

February 17, 2026

Request for Proposal Number: RFP-PSM-ZMB-2026 ITN-WAREHOUSING SERVICES
Warehousing/Distribution Center Services for Insecticide Treated Nets (ITNs) in Lusaka, Zambia

Dear Sir or Madam,

Chemonics International, Inc. (hereinafter referred to as “Chemonics”), under the United States Government (USG) Department of State (DOS) (originally and formerly USAID) Global Health Supply Chain – Procurement and Supply Management (GHSC-GHSC-PSM) Project, with Prime Contract Number No. AID-OAA-I-15-00004; Task Order 2 No. AID-OAA-TO-15-00009, is issuing a Request for Proposals (RFP) for the provision of third party warehousing storage, management, dispatching and distribution center services for Insecticide Treated Nets in Zambia. The attached RFP, below, contains all the necessary information for interested Offerors.

Offerors may have additional questions after reading this RFP. Interested Offerors can submit questions by email to SPDprocurement@ghsc-psm.org, according to the instructions in I.6 Written Questions and Clarifications of the RFP if necessary, Chemonics will circulate answers and clarifications to all RFP recipients who have indicated an interest in this RFP.

This RFP does not oblige 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,
Deogratius Kimera
Country Director
GHSC-PSM in Zambia

Request for Proposals (RFP)

RFP-PSM-ZMB-2026 ITN-WAREHOUSING SERVICES

For the provision of

Warehousing Storage, Management, Dispatching and Distribution Center Services for Insecticide Treated Nets (ITNs) for the FY26 Mass Campaign in Lusaka, Zambia

Contracting Entity:
Chemonics International, Inc.

Funded by:
United States Government (USG) under Department of State (DOS) (Formerly USAID)- Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM)

Prime Contract Number
Prime Contract Number: AID-OAA-I-15-00004
Task Order Numbers: AID-OAA-TO-15-00009

******* 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 <http://www.chemonics.com/OurStory/OurMissionAndValues/Pages/default.aspx>.

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 USG 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 USG and the Office of the Inspector General. In addition, Chemonics will inform DoS 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 Deogratius Kimera 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 to BusinessConduct@chemonics.com or by phone/Skype at 888.955.6881.

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List of Acronyms

API	Application Program Interface
BER	Batches and Expiry Report
CCTV	Closed Circuit Television
CFR	Code of Federal Regulations
CD	Country Director
CV	Curriculum Vitae
DOS	Department of State
EPCMD	End Preventable Child and Maternal Deaths
ERP	Enterprise Resource Planning
FAR	Federal Acquisition Regulations
FEFO	First Expiry First Out
FUP	Fixed Unit Price
GHSC-PSM	Global Health Supply Chain Program–Procurement and Supply Management
GSP	Good Storage Practices
GTDP	Good Trade and Distribution Practices
HF	Health Facilities
IDIQ	Indefinite Delivery Indefinite Quantity
IP	Implementing Partner
ITN	Insecticide Treated Nets
IQS	Indefinite Quantity Subcontract
KPI	Key Performance Indicator
ITNs	Insecticide Treated Nets
MCLS	Malaria Commodities Logistics System
MNCH	Maternal Newborn Child Health
NGO	Nongovernmental organization
NMEC	National Malaria Elimination Centre
PEPFAR	President’s Emergency Plan for AIDS Relief
PMI	President’s Malaria Initiative
PO	Purchase Order
POD	Proof of Delivery
PRH	Population and Reproductive Health
QA	Quality Assurance
QC	Quality Control
RDTs	Rapid Diagnostic Tests
RIRV	Requisition Issue and Receipt Voucher
RFP	Request for Proposals
RFTOP	Request for Task Order Proposals
RO	Requisition Order
RTKs	Rapid Test Kits
SAM	System for Award Management
SDP	Service Delivery Points
SIV	Store Issue Voucher
SOPs	Standard Operating Procedures
STO	Sub-Task Order
DoS	Department of State
UEI	Unique Entity Identifier
U.S.	United States
USD	U.S. Dollar

USG
VAT
WHO
WMS

U.S. Government
Value Added Tax
World Health Organization
Warehousing/Distribution Center Management System

Section I. Instructions to Offerors

I.1. Introduction

Under the United States Government (USG) Department of State (DOS) funded Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project, single award indefinite delivery indefinite quantity (IDIQ) contract number AID-OAA-I-15-00004, Chemonics is soliciting offers from qualified companies and organizations to provide ambient Warehousing/Distribution Center services for Insecticide Treated Nets (ITNs) in Lusaka, Zambia. ITNs will be received, unloaded, stored (short-term), cross docked where applicable, and dispatched from Lusaka to designated service delivery points in different provinces as directed by the National Malaria Elimination Centre (NMEC).

Chemonics intends to award a single Indefinite Quantity Subcontract (IQS) to one company or organization with fixed unit prices. The successful Offeror shall be required to adhere to the statement of work and terms and conditions of the subcontract. 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 Reports**.

Offerors are invited to submit proposals in accordance with **Section I: Instructions to Offerors**. These instructions are provided solely to assist in preparing proposals and will not form part of the subcontract. Any subcontract resulting from this RFP will be governed by **Sections II and III**.

Chemonics intends to award a single subcontract to the offeror that presents the most comprehensive and cost-effective solution to the scope of work.

The anticipated period of performance will not exceed **six months**, from approximately [July 1, 2026] to [December 31, 2026], with the option for Chemonics to extend at its sole discretion.

Please note: This RFP does not obligate Chemonics to award a subcontract or reimburse any costs incurred in proposal preparation. Chemonics reserves the right to reject any or all offers if deemed in its best interest. Unless otherwise specified, all time periods referenced in this RFP are consecutive calendar days.

I.2. Offer Deadline

Offerors shall submit electronic offers no later than 17:00 (Lusaka time) on March 19, 2026. Late offers will be considered at the sole discretion of Chemonics.

Emailed offers must be received by the same time and date at the following address:

Attn: Segolene d'Herlincourt
Deputy Country Director - Operations
SPDprocurement@ghsc-psm.org

Faxed and Hard copy offers will not be considered.

Offerors are responsible for ensuring that their offers are received in accordance with the instructions stated herein. Late offers may be considered at the discretion of Chemonics. Chemonics cannot guarantee that late offers will be considered. For all deadlines related to this RFP, see Section I.6 Chronological List of Proposal Events.

I.3. Submission of Offers

Offerors are responsible for ensuring their proposals are received by GHSC-PSM by the deadline stated in Section I.2.

A. Instructions for the Submission of Electronic Copies

Separate technical and cost proposals must be submitted by email to Attention: Segolene d'Herlincourt, Deputy Country Director – Operations Email: SPDprocurement@ghsc-psm.org by no later than 17:00 (Lusaka time) on March 19, 2026.

The Offeror must submit the proposal electronically with up to three (3) attachments (5 MB limit per attachment) per email compatible with MS Word, MS Excel, readable format, or Adobe Portable Document Format (PDF) in a Microsoft XP environment. Offerors must submit a separate cover email without any attachments to delineate quantity and content of emails to expect with attachments, for clarity of submission. Offerors must not submit zipped files. Those pages requiring original manual signatures should be scanned and sent in PDF format as an email attachment or signed by using e-signatures.

The technical proposal and cost proposal must be kept 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.

I.4. Requirements

Offerors must be legally registered under the laws of Zambia by the anticipated start date and have a local presence in Zambia. International firms may propose in partnership, with the lead responsible for subcontract compliance.

To be determined responsive, an offer must include all documents and sections included in I.4.A and I.4.B.

A. General Requirements

Chemonics will issue a Indefinite Quantity Subcontract (IQS) for ambient warehousing services, priced as a fixed monthly ZMW/square meter (m²) rate as defined in Section III (Cost Proposal). The successful Offeror must adhere to the statement of work and terms and conditions of the subcontract, incorporated in Section III herein.

Offerors must be legally registered under the laws of Zambia by the anticipated start date and have a local presence in Zambia. International firms may propose in partnership, with the lead responsible for subcontract compliance. Chemonics anticipates issuing a subcontract to a Zambian or International company or organization, provided that the entity is legally registered, and recognized under the laws of Zambia and the country where the entity is headquartered, and they comply 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.

Indefinite Quantity Subcontract (IQS)

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 Zambia by the anticipated start date of operations in July 2026.

- (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 services.
- (iii) Companies or organizations must have a local presence in Zambia at the time of proposal submission.
- (iv) Companies or organizations, whether for-profit or non-profit, shall be requested to provide a UEI 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 3.¹

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.

B. Required Proposal Documents

1. Cover Letter

A sample cover letter is provided in Annex 1 of this RFP. The offeror's cover letter 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
- ix. UEI Number
- 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) Copy of trade license, or equivalent document.
 - d) 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.
 - e) Applicable documents listed in I.4.A.
 - f) Evidence of financial capacity and capability to conduct the work.

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 I.4.A above.

2. Technical Proposal

Offerors must prepare and submit a technical proposal. The technical proposal shall comprise the following three parts:

Part 1: Technical Approach and Operations: Offerors shall provide the details regarding their technical approach, current operations, and facilities being offered to provide the services described in the scope of work (Section II of the RFP), with the main general requirements summarized below. This part shall be between 5 and 10 pages long but may not exceed 10 pages. Copies of SOPs and insurance certificate(s) shall be included in an annex to the technical proposal and will not count against the page limit.

Offerors shall provide the details regarding their technical approach and operations as described in the scope of work (Section II), with the main general requirements summarized below:

- Proposed Warehousing/Distribution Center location(s),
 - The warehouse must be used exclusively for the ITNs for the duration of the contract
 - Dimensions of existing or planned physical facilities including access, site drainage, utilities, proximity to Lusaka CBD, communications, warehouse capacity
 - Presence of any material handling equipment (as needed), and security systems including closed-circuit television (CCTV), fencing, visitor control, etc.
 - If the offeror is proposing a facility that is to be leased or renovated, evidence that a suitable facility meeting stipulated requirements shall be provided by the time stipulated by Chemonics.
- Warehouse Management System (WMS) description and functionalities:
 - The WMS must be able to send, receive, and process CSV and PDF files (e.g., inventory reports, orders, shipments) to designated email/Dropbox folders, and receive the same.
- The Offeror shall demonstrate ability to segregate insecticide-treated nets (ITN) from other health commodities and/or must store them in a separate storage area.
- In addition, offerors shall provide a mobilization plan detailing the timeframe for when required organizational and technical infrastructures will be put in place should they not already be in place, including but not limited to the following:
 - Hired qualified staff, who are assigned and trained in each requisite area for proposed facility(ies), and present which staff will be responsible and focal points for each task and interaction with Chemonics.
 - Fully functional physical assets, including but not limited to well-ventilated warehouse structure, IT, security and safety measures, material handling equipment, furniture, and all equipment provided for operations.
 - Required liability, local, building and commodity insurance coverages that are in place.
 - Implemented security plans for the site and facility.
 - Fully functional WMS and automated inventory control management systems. Should no electronic WMS be available, provide a description of WMS and its capabilities that will be installed if awarded the subcontract.

Offeror shall demonstrate through detailed narrative explanation with any supporting documentation thereto, its current capacity as to the preceding enumerated categories of requisite, adequate technology, equipment, and infrastructure that are required for rapid order processing, with minimal requirement to hold inventory in storage.

- Provide Standard Operating Procedures (SOPs). SOPs will be evaluated to confirm consistent procedures for security, receiving, storage, packing, and loading. The SOPs shall be in line with the guidelines for model guidance for the storage of ITNs products, and guidance for loading a truck. SOPs shall include but not be limited to the following:
 - Training in relation to good storage practice, regulations, and safety specific to ITNs goods
 - Premises and facilities.
 - Security
 - Inbound processes
 - Receiving
 - Put away
 - Storage
 - Maintenance of good storage practice
 - Quarantine Sampling and releasing of goods from quarantine.
 - Stock rotation and control
 - Outbound processes
 - Selection picking
 - Auditing / Quality control
 - Dispatch
 - Incident management and reporting
 - Daily operations reporting
 - Force majeure and disaster recovery plan
 - Reverse logistics.
 - Returned goods, handling, and re-evaluation process.
- The offeror shall demonstrate full compliance with local fire, health, and safety regulations with functioning smoke detectors and serviced fire extinguishers.

If the offeror does not have the technical and/or managerial capacity at the time of proposal submission to fully implement the scope of work(s), the offeror shall explain the steps it will take, and the corresponding timeline, to become capable of implementing the scope(s) of work by the proposed start date of implementation.

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 a detailed organogram 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 quality assurance objectives. Qualification of all personnel must be in line with national regulations.

The offeror shall provide a one-paragraph job description, relevant to the scope of work, for each of the following key positions. The offeror shall provide the CVs of staff in these key positions, that will be assigned to the subcontract, and CVs (maximum of 2 pages per CV) of the management personnel which shall be included in an annex to the technical proposal and will not count against the page limit:

- Warehousing/Distribution Center Manager (a minimum of 5 years relevant experience with the requisite certification)
- Inventory Controller
- Inventory Personnel

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

Part 3: Corporate Capabilities, Experience, and Past Performance. Offerors shall have not more than four pages for this Part 3 and must include a description of experience and technical ability by providing details of similar, previous projects, industries the company is engaged in, recognizable partners, etc. Subcontractors shall elaborate on their experience in Warehousing/Distribution Center relevant to health commodities. Furthermore, offerors must include 3 past performance references of similar work (under contracts or subcontracts) previously implemented and contact information for the companies for which such work was completed. Should the Offeror have worked with US government or US government funded projects, please provide past performance references for the same. Contact information must include at a minimum: the name of the point of contact who can speak to the contractor’s performance, name, and address of the company for which the work was performed, and the email and phone number of the point of contact.

Chemonics reserves the right to check for additional references not provided by the 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 reports, and provides a deliverables schedule and report schedule.

3. Cost Proposal

The cost proposal is used in part to determine which proposals represent the best value and serve as a basis of negotiation before awarding a subcontract.

The price of the subcontract to be awarded will be a Indefinite Quantity Subcontract (IQS) including fixed unit rates. No profit, fees, taxes, or additional costs can be added after the award. All cost information must be expressed in Zambian Kwacha. Offerors are strongly encouraged to propose their best and most competitive prices for services.

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

Part 1: Prices for Services

Unit: ZMW per m² per month | Location: Lusaka (single site) | Commodity: ITNs (ambient) | Quantity: approx. 4,042,827 ITNs- approx. 101,070.67 bales

ITN specifications:

Description	Specifications
Weight per ITN	625 grams
ITNs per bale	40 nets
Weight per bale	29 Kg
Volume per bale	0.127m ³
ITNs per 40 ft container	16,800

ITN bales per 40 ft container	420
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A. Inclusions (must be covered by the per-m² monthly rate):

- Premises & Facility Operations: rent/lease, common areas, routine maintenance/cleaning/sanitation, pest control logs, adequate lighting, site drainage, and communications.
- Backup/alternative power for continuous operations (fuel/energy included).
- Security & Safety: 24/7 security, fencing/access control, CCTV with 90-day retention (on- and off-site), intrusion and fire detection/suppression, visitor/vehicle access control, compliance with local fire/health/safety regulations.
- Warehouse Operations: labor for receiving, put-away, storage, , pick/pack/stage, dispatch documentation, QA checks, and incident handling during normal operating hours; supervisory coverage to meet service windows.
- Pallets to ensure off-floor storage and compliant stacking.
- WMS & IT: software licenses, configuration, handheld scanners/barcode readers, user access, support, , daily SOH visibility, batch/lot tracking, CSV/PDF exchange.
- Insurance & Compliance: local property/material damage, employer’s liability, workers’ compensation, warehouse keeper’s liability appropriate to values handled, and mandatory local permits/licenses.
- Administrative & Overheads: all overheads, margins, and any allowable local taxes/levies; audit support; other costs necessary to deliver warehousing services.

B. Exclusions (not included in per-m² rate; if approved, billed separately at fixed unit rates):

- Transportation outside the warehouse.
- Special packaging materials unique to non-standard orders (if pre-approved).
- Extraordinary works (e.g., major facility renovations requested by Chemonics).
- Overtime labor outside agreed normal operating hours (weeknights/weekends/public holidays) and afterhours truck loading/offloading if requested and pre-approved by Chemonics.

C. Space Measurement and Billing Rules: Chargeable space includes pallet positions, staging, and minimum operational aisle space directly required to store/handle ITNs.

D. Minimum Service Levels (included):

- Inventory accuracy: ≥ 99% macro; 100% batch/lot micro accuracy.
- Timely processing: receiving within 48 hours of arrival (or as agreed for bulk), dispatch within agreed windows.
- Reporting: inbound notifications, detailed receiving reports, weekly dispatch summaries (via WMS), monthly consolidated stock status with PODs/ePODs.
- Issue response: acknowledgment of queries and provision of supporting documentation within 2 business days.

E. Assumptions & Constraints: Commodity profile is ambient ITNs; stacking and handling on pallets within height/load limits; segregation from other commodities; normal operating hours with pre-approved occasional extended hours; sustained 24/7 surge requires prior agreement and may invoke overtime rates.

F. Pricing Template (to be completed by Offeror):

Item	Unit	Size of proposed warehouse (storage	Rate per m ² / month (ZMW) (B)	Total monthly amount (A×B)	Notes

		space only) (A)			
All-inclusive Warehouse Rental (Ambient)	m ² / month				Includes premises, utilities, alternative power, labor (normal hours), security, WMS/IT, MHE, pallets/racking, insurance, admin/overheads

- Specify clearly normal working hours:
 - o Monday:
 - o Tuesday:
 - o Wednesday:
 - o Thursday:
 - o Friday:
 - o Saturday:

G. Overtime / After-Hours Fixed Unit Rates (if requested by Chemonics and pre-approved):

Item	Unit	Rate (ZMW)	Notes
Overtime warehouse labor – general	Per hour / per person		Applicable after normal operating hours
Overtime supervisor	Per hour / per person		
After-hours truck loading/off-loading	Per truck		Applies to nights/weekends/public holidays

- Specify clearly what qualifies at overtime/after-hours:
 - o Sunday:
 - o Public holidays:

H. Compliance Statement: By proposing the inclusive per-m² rate above, the Offeror confirms that the rate covers all services and obligations required in the Scope of Work; no additional fees or surcharges will be applied after award unless pre-approved in writing by Chemonics pursuant to the subcontract. Offer validity: 90 calendar days after proposal due date. Rates are fixed for the initial period of performance; no indexation applies unless scope changes are issued by Chemonics.

