May 6, 2021

Request for Proposals # GHSC-PSM/RFP/2021/NAM COVAX Distribution
Request for Proposals (RFP) for Transportation of COVID-19 Vaccine in Namibia

Dear Sir or Madam,

Chemonics International, Inc. (hereinafter referred to as “Chemonics”), under the U.S. Agency for International Development (USAID) Global Health Supply Chain Program – Procurement and Supply is issuing a Request for Proposals (RFP) for the provision of transportation services to support the distribution of roughly 1,350,000 doses (135,000 vials) of COVID-19 vaccines allocated to Namibia by COVAX and other self-financing procurement mechanisms. The attached RFP contains all the necessary information for interested Offerors.

The purpose of the GHSC-PSM project is to ensure uninterrupted supplies of health commodities in support of USG-funded public health initiatives around the world. The GHSC-PSM project in Namibia provides direct procurement and supply chain management support to health programs through the supply of a wide range of health commodities for HIV/AIDS through USG President’s Emergency Plan for AIDS Relief (PEPFAR) and various other essential medicines as well as targeted health systems strengthening technical assistance.

Chemonics realizes that Offerors may have additional questions after reading this RFP. Interested Offerors can submit their questions by email to psmnamibia@gmail.com according to the instructions in Section I.2 Chronological List of Proposal Events of the RFP. If necessary, Chemonics will provide answers to all relevant questions received in an amendment that will be emailed directly to all Offerors who received an offer according to the instructions in Section I.2 Chronological List of Proposal Events of the RFP.

This RFP does not obligate Chemonics to execute a subcontract nor does it commit Chemonics to pay any costs incurred in the preparation and submission of the proposals. Furthermore, Chemonics reserves the right to reject any and all offers, if such action is considered to be in the best interest of Chemonics.

Sincerely,

Harriet Lema
Country Director (Acting) and Procurement Technical Specialist
Contractor for USAID
Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project
100 Robert Mugabe Avenue,
Heritage Square, Ausspannplatz,
Windhoek, Namibia

- [End of PSM/Namibia Letter] -
Request for Proposals

RFP # GHSC-PSM/RFP/2021/NAM COVAX Distribution

For the provision of

Transportation of COVID-19 Vaccine in Namibia

Contracting Entity:
Chemonics International Inc.
100 Robert Mugabe Avenue,
Heritage Square, Windhoek
P.O. Box 40279
Ausspanplatz, Windhoek, Namibia

Funded by:
United States Agency for International Development (USAID)

Funded under:
Global Health Supply Chain Program – Procurement Supply Management (GHSC-PSM)

Contract Number

***** ETHICAL AND BUSINESS CONDUCT REQUIREMENTS *****

Chemonics is committed to integrity in procurement, and only selects suppliers based on objective business criteria such as price and technical merit. Chemonics expects suppliers to comply with our Standards of Business Conduct, available at https://www.chemonics.com/our-approach/standards-business-conduct/.

Chemonics does not tolerate fraud, collusion among offerors, falsified proposals/bids, bribery, or kickbacks. Any firm or individual violating these standards will be disqualified from this procurement, barred from future procurement opportunities, and may be reported to both USAID and the Office of the Inspector General.

Employees and agents of Chemonics are strictly prohibited from asking for or accepting any money, fee, commission, credit, gift, gratuity, object of value or compensation from current or potential vendors or suppliers in exchange for or as a reward for business. Employees and agents engaging in this conduct are subject to termination and will be reported to USAID and the Office of the Inspector General. In addition, Chemonics will inform USAID and the Office of the Inspector General of any supplier offers of money, fee, commission, credit, gift, gratuity, object of value or compensation to obtain business.

Offerors responding to this RFP must include the following as part of the proposal submission:

- Disclose any close, familial, or financial relationships with Chemonics or project staff. For example, if an offeror’s cousin is employed by the project, the offeror must state this.
- Disclose any family or financial relationship with other offerors submitting proposals. For example, if the offeror’s father owns a company that is submitting another proposal, the offeror must state this.
- Certify that the prices in the offer have been arrived at independently, without any consultation, communication, or agreement with any other offeror or competitor for the purpose of restricting competition.
- Certify that all information in the proposal and all supporting documentation are authentic and accurate.
- Certify understanding and agreement to Chemonics’ prohibitions against fraud, bribery and kickbacks.

Please contact Harriet Lema with any questions or concerns regarding the above information or to report any potential violations. Potential violations may also be reported directly to Chemonics at BusinessConduct@chemonics.com or by phone/Skype at 888.955.6881.
RFP Table of Contents

List of Acronyms

Section I Instructions to Offerors

I.1 Introduction
I.2 Chronological List of Proposal Events
I.3 Offer Submission Requirements
I.4 Eligibility Requirements
I.5 Source of Funding, Authorized Geographic Code, and Source and Origin
I.6 Validity Period
I.7 Instructions for the Preparation of the Proposal
I.8 Evaluation and Basis for Award
I.9 Negotiations
I.10 Terms of Subcontract
I.11 Insurance and Services
I.12 Privity

Section II Background, Scope of Work, Deliverables, and Deliverables Schedule

II.1. Background
II.2. Scope of Work
II.3. Deliverables
II.4. Deliverables Schedule

Section III Firm Fixed Price Subcontract (Terms and Clauses)

Annexes

Annex 1 Sample Proposal Cover Letter
Annex 2 Guide to Creating Cost Proposal and Establishing Prices
Annex 3 Required Certifications
Annex 4 DUNS and SAM Registration Guidance
Annex 5 Vehicle Verification Checklist
Annex 6 WHO Good Storage and Distribution Practices
Annex 8 Guidance for loading a truck
Annex 10 Proof of Insurance Form
Annex 11 COVID-19 Vaccine Distribution Plan
## List of Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>API</td>
<td>Application Program Interface</td>
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<tr>
<td>BER</td>
<td>Batches and Expiry Report</td>
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<tr>
<td>CCTV</td>
<td>Closed Circuit Television</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CD</td>
<td>Country Director</td>
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<tr>
<td>CMS</td>
<td>Central Medical Store</td>
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<tr>
<td>CV</td>
<td>Curriculum Vitae</td>
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<tr>
<td>DUNS</td>
<td>Data Universal Numbering System</td>
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<tr>
<td>ERP</td>
<td>Enterprise Resource Planning</td>
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<tr>
<td>FAR</td>
<td>Federal Acquisition Regulations</td>
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<tr>
<td>FEFIO</td>
<td>First Expiry First Out</td>
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<tr>
<td>FUP</td>
<td>Fixed Unit Price</td>
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<tr>
<td>GHSC-PSM</td>
<td>Global Health Supply Chain Program–Procurement and Supply Management</td>
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<td>GSP</td>
<td>Good Storage Practices</td>
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<td>GTDP</td>
<td>Good Trade and Distribution Practices</td>
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<tr>
<td>HF</td>
<td>Health Facilities</td>
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<td>IP</td>
<td>Implementing Partner</td>
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<td>KPI</td>
<td>Key Performance Indicator</td>
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<td>NAD</td>
<td>Namibian Dollar</td>
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<tr>
<td>NGO</td>
<td>Nongovernmental organization</td>
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<tr>
<td>PEPFAR</td>
<td>President’s Emergency Plan for AIDS Relief</td>
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<td>PO</td>
<td>Purchase Order</td>
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<td>POD</td>
<td>Proof of Delivery</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>RDTs</td>
<td>Rapid Diagnostic Tests</td>
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<tr>
<td>RIRV</td>
<td>Requisition Issue and Receipt Voucher</td>
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<td>RFP</td>
<td>Request for Proposals</td>
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<td>Rapid Test Kits</td>
</tr>
<tr>
<td>SAM</td>
<td>System for Award Management</td>
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<tr>
<td>SIV</td>
<td>Store Issue Voucher</td>
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<tr>
<td>SOPs</td>
<td>Standard Operating Procedures</td>
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<tr>
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<td>Targeted Local Procurement</td>
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<td>U.S.</td>
<td>United States</td>
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<td>USAID</td>
<td>U.S. Agency for International Development</td>
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<td>USAID/Namibia</td>
<td>USAID Mission in Namibia</td>
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<td>USD</td>
<td>U.S. Dollar</td>
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<td>U.S. Government</td>
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<tr>
<td>VAT</td>
<td>Value Added Tax</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WMS</td>
<td>Warehousing Management System</td>
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Section I. Instructions to Offerors

I.1. Introduction

Chemonics, under U.S. Agency for International Development (USAID) Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM), single award indefinite delivery indefinite quantity (IDIQ) contract number AID-OAA-I-15-00004, is soliciting offers from companies and organizations to submit proposals to for the provision of transportation services for roughly 1,350,000 doses (135,000 vials) of COVID-19 vaccines allocated to Namibia by COVAX and other self-financing procurement mechanisms. The vaccines will be received in Namibia in tranches and delivered to 35 district hospitals from the Central Medical Store (CMS) every 2 months. GHSC-PSM is also requesting supply of 150 temperature data loggers to be used for monitoring to ensure that cold chain temperatures of 2-8 degrees Celsius are maintained while the vaccines are in transit. The data loggers should be packaged within the cooler boxes at CMS and have the capability for downloadable memory to demonstrate storage conditions. More information on the purpose of GHSC-PSM, its operations in country, and specifics of the services being requested can be found in Section II Background, Scope of Work, Deliverables, and Deliverables Schedule.

The time period for the delivery of transportation services is expected to be one year, Chemonics may choose to extend or reduce the time period at its sole discretion. Chemonics has provided distribution information and quantities (Annex 11), which offerors will use to develop a delivery routing plan and a firm fixed price proposal. All shipments will be picked up from the Central Medical Store (CMS) in Windhoek. The distribution times and quantities indicated may differ slightly from the projections indicated in Annex 11. Other evaluation considerations may include the need for expeditious delivery; the reliability and trustworthiness of the offerors’ performance; past performance references; expertise in scope of work; unforeseen environmental factors that may affect delivery; force majeure factors; directions from Chemonics’ client(s); compelling host-government or beneficiary considerations; and/or any number of other USAID and/or prime contract considerations.

Offerors are invited to submit proposals in response to this RFP in accordance with Section I Instructions to Offerors, which will not be part of the subcontract. The instructions are intended to assist interested Offerors in the preparation of their offer. Any resulting subcontract will be guided by Sections II and III. This RFP does not obligate Chemonics to execute a subcontract nor does it commit Chemonics to pay any costs incurred in the preparation and submission of the proposals. Furthermore, Chemonics reserves the right to reject any and all offers, if such action is considered to be in the best interest of Chemonics.

Unless otherwise stated, the periods named in the RFP shall be consecutive calendar days.

I.2. Chronological List of Proposal Events

The following calendar summarizes important dates in the solicitation process. Offerors must strictly follow these deadlines.

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>RFP released</td>
<td>May 6, 2021</td>
</tr>
<tr>
<td>Deadline for written questions</td>
<td>May 10, 2021</td>
</tr>
<tr>
<td>Answers provided to questions/clarifications</td>
<td>May 13, 2021</td>
</tr>
<tr>
<td>Proposal due date</td>
<td>May 17, 2021</td>
</tr>
<tr>
<td>Subcontract award (estimated)</td>
<td>As soon as possible</td>
</tr>
</tbody>
</table>
The dates above may be modified at the sole discretion of Chemonics. Any changes will be published in an amendment to this RFP.

**Written Questions and Clarifications.** All questions or clarifications regarding this RFP must be in writing and submitted to psmnamibia@gmail.com no later than the date and time stated under Section 1.2 above. Questions and requests for clarification, and the responses thereto, will be circulated to all RFP recipients who have indicated an interest in this RFP.

Only written answers from Chemonics will be considered official and carry weight in the RFP process and subsequent evaluation. Any answers received outside the official channel, whether received verbally or in writing, from employees or representatives of Chemonics International, the GHSC-PSM project, or any other party, will not be considered official responses regarding this RFP.

**Proposal Submission Date.** All proposals must be received by no later than the date and time stated under Section 1.2 above. Late offers will be considered at the discretion of Chemonics.

**Oral Presentations.** Chemonics reserves the option to have select offerors participate in oral presentations with the technical evaluation committee. Interviews may consist of oral presentations of offerors’ proposed activities and approaches. Offerors should be prepared to give presentations to the technical evaluation committee at the GHSC-PSM Namibia project office within 2 days of receiving notification.

**Fleet Evaluation.** Offerors are required to make their vehicles available for inspection and evaluation by Chemonics. The offeror’s vehicles will be inspected and evaluated against the standards outlined in Annex 5. Offerors should be prepared for this evaluation within two (2) days of receiving notification from Chemonics.

**Subcontract Award (estimated).** Chemonics will select the proposal that offers the best value based upon the evaluation criteria stated in this RFP.

I.3. **Offer Submission Requirements**

A. **Instructions for the Submission of Hard-Copies**

No hard copies of the proposal are being collected.

B. **Instructions for the Submission of Electronic Copies**

Separate technical and cost proposals must be submitted by email to the point of contact and email address by no later than the time and date specified in I.2 Offer Deadline.

The Offeror must submit the proposals electronically with up to 3 attachments (30 MB limit) per email. Documents must be in Microsoft Word, Microsoft Excel, or Adobe Portable Document Format (except for the cost matrices as detailed below). **Offerors must NOT submit zipped files.** Those pages requiring original manual signatures should be scanned and sent in PDF format as an email attachment. Font type should be Times New Roman size 12 with single line spacing.

The technical and cost proposals shall be submitted separate from each other. Technical proposals **must NOT** make reference to pricing data in order that the technical evaluation may be made strictly on the basis of technical merit. The cover letter shall be submitted along with the technical proposal in the same email submission. The offeror must submit electronic copies of technical and cost proposals in two different e-
mails to psmnamibia@gmail.com with appropriate titles indicating technical or cost proposal, using the following headings:

Email No. 1: GHSC-PSM/RFP/2021/Nam- Technical Proposal for COVID-19 Vaccine Distribution
Email No. 2: GHSC-PSM/RFP/2021/Nam- Cost Proposal for COVID-19 Vaccine Distribution

Offers must be received by the date and time specified in Section I.2 above.

I.4. Eligibility Requirements

To be determined responsive, an offer must include all of documents and sections included in this section, I.4, and Section I.7 Instructions for the Preparation of the Proposal.

Chemonics anticipates issuing a subcontract to one (or more) company or organization provided it is legally registered and recognized under the laws of the country where it is headquartered and is in compliance with all applicable civil, fiscal, and other applicable regulations. Such a company or organization could include a private firm, non-profit, civil society organization, or university.

The award (or awards) will be in the form of a firm fixed price subcontract (hereinafter referred to as “the subcontract”. The successful Offeror (or Offerors) shall be required to adhere to the statement of work and terms and conditions of the subcontract, which are incorporated in Section III herein.

Companies and organizations that submit proposals in response to this RFP must meet the following requirements:

(i) Companies or organizations, whether for-profit or non-profit, must be legally registered under the laws of the country where they are headquartered upon award of the subcontract and provide proof of registration.
(ii) Firms operated as commercial companies or other organizations or enterprises (including nonprofit organizations) in which foreign governments or their agents or agencies have a controlling interest are not eligible as suppliers of commodities and services.
(iii) Companies or organizations must have a local presence in Namibia at the time the subcontract is signed.
(iv) Companies or organizations, whether for-profit or non-profit, shall be requested to provide a DUNS number if selected to receive a subaward valued at USD$30,000 or more, unless exempted in accordance with information certified in the Evidence of Responsibility form included in the required certifications in Annex 3.

Offerors may present their proposals as a member of a partnership with other companies or organizations. In such cases, the subcontract will be awarded to the lead company in the partnership. The leading company shall be responsible for compliance with all subcontract terms and conditions and making all partnership arrangements, including but not limited to division of labor, invoicing, etc., with the other company(ies). A legally registered partnership is not necessary for these purposes; however, the different organizations must be committed to work together in the fulfillment of the subcontract terms.

I.5. Source of Funding, Authorized Geographic Code, and Source and Origin

Any subcontract resulting from this RFP will be financed by USAID funding and will be subject to U.S. Government and USAID regulations.

The cooperating country for this RFP is Namibia.

Offerors may not offer or supply any products, commodities or related services that are manufactured or assembled in, shipped from, transported through, or otherwise involving any of the following countries: Cuba, Iran, North Korea, Syria. Related services include incidental services pertaining to any/all aspects of this work to be performed under a resulting contract (including transportation, fuel, lodging, meals, and communications expenses).

I.6. Validity Period

Offerors’ proposals must remain valid for 90 calendar days after the proposal deadline.

I.7. Instructions for the Preparation of the Proposal

A. Cover Letter

The offeror’s cover letter shall be submitted along with the technical proposal and shall include the following information:

i. Name of the company or organization
ii. Name and signature of authorized representative
iii. Type of company or organization
iv. Address
v. Telephone
vi. E-mail
vii. Full names of members of the Board of Directors and Legal Representative (as appropriate)
viii. Taxpayer Identification Number (TIN)
ix. DUNS Number\(^1\)
x. Official bank account information
xi. Other required documents that shall be included as attachments to the cover letter:

a) Copy of registration or incorporation in the public registry, or equivalent document from the government office where the offeror is registered.
b) Copy of company tax registration, or equivalent document.
c) Evidence of Responsibility Statement, whereby the offeror certifies that it has sufficient financial, technical, and managerial resources to complete the activity described in the scope of work, or the ability to obtain such resources. This statement is required by the Federal Acquisition Regulations in 9.104-1. A template is provided in Annex 3 Required Certifications.

\(^1\) If Offeror does not have a DUNS number and is unable to obtain one before proposal submission deadline, Offeror shall include a statement in their Evidence of Responsibility Statement noting their intention to register for a DUNS number should it be selected as the successful offeror or explaining why registration for a DUNS number is not possible. Contact Dun & Bradstreet through this webform to obtain a number: https://fedgov.dnb.com/webform

Further guidance on obtaining a DUNS number is available from Chemonics upon request.
d) The insurance form in Annex 10 and proof of insurance, whereby the offeror certifies that it has sufficient insurance to meet the requirements of this scope of work.

e) Applicable documents listed in Section I.4.

At its discretion, Chemonics may request other documents from an offeror to validate elements of the offeror’s proposal or to support the offeror’s claim of meeting the requirements set forth under Section I.4 above.

A sample cover letter is provided in Annex 1 of this RFP.

B. Technical Proposal

Offerors must prepare and submit a technical proposal. Please note that the proposal must be responsive to the detailed information set out in Section II of this RFP, which provides the background, states the scope of work, describes the deliverables, and provides a deliverables schedule.

The technical proposal shall comprise the following three parts.

- Part 1: Technical Approach, Methodology and Detailed Work Plan. This part shall be between 5 and 10 pages long but may not exceed 10 pages.

  a. Approach and Methodology: The Offeror should provide a presentation of their strategy and approach to the scope of work described in Section II.2. Technical proposals should highlight components of the approach including details of the offeror’s response to the specific transportation services responsibilities under schedules 1 and 2 of the scope of work and the resources, technical expertise and equipment which will be utilized to meet the required transportation deliverables detailed under the scope of work of this RFP solicitation during implementation of the proposed subcontract.

  b. Fleet Size, Quality, Variety, and Ownership: This part must include details on the total number, variety, and adequacy of vehicles in offeror’s fleet (with trucks of varying size that meet the specifications included in the RFP). The total number should note which vehicles are leased or rented. Chemonics’ preference is that offerors shall use their own fleet to transport the vaccines for Chemonics, and in that case, must provide proof of fleet ownership (e.g. title and registration). Offerers may use leased or rented vehicles, however, should proper justification be provided within offeror’s proposal. Offeror is responsible for the entirety of the scope of work including but not limited to management, quality assurance, deliverables, and reporting. The offeror must submit proof of insurance for the vehicle as described in the insurance clause of Section III Firm Fixed Price Subcontract (Terms and Clauses). If offerors propose to provide transportation services with vehicles they do not own, they must specify the justification and specify the company or mechanism they plan to use to carry out the activity, along with the number, variety, and adequacy of available vehicles in that company’s fleet. The offeror’s vehicles should at a minimum comply with all of the standards provided under Annex 5 Vehicle Verification Checklist.

  c. Capability for In-Transit Tracking: The offeror must describe the offeror’s capability for real-time in-transit tracking. Chemonics’ preference is that offerors should use Global Positioning (GPS) tracking devices for in-transit tracking, and the capacity to provide route-tracking documentation to Chemonics to verify and validate the specific route taken by any given vehicle that is tasked with delivering the vaccines. If GPS tracking data is not available, offeror shall provide an adequate solution for vehicle tracking, for example detailed vehicle and phone/SMS/GPS location logs using
smart phone maps, which shall be provided to Chemonics upon request. The offeror should include the number of vehicles in its possession or that shall be used in this scope of work which carry GPS tracking equipment. Offeror shall provide route-tracking and route-validation documentation to Chemonics, upon request. Chemonics may confirm the offeror’s proposal with the fleet-evaluation event.

d. Standard Operating Procedures for Security of Commodities: The offeror shall provide standard operating procedures (SOP) that address the full range of security issues related to distribution and the operating environment to assure the quality, security, and integrity of the COVID-19 vaccines being transported. Such issues include, but are not limited to, appropriate vehicle and equipment selection and maintenance (e.g. locks, security seals, alarm systems), preventing unauthorized access to and theft or misappropriation of COVID-19 vaccines, operating procedures while COVID-19 vaccines are in-transit, selecting delivery routes and re-routing as conditions change or concerns arise, capacity to maintain and monitor the cold chain conditions for the specific COVID-19 vaccine, and incident management and reporting. The SOPs should comply with World Health Organization (WHO) Good Storage and Distribution Practices, provided under Annex 6. Alternatively, if the offeror is compliant with country standards and best practices, offeror should submit those for consideration.

e. The offeror must disclose any services that may result in additional fees such as fuel, road conditions, maintenance, expedited services and hours of travel.

f. Standard Operating Procedures for Capacity: The offeror is required to submit with their proposal one (1) copy of the offeror’s established SOP for transportation of all COVID-19 vaccines. The offeror’s SOP should comply with the WHO standards provided under Annexes 6, 7, and 9. Alternatively, if the offeror is compliant with country standards and best practices, offeror should submit those for consideration.

- Part 2: Management, Key Personnel, and Staffing Plan. This part shall be between 2 and 5 pages long but may not exceed 5 pages.

Offerors shall provide an organogram/org chart of staff, with names (can use “to-be-determined” (TBD), if appropriate), titles, and physical location of personnel to be assigned to the implementation of the subcontract. Offerors shall also provide a list of focal points, with phone numbers and other contact information, who will be the direct contacts under the subcontract and provide each focal point’s direct supervisor’s name, title, and contact information. There should be an adequate number of qualified personnel to achieve pharmaceutical quality assurance objectives. Qualification of all personnel must be in line with national regulations.

The offeror shall provide one paragraph job description, relevant to the scope of work, for each of the positions within your distribution organization. The offeror shall provide the CVs of staff in these key positions, that will be assigned to the subcontract, and CVs of the management personnel which shall be included in an annex to the technical proposal and will not count against the page limit. Key positions are as follows, but offeror may modify per their organogram.

Key positions:
- Supervisor
- Transport Manager
- Account Manager
- Logistics/Distribution Manager (the position should ideally have at least two (2) or more years of experience in managing other staff, including drivers, ensuring accurate paperwork
and other data logs are completed reliably and accurately by drivers, ensuring boxes, containers and/or pallets are delivered on time and without damage, ensuring that the cold chain is maintained & monitored, and ensuring that communication between distribution provider and outsourcer is seamless and reliable.

**Additional core positions may include, but not required:**

- Dispatch Personnel
- Receiving Personnel
- Inventory Controller
- Inventory Personnel
- Picking Operations Personnel
- Material Handling Equipment Personnel
- Safety, Health, Environmental & Quality (SHEQ) Manager

- Part 3: Corporate Capabilities, Experience, and Past Performance. This part shall be between 2 and 5 pages long but may not exceed 5 pages.

Part 3 must include a description of the company and organization, with appropriate reference to any parent company and subsidiaries. Offerors must include details demonstrating their experience and technical ability in implementing the Scope of Work in Section II.2 and Deliverables in Section II.3 below. Offerors must also present their experience storing, transporting, and handling vaccines that require cold chain. Offerors should demonstrate in its proposal a clear record of ensuring adequate funds are available for disbursement for high value bulk transactions. Additionally, offerors must include three (3) recent past performance references of similar work (under contracts or subcontracts) previously implemented as well as contact information for the companies for which such work was completed. Contact information must include at a minimum: name of point of contact who can speak to the offeror’s performance, name and address of the company for which the work was performed, and email and phone number of the point of contact. Offerors with experience providing services using US government (USG), USAID, or for humanitarian entities should include this in their past performance and references.

Chemonics reserves the right to check additional references not provided by an offeror.

The sections of the technical proposal stated above must respond to the detailed information set out in Section II of this RFP, which provides the background, states the scope of work, describes the deliverables, and provides a deliverables schedule.

**C. Cost Proposal**

Offerors must prepare and submit a cost proposal to Chemonics. The cost proposal, and prices contained therein, will be used by Chemonics to determine which proposals represent the best value and serves as a basis of negotiation before Chemonics awards an FFP subcontract(s). The negotiated prices will inform the deliverable prices in the FFP subcontract(s). Offerors are strongly encouraged to propose their best and most competitive prices (price per vial) for transportation services.

The maximum aggregate value of all subcontract(s) awarded to the selected subcontractor(s) under is not expected to exceed the **$US 85,000.** Offerors are expected to propose the most efficient and optimized routes from the pickup location at CMS to the distribution points, as outlined in Annex 11, and provide the best value. The estimated quantities to be delivered to each district hospital as well as estimated arrival dates, container storage capacity, and other key order information are provided in Annex 11 as well. Please
note that the pickup locations outlined in this RFP are subject to change but should be used to build the fixed rates as required in Annex 2.

The offerors’ cost proposal shall consist of the following three parts:

Part 1: Price of Services

The cost proposal is used to determine which proposals represent the best value and serves as a basis of negotiation before award of a subcontract.

The price of the subcontract to be awarded will be an all-inclusive fixed price, inclusive of the temperature loggers, which are required for each CMS cooler shipper, labor and all non-labor costs, such as fringe, travel/transport, and other direct cost. Nevertheless, for the purpose of the proposal, offerors must provide:
1) a fixed price table containing a proposed price per vaccine vial using the distribution plan in Annex 11, 2) a budget narrative, 3) a detailed budget showing major line item, and 4) a sample routing plan as requested under Part 2 and 3 below. The separate detailed budget total must in match the fixed priced table to be completed (in the excel distribution plan in Annex 11). Only fixed prices (per vaccine vial) in the pricing table provided in the Annex 11 distribution plan excel sheet will be considered for comparison with other offerors and inclusion in the FFP subcontract. Chemonics may at any time during the evaluation period, and at its sole discretion, require offerors to submit additional information to further assess and validate offerors’ proposed prices for allowability, allocability, and reasonability. No profit, fees, taxes, or additional costs may be added after award.

Please refer to Annex 2 for detailed instructions.

All cost information must be expressed in U.S. Dollars (USD).

Taxes and VAT: Because GHSC-PSM is a USAID funded project and is implemented under a bilateral agreement between the Namibia and the U.S. Government, offerors must not include VAT and customs duties in their cost proposal.

Part 2: Cost Notes

Offerors must prepare and submit Cost Notes (or a brief budget narrative) that explains the basis for their proposed prices. For example, if the offeror proposed $1.65 per vial to ship to Katima Mulilo in the Zambezi region, the offeror should explain all of the various costs that are included in the price of $1.65 per vial (to ship the vials to the Zambezi region). Similarly, if the offeror proposed $1.13 per vial as the price of shipping to Andara in the Kavango West region, the offeror should explain what cost factors are included in its proposed price of $1.13 per vial (to ship to Andara in the Kavango West region). If Chemonics at any time requests additional information from offerors to understand the offerors’ proposed prices, the offerors must submit the additional information requested. The offeror’s cost notes must provide sufficient detail to allow Chemonics to clearly see and understand the type of costs included in the offeror’s proposed fixed prices (such as insurance, fuel, labor, maintenance).

For the award, Chemonics expects route optimization and multi-drop loads, where distribution plans and planning permit, thus allowing for efficiencies and reduced pricing. Chemonics reserves the right to request additional price information if the evaluation committee has concerns of the reasonableness, realism, or completeness of an offeror’s proposed prices.
Part 3: Routing Plan Exercise

Offerors must provide an example routing plan outlining how they have detailed routes and communicated routing plans to clients previously. Chemonics expects to see examples of efficient and optimized routing plans, ideally in MS Excel, to understand the Offerors’ capability to develop optimized routes and how that could affect pricing.

Under no circumstances may cost information be included in the technical proposal. No cost information or any prices, whether for deliverables or line items, may be included in the technical proposal. Cost information must only be shown in the cost proposal.

Please find under Annex 11 the distribution plan as an excel attachment as well as the estimated delivery dates, tentative quantities to be picked up from the CMS and delivered to the 35 district hospitals, and other order information in a separate excel attachment for preparing your cost proposal.

I.8 Evaluation and Basis for Award

An award will be made to the offeror whose proposal is determined to be responsive to this solicitation document, meets the eligibility criteria stated in this RFP, meets the technical, management/personnel, and corporate capability requirements, and is determined to represent the best value to Chemonics. Best value will be decided using the tradeoff process.

This RFP will use the tradeoff process to determine best value. That means that each proposal will be evaluated and scored against the evaluation criteria and evaluation sub-criteria, which are stated in the table below. Cost proposals are not assigned points as part of the Technical evaluation, but for overall evaluation purposes of this RFP, technical evaluation factors other than cost, when combined, are considered significantly more important than cost factors. If technical scores are determined to be equal or nearly equal, cost will become the determining factor.

In evaluating proposals, Chemonics will use the following evaluation criteria and sub-criteria:

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
<th>Evaluation Sub-criteria</th>
<th>Maximum Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical capacity</td>
<td>Approach and Methodology: Does the technical approach and detailed service implementation methodology proposed fulfill the requirements of the Scope of Work and expected deliverables effectively and efficiently?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fleet Size, Quality, and Variety: Total number, variety and adequacy of vehicles (Please refer to Annex 5, the vehicles verification checklist) in offeror’s fleet (with trucks of varying size that meet the specifications included in the RFP);</td>
<td>35 points</td>
</tr>
<tr>
<td></td>
<td>Proof of Fleet Ownership: Chemonics will use the offeror’s title and registration to confirm the whether the offeror owns its entire fleet.</td>
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<tr>
<td></td>
<td>Capability for comprehensive in-transit tracking. Does the offeror have the capacity to track its vehicles on any given route, and provide accurate and genuine route-verification data and reports to Chemonics upon request or as required in the SOW? If offeror has not adopted GPS capabilities, has</td>
<td>10 points</td>
</tr>
<tr>
<td>the offeror sufficiently described its processes and ability to track vehicles in a similar efficient manner?</td>
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<td></td>
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<tr>
<td>Capability to provide proofs of delivery (PODs) with real-time/daily updates. Preference will be given to offerors who can provide electronic POD. If offeror has not implemented electronic PODs, does the offeror sufficiently describe their system or methodology to submit hard copy PODs on-time?</td>
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<tr>
<td>Standard Operating Procedures: The offeror’s standard operating practices:</td>
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<tr>
<td>• Capacity to demonstrate that vaccines were kept under cold chain conditions (2-8 deg Celsius) while in transit using data loggers with downloadable memory.</td>
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</tr>
<tr>
<td>• Capacity for transportation of cold chain pharmaceuticals, preferably vaccines</td>
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<td></td>
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<tr>
<td>• Security, that covers the full range of security issues related to the distribution of products, lives, and property</td>
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<td></td>
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<tr>
<td>• Vehicle and equipment maintenance</td>
<td></td>
<td></td>
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<tr>
<td>• Incident management and reporting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Points – Technical Capacity 65 Points</td>
<td></td>
<td></td>
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<tr>
<td>Performance Capability</td>
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<td></td>
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<tr>
<td>Past Performance - Successful past performance providing services as requested in the RFP. Please include at least three (3) references from current (past 5-7 years) clients as part of proposal submission (including name, address, representative, phone, and email address). Include any USG or USAID funded, or humanitarian clients if relevant.</td>
<td></td>
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<tr>
<td>Successful past performance providing services as requested in the RFP. relevant factors include:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Description of company or organization, including parent company or subsidiaries</td>
<td></td>
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<tr>
<td>• Experience and technical ability to implement the scope of work</td>
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<tr>
<td>• Percentage of on-time delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Number of deliveries per year to municipal and facility levels in Namibia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Track record of dispatching vehicles quickly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Points – Performance Capability 35 points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Points 100 points</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Evaluation points will not be awarded for cost. Cost will primarily be evaluated for realism and reasonableness. If technical scores are determined to be nearly equal, cost will become the determining factor.

This RFP utilizes the tradeoff process set forth in FAR 15.101-1. Chemonics will award a subcontract to the offeror whose proposal represents the best value to Chemonics and the GHSC-PSM project. Chemonics may award to a higher priced offeror if a determination is made that the higher technical evaluation of that offeror merits the additional cost/price.

I.9 Negotiations

Best offer proposals are requested. It is anticipated that a subcontract will be awarded solely on the basis of the original offers received. However, Chemonics reserves the right to conduct discussions, negotiations and/or request clarifications prior to awarding a subcontract. Furthermore, Chemonics reserves the right to conduct a competitive range and to limit the number of offerors in the competitive range to permit an efficient evaluation environment among the most highly-rated proposals. Highest-rated offerors, as determined by the technical evaluation committee, may be asked to submit their best prices or technical responses during a competitive range. At the sole discretion of Chemonics, offerors may be requested to conduct oral presentations. If deemed an opportunity, Chemonics reserves the right to make separate awards per component or to make no award at all.

I.10 Terms of Subcontract

This is a request for proposals only and in no way obligates Chemonics to award a subcontract. In the event of subcontract negotiations, any resulting subcontract will be subject to and governed by the terms and clauses detailed in Section III. Chemonics will use the template shown in section III to finalize the subcontract. Terms and clauses are not subject to negotiation. By submitting a proposal, offerors certify that they understand and agree to all of the terms and clauses contained in section III.

I.11 Insurance and Services

Prior to starting work, the Subcontractor at its own expense, shall maintain in force, on all its operations, insurance as required herein. The Subcontractor shall maintain insurance to cover the following for the duration of the period of performance:

1) Goods In Transit
The Subcontractor shall maintain an insurance policy covering Goods in Transit (GIT) for full replacement value of commodities being transported for the duration of the activity. Upon request, the proof of insurance shall be submitted at award prior to commencement of the activity. The GIT shall meet the following requirements:

(i) Valuation: Liability for cargo loss or damage to Chemonics’ goods shall be based on full replacement value at 110% of commodity value (calculated based on cost of commodities plus freight plus 10%) for all commodities being transported for the duration of the subcontract.
(ii) Coverage: All risks including Fire, Theft, Dishonest Acts, Quake, Flood, and Wind as well as War Clauses and Strikes clauses as applicable
(iii) Product insured: all commodities transported under the subcontract
(iv) **Beneficiary or Loss Payee**: Subcontractor shall be responsible for payment as direct reimbursement to Chemonics within 60 days of loss or damage, unless otherwise agreed in writing by both parties.

2) **Commercial General Liability**

Commercial general liability insurance with a combined bodily injury and property damage limit of not less than **$1,000,000** per event (other than goods/products) which covers, at a minimum, premises, independent contractor, contractual liability, personal and advertising injury.

3) **Workers Compensation**

Workers’ compensation insurance in accordance with the applicable laws of Namibia.

4) **Auto/Vehicle Insurance**

Comprehensive liability insurance for vehicles or other equipment operated, owned or leased by the Subcontractor for the provision of services in accordance with the applicable laws of Namibia.

**Limitation of Liability**

- To the extent the Subcontractor uses any auxiliary employees or subcontractors, or other persons, to perform the services, the Subcontractor shall assume full responsibility and liability pursuant to this agreement for the acts and omissions of such persons as if they were the Subcontractor’s own acts and omissions.
- Unless otherwise stated within this agreement neither party shall be liable for any indirect, pure financial, consequential or punitive losses howsoever arising under this agreement.
- **Notice of Loss or Damage.** The Subcontractor shall remain responsible for the care, custody and control of the goods according to the standards herein and Subcontractor’s SOPs while the goods are in Subcontractor’s care, until the goods are transferred to Chemonics’ identified recipient. The Subcontractor will notify Chemonics in writing of any loss of damage to the goods handled by Subcontractor promptly after discovery of same, and in no case more than forty-eight (48) hours after confirmation of loss or damage.

**I. 12 Privity**

By submitting a response to this request for proposals, offerors understand that USAID is NOT a party to this solicitation and the offeror agrees that any protest hereunder must be presented—in writing with full explanations—to Chemonics International for consideration, as USAID will not consider protests made to it under USAID-financed subcontracts. Chemonics, at its sole discretion, will make a final decision on the protest for this procurement.
Section II  Background, Scope of Work, Deliverables, and Deliverables Schedule

II.1. Background

Chemonics International, Inc. (hereinafter referred to as “Chemonics”), with its consortium partners, implements the U.S. Agency for International Development (USAID) Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) single award indefinite delivery indefinite quantity (IDIQ) contract. The purpose of GHSC-PSM is to ensure an uninterrupted supply of health commodities. GHSC-PSM is fulfilling this purpose by purchasing and delivering health commodities, offering comprehensive technical assistance to strengthen national supply chain systems, and providing global supply chain leadership to ensure that lifesaving health supplies reach those most in need. GHSC-PSM delivers health products for the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the U.S. President’s Malaria Initiative (PMI), USAID’s family planning and reproductive health program, USAID’s maternal, newborn, and child health program, and USAID’s COVID-19 procurement project.

II.2. Scope of Work

The purpose of the final awarded subcontract(s) is to engage the successful offeror(s) to provide services to GHSC-PSM for the handling, transportation and distribution of roughly 1,350,000 doses (135,000 vials) of COVID-19 vaccines from the CMS in Windhoek to some or all of the 35 district hospitals as specified in Annex 11. The selected subcontractor(s) will implement and follow the World Health Organization (WHO) Good Distribution Practices, WHO Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products, (outlined in Annexes 6, 7, and 9) and consultation provided by GHSC-PSM on relevant quality standards. The selected subcontractor(s) shall be responsible for the safety and security of its personnel and property, and of the commodities and property in the Subcontractor’s custody. The final awarded subcontract(s) will utilize firm fixed unit prices for delivery from the Central Medical Store in Windhoek to the 35 district hospitals (see Annexes 2 and 11).

