- *Cages, vaults and temporary holding areas*: Cages, vaults, preparation rooms and other spaces, such as packing, loading and quarantine areas where TTSPPs are handled and stored.
- *Cold chain equipment:* This includes refrigerated or frozen storage equipment used to store TTSPPs (freezer rooms, cold rooms, freezers and refrigerators).
- *Conditioning equipment:* Refrigerators and freezers used to store and condition cold chain packaging materials should ideally be linked into the monitoring system. These materials include ice-packs, cool water-packs, gel packs or PCMs.

2.5.1 Number of monitoring points

For ambient warehousing, controlled ambient stores, preparation rooms, temporary holding areas, freezer rooms, cold rooms and other spaces that people can physically enter, the number of monitoring points depends on the size of the space and on the diurnal and seasonal temperature variations observed during the mapping studies. This may change from one facility to another. Refer to Technical Supplement: *Temperature mapping of storage areas.*

For small-scale reach-in equipment such as refrigerators and freezers, a minimum of one monitoring point or monitoring device should be installed in the storage chamber. *Note:* some national regulatory agencies require two sensors: one positioned at the coolest point and one positioned at the warmest point. The correct locations may be determined by on-site temperature mapping, or they may be determined during laboratory testing at the design qualification (DQ) stage.

2.5.2 Location of monitoring points

As previously noted, monitoring points should be located in all places where TTSPPs are stored or handled. The correct locations are established as follows:

- *Ambient and controlled ambient storage areas:* Position sensors in the places where seasonal hot and cold spots have been observed during the mapping studies.
- *Freezer rooms and cold rooms*: Position sensors in the places where operational hot and cold spots have been observed during the qualification and/or mapping studies.
- *Freezers and refrigerators*: See 2.5.1.

Monitoring points should NOT be placed in areas where transient events such as a door opening may affect the monitoring and generate an abnormally high number of alarms. If

such transient events generate out-of-range temperatures alarms too frequently and the problem cannot be resolved technically or operationally (e.g. by limiting the number of door opening events), these areas should not be used to store TTSPPs and should not be monitored.

Note: Refer to Technical Supplement: *Temperature mapping of storage areas* for further information on how to determine hot and cold spots, based on the analysis of mean temperature.

2.6 Complimentary services

Implementing an effective and reliable monitoring system is a complex task; its installation, operation and maintenance involves a number of complimentary linked services. The scope of these complimentary services need to be clearly defined in terms of:

- *Technical assistance and support:* What is the extent of the proposed technical service? What other technical assistance can the supplier provide? How will system problems (like component failure) be managed? Can spare components be kept at the site?
- *System maintenance and upgrades*: How will maintenance and system or component upgrades be managed? Is the system associated with a preventive maintenance program?
- *Calibration:* How are sensors calibrated and by whom? How is calibration performed without system disruption?
- *Regulatory compliance:* What is the regulatory package provided with the system? (Training, SOPs and Qualification).

2.7 Deploying the system

Deployment is achieved by following a step-by-step process. The relevant departments in the commissioning organization (e.g. Operations, IT, Technical, etc.) must work closely with the system supplier to agree a deployment plan, and this plan must be closely monitored as the installation and commissioning activities proceed.

To streamline implementation, a *monitoring start-up form can* be used to facilitate an exchange between the organization and the supplier and cover all the points related to the system's deployment – see **Annex 1**.

2.8 Post-installation setup and qualification activities

Once the system has been installed, the system operator will need to set the system parameters; this includes defining user privileges, alarm settings, etc. The system should then be operated for a commissioning period so that adjustments can be made and operational problems can be detected and resolved. Once the system is operating correctly it is time to perform final qualification (IQ/OQ/PQ) as described in the companion Technical Supplement: *Guidance on qualification practices for temperature-controlled storage areas.*

References

- Cloud, Phillip A. *Pharmaceutical Equipment Validation: The Ultimate Qualification Guidebook.* Interpharm Press, 1998.
- Health Canada (HPFB Inspectorate). *Good Manufacturing Practices (GMP), Guidelines – 2009 Edition, Version 2, GUI-0001.* http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/docs/gui-0001-eng.pdf
- Health Canada (HPFB Inspectorate). Guide 0069, *Guidelines for temperature Control of Drug Products during Storage and Transportation.* October 17, 2005. http://www.rxcritical.ca/pdf/Guide-0069.pdf
- United States Pharmaceopaedia: Chapter 1079: *Good Storage & Shipping Practices.* https://mc.usp.org/sites/default/files/documents/GeneralChapterPDFs/c1079%20USP36.pdf
- US Food and Drug Administration. *Title 21 --Food and Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H--Medical Devices. Part 820 Quality System Regulation.* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
- US Food and Drug Administration. *Title 21--Food and Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter C--Drugs: General. Part 210--Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General.* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210
- US Food and Drug Administration. *Title 21--Food and Drugs. Chapter I--Food and Drug administration Department of Health and Human Services. Subchapter A--General. Part 11 Electronic Records; Electronic Signatures 21 CFR Part 11.* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11.
- WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical* http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

Annex 1 – Monitoring system start-up form example

SECTION 1: Person in charge

Contact details:

Name: Megapharm

Address: Unit 10, Erehwon Industrial Estate, Erehwon City

Tel: +101 1234 5678

Fax: +101 1234 7891

Website / email: www.erehwon.com

Approvals:

Determine who will be responsible for the approval of the documentation.