Key considerations when implementing this costing/pricing structure:

- The fee for service paid should reflect the resources required and costs incurred by the vendor and encourage improved service performance and a cost reduction culture.
- The fee structure must be sustainable through changes in the customer's operating environment.
- The vendor should improve profit margins by adding value and innovation in performance beyond the basic services and capabilities required pursuant to this RFP and the ultimate subcontract resulting. Therefore, to encourage continued Awardee performance exceeding requirements and demonstrative of its's capacity building, the provision of positive

discounting allows for just compensation of the awardee proportional to the additional value-added and enrichment of the Contractor.

All rates should be based off the current average wage/salary rates for that job/position in Zambia.

As regards the delivery of the services and deliverables outlined in the contract, Chemonics will pay the subcontractor the agreed-upon fixed unit prices.

Fixed unit prices shall be inclusive of all associated costs, taxes, and fees, including salaries, maintenance on machinery and infrastructure, including generators, pallet lifts, plumbing, IT, CCTV, temperature monitoring systems, security systems with full access controls, applicable insurance, and Warehousing/Distribution Center management information system tracking. Offerors must provide a breakdown of these unit processes with substantiating documentation for Chemonics to determine reasonableness, realism, and completeness.

In addition, offerors are expected to utilize technology to automate processes and optimize supply chain efficiency. This includes using a warehouse Warehousing/Distribution Center management system (WMS) with preferably handheld terminals with barcode scanning capability, in addition to basic and cost-effective volumetrics. The warehouse should also have the functionality listed below:

This section shall be between two (2) and five (5) pages long but may not exceed five pages.

- This must include a description of the type of WMS system that the offeror will deploy to manage the receiving, storage, and dispatch of nets. The WMS should meet at a minimum the below listed functions:
 - a) Remote access: The WMS should be able to offer remote access to Chemonics representatives.
 - b) Receiving: The WMS must include an option for receiving goods. This feature of WMS helps to minimize receiving errors by keeping track of discrepancies between the delivery note or bill of lading and the actual products received.
 - c) Inventory Management: The WMS platform must track inventory data via barcode readers or radio frequency identification (RFID) tags, automatically updating information on the software's dashboard to ensure that the most up-to-date information is readily accessible to anybody with permission.
 - d) Picking and Packing: The WMS should ensure that the correct quantities are picked and packed to enable efficient and accurate fulfilment of dispatch orders to the right destinations.
 - e) For each order, the WMS should generate a bill of lading with a tracking number, destination address, drivers' details, vehicle details, and a time stamp showing the date and time the truck was loaded.

Reports: The WMS should be able to generate reports showing ITN receipts, stock on hand, and ITN dispatches to the various destinations on a daily, weekly and, monthly basis as described in **Section 2. Technical Proposal- Part 1** above.

The final subcontract ceiling will be based on the monthly fixed unit price for the warehouse found in **Section 3: Cost proposal- Part 1: Prices for services**. Quotes must be presented in a format like the pricing table found in **Section 3 Cost proposal-subsection F: Price Template** and they must be in **Zambian Kwacha**.

No profit, fees, taxes, or additional costs may be added after award. The agreement under which the potential awarded subcontract is financed does not permit the **financing of any taxes**, VAT, tariffs,

duties, or other levies imposed by any laws in effect in the Cooperating Country. The Offeror must not include such Cooperating Country taxes, VAT, charges, tariffs, duties or levies in their cost proposal.

Part 2: Cost Notes

The cost proposal shall also include a budget narrative that explains the basis for the estimate of every cost element or line item. 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 or questions, including but not limited to the reasonableness, realism, or completeness of an offeror's proposed cost.

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.

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

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

All goods and services offered in response to this RFP or supplied under any resulting award must meet USAID Geographic Code 935 in accordance with the United States Code of Federal Regulations (CFR), 22 CFR §228, available at: <http://www.gpo.gov/fdsys/pkg/CFR-2012-title22-vol1/pdf/CFR-2012-title22-vol1-part228.pdf>.

The cooperating country for this RFP is Zambia.

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. Chronological List of Proposal Events

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

RFP publication: February 17, 2026

Deadline for written questions (17:00): February 24, 2026

Proposal conference pre-registration deadline (17:00): February 27, 2026

Proposal conference (Chemonics GHSC-PSM Office, Lusaka): March 3, 2026

Responses to questions/clarifications issued: March 6, 2026

Proposal due date (17:00): March 19, 2026

Competitive range notification (estimated): April 3, 2026

Site/Premises visits: April 13-17, 2026

Estimated subcontract award: May 5, 2026

The dates above may be modified at the sole discretion of Chemonics. Any relevant and significant changes will be published in an amendment to this RFP.

Proposal Conference. A proposal conference will be held at the Chemonics GHSC-PSM's office located at Plot 2473, 1st Floor, Metropolitan House, Off Danny Pule Road, Lusaka, Zambia on the date provided in the above calendar table to provide interested offerors an opportunity to learn more about the USG-funded GHSC-PSM project and to ask any questions about this RFP and the solicitation process. Chemonics welcomes any organization to attend this proposal conference. Pre-registration to attend the proposal conference is required. Please email your registration request and any advance questions by the date provided in the above calendar table by 17:00 hrs to the email SPDprocurement@ghsc-psm.org

Written notes or questions and answers from the proposal conference will be provided electronically to all registered offerors, including those offerors who submitted written questions prior to the proposal conference, but were unable to attend the proposal conference in person.

Written Questions and Clarifications. All questions or clarifications regarding this RFP must be in writing and submitted to SPDprocurement@ghsc-psm.org no later than by the date provided in the above calendar table at 17:00 hrs. 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, GHSC-PSM or GHSC-PSM subcontractors in Zambia, or any other party, will not be considered official responses regarding this RFP.

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 Chemonics' GHSC-PSM office within two (2) days of receiving notification.

Site/premises visit. Following proposal submission, Chemonics will plan to conduct site visits to all offerors' facilities who are considered by the technical evaluation committee to be in a competitive range. These facilities could either be existing or proposed by the offeror to be obtained by lease. In the case of the latter, the offeror would have provided evidence of being able to finalize the leasing process of the facility within 2 months. Offerors should be prepared to host the technical evaluation committee within 24 hours of receiving notification. Any offeror that is unable to provide for inspection an existing facility or one proposed for lease within the period of notification by Chemonics might be automatically disqualified from the procurement process.

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

I.7. Validity Period

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

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 the best value as set forth in FAR 15.101-1. 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. 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. 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. Cost will primarily be evaluated for realism and reasonableness.

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

Evaluation Criteria	Evaluation Sub-criteria	Maximum Points
Technical Approach, Methodology, and Detailed Work Plan		
Facilities and Equipment	Proposed Warehousing/Distribution Center location(s), dimensions, existing or planned physical facilities (access, site drainage, utilities, proximity, communications, capacity, etc.) and security systems including closed circuit television (CCTV), fencing, visitor control, etc. If offeror is proposing a facility that is to be leased/ renovated, evidence that a suitable facility meeting stipulated requirements shall be provided by the time stipulated by Chemonics	15 points
Warehouse ventilation	<ul style="list-style-type: none"> • Does the proposed warehouse/distribution center have appropriate/ adequate ventilation in terms of structural requirements? Temperature: Ideal storage temperatures range from 25 °C to 33.4 °C. • Relative Humidity: Optimal humidity ranges from 40% to 100%. • Sunlight: Keep nets out of direct sunlight, as UV light and excessive heat break down the pyrethroid insecticides, reducing their efficacy. • Ventilation: Storage areas should be cool and dry, preferably with good ventilation. • Packaging: Store nets in their original unopened packaging. • Storage Setup: Bales should be stacked on pallets to prevent damage from moisture. 	5 points
Inventory Management/ product control	Do the proposed site(s), technical approach, methodology, and relevant SOP(s) meet the required criteria as outlined in the scope of work? This	15 points

	included product handling from receiving to dispatch, and reverse logistics.	
Warehousing/Distribution Center Management System (WMS)	<p>Do the proposed systems meet all the requirements in the scope of work, including software and hardware requirements which include the following:</p> <p>-This must include a description of the type of WMS system that the offeror will deploy to manage the receiving, storage, and dispatch of nets. The WMS should meet at a minimum the below listed functions:</p> <p>Receiving: The WMS must include an option for receiving goods. This feature of WMS helps to minimize receiving errors by keeping track of discrepancies between the delivery note or bill of lading and the actual products received.</p> <p>Inventory Management: The WMS platform must track inventory data via barcode readers, automatically updating information on the software’s dashboard to ensure that the most up-to-date information is readily accessible to anybody with permission.</p> <p>Picking and Packing: The WMS should ensure that the correct quantities are picked and packed to enable efficient and accurate fulfilment of dispatch orders to the right destinations. For each order, the WMS should generate a bill of lading with a tracking number, destination address, drivers’ details, vehicle details, and a time stamp showing the date and time the truck was loaded.</p> <p>Reports: The WMS should be able to generate reports showing LLIN receipts, stock on hand, and LLIN dispatches to the various destinations on a daily, weekly and monthly basis</p>	25 points
Security	Do the proposed security plan, technical approach, methodology, and relevant SOP(s) meet the required criteria as outlined in the scope of work?	5 points
Total Points – Technical Approach		65 points
Management, Key Personnel, and Staffing Plan		
Staffing Plan	As presented in the organogram, list of focal points, and description of key positions, does the offeror have the capability to fulfill the Scope of Work with the staff and management composition of the organization at large and the specific positions assigned to support the subcontract?	5 points

Qualifications of key personnel and management	As presented in the job descriptions and curriculum vitae (CVs) of the key personnel and management, does the offeror have the experience and capabilities to carry out the Scope of Work with the proposed staff?	15 points
Total Points – Management		20 points
Corporate Capabilities, Experience, and Past Performance		
Corporate Capabilities and Experience	Company Background and Experience – Chemonics will evaluate whether the company experience is relevant to the project Scope of Work. Should the offeror have any experience with USG, or other donor funded previous work, the offeror must reference it.	5 points
Past Performance	Chemonics will assess the past performance of the Offerors by contacting three references who may indicate the Offeror's past performance for projects of similar size and scope.	10 points
Total Points – Corporate Capabilities		15 points
Total Points		100 points

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. The highest-rated offerors, as determined by the technical evaluation committee, may be asked to submit their best prices or technical responses within 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 the terms and clauses contained in Section III.

I.11. Privity

By submitting a response to this request for proposals, offerors understand that the United States Government (USG) under the Department of State (DOS) 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 for consideration, as DOS will not consider protests made to it under USG-financed subcontracts. Chemonics, at its sole discretion, will make a final decision on the protest for this procurement.

I.12. Insurance and Services

Within two weeks of signature of this subcontract, the Offeror at its own expense (except that DBA shall be reimbursable to the Offeror at cost), shall procure and maintain in force, on all its operations, insurance in accordance with the charts listed below. The policies of insurance shall be in such form and shall be issued by such company or companies as may be satisfactory to Chemonics. Upon request from Chemonics, the Supplier shall furnish Chemonics with certificates of insurance from the insurance companies which shall specify the effective dates of the policies, the limits of liabilities there under, and contain a provision that the said insurance will not be canceled except upon thirty (30) days' notice in writing to Chemonics. The Supplier shall not cancel any policies of insurance required hereunder either before or after completion of the work without written consent of Chemonics. The full list of Insurance requirements is in Section **II.2.vii Insurance below.**

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

II.1. Background

GHSC-PSM (hereinafter referred to as “Chemonics”), with its consortium partners, implements the U.S. Government funded 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 public health commodities. GHSC-PSM fulfills this purpose by purchasing and delivering health commodities, offering comprehensive technical support 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, the U.S. President’s Malaria Initiative.

GHSC-PSM provides direct procurement and supply chain management support to the USG President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI). GHSC-PSM supports health programs through the supply of a wide range of health commodities for HIV/AIDS, tuberculosis, malaria, infectious diseases, and various other essential medicines.

As part of its mandate, Chemonics in support of PMI and AMF is leading the distribution of Insecticide Treated Nets (ITNs) across a couple of provinces in Zambia to further reduce malaria deaths and substantially decrease malaria morbidity toward the long-term goal of elimination.

The purpose of this RFP is to solicit proposals for warehouse storage, management, and distribution services for Insecticide Treated Nets (ITNs) in Lusaka Zambia. The selected subcontractor(s) will be required to provide warehousing in Lusaka.

Chemonics seeks to partner with best-in-class service provider(s) with a strong background in non-cold chain storage and distribution of high value commodities, the capacity to achieve industry standard performance indicators for Good Storage Practices according to World Health Organization guidelines, and the ability to scale its operational capacity to meet the needs of Chemonics to successfully complete the distribution of the ITNs in Zambia.

II.2. Scope of Work

GHSC-PSM will award a single Indefinite Quantity Subcontract (IQS) with fixed unit prices to Offerors who propose the best value for Warehousing/Distribution Center services.

The Subcontractor shall be responsible for Warehousing/Distribution Center services for Insecticide Treated Nets (ITNs) in Lusaka. The Subcontractor shall be capable of providing adequate equipment and infrastructure suitable for rapid staging and pick, pack dispatch services for ITNs. In the Warehousing/Distribution Center(s), ITNs shall be stored at relatively lesser period of time or may not be stored at all but are rapidly cross docked upon receipt to designated delivery destinations. The Subcontractor shall have all the requisite and adequate technology, equipment and infrastructure that are required for rapid order processing, with some requirement to hold inventory in storage.

The Subcontractor shall be responsible for providing the services and shall maintain the facilities in accordance with World Health Organization (WHO) [Good Storage and Distribution Practices \(Technical Report Series No. 1025, 2020 Annex 7\)](#), GHSC-PSM Guidance for Loading a Truck, [WHO Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products \(Technical Report Series No. 961, 2011\)](#), (Annexes 6, 7, 8 and 9) and consultation provided by Chemonics on relevant quality standards. 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 at the facilities. The

commodities and property shall be stored as requested by Chemonics Field Office (or its designee) until released to the distribution agent, consignee, or another party designated by the project office.

The Subcontractor will always maintain adequate documentation including written instructions and Standard Operating Procedures. SOPs will be evaluated to confirm consistent procedures for security, receiving, storage, packing, and loading. SOPs shall be in line with guidelines for storage of pharmaceutical products, and guidance for loading a truck. SOPs shall include but not be limited to the following:

- Training in relation to good storage practice, regulations and safety specific to temperature-controlled goods, if applicable;
- Premises and facilities;
- Security;
- Inbound processes;
 - Receiving
 - Put away
- Storage;
 - Maintenance of good storage practice;
 - Quarantine Sampling and releasing of goods from quarantine
 - Control of obsolete and outdated products
- Outbound processes;
 - Selection picking
 - Auditing / Quality control
- Dispatch and transportation;
- Incident management and reporting;
- Daily operations reporting;
- Force majeure and disaster recovery plan;
- Reverse logistics;
 - Returned goods;
 - Handling; and
 - Re-evaluation processes

The Subcontractor must ensure that there are no discrepancies between physical inventory and inventory that are reported in the WMS. The Subcontractor shall be required to report on performance as required in reports and deliverables and the key performance indicators in Annex 5 of the sample subcontract (Annex 11). The Subcontractor shall take all directions and instructions as pertains to the GHSC-PSM-supported donor program of commodities from the designated Chemonics representatives and in accordance with the following proposed scope of work. The Subcontractor shall act as a service provider and does not acquire ownership in respect of the goods stored.

II.2.i Facilities and Equipment

The Subcontractor shall operate and maintain pharmaceutical, and ambient facility(ies) in compliance with the following requirements:

- a. No unauthorized personnel shall be permitted access to facilities. Chemonics (or its designee) staff shall be granted access to the facility during business hours, unless otherwise agreed, for the inspection of the goods and facility(ies).
- b. Stock shall be under continuous supervision, with adequate security, which shall be provided on a rotating schedule 24 hours a day, seven days a week.
- c. Facility(ies) shall be fully enclosed with a security parameter fence to prevent intrusion or vandalism.
- d. The following equipment shall be maintained and fully functional at all times:
 - i. All safety and security equipment, including, but not limited to, intrusion detection systems, CCTV systems, access control systems, interior and exterior lighting, perimeter security

- systems, smoke detectors, fire suppression systems, serviced fire extinguishers, and related equipment;
- ii. Material handling equipment, hand trolley, forklifts, reach trucks, and all other Warehousing/Distribution Center equipment if required.
 - iii. Back-up power, to ensure operations seven days per week, 24 hours per day.
- e. CCTV footage must be stored on site and off site for a minimum of 90 days after recording.
 - f. Storage facilities should be clean and free of vermin. A written sanitation and pest control procedure shall be maintained, together with logs recording the use of all pest control agents, including the amount used, method of application, and date and times.
 - g. Environmental, health, and safety requirements are to be adhered to, including adequate fire detection and suppression.
 - h. Facilities shall come with the constant provision of water and electricity. The facility must be equipped with necessary backup power with appropriate capacity to support normal operations of the warehouse.
 - i. Storage areas shall have adequate lighting to enable all operations to be carried out accurately and safely
 - j. There shall be sufficient drainage systems to prevent flooding or water damage;
 - k. Communications technology and equipment shall be installed for the use of telephones, and email.
 - l. Ceilings shall have a height of at least 5.5 meters.

The Subcontractor shall operate and maintain Warehousing/Distribution Centers in compliance with the following requirements:

- a. The interior space of the facility(ies) shall be organized and maintained for the specified per location volume with sufficient staffing to allow for the orderly and rapid receipt, cross docking, pick and pack, and/or storage of ITNs, including products in quarantine, as well as released, rejected, returned or recalled products; if shipments or orders are to be cross docked, it is expected that storage costs shall not apply.
- b. There shall be adequate storage space and staging areas for receiving, picking, packing and dispatch of ITNs.

The Subcontractor shall operate and maintain an **ambient** Warehousing/Distribution Center in compliance with the following requirements:

- a. Facility(ies) must be of concrete or a similar permanent material (e.g. metal reinforced concrete), with smooth concrete flooring.
- b. There must be sufficient pallets available so that ITNs are stored off the floor and suitably spaced to permit cleaning and inspection and stacked no more than 6 meters high.
- c. ITNs must be stored on pallets or racks and not directly on the floor, unless Chemonics provides written instructions otherwise.
- d. Each facility shall be accessible by truck for adequate receipt and dispatch of cargo from vehicles, with two points of entry with minimum measurements of four meters by four meters.
- e. There shall be sufficient protection against climatic and environmental effects such as temperature and humidity.

II.2.ii Temperature and Humidity Controls

Subcontractor(s) shall operate and maintain Warehousing/Distribution Centres in compliance with the following temperature control requirements:

- a. Storage areas shall be clean and dry and maintained within acceptable temperature (25°C to 30°C) and humidity limits depending on product and manufacturers' guidance.