Offerors shall consider the following requirements and guidelines when responding to this request:

- Trucks used for the transportation of COVID-19 vaccines and health commodities will:
  - Use data loggers with downloadable memory to demonstrate that vaccines were kept under cold chain conditions (2-8 deg Celsius) while in transit. The data loggers should be packaged within the cooler boxes at CMS and have the capability for downloadable memory to demonstrate storage conditions.
  - Provide fully enclosed, lockable cargo compartments/clean containers attached to truck at all times during the transport.
  - Be appropriate for the volume and type of commodities being shipped.
  - Be clean, dry, and free of vermin and cleaning records shall be maintained for vehicles and for reusable shipping containers.
  - Well-serviced and regularly maintained in proper working order, with no damage that would impact their ability to operate.
  - Compartments must be well covered and padded to ensure that the temperature within the compartments are conducive and like warehousing storage conditions.
  - Equipment and containers must be suitable for their use, clean, and appropriately protect products from exposure to conditions that could affect their stability or packaging integrity.
  - May not be passenger vehicles leased from public or private transportation organizations.
o Must have a tracking device and GPS data to monitor the location of vehicles and duration of time travelled in the delivery of COVID-19 vaccines and health commodities.

o Ensure that the commodities and quantities match the shipping documents prior to taking possession of the commodities. The Offeror must notify Chemonics immediately of any damage, tampering, theft or missing items upon arrival or during transit.

o Load and transport commodities within 1 day of notification by Chemonics.

o Take the most direct route while in transit.

o Trucks and trailers of trucks to be used for the work will be subject to visual inspection by Chemonics. Prior to any transportation activity, truck make and model, and trailer plate numbers of equipment to be used and locations parked should be provided. All drivers must possess valid driver license.

o Offeror is responsible for loading prior to transit and off-loading at delivery destinations, including labor and other costs associated with off-loading.

o Use a security seal, record the number on the POD, and confirm the condition and number at delivery.

o Maintain the trucks in optimal working conditions throughout the durations of the subcontract.

o Maintenance (mechanical, electrical and otherwise), including the fueling of the truck(s) will be entirely the responsibility of the Offeror and recorded in a maintenance log.

• Drivers used for the transportation of medicines and related medical supplies will:

  o Be sufficient in number to distribute COVID-19 vaccines and health commodities to the destinations in the timeframe specified.

  o Be sufficiently literate to manage the inventory of listed COVID-19 vaccines and health commodities. Drivers may be assigned the responsibilities of keeping the truck movement log and maintenance schedule.

  o Be responsible and accountable for the COVID-19 vaccines and health commodities from the point they are loaded on the trucks, up to the point they are offloaded and delivered and shall ensure all the stipulated documentation is completed to demonstrate clear transfer of custody of commodities between the truck and the recipient.

• Offeror will be legally and financially responsible for the commodities during the transportation process and is required to provide insurance against all loss or damage to products as specified below.

• Offeror must continually assess security in the operating environment and must communicate all changes or concerns immediately to Chemonics.

• Offeror shall deliver COVID-19 vaccines and health commodities safely and securely and in prescribed condition to the recipient and destination, as evidenced by a signed Proof of Delivery (POD). PODs must include: consignee name and physical address, delivery location; date of departure; list and description of commodities delivered; quantity of items delivered; date and time of delivery; batch and lot numbers of the commodities being delivered; name and signature of driver and recipient at destination; remarks or notation of any loss or damages. PODs should be submitted with the subcontractor’s invoice to Chemonics.

• Offeror is responsible for all offloading costs at the point of delivery, including labor.

• Offeror shall supervise the offloading and handover of the correct quantity of commodities to the designated recipient(s).

• SOPs shall be in place for all vehicles and equipment involved in the distribution process, including:

  o Using data loggers with downloadable memory to demonstrate that vaccines were kept under cold chain conditions (2-8 deg Celsius) while in transit. The data loggers should be
packaged within the cooler boxes at CMS and have the capability for downloadable memory to demonstrate storage conditions.

- Cleaning
- Pest control
- Ensuring the product’s identity is maintained
- Prevention of cross-contamination
- Precautions against spillage or breakage
- Procedures for transportation of hazardous products which can present risks of abuse, cleaning, maintenance, fire or explosion (these products are to be stored and transported in safe dedicated containers and vehicles)
- Process wherein unauthorized persons are prevented from entering and/or tampering with vehicles and/or equipment
- Theft or misappropriation thereof.

- Waste shall be disposed of safely and properly at frequent intervals.
- Vehicles must be loaded in a manner that cargo is stable and limits the possibility of shifting during transport. Necessary materials should be used to secure the cargo to prevent movement and subsequent damage to the cargo.

Subcontractor shall be responsible for providing transportation services in accordance with the World Health Organization (WHO) Good Distribution Practices for Pharmaceutical Products, WHO Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products (outlined in Annexes 6, 7, and 9), and consultation provided by GHSC-PSM on relevant quality standards. The Subcontractor shall be responsible for the safety and security of its personnel and property, and of the commodities and property in the Subcontractor’s custody.

II.2.1 Subcontractor Responsibilities

General

For each purchase order issued hereunder, the Subcontractor shall complete the following:

- Load vehicles and confirm that the commodities loaded correspond to the shipment documentation, and the routing plan for each distribution cycle. Discrepancies, damage or other issues shall be noted and reported.
- Offload and deliver the correct quantity of commodities and transfer to the respective warehouse and/or facility in accordance to the distribution plan/delivery order into the designated/identified receiving spaces; transference of custody shall be given to the designated receiving officer.
- Carefully monitor the distribution and rapidly address any issues that arise including issues related to accessibility, vehicle breakdown, lagging delivery times or security. GHSC-PSM shall be notified immediately through phone calls and subsequently with an email within 24 hours regarding any issues that will hinder completion of distribution within the stipulated timelines.
- Provide adequate resources to complete all deliveries to required destinations within the stipulated time intervals.
- Provide licensed drivers that comply with a strict “no drinking” policy.

Distributions

Distribution plans shall be provided on a routine basis, at the discretion of Chemonics.
• Subcontractor shall be required to begin transporting the COVID-19 vaccines within the specified period of time mentioned in the subcontract.
• Deliveries shall be made during normal business hours, excluding public holidays.
• Subcontractor shall provide “emergency order requirements” to service delivery points if requested by Chemonics, provided adequate stock is available, within 48 hours (inclusive of weekends) of notification.

II.2.2 Proof of Delivery Requirements

• PODs shall include the following:
  - Consignee name and physical address
  - Delivery location
  - Date of departure
  - List and description of commodities delivered
  - Unit pack: quantity, weight, volume, batch number, manufactured and expiry dates, and unit prices
  - Details of issuing warehouse/distribution agents and the service delivery point representative
  - Vehicle registration number and security seal number
  - Quantities and volume (in cubic meters) of commodities distributed
  - Date and time of delivery
  - Name and signature of warehouse representative, driver, and recipient at destination
  - Remarks or notation of any loss or damages.

• Subcontractor shall deliver Chemonics’ COVID-19 vaccines safely and securely and in prescribed condition to the recipient and destination, as evidenced by a signed Proof of Delivery (POD).
  o **Electronic proof of delivery (e-POD) systems with real-time cloud access and GPS tracking shall be utilized** to increase accuracy and efficiency.
• Subcontractor will provide written confirmation, i.e. Proof of Delivery (POD), to Chemonics for all delivered shipments. PODs should be submitted with the subcontractor’s invoice to Chemonics.

II.2.3 Chemonics Responsibilities

• Chemonics will provide an updated list of service delivery points per province prior to the commencement of a distribution. Depending on the directives of the USG and/or the needs of supported implementing partners, the location and number of the facilities may vary.
• In line with the information submitted by the Subcontractor or the facility/IP on excess or shortfalls of supplies that may result in expiries or stock out, Chemonics will advise on stock redistribution either from the warehouse and/or other service delivery points as appropriate to avert wastage or expiries.
• Chemonics will prepare and ensure that the state officials, and other relevant stakeholders in the respective states, health workers in the respective health facilities and relevant stakeholders are ready and available for the distribution and receipt of the commodities in the respective facilities.

II.2.4 Security and Disaster Recovery

• Subcontractor shall ensure and deploy reasonable and cost-effective strategies, actions, processes and measures to ensure that all commodities being transported are not lost in transit, from the point of pick up until custody is transferred to the designated recipients. These strategies, actions, processes and measures must be approved by Chemonics and include, but are not limited to the following:
i. Planned routes for transit of vehicles are the safest available, based on an assessment of the various options;
ii. Vehicles are parked in secure locations after close of business to ensure both commodity and vehicle security;
iii. Incidents are investigated.

- Subcontractor shall maintain appropriate disaster recovery and security systems to provide continuity of services in case of causes beyond the control and without the fault or negligence of the Subcontractor such as (1) acts of God or of the public enemy, (2) acts of the government in either its sovereign or contractual capacity, (3) fires, (4) floods, (5) epidemics, (6) quarantine restrictions, (7) strikes, (8) freight embargoes, and (9) unusually severe weather, or (10) security breach (each a “Force Majeure Event”). During a Force Majeure Event, Subcontractor and Chemonics shall discuss the continued and uninterrupted provision of services and Chemonics shall reasonably consider any request by Subcontractor to alter the performance and deliverable timelines for a limited period of time, but in no case longer than thirty (30) days. For purposes of clarity, the parties agree that a Force Majeure Event shall not excuse performance by the Subcontractor in the orders issued hereunder.
- Immediately upon occurrence of any Force Majeure Event, the Subcontractor shall implement the alternate performance deliverable timelines and, unless the parties agree otherwise, make best efforts to recover data and resume operations within forty-eight (48) hours thereafter.
- Should the Subcontractor suffer a Force Majeure Event, the Subcontractor shall use all reasonable efforts to ensure the continuity of services. If after implementation of an approved alternate delivery timetable, the Force Majeure Event prevents the Subcontractor from carrying out its obligations under this Agreement for a continuous period of more than thirty (30) Business Days, Chemonics may terminate this Subcontract in accordance with Section C.6.

II.3. Deliverables

Payment will be made to the awarded offeror(s) on the basis of delivered vaccines, as substantiated by the following documents and in accordance with the schedule set forth in II.4 below.

The deliverables to verify transport of the vaccines from the pickup location at CMS in Windhoek to some or all of the 35 service delivery points in the 14 regions identified in Annex 11 will be specified in the resulting subcontract(s), and content will be developed further based on the successful Offeror’s proposal and Section II of the RFP. The following deliverables are illustrative of what the successful offeror shall submit in order to verify completed orders:

**Deliverable No. 1: Proof of Deliveries (PODs)**

a) Electronic proof of delivery (e-POD) systems with real-time cloud access and GPS tracking shall be utilized to increase accuracy and efficiency. Both hard copies and e-POD shall be used for deliveries.

b) The subcontractor shall provide scanned PODs, at the latest 48 hours after completing the distribution, to the GHSC-PSM in Namibia Field Office and original copies to be submitted with the invoice and activity report.

c) PODs shall be individually and uniquely numbered.

d) Hard copy PODs must come in quadruplicate. The original copy shall be retained by the Offeror(s) and returned to GHSC-PSM for invoicing and payments. After that, it becomes the property of GHSC-PSM. The remaining 3 copies shall be distributed thus: one copy for the receiving district hospital, one copy for the originating warehouse (the...
CMS in Windhoek), and the third one for GHSC-PSM representative supervising and managing the distribution.

e) There shall be a separate, completely signed documentation (POD) for every transfer of COVID-19 vaccines.

f) The Offeror(s) shall be available for the reconciliation that is expected to happen within 48 hours of conclusion of the transportation operations.

g) PODs must be completed using **number of COVID-19 vaccines vials as the standard unit of measure**.

h) The service provider must also provide a summary report detailing which commodities were delivered to which district hospitals (with quantities included) to go along with the POD submissions.

Chemonics may require additional deliverables, such as downloaded memory data from the required temperature loggers packaged within the shipment coolers to verify storage conditions remain at 2-8 degrees Celsius while in transit, based on offerors’ proposal(s) that will be determined during negotiations, and preceding award.

**II.4. Deliverables Schedule**

The successful offeror shall submit the deliverables described above in accordance with the following deliverables schedule:

<table>
<thead>
<tr>
<th>Deliverable Number</th>
<th>Deliverable Name</th>
<th>Due Date</th>
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<tbody>
<tr>
<td>1</td>
<td>PODs</td>
<td>Scanned and electronic: 48 hours after completion of approved distribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Original: four (4) business days</td>
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<tr>
<td>2</td>
<td>Other (TBD) Deliverables</td>
<td>TBD</td>
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</tbody>
</table>

*Deliverable numbers and names refer to those fully described in II.3 above.*
**Section III  Firm Fixed Price Subcontract (Terms and Clauses)**

**FIXED PRICE SUBCONTRACT**

**Between**

CHEMONICS INTERNATIONAL INC.
Hereinafter referred to as the Contractor or Chemonics

And

**(INSERT SUBCONTRACTOR NAME here)**
Hereinafter referred to as the Subcontractor

For

**(insert Contract Name here)**
**USAID PRIME CONTRACT NO.**  **(insert contract number here, and Task Order No. if applicable)**

Subcontract number:  **(insert Subcontract Number here)** (from D365, if applicable)

Start Date:  **(insert date here)**

End Date:  **(insert date here)**

**Total Fixed price:**

[insert amount here – local subcontracts must be in local currency. If total fixed price exceeds $250,000 or 5% of the total prime contract value, CO consent is required per FAR 52.244-2. As Chemonics has an Approved Purchasing System, the project submits a notification to the CO to signal its intent to subcontract, instead of submitting a CO Consent Request (unless the project, at the request of its CO, agreed to continue submitting Subcontracting Consent Requests to the CO)].

**ISSUED BY:**
Chemonics International Inc.
1717 H Street, N.W.
Washington, D.C. 20006

**ISSUED TO:**
**(INSERT SUBCONTRACTOR NAME AND ADDRESS)**

Subcontractor Tax ID Number:  **(INSERT Subcontractor Employer Identification Number (EIN) or local tax reference number as applicable)**

Subcontractor DUNS Number:  **(INSERT Subcontractor DUNS for awards valued at $30,000USD or higher unless exempted. Delete if not applicable).**
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Background, Scope of Work, Deliverables and Deliverables Schedule</td>
<td>26</td>
</tr>
<tr>
<td>B</td>
<td>Reporting and Technical Direction</td>
<td>31</td>
</tr>
<tr>
<td>C</td>
<td>Period of Performance</td>
<td>32</td>
</tr>
<tr>
<td>D</td>
<td>Subcontract Fixed Price, Invoicing and Payment</td>
<td>32</td>
</tr>
<tr>
<td>E</td>
<td>Branding Policy</td>
<td>33</td>
</tr>
<tr>
<td>F</td>
<td>Authorized Geographic Code; Source and Nationality Requirement [AIDAR 752.225-70 (Feb 2012) as altered]</td>
<td>33</td>
</tr>
<tr>
<td>G</td>
<td>Intellectual Property Rights</td>
<td>34</td>
</tr>
<tr>
<td>H</td>
<td>Indemnity and Subcontractor Waiver of Benefits</td>
<td>34</td>
</tr>
<tr>
<td>I</td>
<td>Compliance with Applicable Laws and Regulations</td>
<td>35</td>
</tr>
<tr>
<td>J</td>
<td>Privity of Contract and Communications</td>
<td>35</td>
</tr>
<tr>
<td>K</td>
<td>Protecting Chemonics’ Interests when Subcontractor is Named on Suspected Terrorists or Blocked Individuals Lists, Ineligible to Receive USAID Funding, or Suspended, Debarred or Excluded from Receiving Federal Funds</td>
<td>36</td>
</tr>
<tr>
<td>L</td>
<td>Governing Law and Resolution of Disputes</td>
<td>36</td>
</tr>
<tr>
<td>M</td>
<td>Set-Off Clause</td>
<td>37</td>
</tr>
<tr>
<td>N</td>
<td>Assignment and Delegation</td>
<td>37</td>
</tr>
<tr>
<td>O</td>
<td>Organizational Conflicts of Interest</td>
<td>37</td>
</tr>
<tr>
<td>P</td>
<td>Gratuities and Anti-Kickback</td>
<td>37</td>
</tr>
<tr>
<td>Q</td>
<td>Terrorist Financing Prohibition/ Executive Order 13224</td>
<td>38</td>
</tr>
<tr>
<td>R</td>
<td>Restrictions On Certain Foreign Purchases (FAR 52.225-13)</td>
<td>38</td>
</tr>
<tr>
<td>S</td>
<td>Compliance With U.S. Export Laws</td>
<td>38</td>
</tr>
<tr>
<td>T</td>
<td>Compliance With U.S. Anti-Corruption Regulations</td>
<td>39</td>
</tr>
<tr>
<td>U</td>
<td>Subcontractor Performance Standards</td>
<td>39</td>
</tr>
<tr>
<td>V</td>
<td>Subcontractor Employee Whistleblower Rights</td>
<td>40</td>
</tr>
<tr>
<td>W</td>
<td>Reporting on Subcontractor Data Pursuant to the Requirements of the Federal Funding Accountability and Transparency Act</td>
<td>40</td>
</tr>
<tr>
<td>X</td>
<td>Miscellaneous</td>
<td>41</td>
</tr>
<tr>
<td>Y</td>
<td>Insurance Requirements</td>
<td>42</td>
</tr>
<tr>
<td>YY</td>
<td>Security</td>
<td>43</td>
</tr>
<tr>
<td>YYYY</td>
<td>Standard Expanded Security</td>
<td>44</td>
</tr>
<tr>
<td>YYYYY</td>
<td>Privacy Shield</td>
<td>45</td>
</tr>
<tr>
<td>Z</td>
<td>Federal Acquisition Regulation (FAR) And Agency For International Development Acquisition Regulation (AIDAR) Flowdown Provisions For Subcontracts And Task Orders Under USAID Prime Contracts</td>
<td>46</td>
</tr>
</tbody>
</table>
The Subcontractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein.

The rights and obligations of the parties to this fixed price subcontract shall be subject to and governed by the following documents: (a) this subcontract; (b) such provisions and specifications as are attached or incorporated by reference herein. (Attachments are listed herein.).

For

Chemonics International Inc.
By:

____________
{name}
{title of officer}
Date Signed: {insert date}
Place Signed: {insert place}

For

{Subcontractor’s name}
By:

____________
{name}
{title of officer}
Date Signed: {insert date}
Place Signed: {insert place}

Chemonics is an Equal Opportunity Employer and we do not discriminate on the basis of race, color, sex, national origin, religion, age, equal pay, disability, and genetic information.
Section A. Background, Scope of Work, Deliverables and Deliverables Schedule

A.1. Background

Chemonics International, Inc. (hereinafter referred to as “Chemonics”), with its consortium partners, implements the U.S. Agency for International Development (USAID) Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) single award indefinite delivery indefinite quantity (IDIQ) contract. The purpose of GHSC-PSM is to ensure an uninterrupted supply of health commodities. GHSC-PSM is fulfilling this purpose by purchasing and delivering health commodities, offering comprehensive technical assistance to strengthen national supply chain systems, and providing global supply chain leadership to ensure that lifesaving health supplies reach those most in need. GHSC-PSM delivers health products for the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the U.S. President’s Malaria Initiative (PMI), USAID’s family planning and reproductive health program, USAID’s maternal, newborn, and child health program, and USAID’s COVID-19 procurement project.

A.2. Scope of Work

The purpose of the final awarded subcontract(s) is to engage the successful offeror(s) to provide services to GHSC-PSM for the handling, transportation and distribution of COVID-19 vaccines and health commodities from the pick up location at the CMS in Windhoek to 35 district hospitals in quantities as specified in Annex 11. The selected subcontractor(s) will implement and follow the World Health Organization (WHO) Good Distribution Practices, WHO Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products, (outlined in Annexes 6, 7, and 9) and consultation provided by GHSC-PSM on relevant quality standards. The selected subcontractor(s) shall be responsible for the safety and security of its personnel and property, and of the commodities and property in the Subcontractor’s custody. The final awarded subcontract(s) will utilize firm fixed unit prices per km per truck by truck type based on a) delivery from the Central Medical Store located in Windhoek to 35 district hospitals in all 14 regions of Namibia, and b) the volume and/or weight of vaccines and COVID-19 vaccines and health commodities to be delivered to those locations (see Annex 11).

Offerors shall consider the following requirements and guidelines when responding to this request:

- Trucks used for the transportation of COVID-19 vaccines and health commodities will:
  - Use data loggers with downloadable memory to demonstrate that vaccines were kept under cold chain conditions (2-8 deg Celsius) while in transit. The data loggers should be packaged within the cooler boxes at CMS and have the capability for downloadable memory to demonstrate storage conditions.
  - Provide fully enclosed, lockable cargo compartments/clean containers attached to truck at all times during the transport
  - Be appropriate for the volume and type of commodities being shipped
  - Be clean, dry, and free of vermin and cleaning records shall be maintained for vehicles and for reusable shipping containers
  - Well-serviced and regularly maintained in proper working order, with no damage that would impact their ability to operate
  - Compartments must be well covered and padded to ensure that the temperature within the compartments are conducive and like warehousing storage conditions
  - Equipment and containers must be suitable for their use, clean, and appropriately protect products from exposure to conditions that could affect their stability or packaging integrity
May not be passenger vehicles leased from public or private transportation organizations.

Must have a tracking device and GPS data to monitor the location of vehicles and duration of time travelled in the delivery of COVID-19 vaccines and health commodities.

Ensure that the commodities and quantities match the shipping documents prior to taking possession of the commodities. The Offeror must notify Chemonics immediately of any damage, tampering, theft or missing items upon arrival or during transit.

Load and transport commodities within 1 day of notification by Chemonics.

Take the most direct route while in transit.

Trucks and trailers of trucks to be used for the work will be subject to visual inspection by Chemonics. Prior to any transportation activity, truck make and model, and trailer plate numbers of equipment to be used and locations parked should be provided. All drivers must possess valid driver license.

Offeror is responsible for loading prior to transit and off-loading at delivery destinations, including labor and other costs associated with off-loading.

Use a security seal, record the number on the POD, and confirm the condition and number at delivery.

Maintain the trucks in optimal working conditions throughout the durations of the subcontract.

Maintenance (mechanical, electrical and otherwise), including the fueling of the truck(s) will be entirely the responsibility of the Offeror and recorded in a maintenance log.

Drivers used for the transportation of medicines and related medical supplies will:

Be sufficient in number to distribute COVID-19 vaccines and health commodities to the destinations in the timeframe specified.

Be sufficiently literate to manage the inventory of listed COVID-19 vaccines and health commodities. Drivers may be assigned the responsibilities of keeping the truck movement log and maintenance schedule.

Be responsible and accountable for the COVID-19 vaccines and health commodities from the point they are loaded on the trucks, up to the point they are offloaded and delivered and shall ensure all the stipulated documentation is completed to demonstrate clear transfer of custody of commodities between the truck and the recipient.

Offeror will be legally and financially responsible for the commodities during the transportation process and is required to provide insurance against all loss or damage to products as specified below.

Offeror must continually assess security in the operating environment and must communicate all changes or concerns immediately to Chemonics.

Offeror shall deliver COVID-19 vaccines and health commodities safely and securely and in prescribed condition to the recipient and destination, as evidenced by a signed Proof of Delivery (POD). PODs must include: consignee name and physical address, delivery location; date of departure; list and description of commodities delivered; quantity of items delivered; date and time of delivery; batch and lot numbers of the commodities being delivered; name and signature of driver and recipient at destination; remarks or notation of any loss or damages. PODs should be submitted with the subcontractor’s invoice to Chemonics.

Offeror is responsible for all offloading costs at the point of delivery, including labor.

Offeror shall supervise the offloading and handover of the correct quantity of commodities to the designated recipient(s).

SOPs shall be in place for all vehicles and equipment involved in the distribution process, including:

Using data loggers with downloadable memory to demonstrate that vaccines were kept under cold chain conditions (2-8 deg Celsius) while in transit. The data loggers should be
packaged within the cooler boxes at CMS and have the capability for downloadable memory to demonstrate storage conditions.

- Cleaning
- Pest control
- Ensuring the product’s identity is maintained
- Prevention of cross-contamination
- Precautions against spillage or breakage
- Procedures for transportation of hazardous products which can present risks of abuse, cleaning, maintenance, fire or explosion (these products are to be stored and transported in safe dedicated containers and vehicles)
- Process wherein unauthorized persons are prevented from entering and/or tampering with vehicles and/or equipment
- Theft or misappropriation thereof.

- Waste shall be disposed of safely and properly at frequent intervals.
- Vehicles must be loaded in a manner that cargo is stable and limits the possibility of shifting during transport. Necessary materials should be used to secure the cargo to prevent movement and subsequent damage to the cargo.

Subcontractor shall be responsible for providing transportation services in accordance with the World Health Organization (WHO) Good Distribution Practices for Pharmaceutical Products, WHO Model Guidance for the Storage and Transport of Time - and Temperature-Sensitive Pharmaceutical Products (outlined in Annexes 6, 7, and 9), and consultation provided by GHSC-PSM on relevant quality standards. The Subcontractor shall be responsible for the safety and security of its personnel and property, and of the commodities and property in the Subcontractor’s custody.

A.2.1 Subcontractor Responsibilities

General

For each purchase order issued hereunder, the Subcontractor shall complete the following:

- Load vehicles and confirm that the commodities loaded correspond to the shipment documentation, and the routing plan for each distribution cycle. Discrepancies, damage or other issues shall be noted and reported.
- Offload and deliver the correct quantity of commodities and transfer to the respective warehouse and/or facility in accordance to the distribution plan/delivery order into the designated/identified receiving spaces; transference of custody shall be given to the designated receiving officer.
- Carefully monitor the distribution and rapidly address any issues that arise including issues related to accessibility, vehicle breakdown, lagging delivery times or security. GHSC-PSM shall be notified immediately through phone calls and subsequently with an email within 24 hours regarding any issues that arise that will hinder completion of distribution within the stipulated timelines.
- Provide adequate resources to complete all deliveries to required destinations within the stipulated time intervals.
- Provide licensed drivers that comply with a strict “no drinking” policy.

Distributions

Distribution plans shall be provided on a routine basis, at the discretion of Chemonics.
• Subcontractor shall be required to begin transporting the COVID-19 vaccines within the specified period of time mentioned in the subcontract.
• Deliveries shall be made during normal business hours, excluding public holidays.
• Subcontractor shall provide “emergency order requirements” to service delivery points if requested by Chemonics, provided adequate stock is available, within 48 hours (inclusive of weekends) of notification.

A.2.2 Proof of Delivery Requirements

• PODs shall include the following:
  - Consignee name and physical address
  - Delivery location
  - Date of departure
  - List and description of commodities delivered
  - Unit pack: quantity, weight, volume, batch number, manufactured and expiry dates, and unit prices
  - Details of issuing warehouse/distribution agents and the service delivery point representative
  - Vehicle registration number and security seal number
  - Quantities and volume (in cubic meters) of commodities distributed
  - Date and time of delivery
  - Name and signature of warehouse representative, driver, and recipient at destination
  - Remarks or notation of any loss or damages.

• Subcontractor shall deliver Chemonics’ COVID-19 vaccines safely and securely and in prescribed condition to the recipient and destination, as evidenced by a signed Proof of Delivery (POD).
  - Electronic proof of delivery (e-POD) systems with real-time cloud access and GPS tracking shall be utilized to increase accuracy and efficiency.
• Subcontractor will provide written confirmation, i.e. Proof of Delivery (POD), to Chemonics for all delivered shipments. PODs should be submitted with the subcontractor’s invoice to Chemonics.

A.2.3 Chemonics Responsibilities

• Chemonics will provide an updated list of service delivery points per province prior to the commencement of a distribution. Depending on the directives of the USG and/or the needs of supported implementing partners, the location and number of the facilities may vary.
• In line with the information submitted by the Subcontractor or the facility/IP on excess or shortfall of supplies that may result in expiries or stock out, Chemonics will advise on stock redistribution either from the warehouse and/or other service delivery points as appropriate to avert wastage or expiries.
• Chemonics will prepare and ensure that the state officials, and other relevant stakeholders in the respective states, health workers in the respective health facilities and relevant stakeholders are ready and available for the distribution and receipt of the commodities in the respective facilities.

A.2.4 Security and Disaster Recovery

• Subcontractor shall ensure and deploy reasonable and cost-effective strategies, actions, processes and measures to ensure that all commodities being transported are not lost in transit, from the point of pick up until custody is transferred to the designated recipients. These strategies, actions, processes and measures must be approved by Chemonics and include, but are not limited to the following:
iv. Planned routes for transit of vehicles are the safest available, based on an assessment of the various options;

v. Vehicles are parked in secure locations after close of business to ensure both commodity and vehicle security;

vi. Incidents are investigated.

- Subcontractor shall maintain appropriate disaster recovery and security systems to provide continuity of services in case of causes beyond the control and without the fault or negligence of the Subcontractor such as (1) acts of God or of the public enemy, (2) acts of the government in either its sovereign or contractual capacity, (3) fires, (4) floods, (5) epidemics, (6) quarantine restrictions, (7) strikes, (8) freight embargoes, and (9) unusually severe weather, or (10) security breach (each a “Force Majeure Event”). During a Force Majeure Event, Subcontractor and Chemonics shall discuss the continued and uninterrupted provision of services and Chemonics shall reasonably consider any request by Subcontractor to alter the performance and deliverable timelines for a limited period of time, but in no case longer than thirty (30) days. For purposes of clarity, the parties agree that a Force Majeure Event shall not excuse performance by the Subcontractor in the orders issued hereunder.

- Immediately upon occurrence of any Force Majeure Event, the Subcontractor shall implement the alternate performance deliverable timelines and, unless the parties agree otherwise, make best efforts to recover data and resume operations within forty-eight (48) hours thereafter.

- Should the Subcontractor suffer a Force Majeure Event, the Subcontractor shall use all reasonable efforts to ensure the continuity of services. If after implementation of an approved alternate delivery timetable, the Force Majeure Event prevents the Subcontractor from carrying out its obligations under this Agreement for a continuous period of more than thirty (30) Business Days, Chemonics may terminate this Subcontract in accordance with Section C.6.

A.3. Deliverables

Payment will be made to the awarded offeror(s) on the basis of delivered vaccines, as substantiated by the following documents and in accordance with the schedule set forth in II.4 below.

The deliverables to verify transport of the vaccines from the pickup location at CMS in Windhoek to some or all of the 35 service delivery points in the 14 regions identified in Annex 11 will be specified in the resulting subcontract(s), and content will be developed further based on the successful Offeror’s proposal and Section II of the RFP. The following deliverables are illustrative of what the successful offeror shall submit in order to verify completed orders:

**Deliverable No. 1: Proof of Deliveries (PODs)**

a) Electronic proof of delivery (e-POD) systems with real-time cloud access and GPS tracking shall be utilized to increase accuracy and efficiency. Both hard copies and e-POD shall be used for deliveries.

b) The subcontractor shall provide scanned PODs, at the latest 48 hours after completing the distribution, to the GHSC-PSM in Namibia Field Office and original copies to be submitted with the invoice and activity report.

c) PODs shall be individually and uniquely numbered and use the number of COVID-19 vaccines vials as the standard unit of measure.

d) Hard copy PODs must come in quadruplicate. The original copy shall be retained by the Offeror(s) and returned to GHSC-PSM for invoicing and payments. After that, it becomes the property of GHSC-PSM. The remaining 3 copies shall be distributed thus: one copy for the receiving district hospital, one copy for the
originating warehouse (the CMS in Windhoek), and the third one for GHSC-PSM representative supervising and managing the distribution.

e) There shall be a separate, completely signed documentation (POD) for every transfer of COVID-19 vaccine vials.

f) The Offeror(s) shall be available for the reconciliation that is expected to happen within 48 hours of conclusion of the transportation operations.

g) The service provider must also provide a summary report detailing which commodities were delivered to which district hospitals (with quantities included) to go along with the POD submissions.

Chemonics may require additional deliverables based on offerors’ proposal(s) that will be determined during negotiations, and preceding award (ex: downloaded memory data from the required temperature loggers to verify that cold chain temperatures of 2-8 degrees Celsius are maintained while the vaccines are in transit and/or in storage).

A.4. Deliverables Schedule

The Subcontractor shall submit the deliverables described above in accordance with the following Deliverables Schedule:

<table>
<thead>
<tr>
<th>Deliverable Number</th>
<th>Deliverable Name</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PODs</td>
<td>Scanned and electronic: 48 hours after completion of approved distribution Original: four (4) business days</td>
</tr>
<tr>
<td>2</td>
<td>Other (TBD) Deliverables</td>
<td>TBD</td>
</tr>
</tbody>
</table>

*Deliverable numbers and names refer to those fully described in Section A.3, above.

Chemonics reserves the unilateral right to terminate this fixed price subcontract at any time, paying for all deliverables completed at the time of termination and a pro-rata share of any deliverable in progress, in accordance with FAR Clause 52.249-1, Termination for Convenience of the Government (Fixed Price) (Short Form) (April 1984), which is incorporated by reference herein.

Chemonics may order changes in the scope of work above pursuant to the Federal Acquisition Regulation (FAR) Clause 52.243-1 (Alt.III), Changes—Fixed Price, which is incorporated by reference herein.

Any change in the Subcontractor's scope of work and/or deliverable(s) requires prior written authorization of Chemonics through a modification to this subcontract.

Section B. Reporting and Technical Direction

(a) Only Chemonics’ INSERT ‘Senior Vice President or the Chief of Party’ if the subcontract is within the COP DOA, if not, insert ‘Senior Vice President’) has authority on behalf of Chemonics to make changes to this Subcontract. All modifications must be identified as such in writing and executed by the parties.

(b) (specify name and title -- usually COP or Program Manager) will be responsible for monitoring the Subcontractor’s performance under this fixed price subcontract and may from time to time render assistance or give technical advice or discuss or effect an exchange of information with Subcontractor's personnel concerning the Work hereunder. No such action shall be deemed to be a change under the
"Changes" clause of this Subcontract and shall not be the basis for equitable adjustment. The (specify name and title -- usually COP or Program Manager), or his/her designee, has authority to request, inspect, and accept all services, reports, and required deliverables or outputs.

(c) Except as otherwise provided herein, all notices to be furnished by Subcontractor shall be in writing and sent to (specify name and title -- usually COP or Program Manager) or other authorized project staff member.

Section C. Period of Performance

The effective date of this fixed price subcontract is (fill in date when work must begin, not earlier than signature date), and the completion date is (fill in date). The Subcontractor shall deliver the deliverables set forth in Section A., Background, Scope of Work, Deliverables and Deliverables Schedule to the (designate receiving person) in accordance with the schedule stipulated therein.

In the event that the Subcontractor fails to make progress so as to endanger performance of this fixed price subcontract, or is unable to fulfill the terms of this fixed price subcontract by the completion date, the Subcontractor shall notify Chemonics forthwith and Chemonics shall have the right to summary termination of this fixed price subcontract upon written notice to the Subcontractor in accordance with the incorporated FAR Clause 52.249-8, Default (Fixed-Price Supply and Service).

Section D. Subcontract Fixed Price, Invoicing and Payment

D.1. Subcontract Fixed Price

As consideration for the delivery of all of the products and/or services stipulated in Section A., Chemonics will pay the Subcontractor a total of US$ XX,XXX (Amount must be denominated in local currency if a local subcontract). This figure represents the total price of this subcontract and is fixed for the period of performance outlined in Section C., Period of Performance. Chemonics will pay the total price through a series of installment payments. Chemonics will make each payment subject to Section D.3, below, after Subcontractor’s completion of the corresponding deliverable indicated in the following table:

<table>
<thead>
<tr>
<th>Installment Number and Amount</th>
<th>Corresponding Deliverable Number(s) and Name(s)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. $XX,XXX</td>
<td>1. (Deliverable No. 1 Name)</td>
</tr>
<tr>
<td>2. $YY,YYY</td>
<td>2. (Deliverable No. 2 Name)</td>
</tr>
</tbody>
</table>

*Deliverable numbers and names refer to those fully described in Section A.3, above.

D.2. Invoicing

Upon technical acceptance of the contract deliverables described in Section A., Background, Scope of Work, Deliverables and Deliverables Schedule, by the Chemonics representative identified herein, the Subcontractor shall submit an original invoice to (insert project name) for payment. The invoice shall be sent to the attention of (insert name and designation of person who will receive invoices) and shall include the following information: a) subcontract number, b) deliverables delivered and accepted, c) total amount due in (choose either US dollars or specify a local currency if this is a local subcontract), per Section D.1., above; and d) payment information corresponding to the authorized account listed in D.3, below.

D.3. Payment Account Information
Cohonics shall remit payment corresponding to approved, complete invoices submitted in accordance with the terms herein payable to the Subcontractor via check sent to the Subcontractor’s official address or to the following authorized account:
Account name: (INSERT Account name provided by the Subcontractor)
Bank name: (INSERT Subcontractor’s bank name)
Bank address or branch location: (INSERT Subcontractor's bank address or branch location)
Account number: (INSERT Subcontractor's bank account SWIFT and IBAN reference as applicable)

D.4. Payment

Chemonics will pay the Subcontractor’s invoice within thirty (30) business days after both a) Chemonics’ approval of the Subcontractor’s deliverables, and b) Chemonics’ receipt of the Subcontractor’s invoice. Payment will be made in (choose either US dollars or specify a local currency if this is a local subcontract), paid to the account specified in Section D.3.

Section E. Branding Policy
The Subcontractor shall comply with the requirements of the USAID “Graphic Standard Manual” available at www.usaid.gov/branding, or any successor branding policy, and the Project specific branding implementation and marking plan, which shall be conveyed to the Subcontractor by Chemonics in writing.

Section F. Authorized Geographic Code; Source and Nationality Requirement [AIDAR 752.225-70 (Feb 2012) as altered]

(a) The authorized geographic code for procurement of goods and services under this subcontract is {insert applicable geographic code}.

(b) Except as may be specifically approved by Chemonics, the Subcontractor must procure all commodities (e.g., equipment, materials, vehicles, supplies) and services (including commodity transportation services) in accordance with the requirements at 22 CFR Part 228 —Rules on Procurement of Commodities and Services Financed by USAID Federal Program Funds. Guidance on eligibility of specific goods or services may be obtained from Chemonics.