Type						Name	Title	Department
Contract	User requirements	Specifications	Deployment	Qualification protocol	Change control			
✓				✓	✓		Project manager	Admin
	✓	✓		✓	✓		Quality assurance	QA
			✓				IT manager	IT

Employees in charge:

Determine who will be in charge of the different activities.

Project manager			
Name	**Title**	**Department**	**Phone / email**
Dr A. Projmann	Project Manager	Property Department	

IT			
Name	**Title**	**Department**	**Phone / email**
Ms A. Hardrive	Systems Analyst	IT Department	

SECTION 1: Person in charge			

Employees in charge:

Determine who will be in charge of the different activities.

Quality assurance			
Name	**Title**	**Department**	**Phone / email**
Mr A. Qualman	Quality Manager	QA Department	

Instrumentation			
Name	**Title**	**Department**	**Phone / email**
Mr A. Instman	Quality Assistant	QA Department	

Maintenance			
Name	**Title**	**Department**	**Phone / email**
Ms A. Tidystore	Maintenance Mgr	Property Department	

Security			
Name	**Title**	**Department**	**Phone / email**
Mr A. Guardian	Security Manager	Security Department	

Pager/Alarm			
Name	**Title**	**Department**	**Phone / email**
n/a			

SECTION 1: Person in charge

Dr A. Projmann

Miscellaneous			
Name	**Title**	**Department**	**Phone / email**
n/a			

SECTION 2. Project description

Example:

- Installation of wireless sensors in South warehouse (12,000 square metres), including one walk-in cooler and one walk-in freezer.

SECTION 3. Technological risk

- Very crowded storage area using many different types of RF communication system.
- Energy source not always reliable.

SECTION 4 Regulatory risk

- None

SECTION 5. Data

- None

SECTION 6. Constraints

- Interference with the communication between wireless sensors and readers (antennas) may occur.

SECTION 7. Pre-installation checklist

☒ Availability of floor plan:

- South warehouse plan SW-001B

☒ Location of Ethernet Service Panel:

- 3 locations in storage area plus server room SR01

☒ Availability of power outlet in Ethernet Service Panel:

- Same as above

☒ Availability of power outlet:

- See layout SW-001B

☐ Range of IP addresses:

-

☒ Location of Server Room (also on plan):

- See layout SW-001B, room SR01

☒ All equipment is clearly identified and listed.

-

☐ Location of antenna support panel ☒ Location of server room on plan

☒ Identification of potential causes of interference:

- Care needed in placing sensors and antennae. The warehouse is very crowded and there is much equipment that can interfere with the communication between wireless sensors and readers.

Required component summary

Comm/ PSupp.	Qty	Temp. sensor	Qty	Humidity sensor	Qty	Wall plate/box	Qty
Com manager	1	RF 900MHz	28	RF 900MHz	4	Wall mount	32
Power supply	1						

Comments

None

Revision history

Date	Change summary	Reason for change	Approved

TITLE: Acoustic and/or visual alarm units

Specification reference:	E06/AL01.1
Product verification protocol:	E06/AL01.VP.1
Date of origin:	30 November 2006
Date of last revision:	New specification

Contents:

1. **Scope:**

This specification describes the performance requirements for acoustic and/or visual alarm units to be used as a connected component part of a temperature monitoring system in primary and intermediate vaccine stores.

The alarms specified in this document are intended to be used in conjunction with fixed gas or vapour pressure dial thermometers (with alarm contact option) as described in WHO Performance Specification E06/TH02 and with wall-mounted pen recording thermometers as described in WHO Performance Specification E06/TR04.

Alarms forming a component part of a programmable electronic temperature and event logger system with integral alarm and auto-dialler options are described in WHO Performance Specification E06/TR03.

2. **Normative references:**

EMAS: *European Union Eco-Management and Audit Scheme.*
European Union Directive 2002/96/EC: *Waste Electrical and Electronic Equipment.*
IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*
ISO 9001: 2000: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*

3. **Terms and definitions:**

In writing: means communication by letter, fax or email.
Intermediate vaccine store: stores which receive vaccine from a primary vaccine store where it is stored and distributed to health facilities. Such stores are typically located in a regional or district centre.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling 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.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
Primary vaccine store: stores which receive vaccine directly from the vaccine manufacturer where it is stored and distributed to intermediate vaccine stores. Such stores are typically located in a national or regional centre.
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.