- b. The warehouse /distribution centre must be well ventilated to protect the integrity of the ITNs

II.2.iii Product Control

The Subcontractor shall implement a process that follows below procedures:

- a. The goods receiving bay shall be protected to prevent product contamination, prevent exposure of commodities to direct sunlight, dust, dirt, rain, wind, and from extremes of heat, cold, and solar radiation that could damage the products.
- b. ITNs shall be stored in conditions that provide for adequately maintained stock.
- c. Rejected materials shall be identified and stored in a manner that prevents their use and/or distribution until a final decision is taken on the process to be followed regarding destruction or removal from the Warehousing/Distribution Centre.
- d. Damaged/broken ITNs or suspected to be damaged shall be withdrawn from usable stock and quarantined and Chemonics shall be notified in writing within twenty-four (24) hours of discovery.
- e. If a bale is subject to product recall, guidance and instructions for control shall be requested from Chemonics.

II.2.iv Inventory Management

The Subcontractor shall manage ITNs in compliance with the following requirements:

- a. The Subcontractor shall maintain an automated inventory control and management system (Warehouse Management System). The WMS shall provide the following:
 - i. software: batch and dynamic inventory control that allows for the control of goods in such a manner that prevents contamination, mix-ups and cross-contamination.
 - ii. hardware: handheld terminals with barcode scanning capability, to be used for pick, pack, dispatch, receipt, stock control, order fulfilment, and distribution.
 - iv. WMS should be able to uniquely identify products at SKU level and/or capture GS1 unique entity identifiers
- b. The Subcontractor shall process orders duly authorised by Chemonics (or its designee), and shall pick, pack, dispatch products for such orders, according to the regular delivery schedule and/or special delivery orders provided by Chemonics, ensuring that dispatches correspond with order and proofs of delivery (PODs) or electronic proofs of delivery (ePODs).
- c. Packaging, packing and transportation methods shall comply with manufacturers' requirements for ensuring the safety, efficacy, and quality of the product, and shall be appropriate for distribution in the particular climates and transport and storage conditions encountered in Zambia. If any additional packaging is required that will add an additional cost, the Subcontractor(s) must discuss with GHSC-PSM before the cost are incurred and receive approval for the additional costs. Orders will be received at least 2 days prior to required dispatch. It is recognized by the Subcontractor that flexibility at times will be required and thus orders might be received with less than the 2 days' notice prior to required dispatch and the Subcontractor has to deploy all necessary resources in order to meet the required deadlines for delivery to the recipients including working, if needed in emergency situations (with justification provided by Chemonics) on a rotating schedule 24 hours a day, seven days a week including holidays. The Subcontractor should consider that such circumstances might happen from time to time and incorporate such considerations into their pricing model.
- d. Products shall be stacked in accordance with manufacturers' instructions, with packaging labels free from obstruction, clearly displaying contents, weight, quantity, manufacturer, expiry dates, and any special instructions for handling stacking shipping storage and/or transportation of the contents.
- e. Goods for dispatch must be labeled accordingly.

- f. All goods are required to be stored off the floor on pallets or racks at all times.
- g. Products are to be covered and not left open, except in fine pick locations.
- h. Bales in the bulk storage area are to be resealed where possible. This is especially important after any QA sampling may have occurred.
- i. All pallets used shall be firm and unbroken, clean, free of dirt and insects, and stored or cross-docked in a dry area. Where necessary, pallets are to be scrubbed and vacuumed. Fumigation of pallets may be required for international dispatch into and out of the country.
- j. There shall be adequate resources to ensure that the loading and offloading of health commodities in and out bound vehicles to the facility(ies) is conducted in a timely fashion to ensure there are no unnecessary delays in commodities receipt and dispatch.
- k. Subcontractor(s) shall record the quantities, batch number, expiry date, and temperature reading (on the temperature monitoring device that shall accompany shipments if required) of the product(s) being handed over to the distribution agent, and any other relevant information provided by Chemonics in the manual or electronic delivery slip. The manual or electronic delivery slip shall have a signature from the distribution agent to confirm receipt of product from the facility(ies).
- l. Should the subcontractor be able to recover inventory previously reported as losses with verifiable evidence, the subcontractor will be reimbursed accordingly. Reimbursement is subject to acceptance from Chemonics of the evidence and sufficient remaining shelf life. The approved amount should be reflected in the following invoice. GHSC-PSM reserves the right to send auditors to conduct a stock audit when required to verify the reports submitted.

II.2.v Security

- a. The Subcontractor shall (i) maintain a complete security plan which will include adequate precautions to ensure that no unauthorized personnel have access to the facilities, taking into account the security situation in the part of the country where the services are being provided; (ii) assume all risks and liabilities related to the Subcontractor security and full implementation of the security plan. Chemonics reserves the right to verify whether such a plan is adequate and in place and suggest modifications to the plan when necessary; and (iii) ensure that necessary security regulations are included in the plan and adhered to by all staff. Failure to maintain and implement an appropriate security plan as required may be deemed a breach of contract.
- b. The Subcontractor shall manage the security services in accordance with the Chemonics direction. The Subcontractor shall perform any other related security services as may be required with regard to the project, such as:
 - i. Investigation of incidents.
 - ii. Country/route risk evaluation.
 - iii. Casual (unplanned) guarding (such as required to guard a shipment at an airport/port/other location).
 - iv. Security Equipment; and
 - v. Personnel protection services and escorting.
- c. Within 24 hours, The Subcontractor shall report in writing, any incidences of loss or damage to the commodities in the Warehousing/Distribution Center or any event that can affect the integrity of the commodities including: fire, dampening/wetting of commodities in stock due to leaking roof or flooding, etc.

II.2.vi Insurance

Prior to starting work, the Subcontractor at its own expense, shall procure and maintain in force, on all its operations, insurance in accordance with the clause listed below.

The policies of insurance shall be in such form and shall be issued by such company or companies as may be satisfactory to Chemonics. Upon request from Chemonics, the Subcontractor shall furnish Chemonics with certificates of insurance from the insurance companies which shall specify the effective dates of the policies, the limits of liabilities thereunder, and contain a provision that the said insurance will not be canceled except upon thirty (30) days' notice in writing to Chemonics. The Subcontractor shall not cancel any policies of insurance required hereunder either before or after completion of the work without the written consent of Chemonics.

- 1) Commercial general liability insurance with a combined bodily injury and property damage single limit of \$10,000,000 per occurrence which covers, at a minimum, premises, independent contractor, contractual liability, personal and advertising injury, and broad form property damage with no care, custody, and control exclusion, and with no copyright infringement, trade secrets or software code exclusions.
- 2) Warehouse keeper's liability insurance with limits and coverage sufficient to cover the Subcontractor's contractual liabilities under this agreement but at a minimum \$5,000,000 limit per occurrence.
- 3) Employer's liability insurance in accordance with the applicable laws of Zambia.
- 4) Workers' compensation insurance in accordance with the applicable laws of Zambia.
- 5) a) FAR 52.228-3 WORKER'S COMPENSATION INSURANCE (DEFENSE BASE ACT INSURANCE) (Jul 2014) [Updated by AAPD 22-01- 6-10-22]

The Subcontractor shall (a) provide, before commencing performance under this Subcontract, such workers' compensation or security as the Defense Base Act (DBA) (42 U.S.C. 1651, et seq.) requires and (b) continue to maintain it until performance is completed. The Subcontractor shall insert, in all lower-tier subcontracts authorized by Chemonics under this Subcontract to which the Defense Base Act applies, a clause similar to this clause imposing upon those lower-tier subcontractors this requirement to comply with the Defense Base Act. DBA insurance provides critical protection and limits on liability. The Subcontractor shall provide a proof of DBA insurance coverage to Chemonics upon request. Chemonics will verify coverage for, at least, projects in high-risk environments and where Chemonics may be providing security.

(b) AIDAR 752.228-3 WORKERS' COMPENSATION (DEFENSE BASE ACT) [Updated by AAPD 22-01- 6-10-22] As prescribed in AIDAR 728.308, the following supplemental coverage is to be added to the clause specified in FAR 52.228-3.

- (1) The Subcontractor agrees to procure DBA insurance pursuant to the terms of the contract between USAID and USAID's DBA insurance carrier unless the Subcontractor has a DBA self-insurance program approved by the U.S. Department of Labor or has an approved retrospective rating agreement for DBA.
- (2) If USAID or Subcontractor has secured a waiver of DBA coverage (See AIDAR 728.305-70(a)) for Subcontractor's employees who are not citizens of, residents of, or hired in the United States, the Subcontractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits.

(3) The Subcontractor further agrees to insert in all lower-tier subcontracts hereunder to which the DBA is applicable a clause similar to this clause, including the sentence, imposing on all lower-tier subcontractors authorized by Chemonics a like requirement to provide overseas workmen's compensation insurance coverage and obtain DBA coverage under the USAID requirements contract.

Pursuant to AIDAR 752.228-70, medical evacuation is a separate insurance requirement for overseas performance of USAID funded subcontracts; the Defense Base Act insurance does not provide coverage for medical evacuation. The costs of DBA insurance are allowable and reimbursable as a direct cost to this Subcontract.

Before starting work, the offeror must provide Chemonics with a copy of the DBA coverage policy that covers each of its employees.

(c) AIDAR 752.228-7 INSURANCE ON PRIVATE AUTOMOBILES Pursuant to the clause of this Subcontract entitled "Insurance Liability to Third Persons" (AIDAR 752.228-07), if the Subcontractor or any of its employees, consultants, or their dependents transport or cause to be transported (whether or not at Subcontract expense) privately owned automobiles to the Cooperating Country, or if any of them purchase an automobile within the Cooperating Country, the Subcontractor shall, during the period of this Subcontract, ensure that all such automobiles during such ownership within the Cooperating Country will be covered by a paid-up insurance policy issued by a reliable company providing minimum coverage of US\$10,000/US\$20,000 for injury to persons and US\$5,000 for property damage, or such other minimum coverages as may be set by the cognizant Mission Director, payable in U.S. dollars or its equivalent in the currency of the Cooperating Country. The premium costs of such insurance shall not be a reimbursable cost under this Subcontract.

(d) AIDAR 752.228-70 Medical Evacuation Services (MEDEVAC) Services (July 2007) [Updated by AAPD 06-01].

(1) The Subcontractor shall provide MEDEVAC service coverage to all U.S. citizen, U.S. resident alien, and Third Country National employees and their authorized dependents (hereinafter "individual") while overseas under a USAID-financed direct contract. Chemonics will reimburse reasonable, allowable, and allocable costs for MEDEVAC service coverage incurred under this Subcontract. The USAID Contracting Officer through Chemonics will determine the reasonableness, allowability, and allocability of the costs based on the applicable cost principles and in accordance with cost accounting standards.

(2) Exceptions: (i) The Subcontractor is not required to provide MEDEVAC insurance to eligible employees and their dependents with a health program that includes sufficient MEDEVAC coverage as approved by Chemonics. (ii) The USAID Mission Director through Chemonics, may make a written determination to waive the requirement for such coverage. The determination must be based on findings that the quality of local medical services or other circumstances obviate the need for such coverage for eligible employees and their dependents located at post.

(3) If authorized to issue lower-tier subcontracts, the Subcontractor shall insert a clause similar to this clause in all lower-tier subcontracts that require performance by Subcontractor employees

e) In addition to the foregoing insurance requirements, the Supplier shall, as a minimum, obtain the following insurance in form and substance satisfactory to Chemonics that are covered by the standard fixed rates in Section 3.

TYPE MINIMUM LIMIT

- (a) Defense Base Act or equivalent for waived nationals per FAR 52.228-3 and 52.228-4. The coverage shall extend to Employers Liability for bodily injury, death, and for occupational disease. As required by DBA
- (b) Comprehensive General Liability Each Occurrence Combined Single Limit for Personal Injury and/or Property Damage. \$1,000,000-\$2,000,000
- (c) Automobile Liability Combined Single Limit each occurrence As per AIDAR 752.228-7 and \$1,000,000
- (d) Other Required Insurance- Umbrella Insurance additive to (b) and (c) above \$1,000,000/ \$2,000,000

II.3. Deliverables and Reports

Deliverables (required for payment)

Subcontractor(s) shall deliver to Chemonics the following deliverables, in accordance with the schedule set forth below, accompanied by an invoice.

Activity	Deliverable Title	Deliverable Description	Timing
Warehouse Stock Status Report	Monthly Consolidated Report (includes PODs)	Report of current stocks summarizing receiving, distribution, and closing stock balance monthly for all GHSC-PSM ITNs. This report will indicate the quantity, description, batch number, expiry date, and unit of measure of each item. The report will show the initial quantity in stock at the beginning of the month, the quantity received, the quantity distributed and the final stock at the end of the month informing the shelf life of remaining stocks. This report will also show the total number of pallets used during the month, sorted from earliest expiry date to the longest shelf life remaining. Subcontractor(s) shall send copies of the PODs (or ePODs when available) signed by the party responsible for transportation as evidence of handing over the picked and packed orders to the responsible party.	Five (5) days after the end of the month.

The Subcontractor must ensure that at all times, the total value of stock in any warehouse can be ascertained. Unit prices of commodities must be continually updated as the need arises and must be captured on all reports and documents (e.g., PODs, delivery notes etc.).

Reports

The subcontractor shall provide the following reports based on the timing outlined below. Each report format shall be approved by Chemonics prior to its rollout by the subcontractor. Reports shall be sent according to the timeline in the table below to the following email address: PSMZambia-ITN2026@ghsc-psm.org

Activity	Report Title	Report Description	Timing
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Stock summary	Stock summary report	Subcontractor will send a detailed Stock Summary Report to all parties on a pre-approved distribution list. This report details the daily stock on hand by product and batch number at the beginning of the business day (including: product description, quantities, values, expiry dates, manufacture dates, and remaining shelf life), stock issued and received during the day, details on all orders packed and tendered that day, and the opening and closing balance for that day. Separate tabs should be included, which contain information on any damages, short expiry products, and returns.	Daily with a summary of the activities for the day in review.
Inbound shipment notification	Inbound shipment arrival notification	<p>Upon completion of the delivery of new consignments to the Warehouse Site, Subcontractor shall send an <i>inbound notification email</i> to all parties on a pre-approved distribution list confirming that the commodities have been received at the Warehouse with the following information in attachment form:</p> <ul style="list-style-type: none"> • <i>Purchase Order</i> • <i>Commercial Invoice</i> • <i>Packing List</i> • <i>Airway Bill</i> • <i>Bill of Lading</i> • <i>Certificate of Origin</i> • <i>Certificates of Analysis</i> • <i>As applicable, noted damages to shipment</i> • <i>WMS report showing stock receipt</i> 	Within 12 hours of shipment arrival
Inbound receiving		<p>Within 48 hours of inbound shipment arrival, or within the time period agreed upon for special or large shipments, Subcontractor shall send a detailed receiving report to all designated parties on a pre-approved distribution list that includes the following:</p> <ul style="list-style-type: none"> • <i>Product name</i> • <i>Description</i> • <i>Batch number</i> • <i>Expiry date</i> • <i>Quantity</i> • <i>Notification of any repalletization or packing</i> <p><input type="checkbox"/> In addition, the report will note any</p>	

	Inbound receiving report	<p><i>damages, losses, or discrepancies.</i> If damage was detected, pictures of the vehicle(s) that delivered the commodities and damaged products shall also be shared with Chemonics *WMS report to show record of stock receipt</p>	Within 48 hours with exception of bulk shipments
Outbound Product Processing and Pick, Pack, Loading, Dispatch	Dispatch report	<p>Upon dispatch of outbound shipments, Subcontractor shall send copies of the dispatch notes signed by the party responsible for transportation to Chemonics as evidence of handing over the picked and packed orders to the responsible party. The dispatch note shall contain the name of the intended destination for the product, the date, and time of dispatch. In addition, the dispatch note shall indicate the number, description, batch number, and truck number plate with drivers details. The format of the dispatch note shall be approved by Chemonics prior to its roll out by the subcontractor.</p> <p>Proposed language: A WMS report that shows that commodities have been processed and are dispatched.</p>	Within 24 hours.

**Section III (Full IQS subcontract template attached as ANNEX 10)
 In-Country Warehousing Services Subcontract (Terms and Clauses)**

INDEFINITE QUANTITY SUBCONTRACT

Between

Chemonics International Inc.

And

(add subcontractor name and address here)

Hereinafter referred to as Subcontractor

for

United States Government- Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) project

Prime IDIQ Contract Number No. AID-OAA-I-15-00004

Task Order Nos. [AID-OAA-TO-15-00007; AID-OAA-TO-15-00009

Subcontract number: *(insert Subcontract Number here)*

Start Date: **XX, 20XX**

End Date: **XX, 20XX**

IQS Ceiling: TBD (Maximum aggregate value of all orders awarded)

ISSUED BY:

Chemonics International Inc.

ISSUED TO:

[Insert subcontractor name and address]

Subcontractor Tax ID Number: [insert Subcontractor Employee Identification Number (EIN) or local tax reference number as applicable]

Subcontractor UEI Number:

[insert Subcontractor UEI for awards valued at \$30,000 USD or higher unless exempted. Delete if not applicable.]

Annex 1 Sample Proposal Cover Letter

[Offeror: Insert date]

[Insert name of point of contact for RFP]
[Insert designation of point of contact for RFP]
[Insert project name]
[Insert "XXXXX" or if there is a locally registered entity, use that name]
[Insert project office address]

Reference: Request for Proposals [Insert RFP name and number]

Subject: [Offeror: Insert name of your organization]'s technical and cost proposals

Dear Mr./Mrs. [Insert name of point of contact for RFP]:

[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	_____
UEI Number	_____
Address	_____
Address	_____
Telephone	_____
Fax	_____
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 Putting Together a Pricing Table for the Warehousing/Distribution Center Services Subcontract

The purpose of this annex is to guide Offerors in creating rates, fixed unit prices, and for their cost proposal. The fixed unit prices will be incorporated into the awarded Offeror’s subcontracts and used to invoice Chemonics for services completed and deliverables submitted and accepted by Chemonics. Because the subcontract(s) will be funded under a United States Government-funded project, it is important that all Offerors’ costs conform to this standard format. It is thus 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 described in this RFP, specifically in Section II. Offerors should present and describe this assessment in their technical proposals.

Step 2: Determine the sub-activities and basic cost types (e.g. which salaries, equipment, systems, maintenance, utilities, taxes, etc.) associated with each main activity (as defined in the sample quotation matrix). The cost proposal should provide the best estimate of the costs associated with each main activity.

Step 3: Create a detailed budget that calculates all cost types for each activity to come up with the ultimate monthly price per unit (as described in the quotation matrix) for ITNs stored for the cost proposal. Each Offeror must present the monthly price per unit as structured in the quotation matrix using a spreadsheet program compatible with MS Excel. Clearly state which Warehousing/Distribution Center type/location you are providing a proposal for at the top of the quotation matrix. Use a separate quotation matrix for each location.