(c) Ineligible goods and services. The Subcontractor shall not procure any of the following goods or services under this subcontract:
(1) Military equipment
(2) Surveillance equipment
(3) Commodities and services for support of police and other law enforcement activities
(4) Abortion equipment and services
(5) Luxury goods and gambling equipment, or
(6) Weather modification equipment.

(d) Restricted goods. The Subcontractor shall not procure any of the following goods or services without the prior written approval of USAID obtained through Chemonics:
(1) Agricultural commodities,
(2) Motor vehicles,
(3) Pharmaceuticals and contraceptive items
(4) Pesticides,
(5) Fertilizer,
(6) Used equipment, or
(7) U.S. government-owned excess property.

If Chemonics determines that the Subcontractor has procured any of these specific restricted this subcontract without the prior written authorization of USAID through Chemonics and has received payment for such purposes, Chemonics may require the Subcontractor to refund the entire amount of the purchase.

Section G. Intellectual Property Rights

(a) Subcontractor warrants that the Work performed or delivered under this Subcontract will not infringe or otherwise violate the intellectual property rights of any third party in the United States or any foreign country. Except to the extent that the U.S. Government assumes liability therefor, Subcontractor shall defend, indemnify, and hold harmless Chemonics and its clients from and against any claims, damages, losses, costs, and expenses, including reasonable attorneys’ fees, arising out of any action by a third party that is based upon a claim that the Work performed or delivered under this Subcontract infringes or otherwise violates the intellectual property rights of any person or entity. This indemnity and hold harmless shall not be considered an allowable cost under any provisions of this Subcontract except with regard to allowable insurance costs.

(b) Subcontractor’s obligation to defend, indemnify, and hold harmless Chemonics and its customers under Paragraph (a) above shall not apply to the extent FAR 52.227-1 “Authorization and Consent” applies to Chemonics’ Prime Contract for infringement of a U.S. patent and Chemonics and its clients are not subject to any actions for claims, damages, losses, costs, and expenses, including reasonable attorneys’ fees by a third party.

(c) In addition to any other allocation of rights in data and inventions set forth in this agreement, Subcontractor agrees that Chemonics, in the performance of its prime or higher tier contract obligations (including obligations of follow-on contracts or contracts for subsequent phases of the same program), shall have under this agreement an unlimited, irrevocable, paid-up, royalty-free right to make, have made, sell, offer for sale, use, execute, reproduce, display, perform, distribute (internally or externally) copies of, and prepare derivative works, and authorize others to do any, some or all of the foregoing, any and all, inventions, discoveries, improvements, mask works and patents as well as any and all data, copyrights, reports, and works of authorship, conceived, developed, generated or delivered in performance of this Contract.

(d) The tangible medium storing all reports, memoranda or other materials in written form including machine readable form, prepared by Subcontractor and furnished to Chemonics pursuant to this Subcontract shall become the sole property of Chemonics.

Section H. Indemnity and Subcontractor Waiver of Benefits

The Subcontractor shall defend, indemnify, and hold harmless Chemonics from any loss, damage, liability, claims, demands, suits, or judgments (“Claims”) including any reasonable attorney’s fees, and costs, as a result of any damage or injury to Chemonics or its employees, directors, officers, or agents, or properties, or for any injury to third persons (including, but not limited to Claims by Subcontractor’s employees, directors, officers or agents) or their property which is directly or indirectly caused by the negligence, willful misconduct, breach of this Subcontract, or violation of statutory duties of Subcontractor, or its employees, officers, directors, or agents, arising out of or in connection with the performance of this Subcontract unless such Claim is caused by, or resulting from, a material breach of this Subcontract by Chemonics.
Section I. Compliance with Applicable Laws and Regulations

(a) The Subcontractor shall perform all work, and comply in all respects, with applicable laws, ordinances, codes, regulations, and other authoritative rules of the United States and its political subdivisions and with the standards of relevant licensing boards and professional associations. The Subcontractor shall also comply with the applicable USAID regulations governing this subcontract, which are incorporated by reference into this subcontract, and appear in Section Z, Clauses Incorporated by Reference.

(b) This contract shall be governed and construed under the laws of the District of Columbia, except that subcontract provisions and requirements that are based on government contract laws, regulations, or Federal Acquisition Regulation clauses shall be construed in accordance with the federal common law of Government Contracts as represented by decisions of the Federal Courts, and the Armed Services and Civilian Boards of Contract Appeals.

(c) The Subcontractor shall further undertake to perform the services hereunder in accordance with the highest standards of professional and ethical competence and integrity in Subcontractor’s industry and to ensure that Subcontractor’s employees assigned to perform any services under this subcontract will conduct themselves in a manner consistent therewith.

1. The Subcontractor shall exercise due diligence to prevent and detect criminal conduct and otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with law.

2. The Subcontractor shall timely disclose, in writing, to Chemonics and the USAID Office of the Inspector General (OIG), whenever, in connection with this subcontract, or any Order issued hereunder, if applicable, the Subcontractor has credible evidence that a principal, employee, agent, or subcontractor of the Subcontractor has committed a violation of the provisions against fraud, conflict of interest, bribery or gratuity, or false claims found in this subcontract.

3. The Subcontractor shall refer to FAR 52.203-13 Contractor Code of Business Ethics and Conduct incorporated by reference herein for applicability of additional requirements.”

Section J. Privity of Contract and Communications

The Subcontractor shall not communicate with Chemonics’ client in connection with this Subcontract, except as expressly permitted, in writing, by Chemonics. All approvals required from USAID shall be obtained through Chemonics.

This provision does not prohibit the Subcontractor from communicating with the client with respect to:

(a) matters the Subcontractor is required by law to communicate to the U.S. Government;

(b) an ethics or anti-corruption matter;

(c) any matter for which this Subcontract, including a FAR or AIDAR clause is included in this Subcontract, provides for direct communication by the Subcontractor to the U.S. Government; or

(d) if Subcontractor is a U.S. small business concern, any material matter pertaining to payment or utilization.
Section K. Protecting Chemonics’ Interests when Subcontractor is Named on Suspected Terrorists or Blocked Individuals Lists, Ineligible to Receive USAID Funding, or Suspended, Debarred or Excluded from Receiving Federal Funds

In addition to any other rights provided under this subcontract, it is further understood and agreed that Chemonics shall be at liberty to terminate this subcontract immediately at any time following any of the following conditions:

(a) the Subcontractor is named on any list of suspected terrorists or blocked individuals maintained by the U.S. Government, including but not limited to (a) the Annex to Executive Order No. 13224 (2001) (Executive Order Blocking Property and Prohibiting Transactions with Persons Who Commit, Threaten to Commit, or Support Terrorism), or (b) the List of Specially Designated Nationals and Blocked persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury;

(b) USAID determines that the Subcontractor is ineligible to receive USAID funding pursuant to U.S. laws and regulations; or

(c) the Subcontractor is identified on the U.S. Government’s Excluded Party List System, or successor listing, as being suspended, debarred, or excluded from receiving federal awards or assistance.

Notwithstanding any other provision of the Subcontract, upon such termination the Subcontractor shall have no right to receive any further payments.

Section L. Governing Law and Resolution of Disputes

(a) Governing law. This Subcontract shall be governed and construed under the laws of the District of Columbia, except that subcontract provisions and requirements that are based on government contract laws, regulations, or Federal Acquisition Regulation clauses shall be construed in accordance with the federal common law of Government Contracts as represented by decisions of the Federal Courts, and the Armed Services and Civilian Boards of Contract Appeals.

(b) Disputes based on Client Actions.
1) Any decision of the Government under the Prime Contract, if binding on Chemonics, shall also bind the Subcontractor to the extent that it relates to this Subcontract, provided that Chemonics shall have promptly notified the Subcontractor of such decision and, if requested by Subcontractor, shall have brought suit or filed claim, as appropriate against the Government, or, in alternative, agreed to sponsor Subcontractor’s suit or claim. A final judgment in any such suit or final disposition of such claim shall be conclusive upon the Subcontractor.

2) For any action brought, or sponsored, by Chemonics on behalf of the Subcontractor pursuant to this clause, the Subcontractor agrees to indemnify and hold Chemonics harmless from all costs and expenses incurred by Chemonics in prosecuting or sponsoring any such appeal.

(c) Other Disputes. All disputes not covered under subparagraph (b) above shall be resolved by arbitration administered by the American Arbitration Association in accordance with its Commercial Arbitration Rules. Arbitration shall be conducted in Washington, DC. Arbitrators shall be empowered to award only direct damages consistent with the terms of this Agreement. Each party shall bear its own costs of arbitration, including attorneys’ and experts’ fees. An arbitration decision shall be final and judgment may be entered upon it in accordance with applicable law in any court having jurisdiction.

(d) Duty to Continue to Perform. Notwithstanding any such dispute, the Subcontractor shall proceed diligently with performance under this Subcontract in accordance with the Contractor's directions.

(e) Limitations. Chemonics’ entire liability for claims arising from or related to this Subcontract will in no event exceed the total subcontract fixed price. Except for indemnification obligations, neither the Subcontractor or Chemonics will have any liability arising from or related to this Subcontract for (i) special,
incidental, exemplary, or indirect damages, or for any economic consequential damages, or (ii) lost profits, business, revenue, goodwill or anticipated savings, even if any of the foregoing is foreseeable or even if a party has been advised of the possibility of such damages.

The Subcontractor acknowledges and agrees that it has no direct action against the U.S. Government or USAID for any claims arising under this Subcontract.

Section M. Set-Off Clause

Chemonics reserves the right of set-off against amounts payable to Subcontractor under this Subcontract or any other agreement the amount of any claim or refunds Chemonics may have against Subcontractor.

Section N. Assignment and Delegation

This Subcontract agreement may not be assigned or delegated, in whole or in part, by the Subcontractor without the written consent of Chemonics. Absent such consent, any assignment is void.

Section O. Organizational Conflicts of Interest

It is understood and agreed that some of the work performed under this subcontract may place the Subcontractor or its personnel in the position of having an organizational conflict of interest. Such an organizational conflict of interest may impair the objectivity of the Subcontractor or its personnel in performing the work. To preclude or mitigate any potential conflicts of interest, Subcontractor agrees not to undertake any activity which may result in an organizational conflict of interest without first notifying Chemonics of such potential conflict of interest and receiving Chemonics written approval to undertake such activities.

Section P. Gratuities and Anti-Kickback

(a) Subcontractor shall not offer or give a kickback or gratuity (in the form of entertainment, gifts, or otherwise) for the purpose of obtaining or rewarding favorable treatment as a Chemonics supplier.

(b) By accepting this Subcontract, Subcontractor certifies and represents that it has not made or solicited and will not make or solicit kickbacks in violation of FAR 52.203-7 or the Anti-Kickback Act of 1986 (41 USC 51-58), both of which are incorporated herein by this specific reference, except that paragraph (c)(1) of FAR 52.203-7 shall not apply.

Section Q. Terrorist Financing Prohibition/ Executive Order 13224

The Subcontractor (including its employees, consultants and agents) by entering into this subcontract certifies that it does not engage, support or finance individuals and/or organizations associated with terrorism. The Subcontractor is reminded that U.S. Executive Orders and U.S. law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. A list of entities and individuals subject to restrictions, prohibitions and sanctions can be found at the web site of the Department of Treasury’s Office of Foreign Assets Control (OFAC), at http://treasury.gov/ofac. It is the legal responsibility of the Subcontractor to ensure compliance with the Executive Order 13224 and other U.S. laws prohibiting terrorist financing. This provision must be included in all subcontracts or subawards issued under this subcontract.

Section R. Restrictions on Certain Foreign Purchases (FAR 52.225-13)
Except as authorized by the Department of Treasury’s Office of Foreign Assets Control (OFAC), the Subcontractor shall not acquire for its use in the performance of this subcontract, any supplies or services if any proclamation, U.S. Executive Order, U.S. statute, or OFAC’s implementing regulations (31 CFR Chapter V), would prohibit such a transaction by a U.S. person, as defined by law.

Except as authorized by OFAC, most transactions involving Cuba, Iran, North Korea, and Syria are prohibited, including importing/exporting to/from the United States, engaging in financial transactions, or facilitating any prohibited transactions by third parties. Lists of entities and individuals subject to economic sanctions – which are updated routinely - are included in OFAC’s List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn. It is the Subcontractor’s responsibility to remain informed as to sanctioned parties and to ensure compliance with all relevant U.S. sanctions and trade restrictions. More information about these restrictions, as well as updates, is available in the OFAC’s regulations at 31 CFR Chapter V and/or on OFAC’s website at http://www.treas.gov/offices/enforcement/ofac.

The Subcontractor shall insert this clause, including this paragraph, in all subcontracts and subawards issued under this subcontract.

Section S. Compliance with U.S. Export Laws

Subcontractor warrants and agrees to comply with all U.S. export laws and regulations and other applicable U.S. law and regulations, including but not limited to: (i) the Arms Export Control Act (AECA), 22 U.S.C. 2778 and 2779; (ii) Trading with the Enemy Act (TWEA), 50 U.S.C. App. §§ 1-44; (iii) International Traffic in Arms Regulations (ITAR), 22 C.F.R. Parts 120-130.; (iv) Export Administration Act (EAA) of 1979 and the Export Administration Regulations (EAR) 15 C.F.R. Parts 730-774, (including the EAR anti-boycott provision); (v) the International Emergency Economic Powers Act (IEEPA), 50 U.S.C. 1701-1706 and Executive Orders of the President under IEEPA, 50 U.S.C. app. §§ 2401-2420; (vi) Office of Foreign Asset Controls (OFAC) Regulations, 31 C.F.R. Parts 500-598; and (vii) other applicable U.S. laws and regulations.

As required, subject to Chemonics’ prior approval for all exports or imports under the Subcontract, Subcontractor shall determine any export license, reporting, filing or other requirements, obtain any export license or other official authorization, and carry out any customs formalities for the export of goods or services. Subcontractor agrees to cooperate in providing any reports, authorizations, or other documentation related to export compliance requested by Chemonics. Subcontractor agrees to indemnify, hold harmless and defend Chemonics for any losses, liabilities and claims, including as penalties or fines as a result of any regulatory action taken against Chemonics as a result of Subcontractor’s non-compliance with this provision.

Section T. Compliance with U.S. Anti-Corruption Regulations

Subcontractor represents and warrants that it shall comply fully with the anti-bribery provisions of the U.S. Foreign Corrupt Practices Act, as amended (“FCPA”), as well as the a) UN Convention against Corruption (UNCAC), b) OECD Convention on the Bribery of Foreign Public Officials (OECD Convention); and c) any other applicable local anti-corruption laws, rules, and regulations if any part of this subcontract will be performed outside of the United States of America. Specifically, Subcontractor understands and agrees that it shall be unlawful for the Subcontractor and/or any officer, director, employee or agent of the Subcontractor to make any kind of offer, payment, promise to pay, or authorization of the payment of any money, or offer, gift, promise to give, or authorization of the giving of anything of value to:
1. *any foreign official* (or foreign political party) for purposes of either influencing any act or decision of such foreign official in his official capacity, or inducing such foreign official to do or omit to do any act in violation of the lawful duty of such official, or securing any improper advantage, or inducing such foreign official to use his influence with a foreign government, or instrumentality thereof, to affect or influence any act or decision of such government or instrumentality in order to assist such person in obtaining or retaining business for or with, or directing business to any person; or

2. *any person*, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official (or foreign political party), or to any candidate for foreign political office, for any of the prohibited purposes described above.

For purposes of this Subcontract “foreign official” means any appointed, elected, or honorary official or employee of a) a foreign government (or if this Subcontract is to be performed outside the United States than of the Host Country) or political party, or b) of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization (e.g., the UN, DFID, or WHO, or the World Bank).

For purposes of this Article, the “government” includes any agency, department, embassy, or other governmental entity, and any company or other entity owned or controlled by the government.

Section U. Subcontractor Performance Standards

(a) Subcontractor agrees to provide the services required hereunder in accordance with the requirements set forth in this Subcontract. Subcontractor undertakes to perform the services hereunder in accordance with the highest standards of professional and ethical competence and integrity in Subcontractor’s industry and to ensure that employees assigned to perform any services under this subcontract will conduct themselves in a manner consistent therewith. The services will be rendered by Subcontractor: (1) in an efficient, safe, courteous, and businesslike manner; (2) in accordance with any specific instructions issued from time to time by Chemonics; and (3) to the extent consistent with items (1) and (2), as economically as sound business judgment warrants. Subcontractor shall provide the services of qualified personnel through all stages of this subcontract. Subcontractor represents and warrants that it is in compliance with all the applicable laws of the United States and any other Jurisdiction in which the services shall be performed. Subcontractor shall perform the services as an independent Subcontractor with the general guidance of Chemonics. The Subcontractor’s employees shall not act as agents or employees of Chemonics.

(b) Chemonics reserves the right to request the replacement of Subcontractor personnel and may terminate the subcontract due to nonperformance by the Subcontractor.

(c) Chemonics will use a variety of mechanisms to stay abreast of the Subcontractor’s performance under the subcontract, and of general progress toward attainment of the subcontract objectives. These may include:

1. Business meetings between the subcontract team, Chemonics and/or USAID
2. Feedback from key partners
3. Site visits by Chemonics personnel
4. Meetings to review and assess periodic work plans and progress reports
5. Reports

(d) Evaluation of the Subcontractor’s overall performance under this subcontract shall be conducted by Chemonics. In addition to review of Subcontractor reports and deliverables, Chemonics shall review the quality of Subcontractor performance under this subcontract on an annual basis. These reviews will be used to help determine the Subcontractor’s suitability for future subcontracts. The Subcontractor will be evaluated for:

Quality and timeliness of work. Provides personnel who are technically qualified, who foster a positive working environment, who are effective on the assignment and contribute to a team effort to accomplish tasks. Delegated tasks are completed in a timely manner. Reports are clear, concise, accurate, well-structured, easily comprehended, submitted on-time and contain actionable recommendations.

Responsiveness to Chemonics’ requests. Maintains open, direct, and responsive communications channels with Chemonics. Responses are rapid, helpful, accurate, and without undue delays.

Quality of financial management. Demonstrates cost control in meeting subcontract requirements. Complies with federal acquisition cost principles in terms of allowability, allocability and reasonableness of costs.

Quality of subcontract administration. Conducts contractually required tasks, such as personnel management, submittal of approval requests, and invoice submission, in a timely, compliant, and accurate manner. Recruitment efforts go beyond a simple review of CVs before submission to Chemonics to include first-hand contacts with candidates and performing reference checks.

Section V. Subcontractor Employee Whistleblower Rights

This Subcontract and Subcontractor employees working on this subcontract will be subject to the whistleblower rights and remedies in the pilot program on Contractor employee whistleblower protections established at 41 U.S.C. 4712 by section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L.112-239) and FAR 3.908.

The Subcontractor shall inform its employees in writing, in the predominant language of the workforce, of employee whistleblower rights and protections under 41 U.S.C. 4712, as described in section 3.908 of the Federal Acquisition Regulation.

If lower tier subcontracting is authorized in this subcontract, the Subcontractor shall insert the substance of this clause in all subcontracts over the simplified acquisition threshold.

Section W. Reporting on Subcontractor Data Pursuant to the Requirements of the Federal Funding Accountability and Transparency Act

a) Public Availability of Information.

Pursuant to the requirements of FAR 52.204-10, Chemonics is required to report information regarding its award of subcontracts and sub-task orders under indefinite delivery/indefinite quantity subcontracts to the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS). This information will be made publicly available at http://www.USASpending.gov.

(b) Subcontractor’s Responsibility to Report Identifying Data.
Within 7 days of an award of a subcontract or sub-task order with a value of $30,000 or greater unless exempted, the Subcontractor shall report its identifying data required by FAR 52.204-10 (including executive compensation, if applicable) in the required questionnaire and certification found in Section I.6. If the Subcontractor maintains a record in the System for Award Management (www.SAM.gov), the Subcontractor shall keep current such registration, including reporting of executive compensation data, as applicable. If reporting of executive compensation is applicable and the Subcontractor does not maintain a record in the System for Award Management, Subcontractor shall complete the “FSRS Reporting Questionnaire and Certification” found in Section I.6 within 7 days of each anniversary of the subcontract award date.

(c) Impracticality of Registration.
If obtaining a DUNS number and reporting data is impractical for the Subcontractor, the Subcontractor must notify Chemonics and shall submit to Chemonics within 7 days of subcontract award a memorandum detailing the attempts made by the Subcontractor to obtain registration and a justification of why registration and/or data reporting was impractical. Contractual remedies may apply unless Chemonics concurs with the documented impracticality of registration.

(d) Remedy.
Failure to comply with the reporting requirements in a timely manner as required under this section may constitute a material breach of the Subcontract and cause for withholding payment to the Subcontractor until the required information has been supplied to Chemonics or the Subcontractor demonstrates to Chemonics that its System for Award Management record has been updated. In addition to contractual remedies, Chemonics may make the Subcontractor’s failure to comply with the reporting requirements a part of the Subcontractor’s performance information record.

Section X. Miscellaneous

(a) This Subcontract embodies the entire agreement and understanding among the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings between or among the parties relating to the subject matter hereof. No statement, representation, warranty, covenant, or agreement of any kind not expressly set forth in this Subcontract shall affect, or be used to interpret, change, or restrict the express terms and provisions of this Subcontract. Each of the parties hereto agrees to cooperate with the other parties hereto in effectuating this Subcontract and to execute and deliver such further documents or instruments and to take such further actions as shall be reasonably requested in connection therewith.

(b) All statements, representations, warranties, covenants, and agreements in this Subcontract shall be binding on the parties hereto and shall inure to the benefit of the respective successors and permitted assigns of each Party hereto. Nothing in this Subcontract shall be construed to create any rights or obligations except among the parties hereto, and no person or entity shall be regarded as a third-party beneficiary of this Subcontract.

(c) In the event that any court of competent jurisdiction shall determine that any provision, or any portion thereof, contained in this Subcontract shall be unenforceable or invalid in any respect, then such provision shall be deemed limited to the extent that such court deems it valid or enforceable, and as so limited shall remain in full force and effect. In the event that such court shall deem any such provision partially or wholly unenforceable, the remaining provisions of this Subcontract shall nevertheless remain in full force and effect.
(d) The headings and captions contained in this Subcontract are for convenience only and shall not affect the meaning or interpretation of this Subcontract or of any of its terms or provisions.

(e) Unless otherwise specifically agreed in writing to the contrary: (i) the failure of any party at any time to require performance by the other of any provision of this Subcontract shall not affect such party’s right thereafter to enforce the same; (ii) no waiver by any party of any default by any other shall be valid unless in writing and acknowledged by an authorized representative of the non-defaulting party, and no such waiver shall be taken or held to be a waiver by such party of any other preceding or subsequent default; and (iii) no extension of time granted by any party for the performance of any obligation or act by any other party shall be deemed to be an extension of time for the performance of any other obligation or act hereunder.

(f) Each party has been represented by its own counsel in connection with the negotiation and preparation of this Subcontract and, consequently, each party hereby waives the application of any rule of law that would otherwise be applicable in connection with the interpretation of this Subcontract, including but not limited to any rule of law to the effect that any provision of this Subcontract shall be interpreted or construed against the party whose counsel drafted that provision.

(g) This Agreement may be executed in any number of counterparts, and by different parties hereto on separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Section Y. Insurance Requirements

Prior to starting work, the Subcontractor at its own expense, shall maintain in force, on all its operations, insurance as required herein. The Subcontractor shall maintain insurance to cover the following for the duration of the period of performance:

1) Goods In Transit
The Subcontractor shall maintain an insurance policy covering Goods in Transit (GIT) for full replacement value of commodities being transported for the duration of the activity. Upon request, the proof of insurance shall be submitted at award prior to commencement of the activity. The GIT shall meet the following requirements:

(v) Valuation: Liability for cargo loss or damage to Chemonics’ goods shall be based on full replacement value at 110% of commodity value (calculated based on cost of commodities plus freight plus 10%) for all commodities being transported for the duration of the subcontract.

(vi) Coverage: All risks including Fire, Theft, Dishonest Acts, Quake, Flood, and Wind as well as War Clauses and Strikes clauses as applicable

(vii) Product insured: all commodities transported under the subcontract

(viii) Beneficiary or Loss Payee: Subcontractor shall be responsible for payment as direct reimbursement to Chemonics within 60 days of loss or damage, unless otherwise agreed in writing by both parties.

2) Commercial General Liability

Commercial general liability insurance with a combined bodily injury and property damage limit of not less than $1,000,000 per event (other than goods/products) which covers, at a minimum, premises, independent contractor, contractual liability, personal and advertising injury.
3) Workers Compensation

Workers’ compensation insurance in accordance with the applicable laws of Namibia.

4) Auto/Vehicle Insurance

Comprehensive liability insurance for vehicles or other equipment operated, owned or leased by the Subcontractor for the provision of services in accordance with the applicable laws of Namibia.

Limitation of Liability

- To the extent the Subcontractor uses any auxiliary employees or subcontractors, or other persons, to perform the services, the Subcontractor shall assume full responsibility and liability pursuant to this agreement for the acts and omissions of such persons as if they were the Subcontractor’s own acts and omissions.
- Unless otherwise stated within this agreement neither party shall be liable for any indirect, pure financial, consequential or punitive losses howsoever arising under this agreement.
- Notice of Loss or Damage. The Subcontractor shall remain responsible for the care, custody and control of the goods according to the standards herein and Subcontractor’s SOPs while the goods are in Subcontractor’s care, until the goods are transferred to Chemonics’ identified recipient. The Subcontractor will notify Chemonics in writing of any loss of damage to the goods handled by Subcontractor promptly after discovery of same, and in no case more than forty-eight (48) hours after confirmation of loss or damage.

Section YY. Security

a. Operating Conditions – Assumption of the Risk

Performance of this Subcontract may involve work under dangerous and austere conditions that include, without limitation, social and political unrest, armed conflict, criminal and terrorist activity, unsanitary conditions and limited availability of health care. The Subcontractor warrants that it has assessed and evaluated the location of performance and nature of the work including, without limitation, local laws, regulations, operational and security conditions and assumes all risks of performance including injury to Subcontractor personnel and loss of damage to Subcontractor property, except as expressly provided herein.

(b) Access to Chemonics’ Facilities – Security Requirements

Subcontractor’s access to property under Chemonics’ control is subject to compliance with Chemonics’ security requirements. The Subcontractor agrees to provide all necessary information required for employees to be cleared for access to Chemonics’ facilities. When present on Chemonics’ property, or when Chemonics is providing transportation, the Subcontractor agrees that its employees will comply with Chemonics’ security-related procedures and directions. Failure to adhere to security procedures may lead to an immediate suspension of work, corrective action, or termination of the subcontract.

(c) Security Coordination, Reports of Security Threats and Incidents

The Subcontractor agrees to reasonably cooperate and coordinate with Chemonics to ensure the safety and security of personnel, property and project assets. Such coordination shall
include providing information concerning Subcontractor’s security platform for facilities that may be visited by Chemonics personnel, USAID, or other participants in the project.

The Subcontractor shall report, as soon as possible (in any case no later than 4 hours), any information concerning threats of actions that could result in injury persons, damage to property, or disruption to activities relating to the Subcontract ("Security Threats"). Security Threats must be reported to Chemonics Chief of Party or his/her designee.

The Subcontractor shall promptly report as “Security Incidents” any assault, damage, theft, sabotage, breach of secured facilities, and any other hostile or unlawful acts designed to cause harm to personnel, property, or activities relating to the Subcontract. Such reports must include, at a minimum (a) date, time and place of the location, (b) description of the events, (c) injuries to personnel or damage/loss of property, (d) witnesses, (e) current security assessment, and (f) other relevant information. Security Incident Reports must be sent to Chief of Party or his/her designee.

Section YYY. Standard Expanded Security

The Subcontractor shall be responsible for initiating, undertaking and supervising all safety and security precautions and programs in connection with the services to be provided pursuant to this Subcontract. The Subcontractor shall undertake affirmative actions to assure that adequate safety and security precautions and programs are implemented in all phases of performing services, production, control and distribution including by way of example but not limited to: (i) electronic data processing and information systems, (ii) physical security of plant, production, records and inventory, (iii) production control and control of inventory, (iv) control of distribution systems and (v) control of labor, including employees and officers of the Subcontractor, agents, contract or temporary employees and subconsultants. The Subcontractor shall comply with all applicable laws, rules, regulations and orders of any public authority having jurisdiction for the safety of persons or property. The direction, advice or input by Chemonics with respect to security precautions and programs in connection with the services to be provided shall not relieve the Subcontractor of the responsibility for establishing and maintaining such security precautions.

The Subcontractor shall implement and maintain adequate information security measures to protect against unauthorized access to or use of Users’ Data in accordance with the Gramm-Leach-Bliley Act, as it may be amended, and any regulations promulgated thereunder, including without limitation: (i) access controls on information systems, including controls to authenticate and permit access only to authorized individuals and controls to prevent employees from providing Users’ Data to unauthorized individuals who may seek to obtain this information through fraudulent means; (ii) access restrictions at physical locations containing Users’ Data, such as buildings, computer facilities, and records storage facilities to permit access only to authorized individuals; (iii) encryption of electronic Users’ Data where unauthorized individuals may reasonably foreseeably have access; (iv) procedures designed to ensure that information system modifications are consistent with the information security measures; (v) dual control procedures, segregation of duties, and employee background checks for employees with responsibilities for or access to Users’ Data; (vi) monitoring systems and procedures to detect actual and attempted attacks on or intrusions into information systems; (vii) response programs that specify actions to be taken when the Subcontractor detects unauthorized access to information systems, including immediate reports to Chemonics; (viii) measures to protect against destruction, loss or damage of Users’ Data due to potential environmental hazards, such as fire and water damage or technological failures; (ix) training of staff to implement the
information security measures; (x) regular testing of key controls, systems and procedures of the information security measures by independent third parties or staff independent of those that develop or maintain the security measures; and (xi) reporting to Chemonics on the results of its audit evaluations of the Subcontractor’s information security systems and procedures.

The Subcontractor will provide documentation of its security measures in form satisfactory to Chemonics as part of audit obligations under this subcontract. If the Subcontractor becomes aware of any unauthorized access to or unauthorized use of Chemonics’s data by a person (other than Chemonics, its affiliates, any of their respective employees or any of their other agents (i.e., an agent that is not the Subcontractor or an agent of the Subcontractor) accessing such systems through the service provider or its agents or has reason to believe that such unauthorized access or use will occur, the Subcontractor will promptly at its expense: (i) notify Chemonics in writing; (ii) investigate the circumstances relating to such actual or potential unauthorized access or use; (iii) take commercially reasonable steps to mitigate the effects of such actual or potential unauthorized access or use and to prevent any reoccurrence.

Section YYYY. Privacy Shield

For purposes of compliance with the EU-US Privacy Shield Framework (“Privacy Shield”), the Subcontractor agrees that it shall maintain the implementation of a data protection program which conforms to the same level of protection as is required by the Privacy Shield. To this end the Subcontractor shall:

1. Devise appropriate systems and procedures to ensure that its processing of the Personal Information is protected against unlawful destruction or accidental loss, alteration, unauthorized disclosure or access; and does not place Chemonics in breach of any of the privacy laws, which may include, without limitation, The Fair Credit Reporting Act, The Health Insurance Portability and Accountability Act, the Gramm-Leach-Bliley Act, the EU Directive 95/46/EC, the Regulation (EU) 2016/679, and EU Directive 2002/58/EC (collectively: “Privacy Laws”);

2. Promptly refer to Chemonics any requests, notices or other communication from data subjects, the national data protection authority established in the jurisdiction of Chemonics, or any other law enforcement authority, for such Chemonics to resolve;

3. Provide such information to Chemonics and take such action as Chemonics may reasonably require, and within the timeframes reasonably specified by Chemonics, to allow Chemonics to:
   a. Comply with the rights of data subjects in relation to the Personal Information, as required by law, including (where applicable) subject-access rights and rights of rectification, or with notices served by a national data protection authority; and gain access to information enabling Chemonics to supervise the processing of the Personal Information by the Subcontractor;
   b. Take all reasonable steps to ensure the reliability of any the Subcontractor employees, or other personnel, who have access to the Personal Information; and
   c. Respond to any investigation, inquiry, notice, or similar action by a regulator with proper jurisdiction over the processing of Personal Information undertaken by the Subcontractor.

4. Not transfer any Personal Information from the EU to any country outside of the EU (nor to any subcontractor located outside of the EU) without (i) putting in place appropriate legal safeguards for the protection of such Personal Information, (ii) if required by applicable law, entering into a data transfer and/or processing agreement with each
Chemonics affiliate, consistent with the requirements of applicable Law, and (iii) obtaining the prior written consent of Chemonics; and

5. Only collect, use, disclose, or otherwise process Personal Information upon instruction of Chemonics.

Section Z. Federal Acquisition Regulation (FAR) And Agency For International Development Acquisition Regulation (AIDAR) Flowdown Provisions For Subcontracts And Task Orders Under USAID Prime Contracts

Z.1 INCORPORATION OF FAR AND AIDAR CLAUSES
The FAR and AIDAR clauses referenced below are incorporated herein by reference, with the same force and effect as if they were given in full text, and are applicable, including any notes following the clause citation, to this Subcontract. If the date or substance of any of the clauses listed below is different from the date or substance of the clause actually incorporated in the Prime Contract referenced by number herein, the date or substance of the clause incorporated by said Prime Contract shall apply instead. The Contracts Disputes Act shall have no application to this Subcontract. Any reference to a “Disputes” clause shall mean the “Disputes” clause of this Subcontract.

Z.2 GOVERNMENT SUBCONTRACT
(a) This Subcontract is entered into by the parties in support of a U.S. Government contract.
(b) As used in the AIDAR clauses referenced below and otherwise in this Subcontract:
   1. "Commercial Item" means a commercial item as defined in FAR 2.101.
   2. "Contract" means this Subcontract.
   3. "Contracting Officer" shall mean the U.S. Government Contracting Officer for Chemonics' government prime contract under which this Subcontract is entered.
   4. "Contractor" and "Offeror" means the Subcontractor, which is the party identified on the face of the Subcontract with whom Chemonics is contracting, acting as the immediate subcontractor to Chemonics.
   6. "Subcontract" means any contract placed by subcontractor or lower-tier subcontractors under this Contract.

Z.3 NOTES
The following notes apply to the clauses incorporated by reference below only when specified in the parenthetical phrase following the clause title and date.
   1. Substitute "Chemonics" for "Government" or "United States" throughout this clause.
   2. Substitute "Chemonics Procurement Representative" for "Contracting Officer", "Administrative Contracting Officer", and "ACO" throughout this clause.
   3. Insert "and Chemonics" after "Government" throughout this clause.
   4. Insert "or Chemonics" after "Government" throughout this clause.
   5. Communication/notification required under this clause from/to Subcontractor to/from the USAID Contracting Officer shall be through Chemonics.
   6. Insert "and Chemonics" after "Contracting Officer", throughout the clause.
   7. Insert "or Chemonics Procurement Representative" after "Contracting Officer", throughout the clause.
   8. If the Subcontractor is a non-U.S. firm or organization, this clause applies to this Subcontract only if Work under the Subcontract will be performed in the United States or Subcontractor is recruiting employees in the United States to Work on the Contract.
Z.4 MODIFICATIONS REQUIRED BY PRIME CONTRACT
The Subcontractor agrees that upon the request of Chemonics it will negotiate in good faith with Chemonics relative to modifications to this Subcontract to incorporate additional provisions herein or to change provisions hereof, as Chemonics may reasonably deem necessary in order to comply with the provisions of the applicable Prime Contract or with the provisions of modifications to such Prime Contract. If any such modifications to this Subcontract causes an increase or decrease in the cost of, or the time required for, performance of any part of the Work under this Contract, an equitable adjustment may be made pursuant to the "Changes" clause of this Subcontract.

Z.5 PROVISIONS INCORPORATED BY REFERENCE
This Subcontract includes the appropriate flow-down clauses as required by the Federal Acquisition Regulation and the USAID Acquisition Regulation.

The following Federal Acquisition Regulation (FAR) clauses apply to this Subcontract as indicated:
* The version of the clause in effect as of the date of prime contract award, governs.