4. **Requirements:**

4.1 *General:* Acoustic and/or visual alarm units to be used as a component part of a temperature monitoring system in primary and intermediate vaccine stores. The following types may be offered:

- **Type Ext-1:** Acoustic alarm in weatherproof housing for mounting externally.
- **Type Ext-2:** Visual alarm in weatherproof housing for mounting externally.
- **Type Ext-3:** Acoustic and visual alarm in weatherproof housing for mounting externally.
- **Type Int-1:** Acoustic alarm for mounting internally.
- **Type Int-2:** Visual alarm for mounting internally.
- **Type Int-3:** Acoustic and visual alarm for mounting internally.

4.2 *Performance:*

4.2.1 *Acoustic alarm – Types Ext-1, Ext-3, Int-1 and Int-3:* Sound intensity to be 100dB(A) at a distance of one metre from the sounder. The pattern of the signal is to be an intermittent pulse. The timing and/or pattern of the pulse should be set to ensure that it cannot be confused with the standard for fire alarm sounders applicable in the country of installation. Devices with an adjustable sound profile will be acceptable provided the means for adjustment is not accessible once the device is mounted in its final position.

4.2.2 *Visual alarm – Types Ext-2, Ext-3, Int-2 and Int-3:* Flashing coloured light, clearly visible in full sunlight at an intensity of 100,000 lux when viewed against a white background.

4.2.3 *Ancillary components:* Key-operated switch or keypad used to cancel the alarm signal.

4.2.4 *Power source:* 110/240 volt 50/60 Hz mains-operated wall-mounted audio alarm with rechargeable battery backup with a minimum 48 hr charge. The device is to be supplied with a power lead for wiring directly into an electrical outlet. Plugs are unacceptable as they can be removed by the user.

4.2.5 *Mode of operation:* The alarm is to be triggered by a signal received from either of the following temperature monitoring devices:

- Fixed gas or vapour pressure dial thermometer (with alarm contact option) as described in WHO Performance Specification **E06/TH02**.
- Wall-mounted pen recording thermometer as described in WHO Performance Specification **E06/TR04**.

After an alarm event has been signaled, the alarm is to continue until cancelled by the key operated switch or by means of a code entered on the keypad.

4.2.6 *Casing:* Non-corrodible plastics or metal case.

4.2.7 *IP rating:*

- **Types Ext-1, Ext-2 and Ext-3:** Protection of the product not less than IEC 60529: IP65.
- **Types Int-1, Int-2 and Int-3:** Protection of the product not less than IEC 60529: IP50.

4.2.8 *Battery:* Rechargeable back-up battery with a minimum 48 hr charge capacity with the acoustic and/or visual alarm operating. The battery is to be replaceable.

4.2.9 *Electromagnetic compatibility:* Operation of the device must be unaffected in the normal electromagnetic compatibility environment in which it is intended to work, taking into account disturbance generated by adjacent apparatus which is compliant with relevant ISO, EN, or other internationally recognized

standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions.

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport, storage and use:* -50°C to +55°C

4.3.2 *Ambient humidity range during transport, storage and use:* 0 to 95% RH.

4.3.3 *Resistance to electrical storms:* The functionality of the device must not be affected by intense electrical storm activity.

4.4 *Physical characteristics:*

4.4.1 *Component dimensions:* Not critical.

4.4.2 *Component weight:* Not critical.

4.5 *Interface requirements:* As clause 4.2.4.

4.6 *Human factors:* As clauses 4.3.2 to 4.2.4.

4.7 *Materials:*

4.7.1 *Ozone depleting chemicals:* During manufacture and assembly of the printed circuit boards and final assembly of the product do not use any substance included in Annex A, B or C of the Montreal Protocol.

4.7.2 *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:* The product is to be covered by a 1 year replacement warranty in the event of any component failure.

4.9 *Servicing provision:* The system is to be maintenance-free, apart from routine battery replacement.

4.10 *Disposal and recycling:* The manufacturer is to provide information to the buyer on the hazardous materials contained within the system 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:* Installation and user instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish.

4.12 *Training:* No requirement.

4.13 *Verification:* In accordance with PQS Verification Protocol **E06/AL01.VP.1**

5. Packaging:

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

6. **On-site installation:**
Not applicable.

7. **Product dossier:**
The legal manufacturer or reseller is to provide WHO with a pre-qualification 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 product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 2000 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 product specifications.
- One sample of the product. If the product is available in more than one of the versions described in clause 4.1, provide one sample of each version. The sample(s) will be returned following evaluation provided the manufacturer pays the return carriage charge.
- Indicative cost of the product per unit, per 10 units and per 100 units EXW (Incoterms 2000).

8. **On-site maintenance:**
Not required.

9. **Change notification:**
The legal manufacturer or reseller is required 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 required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Revision history:			
Date	Change summary	Reason for change	Approved
21 Sep 06	4.2.1: adjustable sound profile option added. Clause 4.2.9 added. 5. 'CFC' changed to 'ozone-depleting'. New clause 4.7.2. 4.7.3 and 4.7.4 deleted.	In response to final review comments. EU RoHS Directive material restrictions incorporated.	Yes (UK - 30 November 2006 = PQS secretariat)