Step 4: Write Cost Notes. The spreadsheets shall be accompanied by written notes in MS Word that explain the assumption why a cost is being budgeted as well as how the amount is reasonable.

Item	Unit	Size of proposed warehouse (A)	Rate per m ² / month (ZMW) (B)	Total monthly amount (A×B)	Notes
All-inclusive Warehouse Rental (Ambient)	m ² / month				Includes premises, utilities, alternative power, labor (normal hours), security, WMS/IT, MHE, pallets/racking, insurance, admin/overheads

Overtime / After-Hours Fixed Unit Rates (if requested by Chemonics and pre-approved):

Item	Unit	Rate (ZMW)	Notes
Overtime warehouse labor – general	Per hour / per person		Applicable after normal operating hours
Overtime supervisor	Per hour / per person		
After-hours truck loading/off-loading	Per truck		Applies to nights/weekends/holidays

Fixed unit prices per square meter provided should be inclusive of all associated costs, taxes, and fees, including salaries, maintenance on machinery and infrastructure, including power back up, pallet lifts, plumbing, IT, CCTV, temperature monitoring systems, security systems with full access controls, and Warehousing Center management system tracking. Fixed unit prices per square meter will be fixed for the entirety of the period of performance outlined in Section III. Quoted prices must be in Zambian Kwacha.

Incorporating fee:

- The fee for service paid should fairly reflect the resources required and cost being incurred by the vendor, and as such, encourage improved service performance and a cost reduction culture.
- The fee structure must be sustainable through changes in the customers operating environment.
- The vendor should have the opportunity to improve profit margins through adding value and innovation in performance beyond the basic services and capabilities required pursuant to this RFP and ultimate subcontract resulting. To encourage the Awardee’s continued performance, exceeding requirements, and demonstrative of its capacity building, the provision of positive discounting allows for just compensation of the Awardee proportional to the additional value added and enrichment of the Contractor.

Annex 3 Required Certifications

REQUIRED CERTIFICATIONS

List of certifications:

- **Certification of Independent Price Determination** – (FAR 52.203-2). Certifies that prices in this offer have been arrived at independently, without, for the purposes of restricting competition, any consultation, communication, or agreement with other offeror or competitor relating to – prices, intention to submit an offer, or factors used to calculate prices offered. This is applicable to any solicitation for fixed price subcontracts over \$250,000 only.
- **Subcontractor Certification and Disclosure Regarding Payment to Influence Certain Federal Transactions** – (FAR 52.203-11). Certifies 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 or a Member of Congress on his or her behalf in connection with the awarding of any Federal contract, grant, loan, cooperative agreement, etc. This completed certification from FAR 52.203-11 must be included in the subcontract file for any subcontract expected to exceed \$150,000; in addition, note that Chemonics’ subcontracting templates include additional language to document compliance at the “time of award” for all subcontracts (regardless of value). In addition, a disclosure may be required in accordance with FAR 52.203-11(d), which notes: “*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...*” when applicable, this disclosure must be saved in the subcontract/procurement file with the certification. This certification/disclosure requirement of FAR 52.203-11 is applicable to any solicitations expected to exceed \$150,000.
- **Subcontractor Certification Regarding Responsibility Matters** – (FAR 52.209-5). Certifies that offeror/or any of its Principals are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency. This completed certification from FAR 52.209-5 must be included in the subcontract file for any subcontract expected to exceed \$150,000; in addition, note that Chemonics’ subcontracting templates include additional language to document compliance at the “time of award” per FAR 52.209-6 for all subcontracts (regardless of value). This “Subcontractor Certification Regarding Responsibility Matters” certification from FAR 52.209-5 is applicable to any solicitations expected to exceed \$150,000.
- **Evidence of Responsibility Statement** – Certification describing internal policies and procedures, listing authorized signatories, and stating that the company is able to comply with the terms and conditions of the subcontract. This is applicable to all solicitations regardless of value.
- **Subcontractor Size Self-Certification** – Certification based on the SBA (Small Business Administration) form, completed by the subcontractor to self-certify any small business designations.
- **Certificate of Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking** – (ADS 302mas) Certification that the offeror has instituted a

policy explicitly opposing prostitution and sex trafficking. For use in any new acquisition intended to obligate FY04 or later funds available for HIV/AIDS activities.

- [Subcontractor Certification Regarding Trafficking in Persons Compliance Plan \(March 2, 2015\)](#) – This certification is required for all subcontracts including purchase orders that: 1. are for supplies, other than commercially available off-the-shelf items (COTS), to be acquired outside the United States, or services to be performed outside the United States, and 2. have an estimated value that exceeds \$500,000. The certification requires subcontractors to certify that they are in compliance with the terms and conditions under FAR 52.222-50, and have an anti-trafficking compliance plan in place as required by the FAR clause.
- [Prohibition on Assistance to Drug Trafficking Participant Certification](#)

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.

_____ By (Signature) _____
(Applicant)

TITLE _____ TYPED NAME _____ DATE _____

**52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS
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.

Should the Offeror's circumstances change during the life of any resulting subcontract with respect to the above, the Offeror will notify Chemonics immediately. _____

BY (Signature) _____ TITLE _____

TYPED NAME _____ DATE _____

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 non responsible.

(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

UEI Number: Enter the UEI number assigned to the company

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 No.

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 UEI 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 UEI 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 the 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: _____

Title: _____

Date: _____

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

UEI Number: [enter the UEI number here. Subcontractors must have a UEI, 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.

<input type="checkbox"/> Small Disadvantaged Business	<input type="checkbox"/> 8(a)
<input type="checkbox"/> HUBZone	<input type="checkbox"/> Woman Owned Small Business
<input type="checkbox"/> Veteran Owned	<input type="checkbox"/> Service Disabled Veteran Owned
<input type="checkbox"/> Alaskan Native Corporation	<input type="checkbox"/> 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: _____.

Prohibition on the Promotion or Advocacy of the Legalization or Practice of Prostitution or Sex Trafficking (Acquisition) (June 2010) (a)

This contract is authorized under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Pub.L. No. 108-25), as amended. This Act enunciates that the U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. The contractor shall not use any of the funds made available under this contract to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(b)(1) Except as provided in (b)(2) and (b)(3), by its signature of this contract or subcontract for HIV/AIDS activities, a non-governmental organization or public international organization awardee/sub-awardee agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children.

(b)(2) The following organizations are exempt from (b)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

(b)(3) Contractors and subcontractors are exempt from (b)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

(b)(4) Notwithstanding section (b)(3), not exempt from (b)(1) are contractors and subcontractors that implement HIV / AIDS programs under this contract or subcontract by: (i) providing supplies or services directly to the final populations receiving such supplies or services in host countries; (ii) providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or (iii) providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions). (c) The following definitions apply for purposes of this provision: "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.

"Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9). (d) The contractor shall insert this provision in all subcontracts. (e) Any violation of this provision will result in the immediate termination of this award by USAID. (f) This provision does not affect the applicability of FAR 52.222-50 to this contract. The Offeror (below named organization or firm) certifies that it has () has not () instituted a policy explicitly opposing prostitution and sex trafficking as required under this Request for Proposal and any possible subsequent subcontract.

Company Name: _____

By (Signature): _____

Title: _____

Printed Name: _____ Date: _____

**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 (h)(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 relevant 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 relevant 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 Past Performance Template

The following table must be completed and included in the Technical Volume. Include at least 3 projects that best illustrate experience relevant to this RFP or similar activities. Included projects must have been completed within the past 3 years.

#	Client Name, Address/Location, Telephone Number, Email	Contract or Purchase Order Number	Description of Activities or Work	Date of Work	Cost in (currency)
1					
2					
3					

Chemonics reserves the right to contact provided references to verify and, if applicable, request further information. Chemonics reserves the right to obtain past performance information obtained from sources other than those identified by the offeror. Chemonics determine the relevance of similar past performance information.

Annex 5 UEI and SAM Registration Guidance

What is an UEI Number?

The Unique Entity Identifier, or the UEI, is the official name of the “new, non-proprietary identifier” that will replace the DUNS number. The UEI will be requested in, and assigned by, the System for Award Management (SAM.gov). Businesses and organizations who receive funding from the US government will have to use a Unique Entity Identifier (UEI) created in SAM.gov. The UEI number helps the USG to identify companies.

Why am I being requested to obtain a UEI 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 UEI numbers to uniquely identify businesses and organizations, Chemonics is required to enter subaward data with a corresponding UEI number.

Is there a charge for obtaining a UEI number?

No. Obtaining a UEI 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 UEI number?

UEI numbers can be obtained online at SAM.gov.

What information will I need to obtain a UEI number?

To request a UEI 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 UEI number?

The UEI number is issued immediately upon completion of the request process.

Are there exemptions to the UEI 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 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 UEI 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 UEI 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 UEI 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 UEI 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 registering in SAM for assistance awards (under grants/cooperative agreements) at: https://www.fsd.gov/sys_attachment.do?sys_id=d4d157741ba3c5103565ed3ce54bcb0

Follow the step-by-step guidance for contracts registrations at: https://www.fsd.gov/sys_attachment.do?sys_id=b4c153341ba3c5103565ed3ce54bcbb8

You must have a UEI 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, UEI 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.)

Annex 6. World Health Organization (WHO) [Good Storage and Distribution Practices \(Technical Report Series No. 1025, 2020 Annex 7\)](#)

[Annex 7 WHO Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products](#) (the document is linked here and should be shared with the Subcontract)

[Annex 8 Guidance for loading a truck](#) (should be shared with the Subcontract)

[Annex 9 WHO Technical supplements to Model Guidance for the storage and transport of time- and temperature sensitive pharmaceutical products](#) (the document is linked here and should be shared with the Subcontract)

ANNEX 10 IQS SUBCONTRACT TEMPLATE

Annex 6

Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products

(WHO Technical Report Series, No. 961, 2011), Annex 9

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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).¹ 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 practicably 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

Titles of supplements and model guidance section to which each refers

Title	Section(s)
1. Selecting sites for storage facilities	Section 2
2. Design of storage facilities	Section 2 to 5
3. Estimating the capacity of storage facilities	Section 3.1 to 3.4
4. Security and fire protection in storage facilities	Section 3.7
5. Maintenance of storage facilities	Section 3.10
6. Temperature monitoring of storage areas	Section 4.5.2, 4.5.4
7. Qualification of temperature-controlled storage areas	Section 4.7

¹ http://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1.

Table A5.1 *continued*

Title	Section(s)
8. Temperature mapping of storage areas	Section 4.7
9. Refrigeration equipment maintenance	Section 4.9
10. Checking the accuracy of temperature control and monitoring devices	Section 4.10
11. Qualification of refrigerated road vehicles	Section 6.4, 6.5
12. Temperature-controlled transport operations by road and by air	Section 6.5, 9
13. Qualification of shipping containers	Section 6.8.1 to 6.8.4
14. Transport route profiling qualification	Section 6.8.3, 6.8.4
15. Temperature and humidity monitoring systems for transport operations	Section 6.5, 9
16. Environmental management of refrigerant gases and refrigeration equipment	Section 10.2

1.2 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.

1.3 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”.

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

² http://www.who.int/medicines/areas/quality_safety/quality_assurance.

Supplement 1

Selecting sites for storage facilities

Technical supplement to

Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011), Annex 9.

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- 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*

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Supplement 2

Design and procurement of storage facilities

Technical supplement to

Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011), Annex 9.

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 - 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
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 - 2.3.2 *Working environment and ergonomics*
 - 2.3.3 *Incoming stock*
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 - 2.3.5 *Controlled drugs*
 - 2.3.6 *Waste and returns*
 - 2.3.7 *Location and arrangement of stock*
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2.5 Procuring cold rooms and freezer rooms

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- A2.2 Design and build
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Estimating the capacity of storage facilities

Technical supplement to

Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011), Annex 9.

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Technical supplement to

Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011), Annex 9.

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A3.1.1 Policy

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Technical supplement to

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Technical supplement to

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Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products (WHO Technical Report Series, No. 961, 2011), Annex 9.

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GOOD STORAGE AND DISTRIBUTION PRACTICES

(May 2019)

Please send any comments you may have to Dr Sabine Kopp, Group Lead, Medicines Quality Assurance, Technologies Standards and Norms (kopps@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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SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.793:
GOOD STORAGE AND DISTRIBUTION PRACTICES

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

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

74 guidelines which may be adapted to suit the prevailing situations and conditions in individual
75 countries. National or regional guidelines may be developed to meet specific needs and
76 situations in a particular region or country.

77

78 1.6. To maintain the original quality of medical products, every party active in the supply
79 chain has to comply with the applicable legislation and regulations. Every activity in the storage
80 and distribution of medical products should be carried out according to the principles of good
81 manufacturing practices (GMP), good storage practice (GSP) and good distribution practice
82 (GDP) as applicable.

83

84 1.7. This guideline does not deal with dispensing to patients as this is addressed in the World
85 Health Organization (WHO) good pharmacy practice (GPP) guide (xx). These guidelines
86 should also be read in conjunction with other WHO guidelines (xx).

87

88 **2. SCOPE**

89

90 2.1. This document lays down guidelines for the storage and distribution of medical
91 products. It is closely linked to other existing guidelines recommended by the WHO
92 Expert Committee on Specifications for Pharmaceutical Preparations, such as
93 referenced in section (xyz).

94

95 2.2. Depending on the national and regional legislation, these guidelines may apply equally
96 to products for human and for veterinary use. The guidelines thus cover products for which a
97 prescription is required by the patient, products which may be provided to a patient without a
98 prescription, biologicals, vaccines and medical devices.

99

100 2.3. The document does not specifically cover GMP aspects of finished products in bulk,
101 distribution of labels or packaging as these aspects are considered to be covered by other
102 guidelines. The principles for the distribution of starting materials (active pharmaceutical
103 ingredients (APIs) and excipients) are also not covered here. These are laid down in the WHO
104 guidance “Good Trade and Distribution Practices for Pharmaceutical Starting Materials” (7).

105

106 **3. GLOSSARY**

107

108 The definitions provided below apply to the words and phrases used in this guideline. Although
109 an effort has been made to use standard definitions as far as possible, they may have different
110 meanings in other contexts and documents.

111

112 *active pharmaceutical ingredient (API)*

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

118

119 *ALCOA*

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

121

122 *Auditing*

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

127

128 *batch*

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

131

132 *batch number*

133 A distinctive combination of numbers and/or letters which uniquely identifies a batch, for
134 example, on the labels, its batch records and corresponding certificates of analysis.

135

136

137

138 *consignment*

139 The quantity of pharmaceutical products supplied at one time in response to a particular request
140 or order. A consignment may comprise of one or more packages or containers and may include
141 pharmaceutical products belonging to more than one batch.

142

143 *container*

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

148

149 *contamination*

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

153

154 *contract*

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

156

157 *corrective and preventative actions (CAPA)*

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

162

163 *cross-contamination*

164 Contamination of a starting material, intermediate product or finished pharmaceutical product
165 with another starting material or product during production, storage and transportation.

166

167

168

169

170 *distribution*

171 The procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or
172 movement of pharmaceutical products, with the exception of the dispensing or providing
173 pharmaceutical products directly to a patient or his or her agent.

174

175 *excipient*

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

181

182 *expiry date*

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

187

188 *first expiry/first out (FEFO)*

189 A distribution procedure that ensures that the stock with the earliest expiry date is distributed
190 and/or used before an identical stock item with a later expiry date is distributed and/or used.

191

192 *forwarding agent*

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

196

197 *good distribution practices (GDP)*

198 That part of quality assurance that ensures that the quality of a pharmaceutical product is
199 maintained by means of adequate control of the numerous activities which occur during the
200 distribution process as well as providing a tool to secure the distribution system from

201 counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated,
202 and/or misbranded pharmaceutical products.

203

204 *good manufacturing practices (GMP)*

205 That part of quality assurance which ensures that pharmaceutical products are consistently
206 produced and controlled to the quality standards appropriate to their intended use and as required
207 by the marketing authorization.

208

209 *good pharmacy practice (GPP)*

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

213

214 *good storage practices (GSP)*

215 That part of quality assurance that ensures that the quality of pharmaceutical products is
216 maintained by means of adequate control throughout the storage thereof.

217

218 *good trade and distribution practices (GTDP)*

219 That part of quality assurance that ensures that the quality of pharmaceutical products is
220 maintained by means of adequate control throughout the numerous activities which occur during
221 the trade and the distribution process.

222

223 *heating, ventilation and air conditioning systems (HVAC)*

224 Heating, ventilation and air-conditioning, also referred to as environmental control system
225 (ECS).

226

227 *importation*

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

230

231

232

233 *intermediate product*

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

236

237 *labelling*

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

242

243 *manufacture*

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

246

247 *marketing authorization*

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

261

262

263

264

265 *material*

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

269

270 *packaging material*

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

275

276 *pedigree*

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

279

280 *pharmaceutical product*

281 Any product intended for human use, or veterinary product intended for administration to food-
282 producing animals, presented in its finished dosage form, which is subject to control by
283 pharmaceutical legislation in either the exporting or the importing state and includes products
284 for which a prescription is required, products which may be sold to patients without a
285 prescription, biologicals and vaccines. It does not, however, include medical devices.

286

287 *product recall*

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

292

293 *production*

294 All operations involved in the preparation of a pharmaceutical product, from receipt of
295 materials through processing, packaging and repackaging, labelling and relabelling, to
296 completion of the finished product.

297 *quality assurance*

298 A wide-ranging concept covering all matters that individually or collectively influence the
299 quality of a product. It is the totality of the arrangements made with the object of ensuring that
300 pharmaceutical products are of the quality required for their intended use.

301

302 *quality risk management*

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

305

306 *quality system*

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

310

311 *quarantine*

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

314

315 *retest date*

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

318

319 *sampling*

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

323

324 *shelf life*

325 The period of time during which a pharmaceutical product, if stored correctly, is expected to
326 comply with the specification as determined by stability studies on a number of batches of the
327 product. The shelf life is used to establish the expiry date of each batch.

328

329 *standard operating procedure (SOP)*

330 An authorized, written procedure giving instructions for performing operations not necessarily
331 specific to a given product but of a more general nature (e.g. equipment operation, maintenance
332 and cleaning, validation, cleaning of premises and environmental control, sampling and
333 inspection).

334

335 *storage*

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

337

338 *supplier*

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

340

341 *transit*

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

344

345 *vehicles*

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

348

349 **4. GENERAL PRINCIPLES**

350

351 4.1. There should be collaboration between all parties, including governments, customs
352 agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and
353 entities responsible for the supply of medical products to patients, to ensure the quality and
354 safety of these products; to prevent the exposure of patients to substandard and falsified
355 products and to ensure that the integrity of the distribution chain is maintained.