<table>
<thead>
<tr>
<th>Clause Number</th>
<th>Title</th>
<th>Date*</th>
<th>Notes and Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>52.202-1</td>
<td>DEFINITIONS</td>
<td>NOV 2013</td>
<td>All subcontracts regardless of value</td>
</tr>
<tr>
<td>52.203-3</td>
<td>GRATUITIES</td>
<td>APR 1984</td>
<td>All subcontracts regardless of value (Note 4 applies)</td>
</tr>
<tr>
<td>52.203-5</td>
<td>COVENANT AGAINST CONTINGENT FEES</td>
<td>MAY 2014</td>
<td>All subcontracts regardless of value (Note 1 applies)</td>
</tr>
<tr>
<td>52.203-6</td>
<td>REstrictions on Subcontractor Sales to the Government</td>
<td>SEP 2006</td>
<td>Cost reimbursement subcontracts and cost reimbursement task orders (Note 4 applies)</td>
</tr>
<tr>
<td>52.203-7</td>
<td>ANTI-KICKBACK PROCEDURES</td>
<td>MAY 2014</td>
<td>All subcontracts regardless of value (Note 1 applies)</td>
</tr>
<tr>
<td>52.203-8</td>
<td>CANCELLATION, RECISsion, AND RECOVERY OF FUNDS FOR ILLEGAL OR IMPROPER ACTIVITY</td>
<td>MAY 2014</td>
<td>All subcontracts equal to or greater than the simplified acquisition threshold (Note 1 applies)</td>
</tr>
<tr>
<td>52.203-10</td>
<td>PRICE OR FEE ADJUSTMENT FOR ILLEGAL OR IMPROPER ACTIVITY</td>
<td>MAY 2014</td>
<td>All subcontracts equal to or greater than the simplified acquisition threshold, (Note 1 applies)</td>
</tr>
<tr>
<td>52.203-11</td>
<td>CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS</td>
<td>SEP 2007</td>
<td>All subcontracts equal to or greater than $150,000 (Note 2 applies)</td>
</tr>
<tr>
<td>52.203-12</td>
<td>LIMITATIONS ON PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS</td>
<td>OCT 2010</td>
<td>All subcontracts equal to or greater than $150,000 (Note 2 applies)</td>
</tr>
<tr>
<td>52.203-13</td>
<td>CONTRACTOR CODE OF BUSINESS ETHICS AND CONDUCT</td>
<td>OCT 2015</td>
<td>All subcontracts that have a value in excess of $5.5 million and a performance period of more than 120 days. Disclosures made under this clause shall be directed to the agency Office of the Inspector General,</td>
</tr>
<tr>
<td>Regulation</td>
<td>Description</td>
<td>Date</td>
<td>Conditions</td>
</tr>
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</tr>
<tr>
<td>52.203-14</td>
<td>DISPLAY OF HOTLINE POSTER(S)</td>
<td>OCT 2015</td>
<td>All subcontracts that have a value in excess of $5.5 million except those performed entirely outside of the U.S. (Note 8 applies)</td>
</tr>
<tr>
<td>52.203-17</td>
<td>CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENTS TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS</td>
<td>APR 2014</td>
<td>All Subcontracts equal to or greater than the simplified acquisition threshold</td>
</tr>
<tr>
<td>52.204-06</td>
<td>Unique Entity Identifier</td>
<td>OCT 2016</td>
<td>All Subcontracts equal to or greater than $30,000</td>
</tr>
<tr>
<td>52.204-10</td>
<td>REPORTING EXECUTIVE COMPENSATION AND FIRST TIER SUBCONTRACT AWARDS (Subparagraph (d)(2) does not apply.)</td>
<td>OCT 2018</td>
<td>If the Subcontractor meets the thresholds specified in paragraphs (d)(3) and (g)(2) of the clause, the Subcontractor shall report required executive compensation by posting to the Government's Central Contractor Registration (CCR) database. All information posted will be available to the general public.</td>
</tr>
<tr>
<td>52.204-23</td>
<td>PROHIBITION ON CONTRACTING FOR HARDWARE, SOFTWARE AND SERVICES DEVELOPED BY KASPERSKY LAB AND OTHER COVERED ENTITIES</td>
<td>JUL 2018</td>
<td>Applies to all subcontracts, regardless of value or type. “Contractor” and “Contractor Employee” refer to “Subcontractor” and “Subcontractor Employee.”</td>
</tr>
<tr>
<td>52.204-25</td>
<td>PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT</td>
<td>AUG 2020</td>
<td>All subcontracts regardless of value (Note 1 applies)</td>
</tr>
<tr>
<td>52.209-3</td>
<td>PROHIBITION ON CONTRACTING WITH INVERTED DOMESTIC CORPORATIONS - REPRESENTATION</td>
<td>NOV 2015</td>
<td>All subcontracts regardless of value (Note 1 applies)</td>
</tr>
<tr>
<td>52.209-6</td>
<td>PROTECTING THE GOVERNMENT’S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT</td>
<td>AUG 2013</td>
<td>All Subcontracts &gt; $35,000. (Note 2 applies)</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Date</td>
<td>Notes</td>
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</tr>
<tr>
<td>52.209-10</td>
<td>Prohibition on Contracting with Inverted Domestic Corporations</td>
<td>NOV 2015</td>
<td>All subcontracts regardless of value (Note 1 applies)</td>
</tr>
<tr>
<td>52.215-2</td>
<td>Audits and Records - Negotiation</td>
<td>OCT 2010</td>
<td>All Subcontracts except those below the simplified acquisition threshold. (Note 3 applies. Alternate II applies if the Subcontractor is an educational or non-profit organization.)</td>
</tr>
<tr>
<td>52.215-10</td>
<td>Price Reduction for Defective Certified Cost or Pricing Data Rights and obligations under this clause shall survive completion of the Work and final payment under this Subcontract.</td>
<td>AUG 2011</td>
<td>Applies if submission of certified cost or pricing data was required with Subcontractor’s proposal. (Notes 2 and 4 apply except the first time “Contracting Officer” appears in paragraph (c)(1). “Government” means “Chemonics” in paragraph (d)(1).)</td>
</tr>
<tr>
<td>52.215-11</td>
<td>Price Reduction for Defective Certified Cost or Pricing Data -- Modifications Rights and obligations under this clause shall survive completion of the Work and final payment under this Subcontract.</td>
<td>AUG 2011</td>
<td>Applies if submission of certified cost or pricing data is required for modifications. (Notes 1, 2 and 4 apply.)</td>
</tr>
<tr>
<td>52.215-12</td>
<td>Subcontractor Certified Cost or Pricing Data</td>
<td>OCT 2010</td>
<td>Applies if Subcontract &gt; $750,000 and is not otherwise exempt under FAR 15.403.</td>
</tr>
<tr>
<td>52.215-13</td>
<td>Subcontractor Certified Cost or Pricing Data — Modifications</td>
<td>OCT 2010</td>
<td>Applies if Subcontract &gt; $750,000 and is not otherwise exempt under FAR 15.403.</td>
</tr>
<tr>
<td>52.215-14</td>
<td>Integrity of Unit Prices</td>
<td>OCT 2010</td>
<td>Applies if Subcontract is above the simplified acquisition threshold. Delete paragraph (b) of the clause.</td>
</tr>
<tr>
<td>52.215-15</td>
<td>Pension Adjustments and Asset Reversions</td>
<td>OCT 2010</td>
<td>Applies if Subcontract meets the applicability requirements of FAR 15.408(g). (Note 5 applies.)</td>
</tr>
<tr>
<td>52.215-16</td>
<td>Facilities Capital Cost of Money</td>
<td>JUN 2003</td>
<td>Applies if Subcontract is subject to the Cost Principles at FAR Subpart 31.2 and Subcontractor proposed facilities capital cost of money in its proposal.</td>
</tr>
<tr>
<td>52.215-17</td>
<td>Waiver of Facilities Capital Cost of Money</td>
<td>OCT 1997</td>
<td>Applies if Subcontract is subject to the Cost Principles at FAR Subpart 31.2 and Subcontractor did not propose facilities capital cost of money in its proposal.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Applicable if this Subcontract meets the applicability requirements of FAR 15.408(j).</td>
<td>Note(s) Applies</td>
</tr>
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</tr>
<tr>
<td>52.215-18</td>
<td>REVERSION OR ADJUSTMENT OF PLANS FOR POST-RETIREMENT BENEFITS (PRB) OTHER THAN PENSIONS</td>
<td>JUL 2005</td>
<td>5</td>
</tr>
<tr>
<td>52.215-19</td>
<td>NOTIFICATION OF OWNERSHIP CHANGES</td>
<td>OCT 1997</td>
<td>5</td>
</tr>
<tr>
<td>52.215-20</td>
<td>REQUIREMENTS FOR CERTIFIED COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA</td>
<td>OCT 2010</td>
<td>2</td>
</tr>
<tr>
<td>52.215-21</td>
<td>REQUIREMENTS FOR CERTIFIED COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA - MODIFICATIONS</td>
<td>OCT 2010</td>
<td>2</td>
</tr>
<tr>
<td>52.215-23</td>
<td>LIMITATION ON PASS-THROUGH CHARGES</td>
<td>OCT 2009</td>
<td>1, 2, 4</td>
</tr>
<tr>
<td>52.216-7</td>
<td>ALLOWABLE COST AND PAYMENT Alt II applies to educational institutions. Alt IV applies to non-profit organizations.</td>
<td>AUG 2018</td>
<td>3, 7</td>
</tr>
<tr>
<td>52.216-8</td>
<td>FIXED FEE</td>
<td>JUN 2011</td>
<td>1, 2</td>
</tr>
<tr>
<td>52.216-10</td>
<td>INCENTIVE FEE</td>
<td>JUN 2011</td>
<td>1, 2</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Date</td>
<td>Note</td>
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</tr>
<tr>
<td>52.216-11</td>
<td>COST CONTRACT - NO FEE</td>
<td>APR 1984</td>
<td>Applies only to Cost Reimbursement-No Fee Subcontracts. Does not apply if this is a T&amp;M Subcontract or Task Order. (Notes 1 and 2 apply.)</td>
</tr>
<tr>
<td>52.216-18</td>
<td>ORDERING</td>
<td>OCT 1995</td>
<td>Applies to Indefinite Quantity Subcontracts (IQS) or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.</td>
</tr>
<tr>
<td>52.216-19</td>
<td>ORDER LIMITATIONS</td>
<td>OCT 1995</td>
<td>Applies to Indefinite Quantity Subcontracts (IQS) or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.</td>
</tr>
<tr>
<td>52.216-22</td>
<td>INDEFINITE QUANTITY</td>
<td>OCT 1995</td>
<td>Applies to Indefinite Quantity Subcontracts (IQS) or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.</td>
</tr>
<tr>
<td>52.217-8</td>
<td>OPTION TO EXTEND SERVICES</td>
<td>NOV 1999</td>
<td>Insert “30 days” as the period of time within which Chemonics may exercise the option. (Notes 1 and 2 apply.)</td>
</tr>
<tr>
<td>52.217-9</td>
<td>OPTION TO EXTEND THE TERM OF THE CONTRACT</td>
<td>MAR 2000</td>
<td>Insert “30 days” and “60 days” as the periods of time set forth in the clause. Delete paragraph (c) of the clause. (Notes 1 and 2 apply.)</td>
</tr>
<tr>
<td>52.219-8</td>
<td>UTILIZATION OF SMALL BUSINESS CONCERNS</td>
<td>OCT 2018</td>
<td>Applies to all Subcontracts that are expected to exceed the simplified acquisition threshold except when the Subcontract will be performed entirely outside of the U.S. (Note 8 applies.)</td>
</tr>
<tr>
<td>52.219-9</td>
<td>SMALL BUSINESS SUBCONTRACTING PLAN</td>
<td>AUG 2018</td>
<td>Applies if this Subcontract &gt; $700,000 and if the Subcontract offers lower-tier subcontracting opportunities. The clause does not apply at any value if the Subcontractor is U.S. small business concern. Note 2 is applicable to paragraph (c) only. (Note 8 applies.)</td>
</tr>
<tr>
<td>Clause</td>
<td>Description</td>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>52.222-2</td>
<td>PAYMENT FOR OVERTIME PREMIUMS</td>
<td>JUL 1990</td>
<td>Applicable to Cost Reimbursement Subcontracts which are expected to exceed the simplified acquisition threshold only. Refers to overtime premiums for work performed in the U.S. subject to U.S. Department of Labor laws and regulations. Insert Zero in the blank. (Notes 2 and 3 apply.)</td>
</tr>
<tr>
<td>52.222-3</td>
<td>CONVICT LABOR</td>
<td>JUN 2003</td>
<td>Applies to all Subcontracts above the micro-purchase threshold, when the contract will be performed in the United States, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, or the U.S. Virgin Islands;</td>
</tr>
<tr>
<td>52.222-21</td>
<td>PROHIBITION OF SEGREGATED FACILITIES</td>
<td>APR 2015</td>
<td>(Note 8 applies.) Does not apply to work performed outside the United States by Subcontractor employees who were not recruited within the United States.</td>
</tr>
<tr>
<td>52.222-22</td>
<td>PREVIOUS CONTRACTS AND COMPLIANCE REPORT</td>
<td>FEB 1999</td>
<td>Applies if clause 52.222-26 applies.</td>
</tr>
<tr>
<td>52.222-26</td>
<td>EQUAL OPPORTUNITY</td>
<td>SEP 2016</td>
<td>Does not apply to work performed outside the United States by Subcontractor employees who were not recruited within the United States.</td>
</tr>
<tr>
<td>52.222-29</td>
<td>NOTIFICATION OF VISA DENIAL</td>
<td>APR 2015</td>
<td>Applies to all Subcontracts regardless of type or value.</td>
</tr>
<tr>
<td>52.222-35</td>
<td>EQUAL OPPORTUNITY FOR VETERANS</td>
<td>SEP 2010</td>
<td>Applies if this Subcontract is for $100,000 or more. Does not apply to Subcontracts where the work is performed entirely outside the U.S by employees recruited outside the United States.</td>
</tr>
<tr>
<td>52.222-36</td>
<td>EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES</td>
<td>JUL 2014</td>
<td>Applies if this Subcontract exceeds $15,000. Does not apply to Subcontracts where the work is performed entirely outside the U.S, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island</td>
</tr>
<tr>
<td>52.222-37</td>
<td>EMPLOYMENT REPORTS ON VETERANS</td>
<td>FEB 2016</td>
<td>Applies if this Subcontract is for $150,000 or more. Does not apply to Subcontracts where the work is performed entirely outside the U.S by</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Date</td>
<td>Notes</td>
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</tr>
<tr>
<td>52.222-40</td>
<td>NOTIFICATION OF EMPLOYEE RIGHTS UNDER THE NATIONAL LABOR RELATIONS ACT</td>
<td>DEC 2010</td>
<td>Applies to Subcontracts above the simplified acquisition threshold. Does not apply to Subcontracts performed entirely outside the U.S. Does not apply to Subcontracts where the work is performed entirely outside the U.S. For indefinite-quantity contracts, include the clause only if the value of orders in any calendar year of the contract is expected to exceed the simplified acquisition threshold.</td>
</tr>
<tr>
<td>52.222-50</td>
<td>COMBATING TRAFFICKING IN PERSONS (Alternate I applies when work is performed outside the U.S. and it is included in the Prime Contract)</td>
<td>JAN 2019</td>
<td>Applies to all Subcontracts, regardless of type, value. (Note 2 applies starting in paragraph c. In paragraph (h) Note 1 applies.)</td>
</tr>
<tr>
<td>52.222-54</td>
<td>EMPLOYMENT ELIGIBILITY VERIFICATION</td>
<td>OCT 2015</td>
<td>Applies to Subcontracts which exceed the simplified acquisition threshold except for a) commercial services that are part of the purchase of a Commercial Off-the-Shelf (COTS) item (or an item that would be a COTS item, but for minor modifications), performed by the COTS provider, and are normally provided for that COTS item; b) Subcontracts for work that will be performed outside the United States; or Subcontracts with a period of performance &lt; 120 days.</td>
</tr>
<tr>
<td>52.223-6</td>
<td>DRUG-FREE WORKPLACE</td>
<td>MAY 2001</td>
<td>Applies to all Subcontracts regardless of value or type. (Notes 2 and 4 apply)</td>
</tr>
<tr>
<td>52.223-18</td>
<td>ENCOURAGING CONTRACTOR POLICIES TO BAN TEXT MESSAGING WHILE DRIVING</td>
<td>AUG 2011</td>
<td>Applies to all subcontracts regardless of value.</td>
</tr>
<tr>
<td>52.225-1</td>
<td>BUY AMERICAN ACT -- SUPPLIES</td>
<td>MAY 2014</td>
<td>Applies if the Statement of Work contains other than domestic components. (Note 2 applies.)</td>
</tr>
<tr>
<td>52.225-13</td>
<td>RESTRICTIONS ON CERTAIN FOREIGN PURCHASES</td>
<td>JUN 2008</td>
<td>Applies to all Subcontracts regardless of value or type</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Date</td>
<td>Applicability</td>
</tr>
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</tr>
<tr>
<td>52.225-14</td>
<td>Inconsistency Between English Version and Translation of Contract</td>
<td>FEB 2000</td>
<td>Applies to all Subcontracts regardless of value or type</td>
</tr>
<tr>
<td>52.227-1</td>
<td>Authorization and Consent</td>
<td>DEC 2007</td>
<td>Applies if the Subcontract is above the simplified acquisition threshold. (Notes 4 and 7 apply.)</td>
</tr>
<tr>
<td>52.227-2</td>
<td>Notice and Assistance Regarding Patent and Copyright Infringement</td>
<td>DEC 2007</td>
<td>Applies if this Subcontract is above the simplified acquisition threshold (Notes 2 and 4 apply.)</td>
</tr>
<tr>
<td>52.227-9</td>
<td>Refund of Royalties</td>
<td>APR 1984</td>
<td>Applies if this Subcontract includes royalties.</td>
</tr>
<tr>
<td>52.227-14</td>
<td>Rights in Data - General</td>
<td>MAY 2014</td>
<td>Applies to all subcontracts regardless of type or value. Delete paragraph (d) which is replaced by AIDAR 752.227-14.</td>
</tr>
<tr>
<td>52.228-3</td>
<td>Worker’s Compensation Insurance (Defense Base Act)</td>
<td>JUL 2014</td>
<td>Applies to all Subcontracts, regardless of type or value. See also AIDAR 752.228-3.</td>
</tr>
<tr>
<td>52.228-4</td>
<td>Worker’s Compensation and War-Hazard Insurance Overseas</td>
<td>APR 1984</td>
<td>Applies to all Subcontracts, regardless of type or value, only if the Prime Contracts includes this clause.</td>
</tr>
<tr>
<td>52.228-7</td>
<td>Insurance—Liability to Third Persons</td>
<td>MAR 1996</td>
<td>Applicable to Cost Reimbursement Subcontracts and Task Orders of any value. (Notes 4 and 7 apply)</td>
</tr>
<tr>
<td>52.228-9</td>
<td>Cargo Insurance</td>
<td>MAY 1999</td>
<td>Applicable to Subcontracts of any value if the Subcontractor is authorized to provide transportation-related services. Chemonics will provide values to complete blanks in this clause upon authorizing transportation services. (see also AIDAR 752.228-9)</td>
</tr>
<tr>
<td>52.229-6</td>
<td>Taxes – Foreign Fixed Price Contracts</td>
<td>FEB 2013</td>
<td>Applies to Fixed Price Subcontracts of any value.</td>
</tr>
<tr>
<td>52.229-8</td>
<td>Taxes—Foreign Cost-Reimbursement Contracts</td>
<td>MAR 1990</td>
<td>Applicable to Cost Reimbursement and T&amp;M Subcontracts and Task Orders, regardless of value. Insert name of host country government in first blank in the clause. Insert name of host country in second blank in the clause.</td>
</tr>
<tr>
<td>52.230-2</td>
<td>Cost Accounting Standards</td>
<td>OCT 2015</td>
<td>Applies only when referenced in this Subcontract that full CAS coverage applies. &quot;United States&quot; means &quot;United States&quot;</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Date</td>
<td>Notes</td>
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</tr>
<tr>
<td>52.230-3</td>
<td>DISCLOSURE AND CONSISTENCY OF COST ACCOUNTING PRACTICES</td>
<td>OCT 2015</td>
<td>Applies only when referenced in this Subcontract that modified CAS coverage applies. “United States” means “United States or Chemonics.” Delete paragraph (b) of the clause.</td>
</tr>
<tr>
<td>52.230-4</td>
<td>DISCLOSURE AND CONSISTENCY OF COST ACCOUNTING PRACTICES FOR CONTRACTS AWARDED TO FOREIGN CONCERNS</td>
<td>OCT 2015</td>
<td>Applies only when referenced in this Subcontract, modified CAS coverage applies. Note 3 applies in the second and third sentences.</td>
</tr>
<tr>
<td>52.230-5</td>
<td>COST ACCOUNTING STANDARDS -- EDUCATIONAL INSTITUTIONS</td>
<td>AUG 2016</td>
<td>“United States” means “United States or Chemonics.” Delete paragraph (b) of the Clause. Applies only when referenced in this Subcontract that this CAS clause applies.</td>
</tr>
<tr>
<td>52.230-6</td>
<td>ADMINISTRATION OF COST ACCOUNTING STANDARDS</td>
<td>JUN 2010</td>
<td>Applies if FAR 52.230-2, FAR 52.230-3, FAR 52.230-4 or FAR 52.230-5 applies.</td>
</tr>
<tr>
<td>52.232-20</td>
<td>LIMITATION OF COST</td>
<td>APR 1984</td>
<td>Applies if this Subcontract is a fully funded Cost Reimbursement or T&amp;M Subcontract or Task Order. (Notes 1 and 2 apply.</td>
</tr>
<tr>
<td>52.232-22</td>
<td>LIMITATION OF FUNDS</td>
<td>APR 1984</td>
<td>Applies if this Subcontract is an incrementally funded Cost Reimbursement or T&amp;M Subcontract or Task Order. (Notes 1 and 2 apply.)</td>
</tr>
<tr>
<td>52.232-40</td>
<td>PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS</td>
<td>DEC 2013</td>
<td>Applies if the Subcontractor is a U.S. small business and Chemonics receives accelerated payments under the prime contract. (Note 1 applies.)</td>
</tr>
<tr>
<td>52.233-3</td>
<td>PROTEST AFTER AWARD Alternate I (JUN 1985) applies if this is a cost-reimbursement contract). In the event that Chemonics’ client has directed Chemonics to stop performance of the Work under the Prime Contract under which this Subcontract is issued pursuant to FAR 33.1, Chemonics may, by written order to the Subcontractor, direct the Subcontractor to stop performance of the Work.</td>
<td>AUG 1996</td>
<td>“30 days” means “20 days” in paragraph (b)(2). Note 1 applies except the first time “Government” appears in paragraph (f). In paragraph (f) add after “33.104(h) (1)” the following: “and recovers those costs from Chemonics”.</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Date</td>
<td>Notes</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>52.237-8</td>
<td>RESTRICTION ON SEVERANCE PAYMENTS TO FOREIGN NATIONALS</td>
<td>AUG 2003</td>
<td>Applies to Subcontracts—regardless of type and value—that include provision of host country national personnel.</td>
</tr>
<tr>
<td>52.237-9</td>
<td>INSTRUCTIONS: INCLUDE THIS ONLY IF IT APPEARS IN THE PRIME CONTRACT. WAIVER OF LIMITATION ON SEVERANCE PAYMENTS TO FOREIGN NATIONALS</td>
<td>MAY 2014</td>
<td>Applies to Subcontracts—regardless of type and value—that include provision of host country national personnel ONLY if the Prime Contracts includes this clause.</td>
</tr>
<tr>
<td>52.242-1</td>
<td>NOTICE OF INTENT TO DISALLOW COSTS</td>
<td>APR 1984</td>
<td>Applies to Cost Reimbursement and T&amp;M Subcontracts and Task Orders of any value.</td>
</tr>
<tr>
<td>52.242-3</td>
<td>PENALTIES FOR UNALLOWABLE COSTS</td>
<td>MAY 2014</td>
<td>Applies to all subcontracts &gt; $700,000, regardless of subcontract type.</td>
</tr>
<tr>
<td>52.242-4</td>
<td>CERTIFICATION OF FINAL INDIRECT COSTS</td>
<td>JAN 1997</td>
<td>Applies to Cost Reimbursement and T&amp;M Subcontracts and Task Orders that provide for reimbursement of Subcontractor indirect cost rates, regardless of subcontract value.</td>
</tr>
<tr>
<td>52.242-13</td>
<td>BANKRUPTCY</td>
<td>JUL 1995</td>
<td>Notes 1 and 2 apply.</td>
</tr>
<tr>
<td>52.242-15</td>
<td>STOP-WORK ORDER Alternate I (APR 1984) applies if this is a cost-reimbursement Subcontract.</td>
<td>AUG 1989</td>
<td>Notes 1 and 2 apply.</td>
</tr>
<tr>
<td>52.243-1</td>
<td>CHANGES-FIXED PRICE (Alt III)</td>
<td>AUG 1987</td>
<td>Applies to Fixed Price Subcontracts of any value.</td>
</tr>
<tr>
<td>52.243-2</td>
<td>CHANGES - COST REIMBURSEMENT</td>
<td>AUG 1987</td>
<td>Applies if this is a Cost Reimbursement Subcontract or Task Order.</td>
</tr>
<tr>
<td>52.243-3</td>
<td>CHANGES - TIME-AND-MATERIALS OR LABOR-HOUR</td>
<td>SEP 2000</td>
<td>Applies if this is a T&amp;M Subcontract or Task Order.</td>
</tr>
<tr>
<td>52.244-6</td>
<td>SUBCONTRACTS FOR COMMERCIAL ITEMS</td>
<td>JAN 2019</td>
<td>Applies to Subcontracts for commercial items only.</td>
</tr>
<tr>
<td>52.245-1</td>
<td>GOVERNMENT PROPERTY (APR 2012) (ALT I)</td>
<td>JAN 2017</td>
<td>&quot;Contracting Officer&quot; means &quot;Chemonics&quot; except in the definition of Property Administrator and in paragraphs (h)(1)(iii) where it is unchanged, and in paragraphs (c) and (h)(4) where it includes Chemonics. &quot;Government&quot; is unchanged in the phrases &quot;Government property&quot; and &quot;Government furnished property&quot; and where...</td>
</tr>
<tr>
<td>Section No.</td>
<td>Description</td>
<td>Date</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>52.246-3</td>
<td>Inspection of Supplies - Cost Reimbursement</td>
<td>MAY 2001</td>
<td>Applies to Cost Reimbursement Subcontracts and Task Orders.</td>
</tr>
<tr>
<td>52.246-4</td>
<td>Inspection of Services - Fixed Price</td>
<td>AUG 1996</td>
<td>Applies to Fixed Priced Subcontracts of any value.</td>
</tr>
<tr>
<td>52.246-5</td>
<td>Inspection of Services - Cost Reimbursement</td>
<td>MAY 2001</td>
<td>Applies to Cost Reimbursement Subcontracts of any value. (Note 3 applies in paragraphs (b) and (c). Note 1 applies in paragraphs (d) and (e).)</td>
</tr>
<tr>
<td>52.246-6</td>
<td>Inspection - Time-And-Material and Labor-Hour</td>
<td>MAY 2001</td>
<td>Applies to T&amp;M Subcontracts and Task Orders of any value. In paragraphs (b), (c), (d), Note 3 applies; in paragraphs (e), (f), (g), (h), Note 1 applies.</td>
</tr>
<tr>
<td>52.246-25</td>
<td>Limitation of Liability - Services</td>
<td>FEB 1997</td>
<td>Applies to Subcontracts at or below the simplified acquisition threshold or more.</td>
</tr>
<tr>
<td>52.247-63</td>
<td>Preference for U.S.-Flag Air Carriers</td>
<td>JUN 2003</td>
<td>Applies to all Subcontracts that include international air travel.</td>
</tr>
<tr>
<td>52.247-64</td>
<td>Preference for Privately Owned U.S.-Flag Commercial Vessels</td>
<td>FEB 2006</td>
<td>Applies for Subcontracts that include provision of freight services.</td>
</tr>
<tr>
<td>52.247-67</td>
<td>Submission of Transportation Documents for Audit</td>
<td>FEB 2006</td>
<td>Applies to Subcontracts that include provision of freight services.</td>
</tr>
<tr>
<td>52.249-1</td>
<td>Termination for Convenience of the Government (Fixed-Price) (Short Form)</td>
<td>APR 1984</td>
<td>Applies to all Fixed Price Subcontracts.</td>
</tr>
<tr>
<td>52.249-6</td>
<td>Termination (Cost-Reimbursement) Alternate IV (SEP 1996) applies if this is a time and materials Subcontract.</td>
<td>MAY 2004</td>
<td>Notes 1 and 2 apply. Substitute &quot;90 days&quot; for &quot;120 days&quot; and &quot;90-day&quot; for &quot;120-day&quot; in paragraph (d). Substitute &quot;180 days&quot; for &quot;1 year&quot; in paragraph (f). In paragraph (j) &quot;right of appeal&quot;, &quot;timely appeal&quot; and &quot;on an appeal&quot; shall mean the right to proceed under the &quot;Disputes&quot; clause of this Contract. Settlements and payments under this clause</td>
</tr>
</tbody>
</table>
The following Agency For International Development Acquisition Regulations (AIDAR) clauses apply to this Contract:

<table>
<thead>
<tr>
<th>Clause Number</th>
<th>Title</th>
<th>Date*</th>
<th>Notes and Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>52.249-8</td>
<td>DEFAULT FIXED PRICE SUPPLY &amp; SERVICE</td>
<td>APR 1984</td>
<td>Applies to all Fixed Price Subcontracts.</td>
</tr>
<tr>
<td>52.249-14</td>
<td>EXCUSABLE DELAYS</td>
<td>APR 1984</td>
<td>(Note 2 applies; Note 1 applies to (e). In (a)(2) delete “or contractual”.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clause Number</th>
<th>Title</th>
<th>Date*</th>
<th>Notes and Applicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>752.202-1</td>
<td>DEFINITIONS (ALT 70 AND ALT 72)</td>
<td>JAN 1990</td>
<td>Applies to all Subcontracts, regardless of value or type. “Contractor” and “Contractor Employee” refer to “Subcontractor” and “Subcontractor Employee”.</td>
</tr>
<tr>
<td>752.211-70</td>
<td>LANGUAGE AND MEASUREMENT</td>
<td>JUN 1992</td>
<td>Applies to all Subcontracts, regardless of type or value.</td>
</tr>
<tr>
<td>752.225-70</td>
<td>SOURCE AND NATIONALITY REQUIREMENTS</td>
<td>FEB 2012</td>
<td>Applies to all Subcontracts, regardless of type or value. (Notes 4, 5 and 7 apply)</td>
</tr>
<tr>
<td>752.227-14</td>
<td>RIGHTS IN DATA – GENERAL</td>
<td>OCT 2007</td>
<td>Applies to all Subcontracts regardless of type or value. This clause replaces paragraph (d) of FAR 52.227-14 Rights in Data—General.</td>
</tr>
<tr>
<td>752.228-3</td>
<td>WORKER’S COMPENSATION INSURANCE (DEFENSE BASE ACT)</td>
<td>DEC 1991</td>
<td>The supplemental coverage described in this clause is required in addition to the coverage specified in FAR 52.228-3.</td>
</tr>
<tr>
<td>752.228-7</td>
<td>INSURANCE – LIABILITY TO THIRD PERSONS</td>
<td>JUL 1997</td>
<td>The coverage described in this clause is added to the clause specified in FAR 52.228-7 as either paragraph (h) (if FAR 52.228-7 Alternate I is not used) or (i) (if FAR 52.228-7 Alternate I is used): (See FAR 52.228)</td>
</tr>
<tr>
<td>752.228-9</td>
<td>CARGO INSURANCE</td>
<td>DEC 1998</td>
<td>The following preface is to be used preceding the text of the clause at FAR 52.228-9: Preface: To the extent that marine insurance is necessary or appropriate under this contract, the Subcontractor shall ensure that U.S. marine insurance companies are offered a fair opportunity to bid for such insurance. This requirement shall be included in all lower-tier subcontracts.</td>
</tr>
<tr>
<td>752.228-70</td>
<td>MEDICAL EVACUATION (MEDEVAC) SERVICES</td>
<td>JUL 2007</td>
<td>Applies to all Subcontracts requiring performance outside the U.S.</td>
</tr>
<tr>
<td>752.231-71</td>
<td>SALARY SUPPLEMENTS FOR HG EMPLOYEES (THE SUBCONTRACTOR SHALL FLOW DOWN THIS CLAUSE TO LOWER-TIER SUBCONTRACTS, IF LOWER-TIER SUBCONTRACTING IS AUTHORIZED.)</td>
<td>MAR 2015</td>
<td>Applies to all Subcontracts, regardless of value or type, with a possible need for services of a Host Government employee. (Note 5 applies)</td>
</tr>
<tr>
<td>752.245-71</td>
<td>TITLE TO AND CARE OF PROPERTY</td>
<td>APR 1984</td>
<td>Applies to Subcontracts where the Subcontractor is authorized by Chemonics to purchase property under...</td>
</tr>
<tr>
<td>Clause Number</td>
<td>Description</td>
<td>Date</td>
<td>Applies to</td>
</tr>
<tr>
<td>--------------</td>
<td>------------------------------------------------------------------</td>
<td>---------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>752.247-70</td>
<td>PREFERENCE FOR PRIVATELY OWNED U.S.-FLAG COMMERCIAL VESSELS</td>
<td>OCT 1996</td>
<td>the Subcontract for use outside the U.S. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7001</td>
<td>BIOGRAPHICAL DATA</td>
<td>JUL 1997</td>
<td>Applies to all Cost Reimbursement Subcontracts and Task Orders, and T&amp;M Subcontracts and Task Orders utilizing a multiplier, regardless of value. (Note 3 applies)</td>
</tr>
<tr>
<td>752.7002</td>
<td>TRAVEL AND TRANSPORTATION</td>
<td>JAN 1990</td>
<td>Applies to all Cost Reimbursement and T&amp;M Subcontracts and Task Orders performed in whole or in part outside the U.S., regardless of value. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7004</td>
<td>EMERGENCY LOCATOR INFORMATION</td>
<td>JUL 1997</td>
<td>Applies to all Subcontracts performed in whole or in part outside the U.S., regardless of value. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7005</td>
<td>SUBMISSION REQUIREMENTS FOR DEVELOPMENT EXPERIENCE DOCUMENTS</td>
<td>SEP 2013</td>
<td>Applies to all Subcontracts. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7007</td>
<td>PERSONNEL COMPENSATION</td>
<td>JUL 2007</td>
<td>Applies to all Cost Reimbursement Subcontracts and Task Orders and T&amp;M Subcontracts and Task Orders utilizing a multiplier, regardless of value. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7008</td>
<td>USE OF GOVERNMENT FACILITIES OR PERSONNEL</td>
<td>APR 1984</td>
<td>Applies to all Subcontracts regardless of value or type. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7009</td>
<td>MARKING</td>
<td>JAN 1993</td>
<td>Applies to all Subcontracts. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7010</td>
<td>CONVERSION OF U.S. DOLLARS TO LOCAL CURRENCY</td>
<td>APR 1984</td>
<td>Applies to all Subcontracts, regardless of value or type, involving performance outside the U.S. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7011</td>
<td>ORIENTATION AND LANGUAGE TRAINING</td>
<td>APR 1984</td>
<td>Applies to Cost Reimbursement Subcontracts and Task Orders, regardless of value, involving performance outside the U.S. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7012</td>
<td>PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT</td>
<td>AUG 1995</td>
<td>Applies to any Subcontract, regardless of value or type, which involves research using human subjects. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7013</td>
<td>CONTRACTOR-MISSION RELATIONSHIPS</td>
<td>JUN 2018</td>
<td>Applies to all subcontracts, regardless of value or type. “Contractor” and “Contractor Employee” refer to “Subcontractor” and “Subcontractor Employee.”</td>
</tr>
<tr>
<td>752.7014</td>
<td>NOTICE OF CHANGES IN TRAVEL REGULATIONS</td>
<td>JAN 1990</td>
<td>Applies to Cost Reimbursement and T&amp;M Subcontracts of any value involving work outside the U.S. (Note 2 applies)</td>
</tr>
<tr>
<td>752.7025</td>
<td>APPROVALS</td>
<td>APR 1984</td>
<td>Applies to all Subcontracts. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7027</td>
<td>PERSONNEL</td>
<td>DEC 1990</td>
<td>Applies to all Cost Reimbursement and T&amp;M Subcontracts of any value involving work performed in whole or in part overseas. Paragraphs (f) and (g) of this clause are for use only in cost reimbursement and T&amp;M contracts. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7028</td>
<td>DIFFERENTIALS AND ALLOWANCES</td>
<td>JUL 1996</td>
<td>This clause does not apply to TCN and CCN employees. TCN and CCN</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Date</td>
<td>Details</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>752.7029</td>
<td>POST PRIVILEGES</td>
<td>JUL 1993</td>
<td>For use in all non-commercial subcontracts involving performance overseas.</td>
</tr>
<tr>
<td>752.7031</td>
<td>LEAVE AND HOLIDAYS</td>
<td>OCT 1989</td>
<td>For use in all cost-reimbursement and T&amp;M subcontracts for technical or professional services.</td>
</tr>
<tr>
<td>752.7032</td>
<td>INTERNATIONAL TRAVEL APPROVAL AND NOTIFICATION REQUIREMENTS</td>
<td>APR 2014</td>
<td>Applies to all subcontracts requiring international travel. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7033</td>
<td>PHYSICAL FITNESS (JULY 1997)</td>
<td>JUL 1997, PARTIALLY REVISED AUG 2014</td>
<td>Applies to all Subcontracts of any type or value involving performance outside the U.S. The requirements of this provision do not apply to employees hired in the Cooperating Country or to authorized dependents who were already in the Cooperating Country when their sponsoring employee was hired. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7034</td>
<td>ACKNOWLEDGMENT AND DISCLAIMER</td>
<td>DEC 1991</td>
<td>Applies to Subcontracts of any type or value that include in the Scope of Work publications, videos, or other information/media products. (Note 5 applies)</td>
</tr>
<tr>
<td>752.7101</td>
<td>VOLUNTARY POPULATION PLANNING ACTIVITIES</td>
<td>JUN 2008</td>
<td>If a subcontract with family planning activities is contemplated, add “Alternate 1 (6/2008)” to the clause name.</td>
</tr>
</tbody>
</table>

Z.6 Federal Funding Accountability And Transparency Act (FFATA) Subaward Reporting Questionnaire And Certification For Subcontracts And Sub-Task Orders Under Indefinite Delivery/Indefinite Quantity Subcontracts

Subcontractor Name:
Subcontract or Subcontract Order Number:
Subcontract or Subcontract Start Date:
Subcontract or Subcontract Value:

The information in this section is required under FAR 52.204-10 “Reporting Executive Compensation and First-Tier Subcontract Awards” to be reported by prime contractors receiving federal contracts through the Federal Funding Accountability and Transparency Act (FFATA) Subaward Reporting System (FSRS). As required by the referenced FAR, complete this questionnaire and certification as part of the Subcontract or Sub-Task Order with a value of $30,000 or more, unless exempted from reporting by a positive response to Section A.

A. In the previous tax year, was your company’s gross income from all sources under $300,000?
   ___Yes ___No

B. If “No”, please provide the below information and answer the remaining questions.
Subcontractor DUNS Number:

1. In your business or organization’s preceding completed fiscal year, did your business or organization (the legal entity to which the DUNS number belongs) receive (1) 80 percent or more of its annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and (2) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?:

   ___Yes  ___No

2. Does the public have access to information about the compensation of the executives in your business or organization (the legal entity to which the DUNS number it provided belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986?:

   ___Yes  ___No

3. Does your business or organization maintain a record in the System for Award Management (www.SAM.gov)?

   ___Yes  ___No

4. If you have indicated “Yes” for paragraph (ii) and “No” for paragraph (iii) and (iv) above, provide the names and total compensation* of your five most highly compensated executives** for the preceding completed fiscal year.

   Name:______________________________________________________________
   Amount:_____________________________________________________________

   Name:______________________________________________________________
   Amount:_____________________________________________________________

   Name:______________________________________________________________
   Amount:_____________________________________________________________

   Name:______________________________________________________________
   Amount:_____________________________________________________________

   Name:__________________________
   Amount:_____________________________________________________________

The information provided above is true and accurate as of the date of execution of the referenced Subcontract or Sub-Task Order. Annual certification is required for information provided in paragraph v) above.

*“Total compensation” means the cash and noncash dollar value earned by the executive during the Subcontractor’s preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

1. **Salary and bonus.**
2. **Awards of stock, stock options, and stock appreciation rights.** Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Financial Accounting Standards Board’s Accounting Standards Codification (FASB ASC) 718, Compensation-Stock Compensation.
3. **Earnings for services under non-equity incentive plans.** This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
4. **Change in pension value.** This is the change in present value of defined benefit and actuarial pension plans.
5. **Above-market earnings on deferred compensation which is not tax-qualified.**
(6) Other compensation, if the aggregate value of all such other compensation (e.g., severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.

**“Executive” means officers, managing partners, or any other employees in management positions.

Z.7. REPRESENTATIONS AND CERTIFICATIONS

Any representations and certifications submitted resulting in award of this Subcontract are hereby incorporated either in full text or by reference, and any updated representations and certifications submitted thereafter are incorporated by reference and made a part of this Subcontract with the same force and effect as if they were incorporated by full text. By signing this Subcontract, the Subcontractor hereby certifies that as of the time of award of this Subcontract: (1) the Subcontractor, or its principals, is not debarred, suspended or proposed for debarment or declared ineligible for award by any Federal agency; (2) no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with awarding the contract or this Subcontract; and (3) no changes have occurred to any other representations and certifications made by the Subcontractor resulting in award of this subcontract. The Subcontractor agrees to promptly notify Chemonics in writing of any changes occurring at any time during performance of this Subcontract to any representations and certifications submitted by the Subcontractor.

[End of Subcontract]
Annex 1  Cover Letter

[Offeror: Insert date]

Harriet Lema  
Country Director (Acting) and Procurement Technical Specialist  
Global Health Supply Chain Program – Procurement and Supply Management (GHSC- PSM) project  
100 Robert Mugabe Avenue,  
Heritage Square, Ausspannplatz,  
Windhoek, Namibia

Reference:  Request for Proposals RFP for Transportation of COVID-19 Vaccine in Namibia  
Subject:  [Offeror: Insert name of your organization]’s technical and cost proposals

Dear Mrs. Harriet Lema:

[Offeror: Insert name of your organization] is pleased to submit its proposal in regard to the above-referenced request for proposals. For this purpose, we are pleased to provide the information furnished below:

Name of Organization’s Representative ____________________________________________
Name of Offeror ____________________________________________
Type of Organization ____________________________________________
Taxpayer Identification Number ____________________________________________
DUNS Number ____________________________________________
Address ____________________________________________
Address ____________________________________________
Telephone ____________________________________________
E-mail ____________________________________________

As required by section I, I.7, we confirm that our proposal, including the cost proposal will remain valid for 90 calendar days after the proposal deadline. We are further pleased to provide the following annexes containing the information requested in the RFP.:

[Offerors: It is incumbent on each offeror to clearly review the RFP and its requirements. It is each offeror's responsibility to identify all required annexes and include them]

I. Copy of registration or incorporation in the public registry, or equivalent document from the government office where the offeror is registered.
II. Copy of company tax registration, or equivalent document.
III. Copy of trade license, or equivalent document.
IV. Evidence of Responsibility Statement.

Sincerely yours,

________________________
Signature

[Offeror: Insert name of your organization's representative]

[Offeror: Insert name of your organization]
Annex 2  

Guide to Creating a Financial Proposal for a Fixed Price Subcontract

This annex does not replace or supersede the guidance provided under Section I.7.C. Rather, it provides additional guidance to aid offerors in developing their cost proposals. Because the subcontract will be funded under a United States government-funded project, it is important that all offerors’ budgets conform to this standard format. It is thus strongly recommended that offerors follow the steps described below.

**Under no circumstances may cost information be included in the technical proposal.** No cost information or any prices, whether for deliverables or line items, may be included in the technical proposal. Cost information must only be shown in the cost proposal.

- **Step 1:** Design the technical proposal. Offerors should examine the market for the proposed activity and realistically assess how they can meet the needs as described in this RFP, specifically in Section II. Offerors should present and describe this assessment in their technical proposals.

- **Step 2:** Determine the basic costs associated with delivery to each location outlined in the excel distribution plan in Annex 11 from the pickup location at the Central Medical Store in Windhoek. Please note that the pickup location outlined in this RFP (CMS) should be used to build the fixed rates but is subject to change. The estimated quantities to be picked up and delivered as well as estimated arrival dates and other key order information is provided in the excel file in Annex 11. Offerors should consider best estimate of the all-inclusive costs associated with each deliverable, which should include labor and all non-labor costs, fringe, and other direct costs, such as allowances, travel/transport, etc.

- **Step 3:** Based on the calculated costs associated with delivery to each of the location from the pickup location at CMS in Windhoek, establish a firm fixed price for delivery (*price per vaccine vial*) to each location in the distribution plan pricing table in Annex 11. Each offeror must submit their proposed fixed prices for some or all of the 35 district hospital service delivery points by filling out column Q in the provided Microsoft Excel spreadsheet attachment in Annex 11. The budget should follow the technical proposal. All cost information must be expressed in USD.

- **Step 4:** Write Budget Narrative. The spreadsheets shall be accompanied by written notes in MS Word that explain each cost line item and the assumption why a cost is being budgeted as well as how the amount is reasonable. Supporting information must be provided in sufficient detail to allow for a complete analysis of each cost element or line item. Chemonics reserves the right to request additional cost information if the evaluation committee has concerns of the reasonableness, realism, or completeness of an offeror’s proposed cost.

- If it is an offeror’s regular practice to budget indirect rates, e.g. overhead, fringe, G&A, administrative, or other rate, Offerors must explain the rates and the rates’ base of application in the budget narrative. Chemonics reserves the right to request additional information to substantiate an Offeror’s indirect rates.

*Taxes and VAT:* Because GHSC-PSM is a USAID funded project and is implemented under a bilateral agreement between the Namibia and the U.S. Government, offerors must not include VAT and customs duties in their cost proposal.
Annex 3 Required Certifications

52.203-2 Certificate of Independent Price Determination

As prescribed in 3.103-1, insert the following provision. If the solicitation is a Request for Quotations, the terms “Quotation” and “Quoter” may be substituted for “Offer” and “Offeror.”

Certificate of Independent Price Determination (Apr 1985)
___________________________________________________________ (hereinafter called the "offeror")

(Name of Offeror)

(a) The offeror certifies that—
   (1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to— (i) Those prices;
   (ii) The intention to submit an offer; or
   (iii) The methods or factors used to calculate the prices offered.

   (2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

   (3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory—
   (1) Is the person in the offeror’s organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to paragraphs (a)(1) through (a)(3) of this provision; or
   (2)(i) Has been authorized, in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to paragraphs (a)(1) through (a)(3) of this provision ____________________ [insert full name of person(s) in the offeror’s organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror’s organization];
   (ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) of this provision have not participated, and will not participate, in any action contrary to paragraphs (a)(1) through (a)(3) of this provision; and
   (iii) As an agent, has not personally participated, and will not participate, in any action contrary to paragraphs (a)(1) through (a)(3) of this provision.

(c) If the offeror deletes or modifies paragraph (a)(2) of this provision, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

___________________________________________________________

(Applicant)

BY (Signature) ___________________ TITLE _____________________

TYPED NAME ____________________ DATE _____________________
52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions

Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Sept 2007)

_________________________(hereinafter called the "offeror")

(Name of Offeror)

(a) Definitions. As used in this provision—“Lobbying contact” has the meaning provided at 2 U.S.C. 1602(8). The terms “agency,” “influencing or attempting to influence,” “officer or employee of an agency,” “person,” “reasonable compensation,” and “regularly employed” are defined in the FAR clause of this solicitation entitled “Limitation on Payments to Influence Certain Federal Transactions” (52.203-12).

(b) Prohibition. The prohibition and exceptions contained in the FAR clause of this solicitation entitled “Limitation on Payments to Influence Certain Federal Transactions” (52.203-12) are hereby incorporated by reference in this provision.

(c) Certification. The Offeror, by signing its offer, hereby certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on its behalf in connection with the awarding of this contract.

(d) Disclosure. If any registrants under the Lobbying Disclosure Act of 1995 have made a lobbying contact on behalf of the Offeror with respect to this contract, the Offeror shall complete and submit, with its offer, OMB Standard Form LLL, Disclosure of Lobbying Activities, to provide the name of the registrants. The Offeror need not report regularly employed officers or employees of the Offeror to whom payments of reasonable compensation were made.

(e) Penalty. Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by 31 U.S.C. 1352. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure required to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

(f) Should the Offeror’s circumstances change during the life of any resulting subcontract with respect to the above, the Offeror will notify Buyer immediately.

_________________________

BY (Signature) ___________________ TITLE _____________________

TYPED NAME ____________________ DATE _____________________
52.209-5 Certification Regarding Responsibility Matters

Certification Regarding Responsibility Matters (Apr 2010)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals—

(A) Are □ are not □ presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have □ have not □, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property;

(C) Are □ are not □ presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision;

(D) Have □, have not □, within a three-year period preceding this offer, been notified of any delinquent U.S. Federal taxes in an amount that exceeds $3,000 for which the liability remains unsatisfied.

(1) U.S. Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. § 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of U.S. Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. § 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. § 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has ( ) has not ( ), within a three-year period preceding this offer, had one or more contracts terminated for default by any U.S. Federal agency.
(2) “Principal,” for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror’s responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

PLEASE SIGN AND RETURN

Company Name___________________________

Signature _____________________________   Printed Name _____________________________

Title _____________________________ Date _____________________________
Evidence of Responsibility

1. Offeror Business Information

Company Name: Full Legal Name
Address: Address
DUNS Number: Enter the Data Universal Numbering System reference (DUNS) assigned to the company (Instructions to Offerors: Offerors will provide their registered DUNS number for subawards valued at USD$30,000 and above with Chemonics unless exempted. Exemption may be granted by Chemonics or based on a negative response to Section 3(a) below (ie, the offeror, in the previous tax year, had gross income from all sources under USD$300,000). Dun & Bradstreet regulates the system and registration may be obtained online at http://fedgov.dnb.com/webform. If Offeror does not have a DUNS number and is unable to obtain one before proposal submission deadline, Offeror shall include a statement in their Evidence of Responsibility Statement noting their intention to register for a DUNS number should it be selected as the successful offeror or explaining why registration for a DUNS number is not applicable or not possible. Additional guidance on obtaining a DUNS number is available upon request.)

2. Authorized Negotiators

Company Name proposal for Proposal Name may be discussed with any of the following individuals. These individuals are authorized to represent Company Name in negotiation of this offer in response to RFP # PSM-HAITI-3PL-0617

List Names of Authorized signatories

These individuals can be reached at Company Name office:
Address
Telephone/Fax
Email address

3. Adequate Financial Resources

Company Name has adequate financial resources to manage this contract, as established by our audited financial statements (OR list what else may have been submitted) submitted as part of our response to this proposal.

If the offeror is selected for an award valued at $30,000 or above, and is not exempted based on a negative response to Section 3(a) below, any first-tier subaward to the organization may be reported and made public through FSRS.gov in accordance with The Transparency Acts of 2006 and 2008. Therefore, in accordance with FAR 52.240-10 and 2CFR Part170, if the offeror positively certifies below in Sections 3.a and 3.b and negatively certifies in Sections 3.c and 3.d, the offeror will be required to disclose to Chemonics for reporting in accordance with the regulations, the names and total compensation of the organization’s five most highly compensated executives. By submitting this proposal, the offeror agrees to comply with this requirement as applicable if selected for a subaward.

In accordance with those Acts and to determine applicable reporting requirements, Company Name certifies as follows:

a) In the previous tax year, was your company’s gross income from all sources above $300,000?

☐ Yes ☐ No

b) In your business or organization's preceding completed fiscal year, did your business or organization (the legal entity to which the DUNS number belongs) receive (1) 80 percent or more
of its annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and (2) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?:

☐ Yes ☐ No

c) Does the public have access to information about the compensation of the executives in your business or organization (the legal entity to which the DUNS number it provided belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986? (FFATA § 2(b)(1)):

☐ Yes ☐ No

d) Does your business or organization maintain an active registration in the System for Award Management (www.SAM.gov)?

☐ Yes ☐ No

4. Ability to Comply
Company Name is able to comply with the proposed delivery of performance schedule having taken into consideration all existing business commitments, commercial as well as governmental.

5. Record of Performance, Integrity, and Business Ethics
Company Name record of integrity is (Instructions: Offeror should describe their record. Text could include example such as the following to describe their record: "outstanding, as shown in the Representations and Certifications. We have no allegations of lack of integrity or of questionable business ethics. Our integrity can be confirmed by our references in our Past Performance References, contained in the Technical Proposal."

6. Organization, Experience, Accounting and Operational Controls, and Technical Skills
(Instructions: Offeror should explain their organizational system for managing the subcontract, as well as the type of accounting and control procedure they have to accommodate the type of subcontract being considered.)

7. Equipment and Facilities
(Instructions: Offeror should state if they have necessary facilities and equipment to carry out the contract with specific details as appropriate per the subcontract SOW.)

8. Eligibility to Receive Award
(Instructions: Offeror should state if they are qualified and eligible to receive an award under applicable laws and regulation and affirm that they are not included in any list maintained by the US Government of entities debarred, suspended or excluded for US Government awards and funding. The Offeror should state whether they have performed work of similar nature under similar mechanisms for USAID.)

9. Commodity Procurement
(Instructions: If the Offeror does not have the capacity for commodity procurements - delete this section. If the Offeror does have the capacity, the Offeror should state their qualifications necessary to support the proposed subcontract requirements.)

10. Cognizant Auditor
(Instructions: Offeror should provide Name, address, phone of their auditors – whether it is a government audit agency, such as DCAA, or an independent CPA.)

11. Acceptability of Contract Terms
(Instructions: Offeror should state its acceptance of the proposed contract terms.)

12. Recovery of Vacation, Holiday and Sick Pay
(Instructions: Offeror should explain whether it recovers vacation, holiday, and sick leave through a corporate indirect rate (e.g. Overhead or Fringe rate) or through a direct cost. If the Offeror recovers vacation, holiday, and sick leave through a corporate indirect rate, it should state in this section the number of working days in a calendar year it normally bills to contracts to account for the vacation, holiday, and sick leave days that will not be billed directly to the contract since this cost is being recovered through the corporate indirect rate.)

13. Organization of Firm
(Instructions: Offeror should explain how their firm is organized on a corporate level and on practical implementation level, for example regionally or by technical practice.)

Signature: ________________________________
Name: ________________________________
One of the authorized negotiators listed in Section 2 above should sign
Title: ________________________________
Date: ________________________________

GlobalQMS ID: 681.11, 8 June 2020
Key Individual Certification Narcotics Offenses and Drug Trafficking

I hereby certify that within the last ten years:

1. I have not been convicted of a violation of, or a conspiracy to violate, any law or regulation of the United States or any country concerning narcotic or psychotropic drugs or other controlled substances.

2. I am not and have not been an illicit trafficker in any such drug or controlled substance.

3. I am not and have not been a knowing assistor, abettor, conspirator, or collagen with others in the illicit trafficking in any such drug or substance.

Signature: _______________________________ Date: _____

Name:
Title/Position:
Organization:
Address:
Date of Birth:

NOTICE:

1. You are required to sign this Certification under the provisions of 22 CFR Part 140, Prohibition on Assistance to Drug Traffickers. These regulations were issued by the Department of State and require that certain key individuals of organizations must sign this Certification.

2. If you make a false Certification you are subject to U.S. criminal prosecution under 18 U.S.C. 1001.
Subcontractor Size Self-Certification Form

Reference Number: [enter the funding agency's solicitation or contract number]
Project Name: [enter full name of project]
Primary NAICS Code: [enter the NAICS code that best describes the work being performed under the subcontract, i.e: for technical assistance provision use 541990 or management consulting use 541611. For HHE use 484210 and for GIS use 541360. A list of most common NAICS Codes used by Chemonics is available in the QMS (requires DailyChem access).]
Company Name: Full legal name
Address: Street address
City, State, Zip: City, State Zip
DUNS Number: [enter the Data Universal Numbering System (DUNS) here. Subcontractors must have a DUNS, unless exempted, as a part of receiving a subcontract with Chemonics]
Contact Person: Name, Title
Contact Phone Number: (555) 555-5555
Type of Entity
If you have difficulty ascertaining the business size status, please refer to SBA’s website (www.sba.gov/size) or contact your local SBA office.

☐ Small Business ☐ Large Business ☐ Nonprofit/Educational ☐ Government ☐ Non-US

If “Small Business” is checked above, and if applicable, please identify any additional small business designations under which the company qualifies. You may wish to review the definitions for the below categories in the Federal Acquisition Regulation 19.7 or 52.219-8 (www.acquisition.gov/far/) to determine applicability.

☐ Small Disadvantaged Business ☐ 8(a)
☐ HUBZone ☐ Woman Owned Small Business
☐ Veteran Owned ☐ Service Disabled Veteran Owned
☐ Alaskan Native Corporation ☐ Indian Tribe

By signature below, I hereby certify that the business type and designation indicated above is true and accurate as of the date of execution of this document, and I further understand that under 15 U.S.C. 645(d), any person who misrepresents a business’ size status shall (1) be punished by a fine, imprisonment, or both; (2) be subject to administrative remedies; and (3) be ineligible for participation in programs conducted under the authority of the Small Business Act.

__________________________________________  ___________________________
Signature and Title (required)  Date

************************************************************************CHEMONICS INTERNAL USE ONLY************************************************************************
HUBZone Status has been verified in the System for Award Management database or Dynamic Small Business Database Search as of ___/___/___ conducted by: _________________________________.

GlobalQMS ID: 681.11, 8 June 2020
**52.222-50 SUBCONTRACTOR CERTIFICATION REGARDING TRAFFICKING IN PERSONS COMPLIANCE PLAN (March 2, 2015)**

The Offeror/Subcontractor Certifies that:

(1) It has implemented a compliance plan to prevent any prohibited activities identified in paragraph (b) of the clause at 52.222–50, Combating Trafficking in Persons, and to monitor, detect, and terminate the contract with a subcontractor engaging in prohibited activities identified at paragraph (b) of the clause at 52.222–50, Combating Trafficking in Persons;

(2) The compliance plan applicable to the qualifying subcontract meets the minimum requirements set forth in subsection (b)(3) of clause 52.222-50, including the following:
   a. An awareness program to inform subcontractor employees about the Government’s policy prohibiting trafficking-related activities, the activities prohibited, and the actions that will be taken against the employee for violations.
   b. A process for employees to report, without fear of retaliation, activity inconsistent with the policy prohibiting trafficking in persons, including a means to make available to all employees the hotline phone number of the Global Human Trafficking Hotline at 1-844-888-FREE and its email address at help@befree.org.
   c. A recruitment and wage plan that only permits the use of recruitment companies with trained employees, prohibits charging recruitment fees to the employee, and ensures that wages meet applicable host-country legal requirements or explains any variance.
   d. A housing plan, if the subcontractor intends to provide or arrange housing that ensures that the housing meets host-country housing and safety standards.
   e. Procedures to prevent agents and subcontractors at any tier and at any dollar value from engaging in trafficking in persons (including activities in paragraph (b) of this clause) and to monitor, detect, and terminate any agents, subcontracts, or subcontractor employees that have engaged in such activities.

(3) The Offeror/Subcontractor will post the contents of the compliance plan, no later than the initiation of contract performance, at the workplace (unless the work is to be performed in the field or not in a fixed location) and on the Offeror’s/Subcontractor's Web site (if one is maintained). If posting at the workplace or on the Web site is impracticable, the Offeror/Subcontractor shall provide the contents of the compliance plan to each worker in writing. The Offeror/Subcontractor agrees to inform Chemonics immediately of any credible information it receives from any source (including host country law enforcement) that alleges a contractor employee, subcontractor, subcontractor employee, or their agent has engaged in conduct that violates the policy.

(4) After having conducted due diligence, either—
   (i) To the best of the Offeror’s/Subcontractor’s knowledge and belief, neither it nor any of its proposed agents, subcontractors, or their agents is engaged in any such activities; or,
   (ii) If abuses relating to any of the prohibited activities identified in 52.222–50(b) have been found, the Offeror or proposed Subcontractor has taken the appropriate remedial and referral actions.

PLEASE SIGN AND RETURN THIS CERTIFICATION TO CHEMONICS

Company Name_____________________________________________________

Company Address_________________________________________________________________

Signature___________________________ Printed Name ______________

Title_______________________________ Date_________________________________

NOTE: The Subcontractor is required to recertify annually by signing this document one year from the date signed above and resending it to the Contractor.
Annex 4  

DUNS and SAM Registration Guidance

What is DUNS?

The Data Universal Numbering System (DUNS) is a system developed and regulated by Dun & Bradstreet (D&B) - a company that provides information on corporations for use in credit decisions - that assigns a unique numeric identifier, referred to as a DUNS number, to a single business entity. The DUNS database contains over 100 million entries for businesses throughout the world, and is used by the United States Government, the United Nations, and the European Commission to identify companies. The DUNS number is widely used by both commercial and federal entities and was adopted as the standard business identifier for federal electronic commerce in October 1994. The DUNS number was also incorporated into the Federal Acquisition Regulation (FAR) in April 1998 as the Federal Government's contractor identification code for all procurement-related activities.

Why am I being requested to obtain a DUNS number?

U.S. law – in particular the Federal Funding Accountability and Transparency Act of 2006 (Pub.L. 109-282), as amended by section 6202 of the Government Funding Transparency Act of 2008 (Pub.L. 110-252) - make it a requirement for all entities doing business with the U.S. Government to be registered, currently through the System for Award Management, a single, free, publicly- searchable website that includes information on each federal award. As part of this reporting requirement, prime contractors such as Chemonics must report information on qualifying subawards as outlined in FAR 52.204-10 and 2CFR Part 170. Chemonics is required to report subcontracts with an award valued at greater than or equal to $30,000 under a prime contract and subawards under prime grants or prime cooperative agreements obligating funds of $25,000 or more, whether U.S. or locally based. Because the U.S. Government uses DUNS numbers to uniquely identify businesses and organizations, Chemonics is required to enter subaward data with a corresponding DUNS number.

Is there a charge for obtaining a DUNS number?

No. Obtaining a DUNS number is absolutely free for all entities doing business with the Federal government. This includes current and prospective contractors, grantees, and loan recipients.

How do I obtain a DUNS number?

DUNS numbers can be obtained online at http://fedgov.dnb.com/webform/pages/CCRSearch.jsp or by phone at 1-800-234-3867 (for US, Puerto Rico and Virgin Island requests only).

What information will I need to obtain a DUNS number?

To request a DUNS number, you will need to provide the following information:

- Legal name and structure
- Tradestyle, Doing Business As (DBA), or other name by which your organization is commonly recognized
- Physical address, city, state and Zip Code
- Mailing address (if separate)
- Telephone number
- Contact name
- Number of employees at your location
- Description of operations and associated code (SIC code found at https://www.osha.gov/pls/imis/sicsearch.html)
• Annual sales and revenue information
• Headquarters name and address (if there is a reporting relationship to a parent corporate entity)

How long does it take to obtain a DUNS number?

Under normal circumstances the DUNS is issued within 1-2 business days when using the D&B web form process. If requested by phone, a DUNS can usually be provided immediately.

Are there exemptions to the DUNS number requirement?

There may be exemptions under specific prime contracts, based on an organization’s previous fiscal year income when selected for a subcontract award, or Chemonics may agree that registration using the D&B web form process is impractical in certain situations. Organizations may discuss these options with the Chemonics representative.

What is CCR/SAM?

Central Contractor Registration (CCR)—which collected, validated, stored and disseminated data in support of agency acquisition and award missions—was consolidated with other federal systems into the System for Award Management (SAM). SAM is an official, free, U.S. government-operated website. There is NO charge to register or maintain your entity registration record in SAM.

When should I register in SAM?

While registration in SAM is not required for organizations receiving a grant under contract, subcontract or cooperative agreement from Chemonics, Chemonics requests that partners register in SAM if the organization meets the following criteria requiring executive compensation reporting in accordance with the FFATA regulations referenced above. SAM.gov registration allows an organization to directly report information and manage their organizational data instead of providing it to Chemonics. Reporting on executive compensation for the five highest paid executives is required for a qualifying subaward if in your business or organization’s preceding completed fiscal year, your business or organization (the legal entity to which the DUNS number belongs):

(1) received 80 percent or more of its annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and

(2) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and,

(3) The public have does not have access to information about the compensation of the executives in your business or organization (the legal entity to which the DUNS number it provided belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the US Internal Revenue Code of 1986.

If your organization meets the criteria to report executive compensation, the following sections of this document outline the benefits of and process for registration in SAM.gov. Registration may be initiated at https://www.sam.gov. There is NO fee to register for this site.

Why should I register in SAM?
Chemonics recommends that partners register in SAM to facilitate their management of organizational data and certifications related to any U.S. federal funding, including required executive compensation reporting. Executive compensation reporting for the five highest paid executives is required in connection with the reporting of a qualifying subaward if:

a. In your business or organization's preceding completed fiscal year, your business or organization (the legal entity to which the DUNS number belongs) received (1) 80 percent or more of its annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and (2) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements; and,

b. The public have does not have access to information about the compensation of the executives in your business or organization (the legal entity to which the DUNS number it provided belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986.

What benefits do I receive from registering in SAM?

By registering in SAM, you gain the ability to bid on federal government contracts. Your registration does not guarantee your winning a government contract or increasing your level of business. Registration is simply a prerequisite before bidding on a contract. SAM also provides a central storage location for the registrant to supply its information, rather than with each federal agency or prime contractor separately. When information about your business changes, you only need to document the change in one place for every federal government agency to have the most up-to-date information.

How do I register in SAM?


Follow the step-by-step guidance for contracts registrations at:

You must have a Data Universal Numbering System (DUNS) number in order to begin either registration process.

If you already have the necessary information on hand (see below), the online registration takes approximately one hour to complete, depending upon the size and complexity of your business or organization.

What data is needed to register in SAM?

SAM registrants are required to submit detailed information on their company in various categories. Additional, non-mandatory information is also requested. Categories of required and requested information include:

* General Information - Includes, but is not limited to, DUNS number, CAGE Code, company name, Federal Tax Identification Number (TIN), location, receipts, employee numbers, and web site address.

* Corporate Information - Includes, but is not limited to, organization or business type and SBA-defined socioeconomic characteristics.
* Goods and Services Information - Includes, but is not limited to, NAICS code, SIC code, Product Service (PSC) code, and Federal Supply Classification (FSC) code.

* Financial Information - Includes, but is not limited to, financial institution, American Banking Association (ABA) routing number, account number, remittance address, lock box number, automated clearing house (ACH) information, and credit card information.

* Point of Contact (POC) Information - Includes, but is not limited to, the primary and alternate points of contact and the electronic business, past performance, and government points of contact. * Electronic Data Interchange (EDI) Information* - Includes, but is not limited to, the EDI point of contact and his or her telephone, e-mail, and physical address. (*Note: EDI Information is optional and may be provided only for businesses interested in conducting transactions through EDI.)
### Vehicle Verification Checklist

#### GHSC-PSM PSC VEHICLE INSPECTION TOOL

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>YES</th>
<th>NO</th>
<th>COMMENTS</th>
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</thead>
<tbody>
<tr>
<td>ACTUAL VAN AGREE TO PLANNED VAN</td>
<td></td>
<td></td>
<td>Vehicle Reg. No.:</td>
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<td></td>
<td></td>
<td></td>
<td>Mileage (KM):</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Tonnage:</td>
</tr>
</tbody>
</table>

#### EXTERIOR INSPECTION

- a) Headlights, indicators, reverse and hazard lights working
- b) All mirrors are present, unobstructed, and adjustable
- c) Windshield wipers are wiper fluid pump working
- d) All tires have adequate inflation and acceptable tread wear.
- e) Vehicle has up to date insurance, COF and Class B disks on windshield
- f) Driver has a valid driver's licence matching the type of van
- g) Van is painted white on the outside to insulate commodities against high temperatures
- h) Rear doors are locked securely to prevent the doors from opening during transit and to secure the goods
- i) Cargo cabin entrance sealed to prevent entry of dust or water

#### INTERIOR INSPECTION

- a) The odometer and speedometer are in good working order
- b) The horn is working properly
- d) Driver's cabin separated from the cargo cabin to avoid direct access
- e) Inside of the cargo cabin clean and free of contaminants

<table>
<thead>
<tr>
<th>Name of GHSC-PSM Officer</th>
<th>Signature:</th>
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</thead>
<tbody>
<tr>
<td>Name of Van Driver</td>
<td>Signature:</td>
</tr>
</tbody>
</table>
GOOD STORAGE AND DISTRIBUTION PRACTICES

(May 2019)

DRAFT FOR COMMENTS

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (koppins@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) by 15 June 2019.

Medicines Quality Assurance working documents will be sent out electronically only. They will also be placed on the Medicines website for comment under “Current projects”. If you have not already received our draft working documents, please send your email address (to jonessi@who.int) and we will add you to our electronic mailing list.

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Please send any request for permission to:

Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms, Department of Essential Medicines and Health Products, World Health Organization, CH-1211 Geneva 27, Switzerland, fax: (41 22) 791 4856, email: koppins@who.int.

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## SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.793:
### GOOD STORAGE AND DISTRIBUTION PRACTICES

<table>
<thead>
<tr>
<th>Description of Activity</th>
<th>Date</th>
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<tbody>
<tr>
<td>During the Fifty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP), the Expert Committee recommended consolidation of the <em>Good storage practices</em> and <em>Good distribution practices</em> for pharmaceutical products and the elements of good distribution channel guidance into one document.</td>
<td>22-26 October 2018</td>
</tr>
<tr>
<td>Preparation of first draft working document by Dr André Van Zyl, a member of the Fifty-third ECSPP.</td>
<td>December 2018 - March 2019</td>
</tr>
<tr>
<td>Mailing of working document to the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) inviting comments and posting of the working document on the WHO website for public consultation.</td>
<td>April – June 2019</td>
</tr>
<tr>
<td>Consolidation of comments received and review of feedbacks. Preparation of working document for discussion.</td>
<td>June 2019</td>
</tr>
<tr>
<td>Discussion of working document and feedbacks received during the informal Consultation on Good Practices for Health Products Manufacture and Inspection.</td>
<td>July 2019</td>
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<tr>
<td>Revision of the working document based on comments received during the informal Consultation on Good Practices for Health Products Manufacture and Inspection.</td>
<td>End of July 2019</td>
</tr>
<tr>
<td>Mailing of revised working document to the EAP inviting comments and posting the working document on the WHO website for public consultation.</td>
<td>August – September 2019</td>
</tr>
<tr>
<td>Consolidation of comments received and review of feedbacks. Preparation of working document for discussion.</td>
<td>End of September 2019</td>
</tr>
<tr>
<td>Presentation to the Fifty-fourth meeting of the ECSPP.</td>
<td>14-18 October 2019</td>
</tr>
<tr>
<td>Any other follow-up action as required.</td>
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</table>
GOOD STORAGE AND DISTRIBUTION PRACTICES

1. INTRODUCTION

1.1. Storage and distribution are important activities in the supply chain management of medical products. Various people and entities are generally responsible for handling, storage and distribution. Products may be subjected to various risks at different stages in the supply chain, i.e. during purchasing, storage, distribution, transportation, repackaging, and relabelling. Further, substandard and falsified products are a real threat to public health and safety. Consequently, it is essential to protect the supply chain against the penetration of such products.

1.2. This document sets out appropriate steps to assist in fulfilling the responsibilities involved in the different stages within the supply chain and to avoid the introduction of substandard and falsified products into the market. The relevant sections should be considered as particular roles that entities play in the storage and distribution of medical products.

1.3. This guideline is intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of medical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade, storage and distribution of medical products, manufacturers and wholesalers, as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

1.4. The relevant sections of this guideline should also be considered for implementation by, amongst others, governments, regulatory bodies, international procurement organizations, donor agencies and certifying bodies, as well as all parties involved in any aspect of the trade and distribution of pharmaceutical products, including health care workers.

1.5. The guidelines can also be used as a tool in the prevention of the distribution of substandard and falsified products. It should, however, be noted that these are general
1.6. To maintain the original quality of medical products, every party active in the supply chain has to comply with the applicable legislation and regulations. Every activity in the storage and distribution of medical products should be carried out according to the principles of good manufacturing practices (GMP), good storage practice (GSP) and good distribution practice (GDP) as applicable.

1.7. This guideline does not deal with dispensing to patients as this is addressed in the World Health Organization (WHO) good pharmacy practice (GPP) guide (xx). These guidelines should also be read in conjunction with other WHO guidelines (xx).

2. SCOPE

2.1. This document lays down guidelines for the storage and distribution of medical products. It is closely linked to other existing guidelines recommended by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, such as referenced in section (xyz).

2.2. Depending on the national and regional legislation, these guidelines may apply equally to products for human and for veterinary use. The guidelines thus cover products for which a prescription is required by the patient, products which may be provided to a patient without a prescription, biologicals, vaccines and medical devices.

2.3. The document does not specifically cover GMP aspects of finished products in bulk, distribution of labels or packaging as these aspects are considered to be covered by other guidelines. The principles for the distribution of starting materials (active pharmaceutical ingredients (APIs) and excipients) are also not covered here. These are laid down in the WHO guidance “Good Trade and Distribution Practices for Pharmaceutical Starting Materials” (7).
The definitions provided below apply to the words and phrases used in this guideline. Although an effort has been made to use standard definitions as far as possible, they may have different meanings in other contexts and documents.

**active pharmaceutical ingredient (API)**
Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when used in the production of a drug, becomes an active ingredient of that drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

**ALCOA**
A commonly used acronym for “attributable, legible, contemporaneous, original and accurate”.

**Auditing**
An independent and objective activity designed to add value and improve an organization’s operations by helping the organization to accomplish its objectives by using a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes.

**batch**
A defined quantity of pharmaceutical products processed in a single process or series of processes so that it is expected to be homogeneous.

**batch number**
A distinctive combination of numbers and/or letters which uniquely identifies a batch, for example, on the labels, its batch records and corresponding certificates of analysis.
consignment
The quantity of pharmaceutical products supplied at one time in response to a particular request or order. A consignment may comprise of one or more packages or containers and may include pharmaceutical products belonging to more than one batch.

container
The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product.

contamination
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material, intermediate or pharmaceutical product during handling, production, sampling, packaging or repackaging, storage or transportation.

contract
Business agreement for the supply of goods or performance of work at a specified price.

corrective and preventative actions (CAPA)
A system for implementing corrective actions and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring.

cross-contamination
Contamination of a starting material, intermediate product or finished pharmaceutical product with another starting material or product during production, storage and transportation.
distribution
The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent.

excipient
A substance, other than the active ingredient, which has been appropriately evaluated for safety and is included in a drug delivery system to aid in the processing of the drug delivery system during its manufacture; protect, support or enhance stability, bioavailability, or patient acceptability; assist in product identification; or enhance any other attribute of the overall safety and effectiveness of the drug during storage or use.

expiry date
The date given on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf life to the date of manufacture.

first expiry/first out (FEFO)
A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

forwarding agent
A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and includes a consignment agent.

good distribution practices (GDP)
That part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from
counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products.

good manufacturing practices (GMP)
That part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

good pharmacy practice (GPP)
The practice of pharmacy aimed at providing and promoting the best use of medicines and other health care services and products, by patients and members of the public. It requires that the welfare of the patient is the pharmacist’s prime concern at all times.

good storage practices (GSP)
That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.

good trade and distribution practices (GTDP)
That part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities which occur during the trade and the distribution process.

heating, ventilation and air conditioning systems (HVAC)
Heating, ventilation and air-conditioning, also referred to as environmental control system (ECS).

importation
The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).
intermediate product

Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.

labelling

Process of identifying a pharmaceutical product including the following information, as appropriate: name of the product; active ingredient(s), type and amount; batch number; expiry date; special storage conditions or handling precautions; directions for use, warnings and precautions; names and addresses of the manufacturer and/or the supplier.

manufacture

All operations of purchase of materials and products, production, packaging, labelling, quality control, release, storage and distribution of pharmaceutical products, and the related controls.

marketing authorization

A legal document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality. It must set out, inter alia, the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using International Nonproprietary Names (INNs) or national generic names where they exist), the shelf life and storage conditions, and packaging characteristics. It specifies the information on which authorization is based (e.g. “The product(s) must conform to all the details provided in your application and as modified in subsequent correspondence”). It also contains the product information approved for health professionals and the public, the sales category, the name and address of the holder of the authorization and the period of validity of the authorization. Once a product has been given marketing authorization, it is included on a list of authorized products - the register - and is often said to be “registered” or to “have registration”. Market authorization may occasionally also be referred to as a “licence” or “product licence”.

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material
A general term used to denote starting materials (active pharmaceutical ingredients and excipients), reagents, solvents, process aids, intermediates, packaging materials and labelling materials.

packaging material
Any material, including printed material, employed in the packaging of a pharmaceutical product, but excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

pedigree
A complete record that traces the ownership of and transactions relating to a pharmaceutical product as it is distributed through the supply chain.

pharmaceutical product
Any product intended for human use, or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which 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. It does not, however, include medical devices.

product recall
A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit. The recall might be initiated by the manufacturer, importer, wholesaler, distributor or a responsible agency.

production
All operations involved in the preparation of a pharmaceutical product, from receipt of materials through processing, packaging and repackaging, labelling and relabelling, to completion of the finished product.
quality assurance
A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

quality risk management
A systematic process for the assessment, control, communication and review of risks to the quality of pharmaceutical products across the product life-cycle.

quality system
An appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

quarantine
The status of pharmaceutical products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

retest date
The date when a material should be re-examined to ensure that it is still suitable for use.

sampling
Operations designed to obtain a representative portion of a pharmaceutical product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.

shelf life
The period of time during which a pharmaceutical product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches of the product. The shelf life is used to establish the expiry date of each batch.
standard operating procedure (SOP)
An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises and environmental control, sampling and inspection).

storage
The storing of pharmaceutical products up to the point of use.

supplier
A person or entity engaged in the activity of providing products and/or services.

transit
The period during which pharmaceutical products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.

vehicles
Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceutical products

4. GENERAL PRINCIPLES

4.1. There should be collaboration between all parties, including governments, customs agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of medical products to patients, to ensure the quality and safety of these products; to prevent the exposure of patients to substandard and falsified products and to ensure that the integrity of the distribution chain is maintained.