356

357 4.2. The principles of GSP and GDP should be included in national legislation and
358 guidelines for the storage and distribution of medical products, in a country or region as
359 applicable, as a means of establishing minimum standards. The principles of GSP and GDP are
360 applicable to:

- 361 • products moving forward in the distribution chain from the manufacturer;
362 • products which are moving backwards in the chain, for example, as a result of the return
363 or recall thereof; and
364 • donations of products.

365

366 **5. QUALITY MANAGEMENT**

367

368 *Quality Systems*

369

370 5.1. Entities involved in the storage and distribution of medical products must have a
371 comprehensively designed and correctly implemented, documented, quality system that
372 incorporates good storage practices, good distribution practices, quality risk management and
373 management review.

374

375 5.2. Senior management has the ultimate responsibility to ensure an effective quality system
376 is established, is adequately resourced, implemented and maintained. The effectiveness, roles,
377 responsibilities and authorities should be defined, communicated and implemented throughout
378 the organization.

379

380 5.3. The quality system should ensure that:

381

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

- 393 • there are systems for managing returns, complaints and recalls;
394 • systems are in place to manage changes, deviations and corrective and preventive
395 actions (CAPAs).

396

397 5.4. There should be an authorized, written quality policy describing the overall intentions
398 and requirements regarding quality. This may be reflected in a quality manual.

399

400 5.5. There should be an appropriate organizational structure. This should be presented in
401 an authorized organizational chart. The responsibility, authority and interrelationships of all
402 personnel should be clearly indicated.

403

404 5.6. Duties and responsibilities should be clearly defined and understood by the individuals
405 concerned and recorded as written job descriptions.

406

407 5.7. The quality system should include appropriate procedures, processes and resources.

408

409 **6. QUALITY RISK MANAGEMENT**

410

411 6.1. There should be a system to assess, control, communicate and review risks identified at all
412 stages in the supply chain. The evaluation of the risk should be based on scientific knowledge and
413 experience with the process and ultimately linked to the protection of the patient.

414

415 6.2. Appropriate controls should be developed and implemented to address any risks identified.
416 The effectiveness of the controls implemented should be evaluated at periodic intervals.

417

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

419

420 **7. MANAGEMENT REVIEW**

421

422 7.1. There should be a system for periodic management review. The review should include:

423

- 424 • senior management;

- 425 • review of the quality system and its effectiveness by using quality metrics and key
426 performance indicators;
- 427 • identification of opportunities for continual improvement; and
- 428 • follow-up on recommendations from previous management review meetings.
- 429

430 7.2. Records should be maintained.

431

432 **8. COMPLAINTS**

433

434 8.1. There should be a written procedure for the handling of complaints. A distinction should
435 be made between complaints about a product or its packaging and those relating to distribution.
436 In the case of a complaint about the quality of a product or its packaging, the original manufacturer
437 and/ or marketing authorization holder should be informed as soon as possible.

438

439 8.2. All complaints should be recorded and appropriately investigated. The root cause
440 should be identified and the impact (e.g. on other batches or products) and risk assessed.
441 Appropriate CAPA should be taken.

442

443 8.3. Where required, the national regulatory authority should be informed and a recall
444 initiated where appropriate.

445

446 8.4. The relevant information, such as the results of the investigation of the complaint,
447 should be shared with the relevant parties.

448

449 8.5. Product quality problems or suspected cases of substandard or falsified products are
450 identified and these should be handled according to the relevant procedures. The information
451 should be shared with the appropriate national and/or regional regulatory authorities.

452

453 **9. RETURNED GOODS**

454

455 9.1. Returned medical products should be handled in accordance with authorized
456 procedures.

457 9.2. All returned goods should be placed in quarantine upon receiving. The status of
458 the goods should be clear. Precautions should be taken to prevent access and distribution until
459 a decision has been taken with regard to their disposition. The particular storage conditions
460 applicable to the products should be maintained.

461

462 9.3. When handling returned goods, at least the following considerations should be
463 taken:

464

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

472

473 9.4. Where products are rejected, authorized procedures should be followed, including safe
474 transport.

475

476 9.5. Destruction of products should be done in accordance with international, national and
477 local requirements regarding disposal of such products and with due consideration to the
478 protection of the environment.

479

480 9.6. Records of all returned, rejected and destroyed medical products should be kept for a
481 defined period.

482

483 **10. RECALLS**

484

485 10.1. There should be a written procedure to effectively and promptly recall medical products
486 in compliance with national or regional requirements. A designated person(s) should be
487 responsible for recalls.

488

489 10.2. The effectiveness of the procedure should be checked annually and updated as
490 necessary.

491

492 10.3. The original manufacturer and/or marketing authorization holder, or other relevant contract
493 party, should be informed in the event of a recall.

494

495 10.4. Information on a recall should be shared with the appropriate national or regional
496 regulatory authority.

497

498 10.5. All recalled products should be transported and stored in secure, segregated conditions
499 and clearly labelled as recalled products. The particular storage conditions applicable to the
500 product should be maintained.

501

502 10.6. All customers and competent authorities of all countries to which a given product may
503 have been distributed should be informed promptly of the recall of the product.

504

505 10.7. All records, including distribution records, should be readily accessible to the
506 designated person(s) responsible for recalls. These records should contain sufficient
507 information on products supplied to customers (e.g. name, address, contact detail, batch
508 numbers, quantities, safety features - including exported products).

509

510 10.8. The progress of a recall process should be recorded and a final report issued which
511 includes a reconciliation between delivered and recovered quantities of products.

512

513 **11. SELF-INSPECTION**

514

515 11.1. The quality system should include self-inspections. These should be conducted to
516 monitor implementation and compliance with the principles of regulations, GSP, GDP and
517 other appropriate guidelines.

518

519 11.2. Self-inspections should be conducted periodically according to an annual schedule.

520

521 11.3. The team conducting the inspection should be free from bias and individual members should
522 have appropriate knowledge and experience. Audits by independent third parties may be beneficial.

523

524 11.4. The results of all self-inspections should be recorded. Reports should contain all
525 observations made during the inspection and presented to the relevant personnel as well as
526 management.

527

528 11.5. Necessary CAPAs should be taken and the effectiveness of the CAPAs should be
529 reviewed.

530

531 **12. PREMISES**

532

533 *General*

534

535 12.1. Premises should be suitably located, designed, constructed and maintained to ensure
536 appropriate operations such as receiving, storage, picking, packing and dispatch of medical
537 products.

538

539 12.2. There should be sufficient space, lighting and ventilation to ensure required
540 segregation, appropriate storage conditions and cleanliness.

541

542 12.3. Sufficient security should be provided and access should be controlled.

543

544 12.4. Appropriate controls and segregation should be provided for products requiring specific
545 handling or storage such as radio-active materials, products containing hazardous substances,
546 and products to be stored under controlled temperature and relative humidity conditions.

547

548 12.5. Receiving and dispatch bays should be separate and should protect products from
549 weather conditions.

550

551 12.6. Activities relating to receiving and dispatch such be done in accordance with authorized
552 procedures. Areas should be suitably equipped for the operations.

553 12.7. Premises should be kept clean. Cleaning equipment and cleaning agents should not
554 become possible sources of contamination.

555

556 12.8. Premises should be protected from the entry of birds, rodents, insects and other animals.
557 A rodent and pest control programme should be in place.

558

559 12.9. Toilets, wash, rest and canteen facilities should be separate from other areas. Food,
560 eating, drinking, and smoking should be prohibited in all areas where medical products are
561 stored or handled.

562 *Receiving*

563

564 12.10. Each incoming delivery should be checked against the relevant documentation
565 to ensure that the correct product is delivered from the correct supplier. This may
566 include, e.g. the purchase order, each container, label description, batch number,
567 product and quantity.

568

569 12.11. The consignment should be examined for uniformity of the containers and, if
570 necessary, should be subdivided according to the supplier's batch number should the
571 delivery comprise more than one batch. Each batch should be dealt with separately.

572

573 12.12. Each container should be carefully checked for possible contamination,
574 tampering and damage. Any suspect containers or, if necessary, the entire delivery
575 should be quarantined for further investigation.

576

577 12.13. Receiving areas should be of sufficient size to allow cleaning of incoming
578 containers.

579

580 12.14. When required, samples should be taken only by appropriately trained and
581 qualified personnel and in strict accordance with written sampling procedure and
582 sampling plans. Containers from which samples have been taken should be labelled
583 accordingly.

584

585 12.15. Following sampling, the goods should be subject to quarantine. Batch
586 segregation should be maintained during quarantine and all subsequent storage.

587

588 12.16. Materials and products requiring storage under controlled conditions of
589 temperature and relative humidity should be handled as a priority.

590

591 12.17. Materials and products should remain in quarantine until an authorized release
592 or rejection is obtained.

593

594 12.18. Measures should be taken to ensure that rejected materials and products cannot
595 be used. They should be stored separately from other materials and products while
596 awaiting destruction or return to the supplier.

597

598 *Storage areas*

599

600 12.19. Precautions should be taken to prevent unauthorized persons from entering
601 storage areas.

602

603 12.20. Storage areas should be of sufficient capacity to allow the orderly storage of
604 the various categories of materials and products, such as starting and packaging
605 materials, intermediates, finished products, products in quarantine, and released,
606 rejected, returned or recalled products.

607

608 12.21. Storage areas should be appropriately designed, constructed, maintained or
609 adapted. They should be kept clean and dry and there should be sufficient space and
610 lighting.

611

612 12.22. Storage areas should be maintained within acceptable temperature limits.
613 Where special storage conditions are required on the label (e.g. temperature, relative
614 humidity), these should be provided, controlled, monitored and recorded.

615

616 12.23. Materials and products should be stored off the floor and suitably spaced to
617 permit ventilation, cleaning and inspection. Suitable pallets should be used and kept
618 in a good state of cleanliness and repair.

619

620 12.24. A written sanitation programme should be available indicating the frequency
621 of cleaning and the methods to be used to clean the premises and storage areas.

622

623 12.25. There should be a written programme for pest control. The pest-control agents
624 used should be safe and there should be no risk of contamination of the materials and
625 products.

626

627 12.26. There should be appropriate procedures for the clean-up of any spillage to
628 ensure complete removal of any risk of contamination.

629

630 12.27. Where the status is ensured by storage in separate areas, these areas must be
631 clearly marked and their access restricted to authorized personnel. Any system
632 replacing physical separation and labelling or demarcation should provide equivalent
633 security. For example, computerized systems can be used provided that they are
634 validated to demonstrate security of access.

635

636 12.28. Where required, a separate sampling area should be in place. If sampling is
637 performed in the storage area, it should be conducted in such a way that there is no
638 risk of contamination or cross-contamination. Adequate cleaning procedures should
639 be in place for the sampling areas.

640

641 12.29. Certain materials and products such as highly active and radioactive materials,
642 narcotics and other hazardous, sensitive and/or dangerous materials and products, as
643 well as substances presenting special risks of abuse, fire or explosion (e.g. combustible
644 liquids and solids and pressurized gases), should be stored in a dedicated area that is
645 subject to appropriate additional safety and security measures.

646

647 12.30. Materials and products should be handled and stored in such a manner as to
648 prevent contamination, mix-ups and cross-contamination.

649

650 12.31. Materials and products should be stored in conditions which assure that their
651 quality is maintained and stock should be appropriately rotated. The “first expired/first
652 out” (FEFO) principle should be followed.

653

654 12.32. Rejected materials and products should be identified and controlled under a
655 quarantine system designed to prevent their use until a final decision is taken on their
656 fate.

657

658 12.33. Narcotic products should be stored in compliance with international
659 conventions, and national laws and regulations on narcotics.

660

661 12.34. Broken or damaged items should be withdrawn from usable stock and
662 separated.

663

664 12.35. There should be appropriate procedures for the clean-up of any spillage to ensure
665 complete removal of any risk of contamination.

666

667 *Storage conditions*

668

669 12.36. The storage conditions for materials and medical products should be in
670 compliance with the labelling, which is based on the results of stability testing.

671

672 12.37. Heating, ventilation and air conditioning systems (HVAC) should be
673 appropriately designed, installed, qualified and maintained to ensure that the required
674 storage conditions are maintained.

675

676 12.38. Where required, mapping studies for temperature and relative humidity, as
677 appropriate, should be done to show uniformity across the storage facility. (*Ref: WHO*
678 *Technical Report Series No. 961, Annex 9, Model guidance for the storage and transport*

679 *of time- and temperature-sensitive pharmaceutical products*). This applies, for example, to
680 areas, refrigerators and freezers.

681

682 12.39. Temperature and relative humidity, as appropriate, should be controlled and
683 monitored at regular intervals. Data should be recorded and the records should be
684 reviewed. The equipment used for monitoring should be calibrated and be suitable for
685 their intended use. All records pertaining to mapping and monitoring should be kept
686 for a suitable period of time and as required by national legislation.

687

688 12.40. Temperature and relative humidity, as appropriate, should be controlled and
689 monitored at regular intervals. Data should be recorded and the records should be
690 reviewed. The equipment used for monitoring should be calibrated and be suitable for
691 their intended use. All records pertaining to mapping and monitoring should be kept
692 for a suitable period of time and as required by national legislation.

693

694 *Note: See annexure 1 for recommended storage conditions.*

695

696 **13. STOCK CONTROL AND ROTATION**

697

698 13.1. Periodic stock reconciliation should be performed at defined intervals by comparing
699 the actual and recorded stocks.

700

701 13.2. The root cause for stock discrepancies should be identified and appropriate CAPAs
702 taken to prevent recurrence.

703

704 13.3. Damaged containers should not be issued unless the quality of the material
705 has been shown to be unaffected. Where possible, this should be brought to the
706 attention of the person responsible for quality. Any action taken should be
707 documented.

708

709 13.4. All stocks should be checked regularly for obsolete, to be retested, and
710 expired materials and products.

711 **14. EQUIPMENT**

712

713 14.1. Equipment, including computerized systems should be suitable for their intended
714 use. These should be appropriately designed, located, installed, qualified and maintained.

715

716 14.2. Computerized systems should be capable of achieving the desired output and results.

717

718 14.3. Where electronic commerce (e-commerce) is used, i.e. electronic means are used for
719 any of the steps, defined procedures and adequate systems should be in place to ensure
720 traceability and confidence in the supply chain and products concerned.

721

722 14.4. Electronic transactions (including those conducted via the Internet) relating to the
723 distribution of medical products should be performed only by authorized persons according
724 to defined and authorized access and privileges.

725

726 14.5. Where GXP systems are used, these should meet the requirements of 21 CFR 211
727 Part 11, EU chapter 11 and WHO guidelines on computerized systems.

728

729 14.6. Data should meet ALCOA principles. Procedures should be followed, and records
730 maintained for the back-up and restoration of data.

731

732 **15. QUALIFICATION AND VALIDATION**

733

734 15.1. The scope and extent of qualification and validation should be determined
735 using a documented risk assessment approach.

736

737 15.2. Premises, utilities, equipment and instruments, processes and procedures
738 should be considered. The scope and extent of qualification and validation in case of
739 any significant changes should be identified.

740

741 15.3. Qualification and validation should be done following procedures and
742 protocols. The results and outcome of the qualification and validation should be

743 recorded in reports. Deviations should be investigated and the completion of the
744 qualification and validation should be concluded and approved by responsible
745 personnel.

746

747 **16. PERSONNEL**

748

749 16.1. There should be an adequate number of personnel.

750

751 16.2. Personnel should have appropriate educational qualification, experience and training
752 relative to the activities undertaken.

753

754 16.3. Personnel should have the authority and resources needed to carry out their duties and
755 to follow the quality systems, as well as to identify and correct deviations from the established
756 procedures.

757

758 16.4. There should be arrangements in place to ensure that management and personnel are
759 not subject to commercial, political, financial and other pressures or conflict of interest that
760 may have an adverse effect on the quality of service provided or on the integrity of
761 pharmaceutical products.

762

763 16.5. Safety procedures relating to all relevant aspects including the safety of personnel and
764 property, environmental protection and product integrity, should be in place.

765

766 16.6. Personnel should receive initial and continued training in accordance with a written
767 training programme. The training should cover the requirements of GSP, GDP (as applicable),
768 as well as on-the-job training. Other topics may include product security, product identification,
769 the detection of falsified products.

770

771 16.7. Personnel dealing with hazardous pharmaceutical products (such as highly active
772 materials, radioactive materials, narcotics, and other hazardous, environmentally sensitive
773 and/or dangerous pharmaceutical products, as well as products presenting special risks of
774 abuse, fire or explosion) should be given specific training.

775 16.8. Personnel should be trained in, and observe high levels of, personal hygiene
776 and sanitation.

777

778 16.9. Records of all training, attendance and assessment should be kept.

779

780 16.10. Personnel handling products should wear garments suitable for the activities that they
781 perform. Personnel dealing with hazardous pharmaceutical products, including products
782 containing materials that are highly active, toxic, infectious or sensitizing, should be provided
783 with protective garments as necessary.

784

785 16.11. Appropriate procedures relating to personnel hygiene, relevant to the activities to be
786 carried out, should be established and observed. Such procedures should cover health, hygiene
787 and clothing of personnel.

788

789 16.12. Procedures and conditions of employment for employees, including contract and
790 temporary staff, and other personnel having access to medical products, must be designed and
791 administered to assist in minimizing the possibility of such products coming into the possession
792 of unauthorized persons or entities.

793

794 16.13. Codes of practice and punitive procedures should be in place to prevent and address
795 situations where persons involved in the storage and distribution of medical products are
796 suspected of, or found to be implicated in, any activities relating to the misappropriation,
797 tampering, diversion or falsifying of any product.

798

799 **17. DOCUMENTATION**

800

801 17.1. Documentation includes all procedures and records, whether in paper or electronic
802 form. Documents should be appropriately designed, completed, reviewed, authorized,
803 distributed and kept as required. Documents should be readily available.

804

805 17.2. Written procedures should be followed for the preparation, review, approval, use of and
806 control of all documents relating to the policies and activities for storage and distribution of
807 medical products process.

808

809 17.3. Documents should be laid out in an orderly fashion and be easy to complete, review
810 and check. The title, scope, objective and purpose of each document should be clear.

811

812 17.4. The contents of documents should be accurate, legible, traceable, attributable and
813 unambiguous.

814

815 17.5. All documents should be completed, signed and dated as required by authorized
816 person(s) and should not be changed without the necessary authorization.

817

818 17.6. Documentation should be prepared and maintained in accordance with the national
819 legislation and principles of good documentation practices (*see WHO Technical Report*
820 *Series No. 996, Annex 5, Guidance on good data and record management practices*).

821

822 17.7. The distributor must establish and maintain procedures for the identification,
823 collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable
824 documentation.

825

826 17.8. Documents should be reviewed regularly and kept up-to-date. When a document has
827 been revised, a system should exist to prevent inadvertent use of the superseded version.