4.2. The principles of GSP and GDP should be included in national legislation and guidelines for the storage and distribution of medical products, in a country or region as applicable, as a means of establishing minimum standards. The principles of GSP and GDP are applicable to:
• products moving forward in the distribution chain from the manufacturer;
• products which are moving backwards in the chain, for example, as a result of the return or recall thereof; and
• donations of products.

5. QUALITY MANAGEMENT

Quality Systems

5.1. Entities involved in the storage and distribution of medical products must have a comprehensively designed and correctly implemented, documented, quality system that incorporates good storage practices, good distribution practices, quality risk management and management review.

5.2. Senior management has the ultimate responsibility to ensure an effective quality system is established, is adequately resourced, implemented and maintained. The effectiveness, roles, responsibilities and authorities should be defined, communicated and implemented throughout the organization.

5.3. The quality system should ensure that:

• GSP and GDP is adopted and managed through satisfactory arrangements to ensure, as far as possible, that the medical products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf-life in the supply-chain;
• products are appropriately procured, stored, distributed and delivered to the right recipients;
• operations are clearly specified in a written procedures;
• responsibilities are clearly specified in job descriptions;
• all risks are identified and necessary, effective controls are implemented;
• processes are in place to assure the management of outsourced activities;
• there is a procedure for self-inspection and/or quality audit;
• there is a system for quality risk management (QRM);
there are systems for managing returns, complaints and recalls;

systems are in place to manage changes, deviations and corrective and preventive actions (CAPAs).

5.4. There should be an authorized, written quality policy describing the overall intentions and requirements regarding quality. This may be reflected in a quality manual.

5.5. There should be an appropriate organizational structure. This should be presented in an authorized organizational chart. The responsibility, authority and interrelationships of all personnel should be clearly indicated.

5.6. Duties and responsibilities should be clearly defined and understood by the individuals concerned and recorded as written job descriptions.

5.7. The quality system should include appropriate procedures, processes and resources.

6. QUALITY RISK MANAGEMENT

6.1. There should be a system to assess, control, communicate and review risks identified at all stages in the supply chain. The evaluation of the risk should be based on scientific knowledge and experience with the process and ultimately linked to the protection of the patient.

6.2. Appropriate controls should be developed and implemented to address any risks identified. The effectiveness of the controls implemented should be evaluated at periodic intervals.

(For further reading, see also WHO Guideline on Risk Management and ICH Q9, ISO 31000).

7. MANAGEMENT REVIEW

7.1. There should be a system for periodic management review. The review should include:

• senior management;
7.2. Records should be maintained.

8. **COMPLAINTS**

8.1. There should be a written procedure for the handling of complaints. A distinction should be made between complaints about a product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/or marketing authorization holder should be informed as soon as possible.

8.2. All complaints should be recorded and appropriately investigated. The root cause should be identified and the impact (e.g. on other batches or products) and risk assessed. Appropriate CAPA should be taken.

8.3. Where required, the national regulatory authority should be informed and a recall initiated where appropriate.

8.4. The relevant information, such as the results of the investigation of the complaint, should be shared with the relevant parties.

8.5. Product quality problems or suspected cases of substandard or falsified products are identified and these should be handled according to the relevant procedures. The information should be shared with the appropriate national and/or regional regulatory authorities.

9. **RETURNED GOODS**

9.1. Returned medical products should be handled in accordance with authorized procedures.
9.2. All returned goods should be placed in quarantine upon receiving. The status of the goods should be clear. Precautions should be taken to prevent access and distribution until a decision has been taken with regard to their disposition. The particular storage conditions applicable to the products should be maintained.

9.3. When handling returned goods, at least the following considerations should be taken:

- A risk-based process should be followed when deciding on the fate of the returned goods. This should include, but not be limited to, the nature of the product, storage conditions, condition of the product history, time-lapse since distribution, manner and condition of transport while being returned;
- the terms and conditions of the agreement between the parties; and
- examination of the returned goods, with decisions taken by suitably qualified, experienced and authorized persons.

9.4. Where products are rejected, authorized procedures should be followed, including safe transport.

9.5. Destruction of products should be done in accordance with international, national and local requirements regarding disposal of such products and with due consideration to the protection of the environment.

9.6. Records of all returned, rejected and destroyed medical products should be kept for a defined period.

10. RECALLS

10.1. There should be a written procedure to effectively and promptly recall medical products in compliance with national or regional requirements. A designated person(s) should be responsible for recalls.
10.2. The effectiveness of the procedure should be checked annually and updated as necessary.

10.3. The original manufacturer and/or marketing authorization holder, or other relevant contract party, should be informed in the event of a recall.

10.4. Information on a recall should be shared with the appropriate national or regional regulatory authority.

10.5. All recalled products should be transported and stored in secure, segregated conditions and clearly labelled as recalled products. The particular storage conditions applicable to the product should be maintained.

10.6. All customers and competent authorities of all countries to which a given product may have been distributed should be informed promptly of the recall of the product.

10.7. All records, including distribution records, should be readily accessible to the designated person(s) responsible for recalls. These records should contain sufficient information on products supplied to customers (e.g. name, address, contact detail, batch numbers, quantities, safety features - including exported products).

10.8. The progress of a recall process should be recorded and a final report issued which includes a reconciliation between delivered and recovered quantities of products.

11. **SELF-INSPECTION**

11.1. The quality system should include self-inspections. These should be conducted to monitor implementation and compliance with the principles of regulations, GSP, GDP and other appropriate guidelines.

11.2. Self-inspections should be conducted periodically according to an annual schedule.
11.3. The team conducting the inspection should be free from bias and individual members should have appropriate knowledge and experience. Audits by independent third parties may be beneficial.

11.4. The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and presented to the relevant personnel as well as management.

11.5. Necessary CAPAs should be taken and the effectiveness of the CAPAs should be reviewed.

12. PREMISES

General

12.1. Premises should be suitably located, designed, constructed and maintained to ensure appropriate operations such as receiving, storage, picking, packing and dispatch of medical products.

12.2. There should be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness.

12.3. Sufficient security should be provided and access should be controlled.

12.4. Appropriate controls and segregation should be provided for products requiring specific handling or storage such as radio-active materials, products containing hazardous substances, and products to be stored under controlled temperature and relative humidity conditions.

12.5. Receiving and dispatch bays should be separate and should protect products from weather conditions.

12.6. Activities relating to receiving and dispatch such be done in accordance with authorized procedures. Areas should be suitably equipped for the operations.
12.7. Premises should be kept clean. Cleaning equipment and cleaning agents should not become possible sources of contamination.

12.8. Premises should be protected from the entry of birds, rodents, insects and other animals. A rodent and pest control programme should be in place.

12.9. Toilets, wash, rest and canteen facilities should be separate from other areas. Food, eating, drinking, and smoking should be prohibited in all areas where medical products are stored or handled.

**Receiving**

12.10. Each incoming delivery should be checked against the relevant documentation to ensure that the correct product is delivered from the correct supplier. This may include, e.g. the purchase order, each container, label description, batch number, product and quantity.

12.11. The consignment should be examined for uniformity of the containers and, if necessary, should be subdivided according to the supplier’s batch number should the delivery comprise more than one batch. Each batch should be dealt with separately.

12.12. Each container should be carefully checked for possible contamination, tampering and damage. Any suspect containers or, if necessary, the entire delivery should be quarantined for further investigation.

12.13. Receiving areas should be of sufficient size to allow cleaning of incoming containers.

12.14. When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling procedure and sampling plans. Containers from which samples have been taken should be labelled accordingly.
12.15. Following sampling, the goods should be subject to quarantine. Batch segregation should be maintained during quarantine and all subsequent storage.

12.16. Materials and products requiring storage under controlled conditions of temperature and relative humidity should be handled as a priority.

12.17. Materials and products should remain in quarantine until an authorized release or rejection is obtained.

12.18. Measures should be taken to ensure that rejected materials and products cannot be used. They should be stored separately from other materials and products while awaiting destruction or return to the supplier.

**Storage areas**

12.19. Precautions should be taken to prevent unauthorized persons from entering storage areas.

12.20. Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of materials and products, such as starting and packaging materials, intermediates, finished products, products in quarantine, and released, rejected, returned or recalled products.

12.21. Storage areas should be appropriately designed, constructed, maintained or adapted. They should be kept clean and dry and there should be sufficient space and lighting.

12.22. Storage areas should be maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, controlled, monitored and recorded.
12.23. Materials and products should be stored off the floor and suitably spaced to permit ventilation, cleaning and inspection. Suitable pallets should be used and kept in a good state of cleanliness and repair.

12.24. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.

12.25. There should be a written programme for pest control. The pest-control agents used should be safe and there should be no risk of contamination of the materials and products.

12.26. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

12.27. Where the status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing physical separation and labelling or demarcation should provide equivalent security. For example, computerized systems can be used provided that they are validated to demonstrate security of access.

12.28. Where required, a separate sampling area should be in place. If sampling is performed in the storage area, it should be conducted in such a way that there is no risk of contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.

12.29. Certain materials and products such as highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and products, as well as substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases), should be stored in a dedicated area that is subject to appropriate additional safety and security measures.
12.30. Materials and products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

12.31. Materials and products should be stored in conditions which assure that their quality is maintained and stock should be appropriately rotated. The “first expired/first out” (FEFO) principle should be followed.

12.32. Rejected materials and products should be identified and controlled under a quarantine system designed to prevent their use until a final decision is taken on their fate.

12.33. Narcotic products should be stored in compliance with international conventions, and national laws and regulations on narcotics.

12.34. Broken or damaged items should be withdrawn from usable stock and separated.

12.35. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

Storage conditions

12.36. The storage conditions for materials and medical products should be in compliance with the labelling, which is based on the results of stability testing.

12.37. Heating, ventilation and air conditioning systems (HVAC) should be appropriately designed, installed, qualified and maintained to ensure that the required storage conditions are maintained.

12.38. Where required, mapping studies for temperature and relative humidity, as appropriate, should be done to show uniformity across the storage facility. (Ref: WHO Technical Report Series No. 961, Annex 9, Model guidance for the storage and transport
of time- and temperature-sensitive pharmaceutical products). This applies, for example, to areas, refrigerators and freezers.

12.39. Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for their intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time and as required by national legislation.

12.40. Temperature and relative humidity, as appropriate, should be controlled and monitored at regular intervals. Data should be recorded and the records should be reviewed. The equipment used for monitoring should be calibrated and be suitable for their intended use. All records pertaining to mapping and monitoring should be kept for a suitable period of time and as required by national legislation.

Note: See annexure 1 for recommended storage conditions.

13. STOCK CONTROL AND ROTATION

13.1. Periodic stock reconciliation should be performed at defined intervals by comparing the actual and recorded stocks.

13.2. The root cause for stock discrepancies should be identified and appropriate CAPAs taken to prevent recurrence.

13.3. Damaged containers should not be issued unless the quality of the material has been shown to be unaffected. Where possible, this should be brought to the attention of the person responsible for quality. Any action taken should be documented.

13.4. All stocks should be checked regularly for obsolete, to be retested, and expired materials and products.
14. EQUIPMENT

14.1. Equipment, including computerized systems should be suitable for their intended use. These should be appropriately designed, located, installed, qualified and maintained.

14.2. Computerized systems should be capable of achieving the desired output and results.

14.3. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the supply chain and products concerned.

14.4. Electronic transactions (including those conducted via the Internet) relating to the distribution of medical products should be performed only by authorized persons according to defined and authorized access and privileges.

14.5. Where GXP systems are used, these should meet the requirements of 21 CFR 211 Part 11, EU chapter 11 and WHO guidelines on computerized systems.

14.6. Data should meet ALCOA principles. Procedures should be followed, and records maintained for the back-up and restoration of data.

15. QUALIFICATION AND VALIDATION

15.1. The scope and extent of qualification and validation should be determined using a documented risk assessment approach.

15.2. Premises, utilities, equipment and instruments, processes and procedures should be considered. The scope and extent of qualification and validation in case of any significant changes should be identified.

15.3. Qualification and validation should be done following procedures and protocols. The results and outcome of the qualification and validation should be
recorded in reports. Deviations should be investigated and the completion of the qualification and validation should be concluded and approved by responsible personnel.

16. PERSONNEL

16.1. There should be an adequate number of personnel.

16.2. Personnel should have appropriate educational qualification, experience and training relative to the activities undertaken.

16.3. Personnel should have the authority and resources needed to carry out their duties and to follow the quality systems, as well as to identify and correct deviations from the established procedures.

16.4. There should be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products.

16.5. Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

16.6. Personnel should receive initial and continued training in accordance with a written training programme. The training should cover the requirements of GSP, GDP (as applicable), as well as on-the-job training. Other topics may include product security, product identification, the detection of falsified products.

16.7. Personnel dealing with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion) should be given specific training.
16.8. Personnel should be trained in, and observe high levels of, personal hygiene and sanitation.

16.9. Records of all training, attendance and assessment should be kept.

16.10. Personnel handling products should wear garments suitable for the activities that they perform. Personnel dealing with hazardous pharmaceutical products, including products containing materials that are highly active, toxic, infectious or sensitizing, should be provided with protective garments as necessary.

16.11. Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.

16.12. Procedures and conditions of employment for employees, including contract and temporary staff, and other personnel having access to medical products, must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

16.13. Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the storage and distribution of medical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or falsifying of any product.

17. DOCUMENTATION

17.1. Documentation includes all procedures and records, whether in paper or electronic form. Documents should be appropriately designed, completed, reviewed, authorized, distributed and kept as required. Documents should be readily available.
17.2. Written procedures should be followed for the preparation, review, approval, use of and control of all documents relating to the policies and activities for storage and distribution of medical products process.

17.3. Documents should be laid out in an orderly fashion and be easy to complete, review and check. The title, scope, objective and purpose of each document should be clear.

17.4. The contents of documents should be accurate, legible, traceable, attributable and unambiguous.

17.5. All documents should be completed, signed and dated as required by authorized person(s) and should not be changed without the necessary authorization.

17.6. Documentation should be prepared and maintained in accordance with the national legislation and principles of good documentation practices (see WHO Technical Report Series No. 996, Annex 5, Guidance on good data and record management practices).

17.7. The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

17.8. Documents should be reviewed regularly and kept up-to-date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

17.9. All records must be readily retrievable and be stored and retained using facilities that are safeguarded against unauthorized access, modification, damage, deterioration and/or loss of documentation.

17.10. Records should contain at least the following information:

• date;
• name of the product;
• quantity received, or supplied; and
• name and address of the supplier.

17.11. Comprehensive records should be maintained for all receipts, materials and products stored, and issues or distribution. They should include, for example, the description of the goods, quantity, names and addresses (such supplier, customer), batch number(s), date of receipt/dispatch and expiry date.

17.12. All containers should be clearly labelled with at least the name of the material/product, the batch number, the expiry date or retest date, and the specified storage conditions. Unauthorized abbreviations, names or codes should not be used.

18. ACTIVITIES AND OPERATIONS

18.1. All activities and operations relating to procurement, storage and distribution of medical products should be conducted in accordance with national legislation, GSP, GDP and associated guidelines.

18.2. Storage and distribution of medical products should be done by persons so authorized, in accordance with national legislation.

18.3. Activities and operations should be performed in accordance with documented procedures.

Receiving

18.4. Materials and products should be procured from appropriately authorized suppliers.

18.5. Deliveries should be examined for damage, seal intactness, signs of tampering, labelling, completeness of order and other related aspects, at receipt.
18.6. Containers and consignments not meeting acceptance criteria for receiving should be separated, quarantined and investigated. This includes suspected falsified products.

18.7. Materials and products requiring specific storage conditions, or access control (e.g. narcotics) should be processed without delay and stored in accordance with their requirements.

Storage

18.8. There should be sufficient space for the safe and secure storage of medical products (see section xxx above).

18.9. Appropriate controls should be implemented to prevent contamination and/or mix ups during storage.

18.10. Storage areas should be clean and kept free from litter, birds, dust and pests.

18.11. Controls and procedures should be in place to prevent and handle spillage and breakage.

18.12. Materials and products should be stored under the conditions specified on the label, e.g. controlled temperature and relative humidity when necessary. When specific storage conditions are required, the storage area should be qualified and operated within the specified limits. The storage conditions should be monitored and records maintained. The records should be reviewed and trends and out of limit results investigated.

18.13. Stock should be rotated and the FEFO policy should be implemented.

18.14. Computerized systems used for stock management should be validated.

18.15. Materials and products reaching their expiry date should be separated from usable stock and not be supplied.
Repackaging and relabelling

18.16. Repackaging and relabelling of materials and products are not recommended. Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the applicable national, regional and international requirements, and in accordance with GMP.

18.17. Procedures should be in place for the controlled disposal of original packaging to prevent re-use.

Distribution and transport

18.18. Materials and products should be transported in accordance with the conditions stated on the labels. There should be no risk to the quality of the material or product during transport and distribution.

18.19. Product, batch and container identity should be maintained at all times.

18.20. All labels should remain legible.

18.21. Distribution records should be sufficiently detailed to allow for a recall when required.

18.22. A copy of the original certificate of analysis from the manufacturer should be provided to the customer.

18.23. Drivers of vehicles should be identified and present appropriate documentation to demonstrate that they are authorized to transport medical products.

18.24. Vehicles should be suitable for their purpose, with sufficient space and appropriately equipped to protect materials and products.
18.25. The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the products.

18.26. Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security and traceability of vehicles with products.

18.27. Where possible, dedicated vehicles and equipment should be used for medical products. Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the products will not be compromised. Defective vehicles and equipment should not be used. These should either be labelled as such or removed from service.

18.28. There should be procedures in place for the operation and maintenance of all vehicles and equipment.

18.29. There should be written programmes and records for cleaning and pest control. Records should be kept. The cleaning and fumigation agents used should not have any adverse effect on product quality.

18.30. Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by management.

18.31. Appropriate environmental conditions should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf life of the product distributed plus one year, or longer, if required by national legislation. Records of monitoring data should be made available for inspection by the regulatory or other oversight body.

18.32. Instruments used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.
18.33. Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned products as well as those suspected as falsified. Such goods should be securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

18.34. Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof.

18.35. Shipment containers should have no adverse effect on the quality of the products and should offer adequate protection to materials and products. Containers should be labelled indicating, e.g. handling and storage conditions, precautions, contents and source, safety symbols as appropriate.

18.36. Special care should be taken when using dry ice in shipment containers due to safety issues and possible adverse effects on the quality of products.

18.37. Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

**Dispatch**

18.38. Products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the applicable national legislation. Written proof of such authorization must be obtained prior to the distribution of products to such persons or entities.

18.39. Dispatch and transportation should be undertaken only after the receipt of a valid order which should be documented.

18.40. There should be documented, detailed procedures for the dispatch of products.
18.41. Records for the dispatch of products should be prepared and should include information such as, but not limited to, date of dispatch; complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number, names of contact persons; status of the addressee (e.g. retail pharmacy, hospital or community clinic); a description of the products including, e.g. name, dosage form and strength (if applicable); quantity of the products, i.e. number of containers and quantity per container (if applicable); applicable transport and storage conditions; a unique number to allow identification of the delivery order; and assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability).

18.42. Records of dispatch should contain enough information to enable traceability of the product. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of falsified or potentially falsified products. In addition, the assigned batch number and expiry date of pharmaceutical products should be recorded at the point of receipt to facilitate traceability.

18.43. Vehicles and containers should be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

18.44. Products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

18.45. Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.

18.46. Products should be stored and transported in accordance with procedures such that:

• the identity of the product is not lost;

• the product does not contaminate and is not contaminated by other products;
• adequate precautions are taken against spillage, breakage, misappropriation and theft; and
• appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

18.47. Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature deviations. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient. In cases where the recipient notices the deviation, it should be reported to the distributor.

18.48. Transportation of products containing hazardous substances, or narcotics and other dependence-producing substances, should be transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of applicable international agreements and national legislation should be met.

18.49. Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

18.50. Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority, and investigated.

18.51. Products in transit must be accompanied by the appropriate documentation.

19. OUTSOURCED ACTIVITIES

19.1. Any activity relating to the storage and distribution of a medical product which is delegated to another person or entity should be performed by parties appropriately authorized, in accordance with national legislation, and the terms of a written contract.
19.2. There should be a written contract between the parties. The contract should define the responsibilities of each party (contract giver and contract acceptor) and at least the following:

- compliance with this guideline and the principles of GSP and GDP;
- relevant warranty clauses;
- responsibilities of the contractor for measures to avoid the entry of substandard and falsified products into the distribution chain;
- training of personnel;
- conditions of subcontracting subject to the written approval of the contract giver; and
- periodic audits.

19.3. The contract giver should assess the competence of the contract acceptor before entering into an agreement.

19.4. The contract giver should provide all relevant information relating to the material/products to the contract acceptor.

19.5. The contract acceptor should have adequate resources (e.g. premises, equipment, personnel, knowledge, experience, vehicles as appropriate) to carry out the work.

19.6. The contract acceptor should refrain from performing any activity that may adversely affect the materials or products handled.

20. SUBSTANDARD AND FALSIFIED PRODUCTS

20.1. The quality system should include procedures to assist in identifying and handling materials and products that are suspected to be substandard and or falsified.

20.2. Where these materials and products are identified, the holder of the marketing authorization, the manufacturer and the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, should be informed.
20.3. Such products should be stored in a secure, segregated area and clearly identified to prevent further distribution or sale. Access should be controlled.

20.4. Records should be maintained reflecting the investigations and action taken, such as disposal of the material or products. Falsified materials and products should not re-enter the market.

21. **INSPECTION OF STORAGE AND DISTRIBUTION FACILITIES**

21.1. Storage and distribution facilities should be inspected by inspectors so authorized in terms of national legislation. This should be done at determined periodic intervals.

21.2. Inspectors should have appropriate educational qualifications, knowledge and experience.

21.3. An inspection should normally be conducted by a team of inspectors.

21.4. Inspectors should assess compliance with national legislation, GSP, GDP and related guidelines (GxP) as appropriate.

21.5. Inspections should cover the premises, equipment, personnel, activities, quality system, qualification and validation, and other related aspects as contained in this guideline.

21.6. An inspection report should be prepared and provided to the inspected entity within 30 days from the last day of the inspection. Observations may be categorized based on risk assessment.

21.7. CAPA for observations listed as non-compliances in the inspection report, with the national legislation and guidelines, should be submitted for review by the inspectors within the defined period as stated by the inspectors.

21.8. Inspections should be closed with a conclusion after the review of the CAPAs.
References and further reading

[Note from Secretariat: the references included in the text will be added here in the final version. Proposals for further reading references are invited.]
ANNEXURE 1. RECOMMENDED STORAGE CONDITIONS

Note: Appropriate conditions should be provided for materials and products during storage and distribution. Conditions should be maintained as stated on their labels from the manufacturers and suppliers, during storage and distribution. Where possible, actual limits should be provided by the manufacturers, such as “store below 25°C”. Vague statements such as “store at ambient conditions” should be avoided.

Table 1. Recommended limits for descriptive storage conditions

<table>
<thead>
<tr>
<th>Label description</th>
<th>Recommended limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store at controlled room temperature</td>
<td>20 to 25°C</td>
</tr>
<tr>
<td>Store in a cool place</td>
<td>8 to 15°C</td>
</tr>
<tr>
<td>Store in a refrigerator</td>
<td>2 to 8°C</td>
</tr>
<tr>
<td>Store in a freezer</td>
<td>-25 to -10°C</td>
</tr>
<tr>
<td>Store in a dry place</td>
<td>No more than 60% relative humidity</td>
</tr>
<tr>
<td>Protect from moisture</td>
<td>No more than 60% relative humidity</td>
</tr>
<tr>
<td>Store under ambient conditions</td>
<td>Storage in dry, well-ventilated premises at temperatures of 15–30°C. Extraneous odours, other indications of contamination, and intense light must be excluded.</td>
</tr>
<tr>
<td>Do not store over 30°C</td>
<td>2 to 30°C</td>
</tr>
<tr>
<td>Do not store over 25°C</td>
<td>2 to 25°C</td>
</tr>
<tr>
<td>Do not store over 15°C</td>
<td>2 to 15°C</td>
</tr>
<tr>
<td>Do not store over 8°C</td>
<td>2 to 8°C</td>
</tr>
<tr>
<td>Do not store below 8°C</td>
<td>8 to 25°C</td>
</tr>
<tr>
<td>Protect from light</td>
<td>To be provided in light resistant containers. Light level not exceeding 300 lux.</td>
</tr>
<tr>
<td>Chilled</td>
<td>Refrigerated</td>
</tr>
</tbody>
</table>

These limits are recommended values, based on pharmacopoeia limits and guidelines.
Annex 7

Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products

Abbreviations

Background

Key to conventions used

Glossary

Introduction

Key to conventions used

1. Importation
   1.1 Port handling and customs clearance
      1.1.1 Port of entry
      1.1.2 Offloading
      1.1.3 Temporary storage at port of entry
      1.1.4 Customs clearance

2. Warehousing sites
   2.1 Site layout
      2.1.1 Natural hazards
      2.1.2 Site access
   2.2 Site security
   2.3 Site cleanliness

3. Storage buildings
   3.1 Construction standards
   3.2 Accommodation and layout
   3.3 Loading and receiving bays
      3.3.1 Loading bays
      3.3.2 Receiving bays
   3.4 Goods assembly and quarantine areas
      3.4.1 Goods assembly areas
      3.4.2 Holding area for incoming goods
      3.4.3 Quarantine area
   3.5 Environmental control of ancillary areas
   3.6 Building security
      3.6.1 General building security
3.6.2 Controlled and hazardous substances areas

3.7 Fire protection
3.7.1 Fire protection equipment
3.7.2 Fire prevention, detection and control procedures

3.8 Building hygiene
3.8.1 Building cleanliness
3.8.2 Pest control

3.9 Power supply
3.9.1 Uninterrupted power supply
3.9.2 Power failure contingency plan

3.10 Building maintenance

4. Temperature-controlled storage
4.1 Normative references
4.2 Storage capacity of temperature-controlled stores
4.3 Temperature-controlled storage
4.4 Temperature-controlled storage for controlled and hazardous products
4.5 Temperature and humidity control and monitoring in storage
4.5.1 Temperature control
4.5.2 Temperature monitoring
4.5.3 Humidity control
4.5.4 Humidity monitoring

4.6 Alarm systems
4.6.1 Temperature alarms
4.6.2 Humidity alarms

4.7 Qualification of temperature-controlled stores
4.8 Cleanliness of temperature-controlled stores
4.9 Refrigeration equipment maintenance
4.10 Calibration and verification of control and monitoring devices
4.10.1 Calibration of temperature control and monitoring devices
4.10.2 Calibration of humidity control and monitoring devices
4.10.3 Alarm equipment verification

5. Materials handling
5.1 Materials handling equipment

6. Transport and delivery
6.1 Normative references
6.2 Product stability profiles
6.3 Transport route profiling and qualification
6.4 Temperature-controlled transport
6.4.1 Air and sea transport
6.4.2 Temperature-controlled road vehicles operated by common carriers
6.4.3 Temperature-controlled road vehicles generally
6.4.4 Transport of controlled TTSPPs and TTSPPs with high illicit value
6.5 Temperature and humidity control and monitoring during transit
   6.5.1 Temperature control in temperature-controlled road vehicles
   6.5.2 Temperature monitoring in temperature-controlled road vehicles
   6.5.3 Humidity monitoring in temperature-controlled road vehicles
   6.5.4 Temperature monitoring in passive and active shipping containers
6.6 Qualification of temperature-controlled road vehicles
6.7 Calibration and verification of transport monitoring devices
   6.7.1 Calibration of transport temperature control devices
   6.7.2 Calibration of transport temperature monitoring devices
   6.7.3 Calibration of transport humidity monitoring devices
   6.7.4 Verification of transport alarm equipment
6.8 Shipping containers
   6.8.1 Container selection generally
   6.8.2 Uninsulated containers
   6.8.3 Qualification of insulated passive containers
   6.8.4 Qualification of active containers
6.9 Shipping container packing
6.10 Product handling during packing and transport
6.11 Cleaning road vehicles and transport containers
6.12 Transport of returned and recalled TTSPPs
   6.12.1 Transport of returned TTSPPs
   6.12.2 Transport of recalled TTSPPs

7. Labelling
   7.1 Normative references
   7.2 Labelling
      7.2.1 Labelling generally
      7.2.2 Labelling air-freighted shipments

8. Stock management
   8.1 Stock control systems
      8.1.1 General stock control systems and procedures
      8.1.2 Stock control procedures for controlled and hazardous TTSPPs
   8.2 Incoming goods
      8.2.1 Product arrival checks
      8.2.2 Actions following arrival checks
   8.3 Outgoing goods (external deliveries)
      8.3.1 Management of outgoing goods
      8.3.2 Actions following dispatch
   8.4 Product complaint procedures
   8.5 Suspect product procedures
      8.5.1 Suspect products
   8.6 Product return, recall, withdrawal and disposal procedures
      8.6.1 Return procedures
      8.6.2 Recall procedures
      8.6.3 Disposal procedures
8.7 Traceability or stock tracking

9. General procedures and record-keeping
9.1 Emergencies and contingency planning
9.2 General record-keeping
  9.2.1 Record-keeping
  9.2.2 Content of records
  9.2.3 Record review and retention
9.3 Temperature and humidity records
  9.3.1 Temperature records
  9.3.2 Humidity records

10. Environmental management
  10.1 Normative references
  10.2 Environmental management of refrigeration equipment

11. Quality management
  11.1 Normative references
  11.2 Organizational structure
  11.3 Quality systems
    11.3.1 Quality system
    11.3.2 Self inspections
    11.3.3 Contractors subject to service level agreements
  11.4 Management of documents and standard operating procedures
    11.4.1 Standard operating procedures
  11.5 Document control

12. Personnel/training
  12.1 Training
    12.1.1 General training
    12.1.2 Specialist training

Key references

Further reading

Task force membership
**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CAPA</td>
<td>corrective and preventive action (procedures)</td>
</tr>
<tr>
<td>DCVMN</td>
<td>Developing Countries Vaccine Manufacturers Network</td>
</tr>
<tr>
<td>EEFO</td>
<td>earliest-expiry-first-out. Used in this document as equivalent to FEFO</td>
</tr>
<tr>
<td></td>
<td>(first to expire-first-out)</td>
</tr>
<tr>
<td>FIFO</td>
<td>first-in-first-out</td>
</tr>
<tr>
<td>GDP</td>
<td>good distribution practice</td>
</tr>
<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>GPS</td>
<td>global positioning system</td>
</tr>
<tr>
<td>GSP</td>
<td>good storage practice</td>
</tr>
<tr>
<td>HVAC</td>
<td>heating ventilating and air-conditioning (system)</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IFPMA</td>
<td>International Federation of Pharmaceutical Manufacturers and Associations</td>
</tr>
<tr>
<td>IQ</td>
<td>installation qualification</td>
</tr>
<tr>
<td>PCCIG</td>
<td>Pharmaceutical Cold Chain Interest Group</td>
</tr>
<tr>
<td>PDA</td>
<td>Parenteral Drug Association</td>
</tr>
<tr>
<td>SKU</td>
<td>stock-keeping unit</td>
</tr>
<tr>
<td>SLA</td>
<td>service level agreement</td>
</tr>
<tr>
<td>SMS</td>
<td>short message service</td>
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<tr>
<td>SOP</td>
<td>standard operating procedure</td>
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<tr>
<td>TTSPP</td>
<td>time- and temperature-sensitive pharmaceutical product</td>
</tr>
<tr>
<td>UPS</td>
<td>uninterrupted power supply</td>
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<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
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</table>

**Background**

These guidelines set out the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPPs). They are based upon existing regulations and best practice guidance from a wide range of international sources (see References), while accepting that local legislation and regulations will continue to take precedence. The target audience includes regulators, logisticians and pharmaceutical professionals in industry, government and the international agencies.

The document has been prepared in close consultation with the WHO Task Force on Regulatory Oversight on Pharmaceutical Cold Chain Management which has been central to the review process. A full list of members is given at the end of this annex.

The intention is that the guidance in this document should be directly applicable in less-developed countries as well as in the industrialized world. To this end, supplementary materials will be developed to show
how the requirements can practicably be achieved, particularly in resource-constrained settings. Experience with vaccine supply chain assessments in many less-developed countries demonstrates that the mandatory standards set out in this document can be achieved, and that some countries are also capable of meeting many of the optional requirements.

The document is designed to give a balanced overview of the major aspects of good storage and distribution practice for TTSPPs. As such it deliberately includes references to requirements which can be found in general guides to good manufacturing practice (GMP), good storage practice (GSP) and good distribution practice (GDP). The purpose is not to supplant these source materials, but to ensure that the reader is aware of the relevant GMP, GSP and GDP implications when seen from the particular and specialized perspective of TTSPP management.

Key to conventions used

The following conventions are used in the requirements clauses:

• The imperative voice is used to denote a mandatory or highly desirable requirement. For example: “Ensure that…” , “Provide…” and the like.
• The words “where possible” or “preferably” are used to denote an optional but desirable requirement.
• Many clauses are followed by a brief explanation setting out the underlying reason for including the clause.

Glossary

The definitions given below apply to the terms used in these guidelines. They may have different meanings in other contexts.

*active systems*
Actively powered systems using electricity or other fuel source to maintain a temperature-controlled environment inside an insulated enclosure under thermostatic regulation (e.g. cold rooms, refrigerators, temperature-controlled trucks, refrigerated ocean and air containers).

*change control*
The processes and procedures to manage system changes.

*common carrier*
A seller of distribution services.

*controlled or hazardous time- and temperature-sensitive pharmaceutical products*
Time- and temperature-sensitive pharmaceutical products (TTSPPs) with high illicit value: poisons, narcotics, psychotropic products, inflammable or explosive substances and radioactive materials.
dunnage
Loose packing material used to protect TTSPPs from damage during transport.

external distribution
Transport of TTSPPs through various steps in the customer’s supply chain (i.e. transport from a pharmaceutical manufacturer's distribution centre to commercial customers (including wholesalers, retailers and buying groups), to clinical facilities or direct to the patient).

installation qualification
The process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications and that it functions within predetermined limits when operated in accordance with the operating instructions.

internal distribution
Transport of a TTSP within a pharmaceutical manufacturer’s internal supply chain (i.e. all internal transports from manufacturing facility to packaging facility to warehouse to distribution centre).

net storage capacity
The total volume available for storing TTSPPs, taking account of the type of load support system employed (floor-standing pallets, adjustable pallet racking or shelving units), as modified by the utilization factor that can be achieved in the store.

passive systems
Systems which maintain a temperature-controlled environment inside an insulated enclosure, with or without thermostatic regulation, using a finite amount of pre-conditioned coolant in the form of chilled or frozen gel packs, phase change materials, dry ice or others.

pests
Includes birds, bats, rodents and insects whose uncontrolled presence affects hygiene and cleanliness.

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. It does not, however, include medical devices.¹

qualification
Documented testing that demonstrates, with a high degree of assurance, that a specific process will meet its predetermined acceptance criteria.²

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.

service level agreement (SLA)
A service level agreement or contract is a negotiated agreement between the customer and service provider that defines the common understanding about materials or service quality specifications, responsibilities, guarantees and communication mechanisms. It can either be legally binding, or an information agreement. The SLA may also specify the target and minimum level performance, operation or other service attributes.³

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.

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

storage unit temperature/humidity distribution
The range and pattern of temperatures and/or humidity within a temperature-controlled storage unit during normal operation.

suspect product
A TTSPP whose presentation and/or pharmacological formulation indicates that it has not been manufactured by the company named on the packaging. A TTSPP that shows visible or pharmacological evidence of tampering.

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 predefined limits.

temperature excursion
An excursion event in which a TTSPP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for

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³ Definition from International Air Transport Association (IATA), Chapter 17, 9th ed., June 2009.
storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

*temperature-modified*

Includes any environment in which the temperature is predictably maintained at a level different from that of the surrounding environment, but is not actively or passively controlled within precise predefined limits.

*time- and temperature-sensitive pharmaceutical product (TTSPPP)*

Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

*transport temperature profile*

Anticipated ambient temperature variation and duration to which a TTSPPP may be exposed during transport.

*utilization factor*

The percentage of the total volume available for storing TTSPPPs that can reliably be achieved in practice, taking account of the types of stock-keeping unit (SKU), the types of load support system and the stock management systems used in the store.

*validation*

Documented testing performed under highly controlled conditions, demonstrating that processes, methods, and systems consistently produce results meeting predetermined acceptance criteria.\(^4\)

1. **Importation**

1.1 **Port handling and customs clearance**

1.1.1 **Port of entry**

Import TTSPPPs through a port of entry that is equipped to handle such products. Where this is not possible, ensure that arrangements are in place to provide the necessary level of protection and security.

*Reason:* To minimize the risk of damage.

1.1.2 **Offloading**

As soon as possible after arrival, remove TTSPPP shipments from the wharf or airport apron to a safe and suitable temperature-controlled storage location.

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Reason: To minimize the risk of theft and to avoid exposure to adverse ambient conditions.

1.1.3 Temporary storage at port of entry

Store TTSPP shipments in a secure warehouse under the conditions recommended by the product manufacturer, until the shipment has been authorized for removal by customs.\(^5\)

Reason: To avoid risk of theft or damage during temporary storage.

1.1.4 Customs clearance

Draw up procedures and memoranda of understanding to ensure that TTSPP shipments are cleared through customs as rapidly as possible. This can be facilitated by a pre-clearance procedure carried out by the local health agency, clearing agent or freight forwarder in collaboration with customs. Alternatively the clearance process should be conducted by customs staff, supported by personnel with suitable pharmaceutical training, especially when clearance involves the opening and resealing of temperature-controlled packaging.

Reason: To avoid delays during customs clearance that may cause temperature excursions and place TTSPPs at risk.

2. Warehousing sites

2.1 Site layout

2.1.1 Natural hazards

Select and/or develop storage sites to minimize risks from natural hazards such as floods, landslides and earthquakes and extreme weather conditions such as hurricanes and tornadoes.

Reason: To protect against loss of valuable pharmaceutical products, to ensure continued supply to patients in the market and to protect personnel working in the store.

2.1.2 Site access

Provide vehicular access to storage buildings sufficient to accommodate the largest vehicles visiting the site, including emergency vehicles.

Reason: To ensure convenient operation of the facility.

\(^5\) In some situations, arrangements can be made for formal customs clearance to take place away from the port of entry — for example, at a national vaccine store. In situations where the port of entry is not equipped with suitable cold storage facilities, this can reduce the risk of temperature excursions.
2.2 **Site security**

Provide perimeter protection to ensure security of the grounds and storage buildings against anticipated risks.