828

829 17.9. All records must be readily retrievable and be stored and retained using facilities that
830 are safeguarded against unauthorized access, modification, damage, deterioration and/or loss
831 of documentation.

832

833 17.10. Records should contain at least the following information:

834

- 835 • date;
- 836 • name of the product;

- 837 • quantity received, or supplied; and
- 838 • name and address of the supplier.

839

840 17.11. Comprehensive records should be maintained for all receipts, materials and
841 products stored, and issues or distribution. They should include, for example, the
842 description of the goods, quantity, names and addresses (such supplier, customer),
843 batch number(s), date of receipt/dispatch and expiry date.

844

845 17.12. All containers should be clearly labelled with at least the name of the
846 material/product, the batch number, the expiry date or retest date, and the specified
847 storage conditions. Unauthorized abbreviations, names or codes should not be used.

848

849 **18. ACTIVITIES AND OPERATIONS**

850

851 18.1. All activities and operations relating to procurement, storage and distribution of
852 medical products should be conducted in accordance with national legislation, GSP, GDP and
853 associated guidelines.

854

855 18.2. Storage and distribution of medical products should be done by persons so authorized,
856 in accordance with national legislation.

857

858 18.3. Activities and operations should be performed in accordance with documented
859 procedures.

860

861 *Receiving*

862

863 18.4. Materials and products should be procured from appropriately authorized suppliers.

864

865 18.5. Deliveries should be examined for damage, seal intactness, signs of tampering,
866 labelling, completeness of order and other related aspects, at receipt.

867

868 18.6. Containers and consignments not meeting acceptance criteria for receiving should be
869 separated, quarantined and investigated. This includes suspected falsified products.

870

871 18.7. Materials and products requiring specific storage conditions, or access control (e.g.
872 narcotics) should be processed without delay and stored in accordance with their requirements.

873

874 *Storage*

875

876 18.8. There should be sufficient space for the safe and secure storage of medical products
877 (*see section xxx above*).

878

879 18.9. Appropriate controls should be implemented to prevent contamination and/or mix ups
880 during storage.

881

882 18.10. Storage areas should be clean and kept free from litter, birds, dust and pests.

883

884 18.11. Controls and procedures should be in place to prevent and handle spillage and
885 breakage.

886

887 18.12. Materials and products should be stored under the conditions specified on the label, e.g.
888 controlled temperature and relative humidity when necessary. When specific storage
889 conditions are required, the storage area should be qualified and operated within the specified
890 limits. The storage conditions should be monitored and records maintained. The records
891 should be reviewed and trends and out of limit results investigated.

892

893 18.13. Stock should be rotated and the FEFO policy should be implemented.

894

895 18.14. Computerized systems used for stock management should be validated.

896

897 18.15. Materials and products reaching their expiry date should be separated from usable
898 stock and not be supplied.

899

900 *Repackaging and relabelling*

901

902 18.16. Repackaging and relabelling of materials and products are not recommended. Where
903 they do occur, they should only be performed by entities appropriately authorized to do so and
904 in compliance with the applicable national, regional and international requirements, and in
905 accordance with GMP.

906

907 18.17. Procedures should be in place for the controlled disposal of original packaging to
908 prevent re-use.

909

910 *Distribution and transport*

911

912 18.18. Materials and products should be transported in accordance with the conditions stated
913 on the labels. There should be no risk to the quality of the material or product during transport
914 and distribution.

915

916 18.19. Product, batch and container identity should be maintained at all times.

917

918 18.20. All labels should remain legible.

919

920 18.21. Distribution records should be sufficiently detailed to allow for a recall when required.

921

922 18.22. A copy of the original certificate of analysis from the manufacturer should be provided
923 to the customer.

924

925 18.23. Drivers of vehicles should be identified and present appropriate documentation to
926 demonstrate that they are authorized to transport medical products.

927

928 18.24. Vehicles should be suitable for their purpose, with sufficient space and appropriately
929 equipped to protect materials and products.

930

931 18.25. The design and use of vehicles and equipment must aim to minimize the risk of errors
932 and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or
933 dirt and/or any adverse effect on the quality of the products.

934

935 18.26. Where feasible, consideration should be given to adding technology, such as global
936 positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which
937 would enhance the security and traceability of vehicles with products.

938

939 18.27. Where possible, dedicated vehicles and equipment should be used for medical
940 products. Where non-dedicated vehicles and equipment are used, procedures should be in place
941 to ensure that the quality of the products will not be compromised. Defective vehicles and
942 equipment should not be used. These should either be labelled as such or removed from
943 service.

944

945 18.28. There should be procedures in place for the operation and maintenance of all vehicles
946 and equipment.

947

948 18.29. There should be written programmes and records for cleaning and pest control.
949 Records should be kept. The cleaning and fumigation agents used should not have any adverse
950 effect on product quality.

951

952 18.30. Equipment chosen and used for the cleaning of vehicles should not constitute a source
953 of contamination. Agents used for the cleaning of vehicles should be approved by
954 management.

955

956 18.31. Appropriate environmental conditions should be provided, checked, monitored and
957 recorded. All monitoring records should be kept for a minimum of the shelf life of the product
958 distributed plus one year, or longer, if required by national legislation. Records of monitoring
959 data should be made available for inspection by the regulatory or other oversight body.

960

961 18.32. Instruments used for monitoring conditions, e.g. temperature and humidity, within
962 vehicles and containers should be calibrated at regular intervals.

963 18.33. Where possible, mechanisms should be available to allow for the segregation during
964 transit of rejected, recalled and returned products as well as those suspected as falsified. Such
965 goods should be securely packaged, clearly labelled and be accompanied by appropriate
966 supporting documentation.

967

968 18.34. Measures should be in place to prevent unauthorized persons from entering and/or
969 tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation
970 thereof.

971

972 18.35. Shipment containers should have no adverse effect on the quality of the products and
973 should offer adequate protection to materials and products. Containers should be labelled
974 indicating, e.g. handling and storage conditions, precautions, contents and source, safety
975 symbols as appropriate.

976

977 18.36. Special care should be taken when using dry ice in shipment containers due to safety
978 issues and possible adverse effects on the quality of products.

979

980 18.37. Written procedures should be available for the handling of damaged and/or broken
981 shipment containers. Particular attention should be paid to those containing potentially toxic
982 and hazardous products.

983

984 *Dispatch*

985

986 18.38. Products should only be sold and/or distributed to persons or entities that are
987 authorized to acquire such products in accordance with the applicable national legislation.
988 Written proof of such authorization must be obtained prior to the distribution of products to
989 such persons or entities.

990

991 18.39. Dispatch and transportation should be undertaken only after the receipt of a valid order
992 which should be documented.

993

994 18.40. There should be documented, detailed procedures for the dispatch of products.

995 18.41. Records for the dispatch of products should be prepared and should include
996 information such as, but not limited to, date of dispatch; complete business name and address
997 (no acronyms), type of entity responsible for the transportation, telephone number, names of
998 contact persons; status of the addressee (e.g. retail pharmacy, hospital or community clinic); a
999 description of the products including, e.g. name, dosage form and strength (if applicable);
1000 quantity of the products, i.e. number of containers and quantity per container (if applicable);
1001 applicable transport and storage conditions; a unique number to allow identification of the
1002 delivery order; and assigned batch number and expiry date (where not possible at dispatch, this
1003 information should at least be kept at receipt to facilitate traceability).

1004

1005 18.42. Records of dispatch should contain enough information to enable traceability of the
1006 product. Such records should facilitate the recall of a batch of a product, if necessary, as well
1007 as the investigation of falsified or potentially falsified products. In addition, the assigned batch
1008 number and expiry date of pharmaceutical products should be recorded at the point of receipt
1009 to facilitate traceability.

1010

1011 18.43. Vehicles and containers should be loaded carefully and systematically, where
1012 applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage
1013 and reduce security risks. Extra care should be taken during loading and unloading of cartons
1014 to avoid damage.

1015

1016 18.44. Products should not be supplied or received after their expiry date, or so close to the
1017 expiry date that this date is likely to be reached before the products are used by the consumer.

1018

1019 18.45. Products and shipment containers should be secured to prevent or provide evidence of
1020 unauthorized access. Vehicles and operators should be provided with additional security, as
1021 appropriate, to prevent theft and other misappropriation of products during transportation.

1022

1023 18.46. Products should be stored and transported in accordance with procedures such that:

1024

- 1025 • the identity of the product is not lost;
- 1026 • the product does not contaminate and is not contaminated by other products;

- 1027 • adequate precautions are taken against spillage, breakage, misappropriation and
1028 theft; and
1029 • appropriate environmental conditions are maintained, e.g. using cold chain for
1030 thermolabile products.

1031

1032 18.47. Written procedures should be in place for investigating and dealing with any failure
1033 to comply with storage requirements, e.g. temperature deviations. If a deviation has been
1034 noticed during transportation by the person or entity responsible for transportation, this should
1035 be reported to the distributor and recipient. In cases where the recipient notices the deviation,
1036 it should be reported to the distributor.

1037

1038 18.48. Transportation of products containing hazardous substances, or narcotics and other
1039 dependence-producing substances, should be transported in safe, suitably designed, secured
1040 containers and vehicles. In addition, the requirements of applicable international agreements
1041 and national legislation should be met.

1042

1043 18.49. Spillages should be cleaned up as soon as possible to prevent possible contamination,
1044 cross-contamination and hazards. Written procedures should be in place for the handling of
1045 such occurrences.

1046

1047 18.50. Damage to containers and any other event or problem that occurs during transit must
1048 be recorded and reported to the relevant department, entity or authority, and investigated.

1049

1050 18.51. Products in transit must be accompanied by the appropriate documentation.

1051

1052 **19. OUTSOURCED ACTIVITIES**

1053

1054 19.1. Any activity relating to the storage and distribution of a medical product which is
1055 delegated to another person or entity should be performed by parties appropriately authorized,
1056 in accordance with national legislation, and the terms of a written contract.

1057

1058 19.2. There should be a written contract between the parties. The contract should define the
1059 responsibilities of each party (contract giver and contract acceptor) and at least the following:

1060

- 1061 • compliance with this guideline and the principles of GSP and GDP;
- 1062 • relevant warranty clauses;
- 1063 • responsibilities of the contractor for measures to avoid the entry of substandard and
1064 falsified products into the distribution chain;
- 1065 • training of personnel;
- 1066 • conditions of subcontracting subject to the written approval of the contract giver; and
- 1067 • periodic audits.

1068

1069 19.3. The contract giver should assess the competence of the contract acceptor before
1070 entering into an agreement.

1071

1072 19.4. The contract giver should provide all relevant information relating to the
1073 material/products to the contract acceptor.

1074

1075 19.5. The contract acceptor should have adequate resources (e.g. premises, equipment,
1076 personnel, knowledge, experience, vehicles as appropriate) to carry out the work.

1077

1078 19.6. The contract acceptor should refrain from performing any activity that may adversely
1079 affect the materials or products handled.

1080

1081 **20. SUBSTANDARD AND FALSIFIED PRODUCTS**

1082

1083 20.1. The quality system should include procedures to assist in identifying and handling
1084 materials and products that are suspected to be substandard and or falsified.

1085

1086 20.2. Where these materials and products are identified, the holder of the marketing
1087 authorization, the manufacturer and the appropriate national and/or international regulatory
1088 bodies, as well as other relevant competent authorities, should be informed.

1089

1090 20.3. Such products should be stored in a secure, segregated area and clearly identified to
1091 prevent further distribution or sale. Access should be controlled.

1092

1093 20.4. Records should be maintained reflecting the investigations and action taken, such as
1094 disposal of the material or products. Falsified materials and products should not re-enter the
1095 market.

1096

1097 **21. INSPECTION OF STORAGE AND DISTRIBUTION FACILITIES**

1098

1099 21.1. Storage and distribution facilities should be inspected by inspectors so authorized in
1100 terms of national legislation. This should be done at determined periodic intervals.

1101

1102 21.2. Inspectors should have appropriate educational qualifications, knowledge and
1103 experience.

1104

1105 21.3. An inspection should normally be conducted by a team of inspectors.

1106

1107 21.4. Inspectors should assess compliance with national legislation, GSP, GDP and related
1108 guidelines (GxP) as appropriate.

1109

1110 21.5. Inspections should cover the premises, equipment, personnel, activities, quality
1111 system, qualification and validation, and other related aspects as contained in this guideline.

1112

1113 21.6. An inspection report should be prepared and provided to the inspected entity within
1114 30 days from the last day of the inspection. Observations may be categorized based on risk
1115 assessment.

1116

1117 21.7. CAPA for observations listed as non-compliances in the inspection report, with the
1118 national legislation and guidelines, should be submitted for review by the inspectors within the
1119 defined period as stated by the inspectors.

1120

1121 21.8. Inspections should be closed with a conclusion after the review of the CAPAs.

1122 **References and further reading**

1123

1124 *[Note from Secretariat: the references included in the text will be added here in the final*
1125 *version. Proposals for further reading references are invited.]*

1126

1127

1128

1129

1130 **ANNEXURE 1. RECOMMENDED STORAGE CONDITIONS**

1131

1132 *Note: Appropriate conditions should be provided for materials and products during storage*
1133 *and distribution. Conditions should be maintained as stated on their labels from the*
1134 *manufacturers and suppliers, during storage and distribution. Where possible, actual limits*
1135 *should be provided by the manufacturers, such as “store below 25°C”. Vague statements such*
1136 *as “store at ambient conditions” should be avoided.*

1137

1138 Table 1. Recommended limits for descriptive storage conditions¹

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

1139 ¹These limits are recommended values, based on pharmacopoeia limits and guidelines

1140

1141

Guidance for Loading of a Truck

Distribution space

<https://us001.blueworkslive.com/scr/processes/20000559d2966fd>

Last modified on Jun 23, 2016 5:15 PM

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.

Loading a Truck

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

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

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Key to conventions used

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11.3.1 Quality system

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12.1 Training

12.1.1 General training

12.1.2 Specialist training

Key references

Further reading

Task force membership

Abbreviations

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

Background

These guidelines set out the principal requirements for the safe storage and distribution of time- and temperature-sensitive pharmaceutical products (TTSPs). 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 TTSP 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 TTSPP 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

¹ Definition from *Revision of WHO good distribution practices for pharmaceutical products*. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth report*. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 5.

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 TTSP 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 TTSP whose presentation and/or pharmacological formulation indicates that it has not been manufactured by the company named on the packaging. A TTSP 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 TTSP is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for

² Definition from the Parenteral Drug Association (PDA) Technical Report No. 39, 2007.

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 (TTSP)

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 TTSP may be exposed during transport.

utilization factor

The percentage of the total volume available for storing TTSPs 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 TTSPs 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 TTSP shipments from the wharf or airport apron to a safe and suitable temperature-controlled storage location.

⁴ Definition from PDA Technical Report No. 39, 2007.

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 TTSPS 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 TTSPS 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 TTSPS 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:

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 and
- 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;

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,⁹ 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;¹⁰
- 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.

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 TTSP 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 TTSP 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 TTSPs 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 $\pm 5\%$ 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).

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 $\pm 5\%$ 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

- Directive 94/62/EC. *European Parliament and Council Directive of 20 December 1994 on packaging and packaging waste.* 1994.
- EN 13428:2004. *Packaging. Requirements specific to manufacturing and composition. Prevention by source reduction.*
- EN 13430:2004. *Packaging. Requirements for packaging recoverable by material recycling.*
- EN 13431:2004. *Packaging. Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value.*
- EN 13432:2000. *Packaging. Requirements for packaging recoverable through composting and biodegradation. Test scheme and evaluation criteria for the final acceptance of packaging.*
- IATA *Perishable Cargo Regulations Chapter 17*, 9th Edition, July 2009.
- *Isothermal and refrigerating containers for health products — Thermal performance qualification method.*
- ISTA — 5B: *Focused Simulation Guide for Thermal Performance Testing of Temperature Controlled Transport Packaging.*
- ISTA — 7D: *Thermal Controlled Transport Packaging for Parcel Delivery System Shipment. Basic Requirements: atmospheric conditioning, vibration and shock testing.*
- WHO Technical Report Series, No. 937, 2006. Annex 5: *Good distribution practices for pharmaceutical products.*

6.2 Product stability profiles

Transport TTSPs 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 TTSPs against degradation.

6.3 Transport route profiling and qualification

Profile and qualify transport routes:

- Select the most suitable methods for protecting TTSPs 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.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 TTSP 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 $\pm 5\%$ 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 TTSP within the product's stability profile as stated by the product manufacturer and/or to maintain the TTSP 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 TTSP 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 TTSPs 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 TTSP 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 TTSPs 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 TTSPS shipping containers to:

- the exact specified configuration to ensure that the correct TTSPS 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 orientation 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 TTSPS correctly during packing and transport:

- pack TTSPS 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 TTSPS to outside recipients by the most suitable mode(s) of transport available in order to minimize delivery time; and
- ensure that patients receiving TTSPS deliveries are given clear advice on correct storage of the product before use.

Reason: To maintain TTSPS 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 TTSPS:

- 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 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**

- *IATA Perishable Cargo Regulations Chapter 179th Edition, July 2009. Clauses 17.10.5 and 17.10.6.*

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 TTSP 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 TTSP 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.

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

- ISO 14001: 2004. *Environmental management systems — Requirements with guidance for use.*
- *The Montreal Protocol on Substances that Deplete the Ozone Layer.* UNEP, 2000.

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 CO₂ 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 TTSP 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 TTSPs 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 TTSPs, 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.

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ANNEX 10

INDEFINITE QUANTITY SUBCONTRACT

Between

Chemonics International Inc.

And

(add subcontractor name and address here)

Hereinafter referred to as Subcontractor

for

United States Government- Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) project

United States Government (USG) Prime IDIQ Contract Number No. AID-OAA-I-15-00004
Task Order Nos. AID-OAA-TO-15-00007; AID-OAA-TO-15-00009.

Subcontract number: *(insert Subcontract Number here)*

Start Date: **XX, 20XX**

End Date: **XX, 20XX**

IQS Ceiling: TBD (Maximum aggregate value of all orders awarded)

ISSUED BY:

Chemonics International Inc.

ISSUED TO:

[Insert subcontractor name and address]

Subcontractor Tax ID Number: **[insert Subcontractor Employee Identification Number (EIN) or local tax reference number as applicable]**

Subcontractor UEI Number:

[insert Subcontractor UEI for awards valued at \$30,000 USD or higher unless exempted. Delete of not applicable.]

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INSTRUCTIONS: ADD THE ANNEXES AS ATTACHMENTS TO THE RFP AND THE FINAL CONTRACT.

- Annex 1. [World Health Organization \(WHO\) Good Storage and Distribution Practices \(2020\) Technical Report Series No. 1025](#)
- Annex 2. GHSC-PSM Guidance for Loading a Truck
- Annex 3. [WHO Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products](#)
- Annex 4. [WHO Technical Supplements to Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products](#)
- Annex 5. Key Performance Indicators

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 consideration stated herein. The rights and obligations of the parties to this indefinite quantity subcontract and any orders issued hereunder 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.).

[Instructions: If this is a local subcontract and Chemonics is registered in country as a separate entity, review the registration materials to confirm type of registration and confirm if local entity name should be listed. Confirm associated signatory authorities as needed. Update applicable sections.]

For: **Chemonics International Inc. or Local entity**
 By: _____

For: {Subcontractor’s name}
 By: _____

{name}
 {title of officer}
 Date Signed:
 Place Signed:

{name}
 {title of officer}
 Date Signed:
 Place Signed:

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

A.1. Background

This Indefinite Quantity Subcontract (Subcontract) is made by and between Chemonics International Inc. (or Chemonics Local Entity) (Chemonics) and [insert subcontractor name] [insert subcontractor acronym]. Chemonics is the lead contractor awarded the USG- Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM) project on a prime indefinite delivery, indefinite quantity (IDIQ) contract with orders as referenced on the cover page funded by the United States Government (USG).

GHSC-PSM facilitates the supply of health commodities in support of United States Government (USG) funded public health initiatives in Zambia by providing direct procurement and supply chain management support to United States Government (USG) programs, the President’s Emergency Plan for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI), Population and Reproductive Health (PRH), and United States Government (USG)’s goal to End Preventable Child and Maternal Deaths (EPCMD) as well as provide systems strengthening technical assistance to improve supply chain management and commodity security around the world.

Chemonics desires that the Subcontractor provide warehousing management services including the storage and management of commodities in controlled facility at the [Insert warehouse address].

A.2. Scope of Work

This subcontract represents and comprises Chemonics’ and the Subcontractor’s complete agreement with respect to [Insert warehouse address] Warehouse Site. The Statement of Work, prices and all provisions, terms and conditions herein apply equally to the Subcontractor’s performance of the services at the facility and the party’s respective responsibilities with respect to the facility. Any reference in this Subcontract to a “Warehousing/Distribution Center” or a “facility” or similar term shall apply to [Insert warehouse address] Warehouse Site.

Subcontractor(s) shall be responsible for warehousing services in [Insert warehouse address], for pharmaceutical cold chain, pharmaceutical grade, and ambient health commodities. Subcontractor(s) shall be capable of providing adequate equipment and infrastructure suitable for rapid staging and pick, pack dispatch services for pharma grade and cold chain commodities without necessarily storage. **Cold chain, pharmaceutical grade and ambient commodities** warehousing services shall be managed [Insert warehouse address and Country]. In the warehousing, commodities shall be stored at relatively lesser period of time or may not be stored at all but are rapidly cross docked upon receipt to designated delivery destinations. Subcontractor(s) shall have all the requisite and adequate technology, equipment and infrastructure that are required for the rapid order processing, with minimal requirement to hold inventory in storage.

Subcontractor shall be responsible for providing the services and shall maintain the facilities in accordance with World Health Organization (WHO) [Good Storage and Distribution Practices \(Technical Report Series No. 1025, 2020 Annex 7\)](#), GHSC-PSM Guidance for Loading a Truck, [WHO Model Guidance for the Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products \(Technical Report Series No. 961, 2011\)](#), [WHO Technical Supplements to Model Guidance for the storage and transport of time and temperature sensitive pharmaceutical products](#) (Annex 1-4) and consultation provided by Chemonics on relevant quality standards. 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 at the facilities. The commodities and property shall be stored as requested by Chemonics Field Office (or its designee) until released to the distribution agent, consignee, or another party so designated by the project office.

The Subcontractor will always maintain adequate documentation including written instructions and Standard Operating Procedures. SOPs will be evaluated to confirm consistent procedures for security, receiving, storage, packing, and loading. SOPs shall be in line with guidelines for temperature-controlled drug products during storage, model guidance for the storage of temperature sensitive pharmaceutical products, and guidance for loading a truck. SOPs shall include but not be limited to the following:

- Training in relation to good storage practice, regulations and safety specific to temperature-controlled goods, if applicable;
- Premises and facilities;
- Security;
- Inbound processes;
 - Receiving
 - Put away
- Storage;
 - Maintenance of good storage practice;
 - Product recall;
 - Quarantine Sampling and releasing of goods from quarantine
 - Stock rotation and control/ cycle counting
 - Control of obsolete and outdated products
- Outbound processes;
 - Selection picking
 - Auditing / Quality control
- Dispatch and transportation;
- Incident management and reporting;
- Daily operations reporting;
- Force majeure and disaster recovery plan;
- Reverse logistics;
 - Returned goods;
 - Handling; and
 - Re-evaluation processes

For cold chain, SOPs shall include the following:

- Training in relation to good storage practice, regulations, and safety specific to cold chain goods;
- Management of temperature excursions and other environmental condition excursions;
- Calibration/maintenance of temperature measuring instruments; and
- Receiving and verification of health commodities.

The Subcontractor must ensure that there are no discrepancies between physical inventory and inventory that are reported in the MIS/WMS. The Subcontractor shall be required to report on performance as required in reports and deliverables and for the key performance indicators in Annex 5 of this subcontract. The Subcontractor shall take all direction and instructions as pertains to Chemonics commodities from the designated representatives and in accordance with the following proposed scope of work. The Subcontractor shall act as a service provider and does not acquire ownership in respect of the goods stored in the warehouses.

The Subcontractor shall provide the staffing and coordination services related to all requirements and requests under this agreement.

A. 2.i Facilities and Equipment

Subcontractor(s) shall operate and maintain pharmaceutical cold chain, pharmaceutical grade, and ambient facility(ies) in compliance with the following requirements:

- a. No unauthorized personnel shall be permitted access to facilities. Chemonics (or its designee) staff shall be granted access to any facility during business hours, unless otherwise agreed, for the inspection of the goods and facility(ies).
- b. Stock shall be under continuous supervision, with adequate security, which shall be provided on a rotating schedule 24 hours a day, seven days a week.
- c. Facility(ies) shall be fully enclosed with a security parameter fence to prevent intrusion or vandalism.
- d. The following equipment shall be maintained and fully functional at all times:
 - i. all safety and security equipment including, but not limited to intrusion detection systems, CCTV system, access control systems, interior and exterior lighting, perimeter security systems, smoke detectors, fire suppression systems, serviced fire extinguishers, and related equipment;
 - ii. material handling equipment, hand trolley, forklifts, reach trucks and all other Warehousing equipment/ Distribution Center Equipment;
 - iii. Back-up generators, to ensure operations seven days per week, 24 hours per day.
- e. CCTV footage must be stored on site and off site for a minimum of 90 days after recording.
- f. Storage facilities shall be clean and free of vermin. A written sanitation and pest control procedure shall be maintained, together with logs recording the use of all pest control agents, including the amount used, method of application and date and times.
- g. Environmental, health and safety requirements are to be adhered to, including adequate fire detection suppression.
- h. Facilities shall come with the provision of water and electricity. Facility must be equipped with necessary backup generators with appropriate capacity to support normal operations of the warehouse including maintaining required temperatures for cold chain/frozen commodities.
- i. Storage areas shall provide adequate lighting to enable all operations to be carried out accurately and safely.
- j. There shall be sufficient drainage systems to prevent flooding or water damage;
- k. Communications technology and equipment shall be maintained for the use of telephones, fax, and email.
- l. Ceilings shall have a height of at least 5.5 meters.

Subcontractor shall operate and maintain pharmaceutical **cold chain** and **pharmaceutical grade** warehousing in compliance with the following requirements:

- a. The interior space of the facility(ies) shall be organized and maintained for the specified per location volume with sufficient staffing to allow for the orderly and rapid receipt (to appropriate, environmentally controlled storage area), cross docking, pick and pack, and/or storage of various categories of products, including products in quarantine, as well as released, rejected, returned or recalled products; if shipments or orders are to be cross docked, it is expected that storage costs shall not apply.
- b. There shall be adequate storage space or staging area (in the case of situation where only Warehousing services are to be provided) for the segregation of pharmaceuticals, laboratory reagents/consumables and other health products.

Subcontractor shall operate and maintain **ambient** warehousing in compliance with the following requirements:

- a. Facility(ies) must be of concrete or a similar permanent material (e.g. metal reinforced concrete), with smooth concrete flooring.
- b. There must be sufficient pallets available so that ITNs and/or other non-pharmaceutical health commodities are stored off the floor and suitably spaced to permit cleaning and inspection, and stacked no more than 3 meters high.
- c. Health commodities must be stored on pallets and not directly on the floor, unless Chemonics provides written instructions otherwise.
- d. Each facility shall be accessible by truck for adequate receipt and dispatch of cargo from vehicles, with two points of entry with minimum measurements of four meters by four meters.
- e. There shall be sufficient protections against climatic and environmental effects such as temperature and humidity.

A. 2.ii Temperature and Humidity Controls

Subcontractor shall operate and maintain pharmaceutical **cold chain** and **pharmaceutical** grade warehousing in compliance with the following temperature control requirements:

- a. Storage areas shall be clean and dry and maintained within acceptable temperature and humidity limits depending on product and manufacturers' guidance.
- b. Temperatures and humidity shall be monitored digitally and continuously throughout the facility(ies) Equipment used for monitoring shall be calibrated at acceptable and defined intervals, and Subcontractor shall ensure that temperatures and humidity are maintained at appropriate levels for the commodities being stored, and that temperature and humidity logs are available or easily retrievable for review at the request of Chemonics by means of PDF download.
- c. There shall also be a capability for remote monitoring of the temperature readings. Remote access shall be granted to Chemonics. The remote access shall allow for the easy download of temperature and humidity logs. The software to be deployed must be compatible with regular operating system (OS) softwares. The application software to be deployed must also be capable of sending email and SMS alerts to Chemonics staff and requisite warehouse staff when there are temperature excursions outside normal ranges.
- d. Subcontractor shall submit downloaded temperature and humidity logs, with short summary reports upon request.
- e. Temperature mapping audit shall be conducted at least annually by a qualified third-party firm with the capacity to provide this service and shall show uniformity of temperature across the storage facility(ies). The data generated from temperature mapping shall be provided promptly to Chemonics within 72 hours of completion of the exercise. Subcontractor(s) shall exercise due care in ensuring that no product is stored in identified hot or cold spots as highlighted through mapping. Where possible, Subcontractor(s) shall ensure that corrective measures are implemented to minimize the effects of hot/cold spots as identified through mapping.

Subcontractor shall operate and maintain pharmaceutical **cold chain** warehousing in compliance with the following temperature control requirements:

- a. The shelving for the storage of cold chain commodities shall allow for air flow to prevent freezing risks or increased exposure to heat.
- b. The temperature(s) of the facility(ies) shall be checked, continuously digitally monitored, and recorded. Documentation of adherence to the temperature requirements for cold chain dependent health commodities (2-8 °C) and commodities requiring frozen condition (-10 to -18 °C) shall be provided to Chemonics.
- c. The facility(ies) shall have an alarm system that alerts responsible Chemonics staff and requisite warehouse personnel in the event of any equipment failure, or if there is an excursion during

excursion while commodities are storage or operations. Alarms shall be located at the points representing high risk areas.

- d. All testing to be performed shall validate that the facility(ies) are in compliance with the cold chain requirements of the WHO, Parenteral Drug Association (PDA) and United States Pharmacopeia (USP) guidelines for all seasonal conditions in country.
- e. All cold rooms and freezer rooms shall have dual compressors, which includes having two cooling units that can be inter-changed according to a planned operating schedule and to ensure cold chain continuation in the event of a single compressor failure.
- f. Back-up electric power shall be provided for the operation of critical equipment used to maintain cold chain and/or temperature and humidity conditions; a maintenance program for the cold chain equipment shall be established and documented as well as a testing schedule for the backup generators.
- g. Freezers shall be free of excessive frost build-up.
- h. Refrigerators and freezers shall be of commercial grade and not be of household type, unless they incorporate the above controls. The use of household type refrigerators and freezers is discouraged.
- i. A full contingency and risk recovery plan shall be provided to address the maintenance of the required temperature(s) in the event that a complete cold room failure occurs.

A. 2.iii Product Control

Subcontractor shall implement a written process management procedure that ensures the control of goods in such a manner that prevents contamination, mix-ups and cross contamination in pharmaceutical **cold chain** and **pharmaceutical** grade facility(ies) including:

- a. The goods receiving dock shall be protected to prevent product contamination, prevent exposure of commodities to direct sunlight, dust, dirt, rain, wind, and from extremes of heat, cold, and solar radiation that could damage the products.
- b. Shipments shall be examined upon reception, following written procedures, to ensure controlled conditions (temperature, relative humidity, light, etc.) have been met, and results recorded.
- c. Materials and pharmaceutical products shall be stored in conditions that provide for adequately maintained stock, and the stock shall be appropriately rotated. Dispatches of stock shall follow “the First Expiry First Out (FEFO)” principle, except otherwise directed in writing by Chemonics (or its designee).
- d. Utilization of bin locations shall be optimized and bins consolidated to extent that it does not contravene warehouse best practices.
- e. Narcotic drugs or other controlled drugs or substances shall be stored with written instructions in compliance with international conventions, and national laws and regulations on narcotics.
- f. Rejected materials shall be identified and stored in a manner that prevents their use and/or distribution until a final decision is taken on the process to be followed regarding destruction or removal from the Warehousing/Distribution Center.
- g. Damaged/broken stock or suspected to be damaged shall be withdrawn from usable stock and quarantined and Chemonics shall be properly notified within twenty four (24) hours of discovery.
- h. If a commodity is subject to product recall, guidance and instructions for control shall be requested from Chemonics.
- i. No pallets of shipments of commodities shall sit in the aisles when there are no warehouse floor operations going on – inbound and outbound operations, physical stock count, or cycle count by the end of the day.

Subcontractor shall operate and maintain pharmaceutical **cold chain** warehousing in compliance with the following product control requirements:

- a. Products shall be transferred immediately from truck to appropriate, environmentally controlled storage area.
- b. Heat and cold temperature monitors/indicators shall be checked upon product arrival. If a monitor indicates a possible excursion during shipping, Subcontractor(s) shall document the reading and notify Chemonics within 24 hours. All excursions outside of the labelled storage conditions must be appropriately investigated and the ascertainment of the excursion by the subcontractor shall be supported with adequate documentation and technical justification.
- c. Subcontractor shall follow internal SOPs for good cold chain receiving, and all personnel involved should have the requisite training to be able to make critical decisions in cold chain management and to ensure appropriate handling of temperature sensitive material. Records of this training should be maintained.
- d. Special care shall be taken to ensure safety precautions are taken when using dry ice, and it must be ensured that the health commodities do not come into contact with dry ice as thus may adversely affect product quality, e.g. by freezing.

A. 2.iv Inventory Management

Subcontractor shall manage pharmaceutical **cold chain**, **pharmaceutical** grade, and **ambient** health commodities in compliance with the following requirements:

- a. Subcontractor shall maintain an automated inventory control and management system (Warehousing management system/ Distribution Centre management system) . The WMS shall provide the following:
 - i. software: batch and dynamic inventory control that allows for the control of goods in such a manner that prevents contamination, mix-ups and cross-contamination;
 - ii. hardware: handheld terminals with barcode scanning capability, to be used for pick, pack, dispatch, receipt, stock control, order fulfilment, and distribution;
 - iii. cloud-based customer order management portal:
 - real time client access for stock visibility and reports;
 - electronic ordering and dispatch requests;
 - application programming interface (API) to link with Chemonics enterprise resource planning (ERP), including CSV integrations via FTP/SFTP.cloud-based customer order management portal
 - iv. WMS should be able to uniquely identify products at SKU level and/or capture GS1 unique entity identifiers.:
- b. Subcontractor shall process orders duly authorised by Chemonics (or its designee), and shall pick, pack, dispatch products for such orders, according to the regular delivery schedule and/or special delivery orders provided by Chemonics, ensuring that products are distributed based on the FEFO principle (except otherwise directed in writing by Chemonics) and dispatches correspond with order and proofs of delivery (PODs) (or electronic proofs of delivery (ePODs)).
- c. Packaging, packing and transportation methods shall comply with manufacturers' requirements for ensuring the safety, efficacy and quality of the product, and shall be appropriate for distribution in the particular climates and transport and storage conditions encountered in **Zambia**. If any additional packaging is required that will add any additional cost, the Subcontractor(s) must discuss with GHSC-PSM before the cost are incurred and receive approval for the additional costs. Orders will be received at least 2 days prior to required dispatch. It is recognized by Subcontractor(s) that flexibility at times will be required and thus orders might be received with less than the 2 days' notice prior to required dispatch and the Subcontractor has to deploy all necessary resources in order to meet the required deadlines for delivery to the recipients including working, if needed in emergency situations (with justification provided by Chemonics) on a rotating schedule 24 hours a day, seven days a week including holidays.

Subcontractor should consider that such circumstances might happen from time to time and incorporate such considerations into their pricing model.

- d. Products shall be stacked in accordance with manufacturers' instructions, with packaging labels free from obstruction, clearly displaying contents, weight, quantity, manufacturer, expiry dates, and any special instructions for handling stacking shipping storage and/or transportation of the contents.
- e. Goods for dispatch must be labeled accordingly.
- f. All goods are required to be stored off the floor on pallets or pick flow racks at all times.
- g. In the picking racks/bin location, all items must be in their own fixed-bin location, no more than one item per location is allowed. This is to be managed through the WMS system.
- h. The inventory control personnel in the warehouse / distribution centre are responsible to ensure that separation of batches is maintained.
- i. Products are to be covered and not left open, except in the fine pick locations.
- j. Boxes in the bulk storage area are to be resealed where possible. This is especially important after any QA sampling which may be required.
- k. Boxes used for storing product must either be the warehouse / distribution centre's branded boxes, the vendor's boxes or unprinted boxes. Boxes that are recycled must have all details defaced off the box before they can be reused. All unprinted boxes must have a label showing details of the content.
- l. Mixing of products during picking and packing into original vendor's boxes shall not be permitted. If it is in a vendor's branded box, other products cannot be picked or packed into that same box.
- m. Mixing of products in unprinted boxes during picking and packing in the warehouse is permitted but shall be well labeled (product description, batches and expiry date, quantity, temperature requirement).
- n. All pallets used shall be firm and unbroken, clean, free of dirt and insects, and stored or cross docked in a dry area. Where necessary, pallets are to be scrubbed and vacuumed. Fumigation of pallets may be required for international dispatch into and out of the country.
- o. There shall be adequate resources to ensure that the loading and offloading of health commodities in and out bound vehicles to the facility(ies) is conducted in a timely fashion to ensure there are no unnecessary delays in commodities receipt and dispatch.
- p. Subcontractor shall record the quantities, batch number, expiry date, and temperature reading (on the temperature monitoring device that shall accompany shipments if required) of the product(s) being handed over to the distribution agent, and any other relevant information provided by Chemonics in the electronic delivery slip. The electronic delivery slip shall have an electronic signature from the distribution agent to confirm receipt of product from the facility(ies).
- q. WMS should be able to uniquely identify products at SKU level and or capture GS1 unique identifiers. GHSC-PSM commodities should not be captured at the generic level.
The subcontractor is expected to manage the stock at 100% accuracy and will be held financially liable for all net inventory variances per SKU, per donor, and per location. Both positive and negative variances shall be reimbursable to Chemonics. When a variance is identified, Chemonics will submit a claim letter requesting the subcontractor for reimbursement. The subcontractor shall maintain compliance with World Health Organization (WHO) [Good Storage and Distribution Practices \(Technical Report Series No. 1025, 2020 Annex 7\)](#), section 13. stock control and rotation.
- r. Should the subcontractor be able to recover inventory previously reported as losses with verifiable evidence, the subcontractor will be reimbursed accordingly. Reimbursement is subject to acceptance from Chemonics of the evidence and sufficient remaining shelf life. The approved amount should be reflected in the following invoice. GHSC-PSM reserves the right to send auditors to conduct a stock audit when required to verify the reports submitted.