*Reason*: To protect against vandalism, theft and other illegal incursions. Security arrangements should be appropriate to the site location and the value of goods stored there.

2.3 **Site cleanliness**

Keep the site free of accumulated dust, dirt, waste and debris. Ensure that pests are kept under control within the site area. Collect waste in designated closed containers and arrange for safe disposal at frequent intervals.

*Reason*: To help protect storage buildings against ingress by dust, dirt and pests.

3. **Storage buildings**

3.1 **Construction standards**

Construct or procure storage buildings that are:

— purpose-designed for the storage of TTSPPs, or well-adapted for this purpose;
— designed to suit the prevailing climate, making maximum use of passive heating, cooling and ventilation;
— designed and equipped to minimize the consumption of electricity and other fuel sources;
— constructed using materials and finishes that are robust, easy to clean and which are selected to minimize long-term maintenance;
— constructed using locally available materials and building technologies; and
— built to minimize hiding and nesting places for pests.

*Reasons*: Storage in unsuitable and poorly-designed buildings places TTSPPs at risk and increases storage costs. Buildings constructed using inappropriate materials and technologies are difficult to operate and maintain in resource-constrained settings.

3.2 **Accommodation and layout**

Ensure that the storage buildings are well laid out and contain all the necessary storage areas, goods assembly, receiving and dispatch bays and office accommodation needed for efficient operation of the TTSPP store.
3.3 **Loading and receiving bays**

3.3.1 **Loading bays**

Ensure that receiving and dispatch bays are designed to avoid conflict between incoming and outgoing goods and are protected from direct sunlight, dust, dirt, rain, snow and wind, and from extremes of heat, cold and solar radiation that could damage TTSPPs, and measures are taken to minimize pest activity in these areas.

*Reason:* Protection against damage and maintenance of product quality.

3.3.2 **Receiving bays**

Provide receiving areas with suitable equipment to clean reusable transport containers after their contents have been unloaded, and before the containers are stored for re-use.

*Reason:* Protection against contamination of outgoing TTSPPs.

3.4 **Goods assembly and quarantine areas**

3.4.1 **Goods assembly areas**

Provide sufficient space to receive, assemble and pack TTSPPs for dispatch under temperature-modified conditions. Preferably, these areas should be physically close to the temperature-controlled storage area.

*Reason:* Protection of TTSPPs during arrival, order assembly and dispatch.

3.4.2 **Holding area for incoming goods**

Provide a temperature-controlled holding area for incoming TTSPPs pending their acceptance into the main storage area. The holding area may be a physically separated zone, or it may be defined using a suitable stock control information system, or by a combination arrangement. Where goods are held in bond in the warehouse, awaiting customs clearance, they must be physically separated and secured.

*Reason:* Incoming items may need inspection and/or regulatory clearance, including laboratory testing.

3.4.3 **Quarantine area**

Provide a quarantine area for the isolation of returned, faulty, recalled and otherwise withdrawn goods pending a decision on disposal or re-stocking by the qualified person or department. Materials within quarantine areas must be clearly identified with their status.

— with temperature control, for items returned for re-stocking;
— with temperature control, for items recalled for testing;
— without temperature control, for items awaiting disposal.

The quarantine area may be a physically separated zone, or it may be defined using a suitable stock control information system, or by a combination arrangement.

Reason: Items for re-stocking, testing and disposal should be kept separate to avoid the risk of inappropriate use.

3.5 **Environmental control of ancillary areas**

Ensure, where possible, that ancillary areas where TTSPPs are temporarily held during arrival, order assembly or dispatch are:

— maintained within the temperature range specified for the goods being handled;
— maintained within the humidity range specified for goods that are adversely affected by high relative humidity and are not sufficiently protected by their packaging;\(^6\)
— protected from undue exposure to direct sunlight;
— protected from the weather;
— protected against dust, dirt and waste accumulation;
— adequately ventilated;
— adequately lit to enable operations to be carried out accurately and safely;
— monitored during the times when TTSPPs are handled; and monitored during the times when TTSPPs are handled (see 4.5.1-4.5.4).

Reason: Protection of TTSPP quality during arrival, order assembly or dispatch.

3.6 **Building security**

3.6.1 **General building security**

Ensure that buildings used to store TTSPPs have sufficient security to prevent unauthorized access and to prevent misappropriation of goods.

Reason: To protect against vandalism, theft and other illegal incursions. Security arrangements should be appropriate to the site location and to the value of goods stored there.

3.6.2 **Controlled and hazardous substances areas**

Ensure that all areas that are used to store controlled or hazardous TTSPPs are:

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\(^6\) Active environmental control of ancillary areas may not be needed if all TTSPPs are kept in temperature-controlled packaging and/or humidity-protective packaging when passing through these areas.
— dedicated, securely locked facilities that comply fully with all legislative and regulatory requirements applicable in the country where the store is located;
— only accessible to authorized staff;
— protected by automatic intruder and/or fire and smoke, and/or chemical and/or radiological sensor alarm systems appropriate to the type(s) of product being stored;\(^7\)
— designed to be explosion-proof, where explosive TTSPPs are stored;\(^8\)
— continuously monitored by security staff.

*Reason*: Protection of property and life.

### 3.7 Fire protection

#### 3.7.1 Fire protection equipment

Provide suitable fire detection and fire-fighting equipment, including fire hydrants, in all TTSPP storage areas and ensure that:

— systems and equipment are appropriate for the class of occupancy and product storage arrangements and are approved by the local fire authority; and
— equipment is regularly serviced in accordance with the equipment manufacturers’ recommendations and local regulations.

*Reason*: Protection of property and life.

#### 3.7.2 Fire prevention, detection and control procedures

Follow standard operating procedures (SOPs) for fire prevention, detection and control. Train staff and carry out regular fire drills. Prohibit smoking in all areas.

*Reason*: Protection of property and life.

### 3.8 Building hygiene

#### 3.8.1 Building cleanliness

Implement a cleaning programme for all areas:

- do not allow the accumulation of dust, dirt and waste, including packaging waste;
- take precautions against spillage or breakage, and cross-contamination;

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\(^7\) Zoned sprinkler systems are recommended to control fires and to localize product damage in the event of system activation.

\(^8\) Explosion-proof stores must have a blast roof or wall. Preferably, explosive substances should be stored in an independent building, well separated from the main store.
• collect waste in designated closed containers and arrange for safe disposal at frequent intervals;
• do not permit consumption of food or beverages other than in designated areas; and
• maintain cleaning records to demonstrate compliance.

_Reason:_ Protection against damage and contamination of TTSPPs and to minimize the risk of pest infestation.

### 3.8.2 Pest control

Implement a programme to keep all areas free of pests. This should include enclosed receiving and loading bays. Maintain records to demonstrate compliance with a robust pest control programme.

_Reason:_ Protection against damage and contamination of TTSPPs.

### 3.9 Power supply

#### 3.9.1 Uninterrupted power supply

Where possible, and where necessary, ensure that all temperature-controlling equipment for TTSPP storage (i.e. refrigerators, freezers, building management systems, heating, ventilation and air-conditioning (HVAC) systems, compressors, air-handling units, monitoring systems, alarms and related computer equipment) are connected to an uninterrupted power supply (UPS) system. Where a generator and associated control equipment is used it should:

— be able to manage the combined start-up load of all connected temperature-controlling and temperature-monitoring equipment;
— not exceed the defined parameters of the mains power supply;
— be equipped with automatic mains failure start-up and automatic shutdown when power is restored; and
— have adequate fuel tank capacity and sufficient fuel to cover a prolonged power outage.

Regularly test and service UPS equipment and generators. Maintain records to demonstrate compliance.

_Reason:_ Loss prevention.

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9 UPS systems may be unnecessary in countries with a very reliable electricity supply. In smaller stores in countries where electricity is only available for a limited period each day, or is entirely absent, an alternative approach to UPS is to use refrigeration equipment with extended holdover capacity, for example, ice-lined refrigerators, or gas, kerosene or solar-powered refrigerators.

10 The installed capacity of the UPS system can be minimized by fitting electronic controls which reduce compressor start-up loads.
3.9.2 Power failure contingency plan

Develop and maintain a contingency plan to protect TTSPPs in the event of power failure which places products at risk. Alternative emergency cooling systems (e.g. liquid nitrogen or dry ice) are acceptable.

Reason: Loss prevention.

3.10 Building maintenance

Implement a planned preventive maintenance programme to ensure that storage buildings and building utilities are well maintained. Keep records to demonstrate compliance with the programme.

Reason: To ensure that storage buildings continue to protect stored products against damage.

4. Temperature-controlled storage

4.1 Normative references

- EN 60068-3 parts 5, 6, 7 and 11: Environmental testing. Guidance. Confirmation of the performance of temperature chambers
- International Air Transport Association (IATA) Perishable cargo regulations chapter 17. 10th ed, July 2010
- USP <1079> Good storage and shipping practices
- USP <1118> Monitoring devices — time, temperature and humidity

4.2 Storage capacity of temperature-controlled stores

Ensure that the net storage capacity of the temperature-controlled stores is sufficient to accommodate peak TTSPP stock levels and their associated transit temperature protection components (i.e. freezer blocks, flexible ice blankets, refrigerated gel packs, phase change materials and insulated packaging, if retained), under correct temperature conditions and in a manner which enables efficient and correct stock management operations to take place.

Reason: To avoid the risks associated with overstocking and to ensure that good warehousing practices can be adopted (i.e. first in-first out (FIFO) or earliest expiry-first out (EEFO)). Overstocking makes FIFO or EEFO handling difficult or impossible and hinders accurate physical stock counts.

4.3 Temperature-controlled storage

Ensure that TTSPPs are stored in temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers which comply with the following requirements.
Temperature-controlled rooms, cold rooms and freezer rooms should be:

- capable of maintaining the temperature range defined by the system set points over the full annual ambient temperature range experienced at the store location;
- preferably equipped with an auto-defrost circuit which has a minimal effect on temperature within the unit during the defrost cycle and maintains temperature within specification for this period;
- equipped with a low temperature protection circuit in cold climates where there is a risk of breaching the low temperature set point for TTSPPs that are damaged by exposure to low temperatures;
- connected to a UPS as described in clause 3.9.1;
- equipped with a calibrated continuous temperature monitoring system with sensors located at points representing greatest temperature variability and temperature extremes;
- preferably equipped with continuous humidity monitoring devices with sensors located at points representing humidity extremes;
- equipped with alarms to indicate temperature excursions and/or refrigeration failure;
- fitted with lockable doors, or an access control system, as necessary; locks must have a safety device so that doors can be freely opened from the inside; and
- qualified as defined in clause 4.7.

Refrigerators and freezers should be:

- purpose-designed for the storage of TTSPPs; household-style units are only acceptable if they have been independently tested and found to comply with the temperature control requirements of a recognized standard for pharmaceutical refrigerators and freezers;\(^{11}\)
- capable of maintaining the temperature range specified by the TTSPP manufacturer over the full annual ambient temperature range experienced at the storage site;
- equipped with calibrated temperature monitoring devices appropriate to the level of risk but preferably capable of continuous recording and with sensor(s) located at a point or points within the cabinet which most accurately represents the temperature profile of the equipment during normal operation;
- preferably equipped with alarms to indicate temperature excursions and/or refrigeration failure;
- fitted with lockable doors or lids, or access control system, as necessary; and
- qualified and/or tested as defined in clause 4.7.

\(^{11}\) For example, WHO PQS standards for refrigerators and freezers are available at: http://www.who.int/immunization_standards/vaccine_quality/pqs_e03_fridges_freezers/en/index.html.
Reason: To maintain labelled TTSP storage temperatures during long-term storage.

4.4 Temperature-controlled storage for controlled and hazardous products

Ensure that controlled and hazardous TTSPs are securely stored:

• Provide dedicated temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers for these TTSPs, in separate secure areas, as described in clause 3.6.2.
• Alternatively, but only if acceptable to the regulatory authority, bulk stocks of TTSPs with high illicit-value may be stored in a securely locked section of a general temperature-controlled storage area.

Reason: To protect this category of TTSPs against theft and misuse and to safeguard workers and general storage areas in the event of an accident involving hazardous substances.

4.5 Temperature and humidity control and monitoring in storage

4.5.1 Temperature control

Provide thermostatic temperature control systems for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers, used to store TTSPs. Comply with the following minimum requirements:

• system able continuously to maintain air temperatures within the set point limits throughout the validated storage volume;
• control sensors accurate to ± 0.5 °C or better;
• control sensors calibrated as described in clause 4.10.1;
• control sensors located in areas where greatest variability in temperature is expected to occur in order to maximize available safe storage volume;
• control sensors positioned at the hot and cold spots determined by temperature mapping, even if affected by door opening, unless recommendations are being made not to store products in such areas; and
• control sensors independent of the temperature monitoring system.

4.5.2 Temperature monitoring

Provide air temperature monitoring systems and devices for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers, used to store TTSPs. Comply with the following minimum requirements:

General requirements
• Monitoring sensors accurate to ± 0.5 °C or better for electronic devices and ± 1 °C or better for alcohol, bi-metal gas or vapour pressure thermometers.
• Monitoring sensors calibrated as described in clause 4.10.1.
• Monitoring sensors located in areas where greatest variability in temperature is expected to occur within the qualified and/or tested storage volume as defined in clause 4.7.
• Monitoring sensors positioned so as to be minimally affected by transient events such as door opening.
• Temperature monitoring devices, temperature traces or electronic temperature records manually checked at least twice a day, in the morning and evening, seven days a week, including public holidays.

Temperature-controlled rooms, cold rooms and freezer rooms
• Provide a temperature record with a minimum recording frequency of six times per hour for each monitoring sensor position.
• Provide documentation for each monitoring sensor position which can be stored and accessed.
• Continue to operate independently in the event of a power failure.12

Refrigerators and freezers
• Preferably, connect refrigerators and freezers to a multipoint monitoring system with a minimum recording frequency of six times per hour for each sensor position which can operate independently in the event of a power failure.
• Alternatively use battery-powered portable temperature monitoring devices with a minimum recording frequency of six times per hour.
• The least preferred option is a thermometer or maximum/minimum thermometer.
• Provide documentation for each appliance which can be stored and accessed.

Reasons: To maintain labelled TTSPPs temperatures during long-term storage. Thermometers provide only limited and discontinuous temperature information. For this reason, continuous recording devices are preferable.

4.5.3 Humidity control

Provide humidity control in temperature-controlled rooms that are used to store TTSPPs which are adversely affected by high relative humidity and are not sufficiently protected by their packaging. Such products are typically labelled “store in a dry place”, or carry similar wording and require a humidity-controlled environment.

12 Where there is no UPS, the autonomy period for the device should be matched to the maximum length of anticipated power outages.
4.5.4 **Humidity monitoring**

Provide humidity monitoring systems and devices in temperature-controlled rooms that are used to store TTSPPs which require a humidity-controlled environment. Comply with the following minimum requirements:

- sensors accurate to ± 5% RH;
- sensors calibrated as per clause 4.10.2;
- sensors located to monitor worst-case humidity levels within the qualified storage volume defined in clause 4.7;
- sensors positioned so as to be minimally affected by transient events such as door opening;
- provides a humidity record with a minimum recording frequency of six times per hour for each sensor position;
- provides documentation for each sensor position which can be stored and accessed; and
- continues to operate independently in the event of a power failure.13

**Reason:** To maintain labelled TTSPP humidity conditions during long-term storage.

4.6 **Alarm systems**

4.6.1 **Temperature alarms**

Provide temperature alarm systems for temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers, used to store TTSPPs. Comply with the following minimum requirements:

**General requirements**

- Sensors accurate to ± 0.5 °C.
- Sensors calibrated as described in clause 4.10.1.
- Sensors located to monitor worst-case temperatures within the validated storage volume defined in clause 4.7; where the alarm system is not integrated with the temperature monitoring system, sensors should be located close to the temperature monitoring sensors.
- Sensors positioned so as to be minimally affected by transient events such as door opening.

**Temperature-controlled rooms, cold rooms and freezer rooms**

- High/low alarms set points to trigger appropriately located visual alarm(s).
- Preferably there should also be appropriately located audible alarm(s) in addition to the visual alarm(s).

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13 Where there is no UPS the autonomy period for the device should be matched to the maximum length of anticipated power outages.
• Preferably there should be an automatic telephone dial-up or SMS text warning system to alert on-call personnel when an alarm is triggered outside working hours.

Refrigerators and freezers
• Preferably there should be a visual and/or audible alarm system; this may be integrated with a portable continuous temperature monitoring device.

Reason: Loss prevention.

4.6.2 Humidity alarms
Provide humidity alarm systems for temperature-controlled rooms used to store TTSPPs that require a humidity-controlled environment. Comply with the following minimum requirements:

• sensors accurate to ± 5% relative humidity (RH);
• sensors calibrated as described in clause 4.10.2;
• sensors located to monitor worst-case humidity levels within the validated storage volume defined in clause 4.7; where the alarm system is not integrated with the humidity monitoring system, sensors should be located close to the humidity monitoring sensors;
• sensors positioned so as to be minimally affected by transient events such as door opening;
• high/low alarms set points to trigger appropriately located visual alarm(s);
• preferably there should also be appropriately located audible alarm(s) in addition to the visual alarm(s); and
• preferably there should be an automatic telephone dial-up or SMS text warning system to alert on-call personnel when an alarm is triggered outside working hours.

Reason: Loss prevention.

4.7 Qualification of temperature-controlled stores
Qualify new temperature-controlled storage areas and new refrigeration equipment before it becomes operational. The qualification procedure should:

• demonstrate the air temperature profile throughout the storage area or equipment cabinet, when empty and in a normal loaded condition;
• define zones which should not be used for storage of TTSPPs (for example areas in close proximity to cooling coils, cold air streams or heat sources); and
• demonstrate the time taken for temperatures to exceed the designated limits in the event of power failure.

Fully document the initial qualification. Carry out additional qualification exercises whenever modifications are made to the storage area that may
increase loading or affect air circulation, or when changes are made to the refrigeration equipment, such as a change in the set point. Consider the need for requalification whenever temperature and/or humidity monitoring shows unexplained variability that is greater than normal.

Qualification may not be required for equipment which requires little or no site assembly or commissioning, such as vaccine refrigerators and freezers that have been independently tested and found suitable for the storage of TTSPPs. Independent testing must be carried out between the chosen set points and under the ambient temperature conditions to which the equipment will be exposed during operation. Prequalified equipment of this type must be correctly installed in each location in accordance with written guidance.

*Reason:* To ensure that labelled TTSPP temperatures can be maintained during long-term storage and that the facility can demonstrate to the regulatory authorities and other interested parties that due diligence has been observed.

### 4.8 Cleanliness of temperature-controlled stores

Implement a cleaning and decontamination programme for all temperature-controlled rooms:

- Ensure that floor areas are fully accessible for cleaning. Do not store goods directly on the floor.
- Do not permit storage of any non-pharmaceutical products except transport-related items such as icepacks, gel packs and the like.
- Do not allow the accumulation of dust, dirt and waste, including packaging waste.
- Take precautions against spillage or breakage, and cross-contamination.
- Do not allow accumulation of frost and ice, particularly ice contaminated by spillages.
- Collect waste in designated closed containers and arrange for safe disposal at frequent intervals.

Maintain cleaning records to demonstrate compliance.

*Reason:* Protection against damage and contamination of TTSPPs and hazards to workers, arising from spillage or breakage.

### 4.9 Refrigeration equipment maintenance

Implement a maintenance programme for all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers:

- Carry out regular planned preventive maintenance on all temperature-controlling equipment.
• Make arrangements to ensure that emergency maintenance is carried out within a time period that does not place TTSPPs at risk of damage.
• Ensure that there is a contingency plan to move products stored in non-functioning equipment to a safe location before damage to the product occurs in the event that equipment cannot be repaired in a timely manner.

Maintain records to demonstrate compliance.

*Reason: Loss prevention.*

4.10 **Calibration and verification of control and monitoring devices**

4.10.1 **Calibration of temperature control and monitoring devices**
Calibrate devices against a certified, traceable reference standard at least once a year, unless otherwise justified. Calibration should demonstrate the accuracy of the unit across the entire temperature range over which the device is designed to be used. Single-use devices that are supplied with a manufacturer’s calibration certificate do not need to be re-calibrated.

4.10.2 **Calibration of humidity control and monitoring devices**
Calibrate devices against a certified, traceable reference standard at least once a year unless otherwise justified. Single-use devices that are supplied with a manufacturer’s calibration certificate do not need to be re-calibrated.

4.10.3 **Alarm equipment verification**
Check functionality of temperature and humidity alarms at least once every six months at the designated set points.

Maintain records to demonstrate compliance.

*Reason: To ensure that labelled TTSPP storage temperatures and humidity control can be maintained during long-term storage and that the store can demonstrate to the regulatory authorities and other interested parties that due diligence has been observed.*

5. **Materials handling**

5.1 **Materials handling equipment**
Where powered materials handling equipment is used in temperature-controlled rooms, cold rooms or freezer rooms, select equipment which is certified for safe use in confined spaces.

*Reason: Protection of the workforce.*
6. **Transport and delivery**

6.1 **Normative references**

- EN 13431:2004. *Packaging. Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value.*
- EN 13431:2004. *Packaging. Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value.*

6.2 **Product stability profiles**

Transport TTSPPs in such a manner that transport temperatures meet local regulatory requirements at the sending and receiving sites and/or so that temperature excursions above or below the manufacturer’s labelled storage temperature range do not adversely affect product quality. Product stability data must demonstrate the acceptable temperature excursion time during transport.

*Reason:* Protection of TTSPPs against degradation.

6.3 **Transport route profiling and qualification**

Profile and qualify transport routes:

- Select the most suitable methods for protecting TTSPPs against anticipated ambient temperature and humidity conditions throughout the year.
- Use suitable methods, including published standards, weather data, laboratory tests and field tests to select suitable transport equipment and shipping containers.
Reason: To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

6.4 Temperature-controlled transport

6.4.1 Air and sea transport

Ensure that any carrier contracted to transport TTSPPs by air or by sea operates under the terms of a formal service level agreement (SLA) drawn up between the parties. The carrier is to be made responsible for maintaining load temperatures within the transport temperature profile defined for each product.

Reason: To ensure that the carrier is made responsible for maintaining load temperatures within the transport temperature profile defined for each product and that compliance can be demonstrated to the contracting organization, the regulatory authorities and other interested parties.

Temperature-controlled road vehicles operated by common carriers

Temperature control in vehicles operated by a common carrier must be qualified and the details and responsibilities for this process should be set out in a formal SLA drawn up between the parties.

Reason: To ensure that the carrier is made responsible for maintaining load temperatures within the transport temperature profile defined for each product and that compliance can be demonstrated to the contracting organization, the regulatory authorities and other interested parties.

6.4.2 Temperature-controlled road vehicles generally

Ensure that temperature-controlled road vehicles used for the transport of TTSPPs are:

- capable of maintaining the temperature range defined by the system set points over the full annual ambient temperature range experienced over known distribution routes and when the vehicle is in motion, or parked with the main engine stopped;
- equipped with a low temperature protection circuit in cold climates where there is a risk of breaching the low temperature set point for TTSPPs that are damaged by exposure to low temperatures;
- equipped with calibrated temperature monitoring devices with sensors located at points representing temperature extremes;
- equipped with alarms to alert the driver in the event of temperature excursions and/or refrigeration unit failure;
- fitted with doors with security seals and/or security locks that protect against unauthorized access during transit;
• qualified as defined in clause 6.6; and
• regularly calibrated and maintained and records kept to demonstrate compliance.

*Reason:* To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

6.4.3 **Transport of controlled TTSPPs and TTSPPs with high illicit value**

Ensure that controlled TTSPPs and TTSPPs with high illicit value are transported in the following manner:

• Transport practices comply with all relevant local legislation and regulations.
• Vehicles are equipped with lockable doors and an intruder alarm.
• Vehicles use unique seal lock indicating devices such as cable seal locks with unique identifiers that are tamper-resistant to protect against unauthorized access during transit.\(^\text{14}\)
• Security-cleared delivery drivers are employed.
• All deliveries are documented and tracked.
• Signed dispatch and arrival records are kept.
• Shipments are fitted with security equipment appropriate to the product being transported and the assessed security risk, such as global positioning system (GPS) devices located in the vehicle and/or hidden in the product.
• Drivers are informed about the perishability of the product and the maximum acceptable transport time.

*Reason:* To prevent theft and misappropriation of this category of TTSPPs and to ensure the security and safety of the driver.

6.5 **Temperature and humidity control and monitoring during transit**

6.5.1 **Temperature control in temperature-controlled road vehicles**

Provide thermostatic temperature control systems for all temperature-controlled vehicles used to transport TTSPPs. Comply with the following minimum requirements:

• system able continuously to maintain air temperatures within the set point limits throughout the validated storage volume defined in clause 6.6;
• control sensors accurate to ± 0.5 °C;
• control sensors calibrated as described in clause 6.7.1;

\(^{14}\) Refer to ISO/PAS 17712: Freight containers — Mechanical seals.
- control sensors located to control worst-case temperatures in order to maximize available safe storage volume;
- control sensors positioned in the return air stream; and
- control sensors independent of the temperature monitoring system.

6.5.2 **Temperature monitoring in temperature-controlled road vehicles**

Provide air temperature monitoring systems and devices for vehicles used to transport TTSPPs. Comply with the following minimum requirements:

- monitoring sensors accurate to ± 0.5 °C;
- monitoring sensors calibrated as described in clause 6.7.2;
- monitoring sensors located to monitor worst-case temperatures within the qualified storage zone defined in clause 6.6;
- monitoring sensors positioned so as to monitor worst-case positions;
- provide a temperature record with a minimum recording frequency of six times per hour for each sensor position;\(^{15}\) and
- provide documentation which can be stored and accessed.

Establish transit temperature specifications and document transit temperatures for every internal and external shipment.

6.5.3 **Humidity monitoring in temperature-controlled road vehicles**

Preferably provide humidity monitoring systems and devices for temperature-controlled vehicles which are used to transport TTSPPs that require a humidity-controlled environment. Systems and devices should comply with the following minimum requirements:

- sensors accurate to ± 5% RH;
- sensors calibrated as described in clause 6.7.3;
- sensors located to monitor worst-case humidity levels within the qualified storage zone defined in clause 6.6;
- sensors positioned so as to be minimally affected by transient events such as door opening;
- provide a humidity record with a minimum recording frequency of six times per hour for each sensor position; and
- provide documentation which can be stored and accessed.

Establish transit humidity specifications and document transit humidity conditions for internal and external shipments where required.

\(^{15}\) Recording frequency should take account of the storage capacity of the data logger and the expected transport period.
6.5.4 Temperature monitoring in passive and active shipping containers

Use chemical or electronic freeze indicators, electronic loggers (with or without alarms) and/or other suitable indicators to monitor temperature and/or humidity exposure during internal distribution. Preferably use these devices for external distribution. Monitor and document indicator status upon arrival.

Reason: To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

6.6 Qualification of temperature-controlled road vehicles

Where temperature-controlled vehicles are directly owned and/or operated, qualify each vehicle before it becomes operational, wherever possible. The qualification procedure should:

• demonstrate that the air temperature distribution is maintained within the limits specified throughout the temperature-controlled compartment for both air and product temperatures for commonly used load layouts and at the ambient temperature extremes anticipated during normal operation over known routes;
• demonstrate the humidity distribution throughout the temperature-controlled compartment for commonly used load layouts, where products are being transported that require a humidity-controlled environment;
• define zones within the vehicle’s payload area which should not be packed with TTSPPs (for example areas in close proximity to cooling coils or cold air streams);
• demonstrate the time taken for temperatures to exceed the designated maximum in the event that the temperature-controlling unit fails; and
• document the qualification exercise.

An alternative approach is to perform an initial full qualification on each trailer/refrigeration unit type combined with an installation qualification (IQ) for each example when a new vehicle becomes operational.

Carry out additional qualification exercises whenever significant modifications are made to the vehicle. Consider the need for requalification whenever temperature and/or humidity monitoring shows unexplained variability that is greater than normal.

Reason: To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.
6.7 Calibration and verification of transport monitoring devices

6.7.1 Calibration of transport temperature control devices
Calibrate devices against a certified, traceable reference standard at least once a year, unless otherwise justified.

6.7.2 Calibration of transport temperature monitoring devices
Calibrate devices against a certified, traceable reference standard at least once a year, unless otherwise justified.

6.7.3 Calibration of transport humidity monitoring devices
Calibrate devices against a certified, traceable, reference standard at least once a year, unless otherwise justified.

6.7.4 Verification of transport alarm equipment
Check functionality of temperature and humidity alarms at the designated set points. Check functionality of security alarm systems. Carry out these checks at least once a year, unless otherwise justified.

Maintain records to demonstrate compliance.

Reason: To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

6.8 Shipping containers

6.8.1 Container selection generally
Select shipping containers that:

• comply with applicable national and international standards relevant to the product type and the chosen transport route and mode(s);
• protect personnel and the general public from hazards arising from spillage, leakage or excessive internal pressure;
• protect the product being transported against mechanical damage and the anticipated ambient temperature range that will be encountered in transit; and
• can be closed in a manner that allows the recipient of the consignment to establish that the product has not been tampered with during transport.

Reason: Quality assurance and safety.

6.8.2 Uninsulated containers
Ensure that uninsulated containers are correctly used, in a manner which protects their contents:
• transport uninsulated containers in a qualified temperature-controlled environment such as an actively or passively temperature-controlled vehicle;
• ensure that the transport system is able to maintain the temperature of the TTSPP within the product’s stability profile as stated by the product manufacturer and/or to maintain the TTSPP within the transit temperature specification requirements specified by the regulatory authorities at both the sending and receiving locations.

Reason: Quality assurance and safety.

6.8.3 Qualification of insulated passive containers
Qualify insulated passive containers, including any and all necessary ancillary packaging such as temperature stabilizing medium, dry ice, ice or gel packs, cool water packs or warm packs, phase change materials, partitions, bubble wrap and dunnage:
• ensure that the qualified packaging system is capable of maintaining the TTSPP within the temperature range needed to meet the product stability profile as stated by the product manufacturer. Container qualification should include full details of the packaging assembly, the thermal conditioning regime and the minimum and maximum shipping volume, weight and thermal mass that can safely be accommodated in the container. Qualification should also include the correct placement of temperature monitors where these are used;
• take account of the transport route and of the anticipated ambient temperature profile over the duration of transport, measured from the point of departure to the point of arrival in the recipient’s temperature-controlled store.

Reason: To ensure that TTSPPs can safely be transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.

6.8.4 Qualification of active containers
Qualify active containers:
• ensure that the container is capable of maintaining the TTSPP within the temperature range needed to meet the product stability profile as stated by the product manufacturer;
• take account of the transport route and of the anticipated ambient temperature profile over the duration of transport, measured from the point of departure to the point of arrival in the recipient’s temperature-controlled store.

Reason: To ensure that TTSPPs can be safely transported within the transport temperature profile defined for each product and that compliance can be demonstrated to the regulatory authorities and other interested parties.
6.9 **Shipping container packing**

Pack TTSSPP shipping containers to:

- the exact specified configuration to ensure that the correct TTSSPP temperature range is maintained;
- minimize the risk of theft and fraud and assure the recipient that the goods have not been tampered with while in transit, for example by using locked containers or shrink-wrapped pallets;
- minimize the risk of mechanical damage during transport;
- protect freeze-sensitive products against temperatures below 0 °C when frozen packs are used;
- protect products against light, moisture and contamination or attack by microorganisms and pests;
- protect products against adverse effects when dry ice is used as a coolant;
- clearly label containers to identify the correct transport temperature range and to show correct or identification for handling; and
- ensure that packages containing dangerous goods (including dry ice) are labelled in compliance with relevant transport regulations and requirements.

**Reason:** To ensure that shipping containers are systematically used in the manner defined during the container qualification process and that this can be demonstrated to the regulatory authorities and other interested parties.

6.10 **Product handling during packing and transport**

Handle TTSSPPs correctly during packing and transport:

- pack TTSSPPs in an area set aside for the assembly and packaging of these products as specified in clause 3.3.1;
- take precautions against spillage or breakage, contamination and cross-contamination;
- deliver TTSSPPs to outside recipients by the most suitable mode(s) of transport available in order to minimize delivery time; and
- ensure that patients receiving TTSSPP deliveries are given clear advice on correct storage of the product before use.

**Reason:** To maintain TTSSPP quality during transport.

6.11 **Cleaning road vehicles and transport containers**

Implement a cleaning and decontamination programme for all road vehicles and reusable shipping containers used to transport TTSSPPs:

- ensure that all internal surfaces of load compartments are regularly cleaned;
• do not allow the accumulation of dust, dirt and waste, including packaging waste in load compartments, or in reusable shipping containers;
• take precautions against spillage or breakage, and cross-contamination;
• do not allow accumulation of frost and ice in refrigerated vehicles, particularly ice contaminated by spillages; and
• collect waste in designated closed containers and arrange for safe disposal at frequent intervals.

Maintain cleaning records for vehicles and reusable shipping containers to demonstrate compliance.

Reason: Protection against damage and contamination of TTSPPs and hazards to workers arising from spillage or breakage.

6.12 Transport of returned and recalled TTSPPs

6.12.1 Transport of returned TTSPPs

Ensure that that returned TTSPPs are transported under the same conditions as those used for the initial delivery:

• the sender and recipient must work together so that the product is maintained within the temperature range needed to meet the manufacturer’s stated product stability profile;
• take account of the anticipated ambient temperature profile over the duration of transport, measured from the point of departure to the point of return; and
• quarantine returned TTSPPs in temperature-controlled storage pending a decision by the quality control department or qualified person to dispose of the product or to return it to stock.

Reason: To ensure that returned and recalled TTSPPs are maintained within the correct transport temperature profile so that they can safely be re-stocked if a decision to do so is made.

6.12.2 Transport of recalled TTSPPs

Ensure that recalled TTSPPs are:

• marked for disposal as either “recalled” or “withdrawn”;
• transported back from the recipient and quarantined under secure conditions pending a final decision on disposal as described in clause 8.6.3.

7. Labelling

7.1 Normative references

7.2 **Labelling**

7.2.1 *Labelling generally*

Label internal shipping and external distribution containers containing TTSPPs as follows:

- identify the product in accordance with all national and international labelling requirements relevant to the container content, transport route and mode(s);
- identify hazardous products in accordance with relevant national and international labelling conventions; and
- indicate the appropriate temperature and humidity ranges within which the product is to be transported and/or stored.

7.2.2 *Labelling air-freighted shipments*

In cases where TTSPPs are to be air-freighted, the package(s) should be labelled using the standard International Air Transport Association (IATA) time and temperature-sensitive symbol, in accordance with the conditions outlined in Chapter 17 of the IATA Perishable Cargo Regulations. Apply the label to the outer surface of individual shipping packages, overpacks or bulk containers.

*Reason:* To ensure that products are correctly and safely handled at all points in the supply chain.

8. **Stock management**

8.1 **Stock control systems**

8.1.1 *General stock control systems and procedures*

TTSPP stock control systems and procedures meet the following minimum requirements:

- allow access only to authorized persons;
- record all receipts and dispatches;
- record batch numbers and expiry dates;
- record short-dated and expired products;
- record product status (i.e. released, quarantined, hold, reject);
- record all product returns, recalls, withdrawals, damage and disposals;
- manage the issue of products in EEFO order; and
- take regular physical inventories and reconcile stock records with the actual physical count. Investigate and report on stock discrepancies in accordance with agreed procedures. Preferably physical counts should be made at least twice a year.

*Reason:* To ensure that accurate and complete stock records are kept at all times.
8.1.2 *Stock control procedures for controlled and hazardous TTSPPs*

In addition to the requirements set out in clause 8.1.1, implement the following procedures:

- Institute a customer verification process to ensure that all recipients of these products are authorized to receive them.
- Maintain stock records which specifically identify products in these categories.
- Carry out regular audits and make audit reports available to the responsible authorities.
- Comply with all record-keeping procedures specified in local legislation and regulations. Retain product transaction and delivery records for at least the minimum time period required by local regulations.

*Reason:* To ensure that accurate and complete stock records are kept at all times and to satisfy the requirements of the regulatory authorities.

8.2 *Incoming goods*

8.2.1 *Product arrival checks*

Check and record the following for all incoming TTSPPs:

- product name, item code (identifier), strength, and batch/lot number;
- quantity received against order;
- name and address of the supplying site;
- examine containers for tampering, damage or contamination;
- examine expiry dates — accept short-dated products only if prior agreement has been reached with the supplier; do not accept products that have expired or which are so close to their expiry date that this date is likely to occur before use by the consumer;
- delays encountered during transport;
- status of any attached temperature recording device(s) and/or time/temperature indicators; and
- verify that required storage and transport conditions have been maintained.

8.2.2 *Actions following arrival checks*

- Enter product details, including product name/number, strength, batch numbers, quantities received, expiry dates and acceptance status into the stock recording system.
- Store checked goods under the correct temperature and security regime immediately upon receipt.
- Quarantine defective or potentially defective products, products with incomplete or missing paperwork, products that experienced unacceptable temperature excursions during transport, or products suspected to be counterfeit. Do not release until checks have been completed satisfactorily.
All unacceptable temperature excursions should be evaluated to determine their effect on the product.

- Report any defects to the supplying store or holder of the marketing authorization.
- Do not transfer to saleable stock until all relevant disposition procedures have been completed.

*Reason:* To ensure that incoming TTSPPs are in acceptable condition, accurately recorded and correctly stored and that defective and/or incorrect shipments are followed up with the supplier.

### 8.3 Outgoing goods (external deliveries)

#### 8.3.1 Management of outgoing goods

Implement outgoing goods procedures to ensure that:

- Transport vehicle conformity, including conformity with SLA or quality assurance (QA) agreements, is checked before loading goods.
- Expired products are never issued.
- Products with short expiry dates are not issued unless the recipient accepts that they can be consumed before the expiry date is reached.
- Products are distributed in strict EEFO order unless a product-based time-temperature exposure indicator, such as a vaccine vial monitor, demonstrates that a batch should be distributed ahead of its EEFO order.
- Details of any temperature monitoring devices packed with the external distributions are recorded.
- Details of outgoing products, including product name/number, strength, batch numbers, expiry dates and quantities distributed, are entered into the stock recording system.

#### 8.3.2 Actions following dispatch

Monitor TTSPPs following dispatch in order to:

- trace products to their intended destination;
- record and retain records to provide assurance of goods arrival status. A suitable delivery report from the carrier is an acceptable alternative; and
- take appropriate action in the event of returns, recalls or complaints.

*Reason:* To ensure that outgoing TTSPPs are in acceptable condition, that short-dated stock does not accumulate in the store and that evidence is kept to demonstrate that correct quantities are distributed and received in good condition.

### 8.4 Product complaint procedures

Manage product complaints as follows:
• If a product defect is discovered or suspected in a batch of TTSPPs, cooperate with the regulatory authority to determine whether other batches are affected and recall products if required to do so by the regulatory authority.
• Where complaints or defects relate to a product or its packaging, immediately notify the holder of the marketing authorization for the product.
• Where complaints or defects arise as a result of errors or omissions within the organization, immediately evaluate the causes and take remedial measures to prevent a recurrence.
• Record all complaints and the remedial actions taken. Monitor and analyse trends in the complaint records.

*Reason:* Protection of the public and of the reputation of the supplying organization.

8.5 **Suspect product procedures**

8.5.1 **Suspect products**

Implement systems for identifying and managing suspect products found in the supply chain as follows:

• Physically segregate any suspect TTSPPs found in the supply chain and store securely until legal investigations are complete.
• Label them clearly as “Not for use” or other similar phrase;
• Immediately notify the regulatory authority or authorities and any other relevant authorities, as well as the holder of the marketing authorization of the product.
• Cooperate with regulatory authorities to assist with investigating the source of suspect products and implement appropriate remedial action(s).
• Document the decision-making process for disposal or return of condemned or defective TTSPPs and make these records available to the relevant authorities.

*Reason:* Protection of the public, protection of legitimate suppliers and manufacturers and conformity with regulatory requirements.

8.6 **Product return, recall, withdrawal and disposal procedures**

8.6.1 **Return procedures**

Manage product returns as follows:

• Quarantine returned TTSPPs in a suitable temperature-controlled area and under the security conditions applicable to the product type.
• Do not return to saleable stock unless storage and transport temperature conditions after dispatch from the distribution site have been fully verified and documented, including the return leg to the distribution site.
• Where appropriate, obtain written advice from the holder of the marketing authorization regarding handling and/or disposal of the returned TTSP.
• If returned stock is re-issued, distribute in EEFO order or in accordance with the exposure status of any product-mounted time-temperature indicator device.
• Quarantine returned TTSPs that have been exposed to unacceptable storage and/or transport temperatures and mark for disposal.
• Maintain records of all returned TTSPs.

*Reason*: Protection of the public.

### 8.6.2 Recall procedures

Manage product recalls as follows:

• Conduct urgent and non-urgent TTSP recalls in accordance with an agreed emergency plan.
• Notify the local regulatory authority or authorities.
• Notify overseas regulatory counterparts where the product has been exported.
• Notify all affected customers as applicable.
• Quarantine any remaining inventory of recalled TTSPs and mark for further investigation before disposal.
• Maintain records of all TTSP recalls, including reconciliation of quantity sold, quantity returned, quantity remaining or quantity consumed.

*Reason*: Protection of the public and conformity with regulatory requirements.

### 8.6.3 Disposal procedures

Manage product awaiting board of survey or disposal as follows:

• Ensure that rejected and/or recalled or withdrawn TTSPs cannot be used, released or cause contamination to other products. Store separately from other products, in accordance with local regulations, to await destruction or return to the supplier.
• Safely dispose of rejected and/or recalled/withdrawn products in accordance with local regulations, including where relevant, regulations covering the disposal of hazardous and controlled drugs.
• Maintain disposal records.

*Reason*: Protection of the public and the environment.

### 8.7 Traceability or stock tracking

Ensure that stock and distribution records enable traceability, or stock tracking, of TTSPs from the point of supply to the end-user or patient.
Traceability should include records of the temperature exposure of the product during internal shipping and storage. These records should include:

- for incoming goods: status of shipping indicators used (if any), status of product-based time-temperature indicators (if any) and physical condition of goods and time of receipt;
- for outgoing goods: type of shipping indicators used (if any), status of product-based time-temperature indicators (if any) and physical condition of goods and time of dispatch.

Monitor, record, and investigate discrepancies.

Reason: To demonstrate that TTSPPs have been correctly distributed and to facilitate product recalls and detect theft and fraud.

9. **General procedures and record-keeping**

9.1 **Emergencies and contingency planning**

Make contingency arrangements for the safe storage of TTSPPs in the event of emergencies, including, but not confined to:

— extended power supply outages;
— equipment failure; and
— vehicle breakdown during transport of TTSPPs.

Prepare action plans to deal with products subjected to temperature excursions.

Ensure that the responsible staff know, and have rehearsed, the appropriate actions to be taken in the event of the identified emergency scenarios.

Reason: Loss prevention.

9.2 **General record-keeping**

9.2.1 **Record-keeping**

Maintain comprehensive records and ensure that they are laid out in an orderly fashion and are easy to check.

Paper records must be:

— stored and maintained so that they are accessible and easily retrievable;
— labelled, dated and filed for easy identification;
— protected against deterioration and loss due to fire, flood or other hazards;
— kept secure and protected against unauthorized access; and
— signed and dated by authorized persons and not changed without due authorization.
Computer records must be:

— logically filed for easy identification and retrieval;
— kept secure and protected against unauthorized access;
— where feasible, manually signed, dated and scanned or when electronically archived dated, encrypted and with check-sum;\(^{16}\)
— regularly backed-up and archived on media that are independent of the record-keeping computer system(s). Back-up media may be a separate secure server, a separate hard disc, a flash drive or other digital media appropriate to the scale of the operation.

9.2.2 Content of records

Ensure that the following traceability data is recorded for each TTSPP batch number, as applicable:

— status of product on arrival;
— temperature and humidity records including records of excursions outside labelled storage and/or transit temperature specification conditions;
— general TTSPP stock transactions, including purchase and sale records;
— controlled drug audits;
— audits for products with high illicit value;
— audits for hazardous products;
— stock tracking;
— return, recall, withdrawal and disposal reports, where relevant;
— product complaint reports, where relevant; and
— counterfeit product reports, where relevant.

Maintain all records in accordance with local legislation and regulations.

9.2.3 Record review and retention

Ensure that records are reviewed and approved on a regular basis by a designated member of the quality management team. Ensure that records are accessible for review by end-users, the regulatory authority and other interested parties. Retain records for the minimum period required under local legislation, but for not less than three years.

Reason: Internal quality control, transparency and external inspection by the regulatory authorities and other interested parties.

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\(^{16}\) Electronic records from data loggers are usually encrypted and protected by check-sums. This ensures compliance with FDA Title 21 CFR Part 11:Electronic Records; Electronic Signatures; Final Rule (1997).
9.3 Temperature and humidity records

9.3.1 Temperature records

Monitor and record storage temperatures in all temperature-controlled rooms, cold rooms, freezer rooms, refrigerators and freezers, as follows:

- Check and record temperatures at least twice daily — in the morning and evening — and preferably continuously.
- Review temperature records monthly and take action to rectify systematic excursions.
- Systematically file temperature records for each storage environment or piece of equipment to ensure traceability. Keep records for at least one year after the end of the shelf-life of the stored material or product, or as long as required by national legislation.

9.3.2 Humidity records

When storing products which are adversely affected by high relative humidity (see clause 4.5.3), monitor and record humidity levels in all temperature-controlled rooms as follows:

- Record humidity at least twice every 24 hours or preferably continuously.
- Check humidity records daily.
- Review humidity records monthly and take action to rectify systematic excursions.
- Systematically file humidity records for each temperature-controlled room to ensure traceability. Keep records for at least one year after the end of the shelf-life of the stored material or product, or as long as required by national legislation.

*Reason:* Internal quality assurance and availability of records for review by the regulatory authorities and other interested parties.

10. Environmental management

10.1 Normative references


10.2 Environmental management of refrigeration equipment

Ensure that all new refrigeration equipment for temperature-controlled storage and transport is specified to:
• use refrigerants that comply with the Montreal Protocol;
• minimize or eliminate the use of refrigerants with high global warming potential (GWP); and
• minimize CO$_2$ emissions during operation.

Select equipment to minimize whole-life environmental impact and employ best practice to eliminate leakage of refrigerant into the environment during installation, maintenance and decommissioning of refrigeration equipment.

*Reason:* Compliance with international protocols and accords on climate change and environmental protection.

11. **Quality management**

11.1 **Normative references**

• ICH, 2005: *ICH Harmonized Tripartite Guideline: Quality risk management Q9*
• ISO 9000:2005. *Quality management systems — Fundamentals and vocabulary*
• ISO 9001:2008. *Quality management systems — Requirements*
• ISO 9004:2000. *Quality management systems — Guidelines for performance improvements*
• ISO 10005:2005. *Quality management systems — Guidelines for quality plans*
• ISO 19011:2002. *Guidelines for quality and/or environmental management systems auditing*

11.2 **Organizational structure**

Establish, document and maintain an organizational structure for the TTSPPs, storage and shipping and distribution operations which clearly identifies all key management responsibilities, and the personnel who are accountable.

*Reason:* Quality management.

11.3 **Quality systems**

11.3.1 **Quality system**

Establish, document and maintain a quality system for the management of TTSPPs including, the following, as applicable:

— standard quality system(s) and associated auditing procedures;
— written procedures and specifications;
— record storage, record retention and record destruction programme;
— risk management;
— calibration programme;
— stability programme;
— qualification and validation programme;
— deviation and root cause investigation programme;
— corrective and preventive action (CAPA) procedures;
— training programme;
— periodic temperature-controlled process assessment;
— change control programme;
— maintenance programme;
— management controls;
— product return and recall/withdrawal policies, including emergency recalls;
— product complaint policies;
— material destruction programme;
— warehouse and storage programme;
— shipping and distribution programme;
— notification systems for regulatory agencies; boards of health and ministries of health; and
— self-inspection programme and continuous quality improvement.

Carry out annual reviews of the quality management system to ensure that it remains appropriate, relevant, and effective.

*Reason:* Quality assurance.

11.3.2 *Self inspections*

Conduct regular self-inspections to ensure continuing compliance with quality management standards GSP and GDP; record results, follow-up with the corrective actions needed to rectify areas of non-compliance and document the changes made.

11.3.3 *Contractors subject to service level agreements*

Ensure that every contractor with whom there is an SLA provides periodic evidence of compliance with the GSP and/or GDP standards incorporated into the SLA.

*Reason:* To demonstrate compliance with applicable quality management standards.

11.4 *Management of documents and standard operating procedures*

11.4.1 *Standard operating procedures*

Develop and maintain SOPs covering correct storage, internal shipping and external distribution of TTSPPs, including, but not limited to, the following topics:
— security, including management of controlled and hazardous TTSPPs;
— safe handling of TTSPPs;
— temperature monitoring;
— calibration of temperature and humidity monitoring devices and alarm systems;
— qualification and validation procedures, including temperature mapping;
— maintenance of controlled-temperature equipment;
— facility cleaning and pest control;
— facility maintenance;
— product arrival (receiving) procedures and records;
— stock storage and warehousing procedures (put away, replenishment, order fulfilment, packing);
— stock control procedures and records;
— distribution procedures and records;
— management of temperature excursions;
— product return and recall/withdrawal procedures and records;
— product complaint procedures and records;
— safe disposal of damaged, expired and quarantined products and records which are no longer required;
— temperature-controlled packaging and route qualification;
— temperature-controlled vehicle operation, including management of security locks and seals;
— emergency response procedures; and
— environmental management.

Ensure that all documents are clear and unambiguous and that document change control procedures are in place as specified in clause 11.5.

Reason: Quality management and staff training.

11.5 Document control

Ensure that all quality manuals, SOPs and similar documents are:
— authorized by an appropriate person;
— recorded in a document register;
— regularly reviewed and kept up to date, with all changes recorded and authorized;
— version controlled;
— issued to all relevant personnel; and
— withdrawn when superseded.

Withdraw superseded documents and retain record copies for document history files and for the minimum period(s) required by the regulatory authorities and for duty-of-care purposes.

Reason: Good quality management practice.
12. **Personnel/training**

12.1 **Training**

12.1.1 **General training**

Provide regular and systematic training for all relevant personnel responsible for storage, loading and unloading areas used for non-hazardous TTSPPs, covering the following:

— applicable pharmaceutical legislation and regulations;
— SOPs and safety issues; and
— response to emergencies.

Ensure that each employee understands his or her specific responsibilities. Provide similar training for drivers who are responsible for transporting these substances. Maintain individual training records to demonstrate compliance and regularly evaluate the effectiveness of training programmes.

*Reason:* To ensure that all relevant personnel are competent to carry out their duties.

12.1.2 **Specialist training**

In addition to the training described in clause 12.1.1, provide regular and systematic additional training for relevant personnel responsible for storage, loading and unloading of controlled or hazardous TTSPPs. Training should cover the following:

— applicable legislation and regulations;
— security and safety risks; and
— response to emergencies.

Ensure that each employee understands his or her specific responsibilities. Maintain training records to demonstrate compliance and perform effectiveness checks on training. Provide similar training for drivers who are responsible for transporting these substances.

*Reason:* To ensure that all relevant personnel are competent to handle controlled or hazardous TTSPPs.

**Key references**


Further reading


### Task force membership

<table>
<thead>
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<th>Name</th>
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<th>Category</th>
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</tr>
<tr>
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<td>Biological Dept Pharmaceutical &amp; Narcotics</td>
<td>Regulatory</td>
<td>Iran (Islamic Republic of)</td>
</tr>
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<td>Merck</td>
<td>IFPMA</td>
<td>Netherlands (the)</td>
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<td>Andrew Garnett</td>
<td>Author — Group leader</td>
<td>Consultant</td>
<td>United Kingdom of Great Britain and Northern Ireland</td>
</tr>
<tr>
<td>Ümit Karto.lu</td>
<td>Family and Community Health/Quality, Safety and Standards-Chair</td>
<td>WHO</td>
<td>Switzerland</td>
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<td>Denis Maire</td>
<td>Family and Community Health/Quality, Safety and Standards</td>
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<td>Family and Community Health/Quality, Safety and Standards</td>
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<td>Family and Community Health/Quality, Safety and Standards</td>
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Guidance for Loading of a Truck

1. Loading a Truck

1.1. Boxes used for delivery of health commodities shall be clean and provide adequate protection to the commodities.

1.2. Ensure that the truck appears to be in proper working order, with no visible damage that would impact its ability to operate properly.

1.3. The interior of vehicles and containers shall remain clean and dry whilst in transit.

1.4. Ensure the truck is appropriate for type of product being transported.

1.5. Sufficient security shall be provided by the vehicle and driver to prevent theft, misappropriation, and unauthorized access to products being transported.

1.6. Ensure the size of the truck is appropriate for volume of commodities being shipped. In order to prevent being over charged, PSM staff should be present at loading to ensure the size truck being used is what is actually needed for the volumes being transported.

1.7. Ensure trucks are loaded in a manner that cargo is stable and limits the possibility of shifting during transport. Necessary materials should be used to secure the cargo to prevent movement and subsequent damage to the cargo.

1.8. Ensure there is an agreed upon POD form used by the warehouse and transporter that meets the needs of PSM, and is filled out completely. Check to make sure all information listed is correct.

1.9. Security seal is used and the identification number is recorded on the POD

1.10. Pharmaceutical products in transit must be accompanied by the appropriate documentation

1.11. Damage to containers and any other event or problem which occurs during transit must be recorded, reported and investigated.
Annex 9

Technical supplements to
Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

1. The technical supplement series 97
   1.1 Topics covered 97
   1.2 Target readership 98
   1.3 Document development and review process 98

Supplement 1
Selecting sites for storage facilities 100

Supplement 2
Design and procurement of storage facilities 101

Supplement 3
Estimating the capacity of storage facilities 103

Supplement 4
Building security and fire protection 104

Supplement 5
Maintenance of storage facilities 106

Supplement 6
Temperature and humidity monitoring systems for fixed storage areas 107

Supplement 7
Qualification of temperature-controlled storage areas 109

Supplement 8
Temperature mapping of storage areas 111

Supplement 9
Maintenance of refrigeration equipment 112

Supplement 10
Checking the accuracy of temperature control and monitoring devices 114

Supplement 11
Qualification of refrigerated road vehicles 115
Supplement 12
Temperature-controlled transport operations by road and by air 117

Supplement 13
Qualification of shipping containers 118

Supplement 14
Transport route profiling qualification 119

Supplement 15
Temperature and humidity monitoring systems for transport operations 120

Supplement 16
Environmental management of refrigeration equipment 121
1. The technical supplement series

This series of technical supplements has been written to amplify the recommendations given in Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011, Annex 9). This document sets out the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPPs).

The introduction to the guidance documents states that: “... supplementary materials will be developed to show how the requirements can practically be achieved, particularly in resource constrained settings.” The technical supplements, which make up this volume, are intended to provide this additional material; each one is linked back to a specific clause or clauses in the parent document. All 16 documents are written in a standard format and each contains a reference section with hyperlinks to relevant supporting materials. Most of these materials are available free online. References to print publications are minimized to avoid the difficulties associated with purchasing books and journals.

1.1 Topics covered

Table A5.1 lists the titles of the supplements and the model guidance sections to which each one refers.

Table A5.1

<table>
<thead>
<tr>
<th>Title</th>
<th>Section(s)</th>
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<tbody>
<tr>
<td>1. Selecting sites for storage facilities</td>
<td>Section 2</td>
</tr>
<tr>
<td>2. Design of storage facilities</td>
<td>Section 2 to 5</td>
</tr>
<tr>
<td>3. Estimating the capacity of storage facilities</td>
<td>Section 3.1 to 3.4</td>
</tr>
<tr>
<td>4. Security and fire protection in storage facilities</td>
<td>Section 3.7</td>
</tr>
<tr>
<td>5. Maintenance of storage facilities</td>
<td>Section 3.10</td>
</tr>
<tr>
<td>6. Temperature monitoring of storage areas</td>
<td>Section 4.5.2, 4.5.4</td>
</tr>
<tr>
<td>7. Qualification of temperature-controlled storage areas</td>
<td>Section 4.7</td>
</tr>
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</table>
### Target readership

The target readership for the model guidance, and for the technical supplements, includes regulators, logisticians and pharmaceutical professionals in industry, government and international agencies.

### Document development and review process

The technical supplements have been written by specialist authors. All 16 supplements passed through the following editorial and public review process.

1. Each document was prepared over the course of several drafts in consultation with the series editor.
2. Acronyms and glossary definitions were harmonized throughout.
3. Public consultation drafts were posted on the WHO website in mid-2014. Review comments were received from a number of people and organizations.
4. Reviews were consolidated by the series editor and sent to the individual authors for initial comment.
5. Amended documents were prepared containing the consolidated comments categorized as “accepted”, “rejected” and “for discussion”.

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Table A5.1 continued

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<td>Section 4.7</td>
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<td>9. Refrigeration equipment maintenance</td>
<td>Section 4.9</td>
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<td>10. Checking the accuracy of temperature control and monitoring devices</td>
<td>Section 4.10</td>
</tr>
<tr>
<td>11. Qualification of refrigerated road vehicles</td>
<td>Section 6.4, 6.5</td>
</tr>
<tr>
<td>12. Temperature-controlled transport operations by road and by air</td>
<td>Section 6.5, 9</td>
</tr>
<tr>
<td>13. Qualification of shipping containers</td>
<td>Section 6.8.1 to 6.8.4</td>
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<td>14. Transport route profiling qualification</td>
<td>Section 6.8.3, 6.8.4</td>
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<td>15. Temperature and humidity monitoring systems for transport operations</td>
<td>Section 6.5, 9</td>
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<td>16. Environmental management of refrigerant gases and refrigeration equipment</td>
<td>Section 10.2</td>
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These new drafts were sent back to the individual authors for further comment.

6. The series editor prepared final drafts based on the authors’ responses and these drafts were checked, reviewed and signed off.

7. On the basis of these final comments, clean versions were prepared for review by the Expert Committee on Specifications for Pharmaceutical Preparations and by the Expert Committee on Biological Standardization.

On the following pages, the contents pages of the 16 technical supplements are reproduced. The full texts will be made available in electronic form on the CD-ROM of *Quality assurance of pharmaceuticals* (2015 and updates) and on the website.²

Supplement 1

Selecting sites for storage facilities

Technical supplement to


Contents

Acknowledgements
Abbreviations
Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Designing and costing the supply chain
   2.3 Logistics network planning
   2.4 Finding a potential site
      2.4.1 Establish the size of the warehouse
      2.4.2 Narrow down the choices
      2.4.3 Choose a secure site
      2.4.4 Choose a future-proof site
      2.4.5 Ensure labour availability
      2.4.6 Assess flood risks
      2.4.7 Assess weather and climate-related risks
      2.4.8 Assess fire hazards
      2.4.9 Assess other natural hazards
   2.5 Detailed site investigation: identifying risks and opportunities
      2.5.1 Ground conditions and pollution hazards
      2.5.2 Existing underground and overhead services
      2.5.3 Site survey
      2.5.4 Site clearance costs
      2.5.5 Building surveys
      2.5.6 Service connections to the site
      2.5.7 Low carbon energy potential
      2.5.8 Environmental impact assessment

References
Revision history
Supplement 2

Design and procurement of storage facilities

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Design of pharmaceutical warehouses
      2.2.1 Low-carbon design and environmental auditing
      2.2.2 Warehouse layouts
      2.2.3 Temperature-controlled storage areas
      2.2.4 Cold rooms and freezer rooms
      2.2.5 Order assembly and packing area
      2.2.6 Staging area
      2.2.7 Loading docks
      2.2.8 Other areas
      2.2.9 Temperature monitoring, mapping and qualification
   2.3 Design of dispensing facilities
      2.3.1 Workflow
      2.3.2 Working environment and ergonomics
      2.3.3 Incoming stock
      2.3.4 Refrigerators
      2.3.5 Controlled drugs
      2.3.6 Waste and returns
      2.3.7 Location and arrangement of stock
      2.3.8 Separation of stock
      2.3.9 Patient areas
      2.3.10 Supervised consumption
   2.4 Building procurement
      2.4.1 Preparing and agreeing the brief
2.4.2 Appointing and working with the consultant team
2.4.3 Design risk assessment
2.4.4 Choosing a procurement route for new buildings
2.4.5 Choosing a procurement route for building alterations or refurbishment
2.4.6 The client’s role in tendering
2.4.7 The client’s role during the construction stage
2.4.8 Commissioning and handover

2.5 Procuring cold rooms and freezer rooms

References

Annex 1

Briefing documents
   A1.1 Statement of need
   A1.2 Strategic brief
   A1.3 Project brief

Annex 2

Alternative contracts
   A2.1 Lump sum contract
   A2.2 Design and build
   A2.3 Design, build, finance and operate

Revision history
Supplement 3

Estimating the capacity of storage facilities

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Inventory management concepts
   2.3 Collecting product data
      2.3.1 Vaccines
      2.3.2 General pharmaceuticals, including non-vaccine TTSPPs
      2.3.3 Volume data and SKU types
   2.4 Calculating maximum inventory volumes
      2.4.1 Vaccines and related supplies
      2.4.2 General pharmaceuticals and supplies, including non-vaccine TTSPPs
   2.5 Calculating net storage capacity requirements
      2.5.1 Classifying products by storage temperature and security category
      2.5.2 Load support systems
      2.5.3 The utilization factor concept
      2.5.4 Pallet bay calculation
      2.5.5 Shelving unit calculation
      2.5.6 Closed shelving units and safety cabinets
      2.5.7 Refrigerators and freezers
      2.5.8 Load optimization tools

References

Tools

Revision history
Supplement 4

Building security and fire protection

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target audience
   1.4 Associated materials and equipment

2. Guidance
   2.1 Site security and emergency access
   2.2 General building security
   2.3 Controlled and hazardous substances areas
   2.4 Fire detection systems
   2.5 Fire suppression equipment
      2.5.1 Smoke ventilation systems
   2.6 Compartmentation
      2.6.1 Sprinkler systems
   2.7 Fire prevention, training and control procedures
      2.7.1 Risk assessment
      2.7.2 Fire prevention
      2.7.3 Fire safety training
      2.7.4 Fire control procedures

References

Annex 1

SOP: fire safety housekeeping
   A1.1 Policy and objectives
      A1.1.1 Policy
      A1.1.2 Objectives
   A1.2 Responsibility
   A1.3 Associated materials and equipment
A1.4  Procedure
   A1.4.1  Reducing ignition sources
   A1.4.2  Reducing fuel load
   A1.4.3  Maintenance of fire protection measures

A1.5  Related documents

Annex 2
SOP: routine inspection and maintenance
A2.1  Policy and objectives
   A2.1.1  Policy
   A2.1.2  Objectives
A2.2  Responsibility
A2.3  Associated materials and equipment
A2.4  Procedure
   A2.4.1  Daily inspections
   A2.4.2  Weekly inspections
   A2.4.3  Monthly inspections
   A2.4.4  Three-monthly inspections
   A2.4.5  Six-monthly inspections
   A2.4.6  Yearly inspections
A2.5  Related documents

Annex 3
SOP: fire drills
A3.1  Policy and objectives
   A3.1.1  Policy
   A3.1.2  Objectives
A3.2  Responsibility
A3.3  Associated materials and equipment
A3.4  Procedure
   A3.4.1  Conducting test evacuations
A3.5  Related documents

Revision history
Supplement 5

Maintenance of storage facilities

Technical supplement to

Contents

Acknowledgements
Abbreviations
Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 What is maintenance and why is it important?
   2.3 The building design and construction phase
      2.3.1 The operation and maintenance manual
      2.3.2 The health and safety file
   2.4 Maintenance management
      2.4.1 Establish an institutional or contractual framework
      2.4.2 Preventive maintenance and replacement: standards and schedules
      2.4.3 Establish a multiyear maintenance plan
      2.4.4 Planned periodic inspections
      2.4.5 Planned service inspections
      2.4.6 Curative maintenance
      2.4.7 Organizing and managing the work
      2.4.8 Inspecting and signing off the work

References

Annex 1
   Uniclass: building elements

Annex 2
   Checklist for building weatherproofing

Revision history
Supplement 6
Temperature and humidity monitoring systems for fixed storage areas

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary
1. Introduction
   1.1 Requirements
      1.1.1 Temperature monitoring systems
      1.1.2 Humidity monitoring systems
      1.1.3 Alarm systems
   1.2 Objectives
   1.3 Target readership
2. Guidance
   2.1 Associated materials and equipment
   2.2 Related activities
   2.3 Choosing a monitoring system
      2.3.1 Prepare a user requirements specification
      2.3.2 Select the basic system type
      2.3.3 Match the system to the needs
      2.3.4 Automated continuous monitoring
      2.3.5 Data collection: wireless versus wired data transmission
      2.3.6 Specific requirements for wireless networks
      2.3.7 Web-based systems
      2.3.8 Alarm system
      2.3.9 User controls
      2.3.10 Adaptability and expandability
      2.3.11 Security and compliance
   2.4 Maintenance and support
   2.5 System extent
      2.5.1 Number of monitoring points
      2.5.2 Location of monitoring points
2.6 Complementary services
2.7 Deploying the system
2.8 Post-installation setup and qualification activities

References

Annex 1

Example of form for monitoring system start-up

Revision history
Supplement 7

Qualification of temperature-controlled storage areas

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Introduction to qualification
      2.2.1 Qualification applied to temperature-controlled storage
      2.2.2 Installation qualification
      2.2.3 Operational and performance qualification
   2.3 Qualification protocols
      2.3.1 Approval page and change control history
      2.3.2 Acronyms and glossary
      2.3.3 Description and rationale
      2.3.4 Scope and objectives
      2.3.5 Key parameters
      2.3.6 Procedures
      2.3.7 Qualification report template
      2.3.8 Approval process
   2.4 Installation qualification
      2.4.1 Identifying critical components
      2.4.2 Checking installed systems, subsystems and components
      2.4.3 Checking electrical systems and requirements
      2.4.4 Checking environmental conditions
      2.4.5 Checking spare parts
      2.4.6 Checking auxiliary equipment
      2.4.7 Checking information needed for the preventive maintenance programme
2.4.8 Writing the IQ report

2.5 Operational qualification

2.5.1 Checking installed systems, subsystems and components
2.5.2 Calibration of controllers and sensors
2.5.3 Standard operating procedures
2.5.4 Control panel
2.5.5 Alarm tests
2.5.6 Temperature mapping – empty
2.5.7 Power failure test
2.5.8 Writing the OQ report

2.6 Performance qualification

2.6.1 Checking installed systems, subsystems and components
2.6.2 Temperature mapping – full
2.6.3 Temperature recovery after door opening
2.6.4 Writing the PQ report

2.7 Specific requirements for small-scale equipment

References

Revision history

Annex 1

Form for reporting deviations and corrective action
Supplement 8

Temperature mapping of storage areas

Technical supplement to

Contents

Acknowledgements
Abbreviations
Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 The mapping protocol
      2.2.1 Approval page and change control history
      2.2.2 Acronyms and glossary
      2.2.3 Description and rationale
      2.2.4 Scope
      2.2.5 Objectives
      2.2.6 Methodology
      2.2.7 Mapping report template
   2.3 Conducting the mapping exercise
   2.4 Analysing the data and preparing the mapping report
      2.4.1 Preliminary analysis
      2.4.2 Minimum and maximum temperatures and hot and cold spots
      2.4.3 Mean temperatures
      2.4.4 Interpreting the results and making recommendations
      2.4.5 Report auditing
   2.5 Implementing the mapping report recommendations

References

Annex 1
   Test data sheets
      A1.1 Test data sheet: temperature data logger locations
      A1.2 Test data sheet: temperature distribution
      A1.3 Test data sheet: temperature distribution

Revision history
Supplement 9

Maintenance of refrigeration equipment

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary
1. Introduction
1.1 Requirements
1.2 Objectives
1.3 Target readership
2. Guidance
2.1 Associated materials and equipment
2.2 Active and passive transport containers
2.3 Refrigerators and freezers
2.4 Freezer rooms, cold rooms and controlled ambient stores
  2.4.1 Maintenance overview
  2.4.2 Maintaining the cooling system
  2.4.3 Maintaining insulated panels and vapour control sealing
  2.4.4 Condensation control outside the cold store enclosure
  2.4.5 Frost-heave control
  2.4.6 Cold store panel insulation
  2.4.7 Insulation for refrigeration pipes and other penetrations
  2.4.8 Cold store maintenance schedule
2.5 Refrigerated vehicles
  2.5.1 Refrigerated vans
  2.5.2 Refrigerated rigid bodies
  2.5.3 Refrigerated semi-trailer
2.6 Refrigerated containers
2.7 Maintenance management
2.8 Decommissioning
2.9 Staff training
References
Annex 1

Checking refrigerated vehicles
A1.1 Checking insulation on a refrigerated vehicle
A1.2 Checking cooling equipment on a refrigerated van
A1.3 Checking cooling equipment on a rigid vehicle or semi-trailer

Revision history
Supplement 10

Checking the accuracy of temperature control and monitoring devices

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Procedure
      2.2.1 Prerequisites
      2.2.2 Establishing the ice-point bath (excerpt from ASTM E563-11)
      2.2.3 Placing the device in the bath
      2.2.4 Carrying out the accuracy check, step by step
      2.2.5 Maintaining the bath temperature
      2.2.6 Actions to take following the test

References

Annex 1
   Generic temperature accuracy check form

Revision history
Supplement 11

Qualification of refrigerated road vehicles

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
      1.2.1 Verification
      1.2.2 Qualification
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Preliminary construction validation
      2.2.1 Temperature-controlling equipment
      2.2.2 Thermal insulation
      2.2.3 Performance checks
   2.3 Field shipment test
      2.3.1 Purpose
      2.3.2 Loading
      2.3.3 Temperature probe placement
      2.3.4 Test procedure
      2.3.5 Acceptance criteria
   2.4 Temperature-control failure test
      2.4.1 Purpose
      2.4.2 Loading
      2.4.3 Temperature probe placement
      2.4.4 Test procedure
      2.4.5 Acceptance criteria
   2.5 Documentation
      2.5.1 Designation of the vehicle
      2.5.2 Results of the qualification
   2.6 Vehicle qualification failure
   2.7 Calibration
References

Annex 1

Placing EDLMs or temperature sensors

Revision history
Supplement 12

Temperature-controlled transport operations by road and by air

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary
1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership
2. Guidance
   2.1 Associated materials and equipment
   2.2 Available shipping systems
      2.2.1 Refrigerated vehicles – temperature-controlled
      2.2.2 Refrigerated vehicles – temperature-modified
      2.2.3 Passive shipping systems
      2.2.4 Active shipping systems for air transport
   2.3 Quality agreements
      2.3.1 User requirements specification
      2.3.2 Service level agreements
   2.4 Identifying and controlling risk
   2.5 Managing refrigerated road shipments
   2.6 Managing passive container road shipments
   2.7 Introduction to air transport
      2.7.1 Types of air carrier
      2.7.2 Air transport labelling for TTSPPs
   2.8 Air transport processes
   2.9 Managing air shipments
References
Annex 1
   Packing a refrigerated vehicle
Revision history
Supplement 13
Qualification of shipping containers

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 The three stages of qualification
      2.1.1 Design qualification
      2.1.2 Operational qualification
      2.1.3 Performance qualification
      2.1.4 Requalification of reusable container systems
   2.2 Associated materials and equipment
      2.2.1 Test equipment for design and operational qualifications
      2.2.2 Test equipment for performance qualification
   2.3 The performance qualification test protocol
      2.3.1 Protocol title
      2.3.2 Protocol approvals
      2.3.3 Introduction
      2.3.4 Purpose
      2.3.5 Scope
      2.3.6 Acceptance criteria
      2.3.7 Responsibilities
      2.3.8 Test procedure
      2.3.9 Data analysis
   2.4 The performance qualification test
   2.5 The performance qualification report

References
Revision history
Supplement 14

Transport route profiling qualification

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Study protocol
   2.3 Carrying out the study
   2.4 Data retrieval
   2.5 Understanding temperature exposure: the degree–hour concept
   2.6 Organizing, analysing and using the data
      2.6.1 Method A for designing and testing packaging solutions
      2.6.2 Method B for passive containers with known performance characteristics

References

Annex 1

Method B examples
   A1.1 Using the data
   A1.2 The warm climate case
      A1.2.1 Step 1: organize and analyse the route profile data
      A1.2.2 Step 2: assess container suitability
   A1.3 The cold climate case
      A1.3.1 Step 1: organize and analyse the route profile data
      A1.3.2 Step 2: assess container suitability

Revision history
Supplement 15
Temperature and humidity monitoring systems for transport operations

Technical supplement to

Contents
Acknowledgements
Abbreviations
Glossary
1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership
2. Guidance
   2.1 Associated materials and equipment
   2.2 Temperature and humidity monitoring devices
      2.2.1 Device types
      2.2.2 Data collection, storage and retrieval
References
Revision history
Supplement 16

Environmental management of refrigeration equipment

Technical supplement to


Contents

Acknowledgements

Abbreviations

Glossary

1. Introduction
   1.1 Requirements
   1.2 Objectives
   1.3 Target readership

2. Guidance
   2.1 Associated materials and equipment
   2.2 Montreal Protocol
   2.3 Selection of refrigerants and blowing agents
      2.3.1 Use of chlorofluorocarbons
      2.3.2 Use of hydrochlorofluorocarbons
      2.3.3 Use of hydrofluorocarbons
      2.3.4 Use of hydrofluoro-olefin
      2.3.5 Use of hydrocarbons
      2.3.6 Ammonia and carbon dioxide
      2.3.7 Other cooling technologies
   2.4 Counterfeit refrigerants
   2.5 Thermal insulation
   2.6 CO₂ emissions
      2.6.1 Kyoto Protocol
      2.6.2 CO₂ emissions from prime mover
      2.6.3 ODP and high GWP refrigerants
   2.7 Installation and maintenance
   2.8 Decommissioning
   2.9 Staff training

References

Annex 1

Montreal Protocol: non-Article 5 countries

Revision history
Annex 10. Proof of Insurance Form

STORAGE RISK INSURANCE

**QUESTIONNAIRE / APPLICATION FORM**

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<th>Contact Person:</th>
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**GENERAL INFORMATION**

- **Storage Location (Name/Address):**

- **Goods/stocks owner:**

- **Sum to be insured (replacement value):** ______________ USD / ______________ (local currency)

- **Floating Limit required:** ______________ USD / ______________ (number of months)

- **Requested perils to be insured:**
  - [ ] Accidental damage
  - [ ] Flexa (fire, lightning, explosion, falling aircraft);
  - [ ] Extended Coverage (civil commotion, malicious mischief, strike or lock-out, vehicle impact, smoke, sonic boom, sprinkler leakage, tap water, burglary);
  - [ ] Natural Perils (e.g. windstorm, hail, flood, earthquake, volcanic eruption, snow pressure, etc.);

- **Insurance period storage risks:** ___________ until ___________ – 12.00 noon local time

- **Stock description (kind of stocks/goods):**

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

  ____________________________________________________________

GlobalQMS ID: 681.11, 8 June 2020
RISK INFORMATION

Please use only one questionnaire/application for each location to be insured.

Location

(Address):

Building construction:  
- concrete
- non-combustible
- combustible
- wooden

Year of construction:  
- owned
- hired

Ground area:  
- square feet
- square meter

CCTV

Total storage area:  
- square feet
- square meter

Storage level max.:  
- feet
- meter

High rack storage area:  
- YES;
- NO

Smoking permitted:  
- YES;
- NO

Kind of packing:  
- without
- non-combustible
-Only protection of the borders combustible
- wood, paper, plastics
- foam plastic packing as in/out side package

Automatic sprinkler system:  
- Complete
- mainly ___ %
- none

Alarm to:  
- fire department
- watchman service 24 hour
- local/none

Automatic smoke detectors:  
- Complete
- mainly ___ %
- none

Alarm to:  
- fire department
- watchman service 24 hour
- local/none

Automatic burglary alarm detectors:  
- Complete
- mainly ___ %
- none

Alarm to:  
- police
- watchman service 24 hour
- local/none

Other protection systems:  
- YES.
- NO

Alarm to:  
- police/fire department
- watchman service 24 hour
- local/none

Professional watchman service:  
- YES
- NO

Other building security features:  
- YES
- NO

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(Place, Date)
Annex 11 COVID-19 Vaccine Distribution Plan

*(included as a separate Microsoft Excel attachment)*