- s. In alignment with industry best practices, Chemonics strongly encourages Subcontractors to employ perpetual inventory management practices in order to maintain the 100% inventory accuracy requirement. Should perpetual inventory practices be adopted, Chemonics recommends that each WMS location be counted a minimum of once per quarter, and that daily and monthly cycle count results be displayed in the warehouse common area.

A. 2.v Security

- a. Subcontractor shall (i) maintain a complete security plan which will include adequate precautions to ensure that no unauthorized personnel have access to the facilities, taking into account the security situation in the part of the country where the services are being provided; (ii) assume all risks and liabilities related to Subcontractor(s) security and full implementation of the security plan. Chemonics reserves the right to verify whether such a plan is adequate and in place and suggest modifications to the plan when necessary; and (iii) ensure that necessary security regulations are included in the plan and adhered to by all staff. Failure to maintain and implement as appropriate security plan as required may be deemed a breach of contract.
- b. Subcontractor shall manage the security services and direction. Subcontractor shall perform any other related security services as may be required with regard to the project such as:
- i. Investigation of incidents;
 - ii. Country/route risk evaluation;
 - iii. Casual (unplanned) guarding (such as required to guard a shipment at an airport/port/other location);
 - iv. Security Equipment; and
 - v. Personnel protection services and escorting.
- c. Within 24 hours, subcontractor(s) shall report any incidences of loss or damage to the commodities in the Warehousing/Distribution Center or any event that can affect the integrity of the commodities including: fire, dampening/wetting of commodities in stock due to leaking roof or flooding, etc.

A. 2.vi Force Majeure and Disaster Recovery Planning

Subcontractor shall maintain appropriate disaster recovery and security systems to provide continuity of services in case of causes established to be beyond the control and without the fault or negligence of Subcontractor(s) 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) pandemics and/or epidemics, (6) quarantine restrictions, (7) strikes, (8) freight embargoes, and (9) unusually severe weather, or (10) security breach (each a “**Force Majeure Event**”) as provided below. During a Force Majeure Event, Subcontractor(s) and Chemonics will discuss the continued and uninterrupted provision of Services and Chemonics will reasonably consider any request by Subcontractor(s) 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 Subcontractor(s) hereunder.

Within twenty (20) Business Days after the Effective Date, Subcontractor(s) shall develop for Chemonics’s approval a plan to reasonably deal with a Force Majeure Event (such plans and any plan Chemonics may adopt to deal with any of Force Majeure Event, a “**Contingency Plan**”) describing the measures it will take in the event of a Force Majeure Event. Each Contingency Plan must address the following:

- a. Provisions covering the total or partial loss of each facility and the product contained in it or the total or partial loss of the ability to complete the SOW/SOP;
- b. Temporary arrangements for shipments to and/or from alternative facilities;
- c. Prompt restoration of warehousing services and shipment processing at an alternative facility; and
- d. For facilities where Subcontractor(s) maintains computer hardware or software for operations, including shipment tracking there, shall be provisions for maintenance of software and data in segregated, offsite locations; and for hardware at alternative locations.

Immediately upon occurrence of any Force Majeure Event, Subcontractor shall implement the relevant Contingency Plan(s) approved by Chemonics and, unless the parties agree otherwise, make best efforts to recover data and resume operations within forty-eight (48) hours thereafter. Subcontractor(s) will also assist Chemonics to implement any Contingency Plan adopted by Chemonics to the extent it relates to or impacts the Services.

Should Subcontractor suffer a Force Majeure Event, Subcontractor(s) shall use all reasonable efforts to ensure the continuity of Services by activating the Contingency Plan. If after implementation of the Contingency Plan, the Force Majeure Event prevents Subcontractor(s) from carrying out its obligations under this Agreement for a continuous period of more than ninety (90) Business Days, Chemonics may terminate this Subcontract in accordance with Section G. Term and Termination.

A.3. Chemonics/GHSC-PSM Responsibilities

1. Chemonics/GHSC-PSM will be responsible for all distribution of Chemonics commodities to and from the Warehouse Site. Should Chemonics agree to store goods for other donor programs in the Warehouse Site, those other programs may be responsible for distribution.
2. A Chemonics representative will coordinate with the designated point of contact for the Subcontractor for the receipt and storage of Chemonics' inventory at the Warehouse Site. The Chemonics representative will coordinate with the Subcontractor's designated point of contact on a regular basis to inform him/her when new shipments will arrive at the Warehouse and when goods will be shipped from the Warehousing Center. The Chemonics representative will have access to inspect such goods in the Warehouse to ensure that the goods are maintained in good condition and to coordinate inventory lists between the two companies.
3. Chemonics will provide the Subcontractor with an advanced shipment notification for inbound shipments at least 48 hours prior to arrival at the Subcontractor's facility. Chemonics will make best efforts to ensure this notification includes relevant shipping documents and the following data:
 - a. Date and mode of shipment
 - b. Donor
 - c. Stock code(s) and description(s) of products
 - d. Number of pallets/packages
 - e. Batch numbers and quantities per batch
 - f. Any special conditions pertaining to storage conditions (i.e. fridge, quarantine, etc.)
4. Chemonics will use its best efforts to provide the Subcontractor a delivery order and routing plan at least 48 working hours prior to required dispatch, consisting of types of products to be picked/packed, quantities, and delivery locations.

5. Chemonics will review the dispatch note template currently in use by the Subcontractor, and either approve or request changes to the format prior to the first distribution. Chemonics shall have the right to request adjustments to the template if necessary throughout the life of the subcontract.
6. Chemonics staff will provide periodic management oversight for inbound arrivals, picking/packing, outbound shipments, and cycle stock counts at the Subcontractor’s facility, as time permits.
7. **Non-exclusive Dealing and Forecasts**
 Chemonics, under the terms of this Subcontract, retains the right to procure similar services from other sources during the period of this Subcontract. Chemonics does not guarantee or commit to any specific number or amount of shipments, volume, tonnage, services, or revenue to the Subcontractor. Any volume or other requirement forecasts provided to the Subcontractor by Chemonics, GHSC-PSM, or UNITED STATE GOVERNMENT (USG) shall be estimates only and shall be non-binding and create no legal obligation on Chemonics, GHSC-PSM, or UNITED STATE GOVERNMENT (USG).

A.4. Deliverables and Reports

Deliverables (required for payment)

Subcontractor(s) shall deliver to Chemonics the following deliverables, in accordance with the schedule set forth below, accompanied by an invoice.

Activity	Deliverable Title	Deliverable Description	Timing
Warehouse Stock Status Report	Monthly Consolidated Report (includes PODs)	<p>Report of current stocks summarizing receiving, distribution, and closing stock balance monthly for all GHSC-PSM commodities. This report will indicate the quantity, description, batch number, expiry date, unit of measure, and dosage of each item. The report will show the initial quantity in stock at the beginning of the month, the quantity received, the quantity distributed and the final stock at the end of the month informing the shelf life of remaining stocks. This report will also show the total number of pallets used during the month, sorted from earliest expiry date to the longest shelf life remaining.</p> <p>Subcontractor(s) shall send copies of the PODs (or ePODs when available) signed by the party responsible for transportation as evidence of handing over the picked and packed orders to</p>	Five (5) days after the end of the month.

		the responsible party.	
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The Subcontractor(s) must ensure that at all times, the total value of stock in any warehouse can be ascertained. Unit prices of commodities must be continually updated as the need arises and must be captured on all reports and documents (e.g., PODs, delivery notes etc.).

Reports (Section to be edited to reflect RFP requests)

The subcontractor shall provide the following reports based on the timing outlined below. Each report format shall be approved by Chemonics prior to its roll out by the subcontractor. Reports shall be sent according to the timeline in the table below to the following email address: PSMZambia-ITN2026@ghsc-psm.org. Upon creation of RFP and Subk, the country team should confirm reports with the [W&D HSS team](#).

Note: the following reports should NOT be tied to payment

Activity	Report Title	Report Description	Timing
Variance reconciliation	Quarterly Inventory Financial Variance Report N.B. this report only applies if a stock take is occurring each quarter.	• This report will detail the positive and negative variances identified during the daily cycle count across the period of a quarter. This report must contain the following product details: <ul style="list-style-type: none"> • Full product name • Quantity • Batch/lot number • Expiry date • Program (e.g., HIV, TB, malaria, etc.) • Name of Donor • Values of the Product 	Quarterly

<p>Stock summary</p>	<p>Monthly Consolidated Stock Summary Report</p>	<p>Subcontractor will send a detailed Stock Summary Report. The report will indicate current stock levels summarizing receiving, distributing and final stock on a monthly basis for all Chemonics commodities, identified by donor program. This report will include:</p> <ul style="list-style-type: none"> • Full product name • Quantity • Batch/lot number • Expiry date • Program (e.g., HIV, TB, malaria, etc.) • Name of Donor • GS1 serial numbers of items dispatched in the shipment. • Product SKU level • Opening balance at the beginning of the month • Quantity received • Quantity distributed • Final/closing stock balance at the end of the month <p>This report will also show the total number of pallet spaces used during the month.</p> <p>Inventory Transaction Details (ITD) by Implementing Partner (IPs): This report contains the list of commodities given to each IPs with quantities and values. This list is sequential by IP.</p> <p>ITD by Program: This report contains a list of commodities given to IPs with quantities and values from a particular program [Malaria, HIV, Family Planning, Maternal Newborn Child Health (MNCH), Global Fund, other programs etc.] This list is sequential by IPs and program. ITD by Product (Stock Ledger): This report gives detailed transactions by product with a quantity/value summation.</p> <p>Inventory Activity Report: All commodities Received/Issued for the period with transaction references (PO numbers, ASN no., AWB no. for all Inbound and WCOF no. for all Outbound).</p>	<p>Monthly</p>
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		<p>Batches and Expiry Report (BER): This shows batches and expiry date of current stock balances, sorted from earliest expiry date to the longest shelf life remaining.</p> <p>Monthly updates of stock aging analysis and reporting.</p>	
<p>Inbound Receiving</p>	<p>Inbound Receiving Report</p>	<p>Upon receipt of consignments into the warehouse(s), the subcontractor shall email the following distribution list [insert email address] with:</p> <ol style="list-style-type: none"> a. Subject Line: Inbound Shipment Arrival Notification – GHSC-PSM [Country] b. Body of email: Please be aware that a shipment has arrived at [insert warehouse name and address] on mm/dd/yy. <p>Details:</p> <ol style="list-style-type: none"> i. Program: GHSC-PSM [Country] ii. RO Number/ASN - PQ Number iii. Information on the waybill/ POD regarding number of pallets/cartons iv. Status of delivery- complete / incomplete <p>Within two business days of inbound shipment arrival, or within the time period agreed upon for special or large shipments, Subcontractor shall send a detailed receiving report list [insert email address] that includes copies of Signed POs and the following information:</p> <ul style="list-style-type: none"> • Full product name • Quantity received compared to quantity expected on the commercial shipping paperwork from the supplier • Batch/lot number 	<p>Within two business days with exception of bulk shipments (e.g., large LLIN orders). In the case that the subcontractor is unable to meet two-business day deadline, they must communicate this to GHSC-PSM in writing.</p>

		<ul style="list-style-type: none"> • Expiry date • Program (e.g., HIV, TB, malaria, etc.) • Name of Donor • Whether products are marked (UNITED STATE GOVERNMENT (USG)) <p>The report shall note any damages, losses, or discrepancies. If damage was detected, pictures of the vehicle(s) that delivered the commodities and damaged products shall also be shared with Chemonics.</p> <p>For cold chain pharmaceuticals, the subcontractor shall also:</p> <ul style="list-style-type: none"> • Confirm that the shipment arrived with a temperature monitoring device (TMD) and/or temperature control device (e.g., ice packs) • Stop the TMD and download the data from the TMD. The downloaded shall be shared as part of the receipt report. • The subcontractor shall check condition of ice pack and/or dry ice. • Take adequate number of pictures of the shipment, showing clearly how the shipment was packed and the position of the TMD, position of temperature control device and the condition of temperature control devices. • Notify Chemonics immediately via email and phone, in the case that a cold chain shipment arrives without TMD and/or temperature control device (e.g., ice packs), the subcontractor. 	
<p>Outbound Pallet Processing and Pick, Pack, Loading, Dispatch</p>	<p>Dispatch Report</p>	<p>The Dispatch Report contains inventory transaction details (ITD) and must contain the following information (at minimum):</p> <ul style="list-style-type: none"> • Name receiving health facility or warehouse • Date and time of dispatch • Full product name 	<p>Within two business days of being dispatched from the warehouse.</p>

		<ul style="list-style-type: none"> • Batch/lot number • Quantity • Expiry date • Donor Name • Program (e.g., HIV, TB, malaria, etc.) <p>The report must be provided in a flat file format (i.e., CSV or XLS).</p>	
Various	Various	<p>When applicable or as requested in writing, Subcontractor shall provide the following to Chemonics:</p> <ol style="list-style-type: none"> a. Copies of any insurance claim filed on behalf of Chemonics for products lost or stolen from the Warehousing Center (optional). b. Copy of a valid insurance certificate(s) – if insurance is requested by Chemonics – which must also include fidelity all risk insurance including but not limited to collusion and theft, covering goods in the Warehousing/Distribution Center (highly recommended). c. Copies of the Subcontractor’s written sanitation and pest control procedure, together with logs recording the use of all pest control agents including amount used, method of application, and date and time (required). d. Status of actions based on any insurance company inspection. Subcontractor shall take actions necessary, within the timeframe specified by the insurance inspector and Chemonics, to respond to inspection survey or report findings to ensure that facility and warehouse services meet the standards of the insurance program covering Chemonics’ goods in the warehouse (highly recommended). e. Copies of temperature mapping reports, certified and endorsed by qualified entities (required). f. Any other documentation(s) and/or certification(s) relating to but not limited to quality assurance of 	See “Report Description” for requirements.

		warehousing operations (required). g. The Subcontractor(s) must ensure that at all times, the total value of stock in any warehouse can be ascertained. Unit prices of commodities must be continually updated as the need arises and must be captured on all reports and documents (e.g. PODs, delivery notes etc.) (required).	
Additional Reports	Warehouse capacity	Subcontractor shall inform Chemonics in writing; written notification shall include statement that commodity shipments will not be received beyond available, compliant, warehouse space.	When 90% warehouse space is occupied
	Temperature monitoring	Subcontractor shall submit all temperature logs downloaded from continuous temperature monitoring devices to Chemonics.	Every Monday by 9:00am
Daily geographic cycle count* N.B. this report only applies if the Subcontractor has implemented perpetual inventory management	Monthly Inventory Variance Report	This report shall contain monthly cycle count results showing each of the bin locations counted, totals, and any variances in quantity and financial value. This report must contain the following product details: <ul style="list-style-type: none"> • Full product name • Quantity • Batch/lot number • Expiry date • Program (e.g., HIV, TB, malaria, etc.) • Name of Donor • Values of the Product 	Monthly

"Content will be developed further based on the successful Offeror's proposal and Section II of the RFP."

A.5. Deliverables Schedule

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

"Content will be developed further based on the successful Offeror's proposal and Section II of the RFP."

*Deliverable numbers and names refer to those fully described in Section A.4 above.

Section B. Subcontract Type and Orders

B.1 Subcontract Type

(a) This is an Indefinite Quantity Subcontract (IQS) with sub task orders to be priced utilizing firm fixed prices for services and deliverables. These orders will be issued as the need arises. The quantities of supplies and services specified under this subcontract are estimates only and are not purchased by this subcontract.

A Fixed Price Sub-Task Order is a subcontract for services, reports, or other concrete deliverables provided to and accepted by Chemonics on behalf of GHSC-PSM and/or UNITED STATE GOVERNMENT (USG). As the name implies, the price of the sub-task order is fixed, and it is not subject to any adjustment on the basis of the Subcontractor's cost experience in performing the work.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering Procedures in Section C.3. The Subcontractor shall furnish to Chemonics, when and if ordered, the services specified in the SOW of this subcontract in accordance with B.3 Minimum Obligated Amount and B.4 Maximum Ordering Amount.

(c) Except for any limitations on quantities in the sub-task order Limitations clause there is no limit on the number of orders that may be issued. Chemonics may issue orders requiring delivery to multiple destinations or performance at multiple locations.

B.2 Sub-Task Order Prices

Sub-task orders will contain the following: (1) a firm fixed price for the services to be provided; (2) a schedule of deliverables to be provided; and (3) a schedule of payments that the Subcontractor will receive upon receipt and acceptance by the GHSC-PSM representative named below or as specified in each sub-task order for a single or group of deliverables.

Description of Services	Fixed Unit Rate(s)
1. (Service 1 Name)	1. Enter Fixed Unit Rate
2. (Service 2 Name)	2. Enter Fixed Unit Rate

B.3 Minimum Obligated Amount

This subcontract includes an initial obligation of funds in the amount of ZMW 5,000 to cover the minimum order guarantee. Chemonics is required to order and the Subcontractor is required to furnish the minimum order amount of services. This minimum order guarantee and initial obligation shall be met through the first sub-task order placed hereunder. Individual sub-task orders will obligate funds to cover the work required under each sub-task order.

B.4 Maximum Ordering Limitation

Maximum Ordering Limitation. This subcontract includes a ceiling price in the amount of [Insert the anticipated IQS ceiling price here. Needs to match what is in the front page]. All sub-task orders issued under this subcontract shall not exceed the subcontract total ceiling amount and the Subcontractor shall not be paid any amount in excess of the subcontract's ceiling price without advance, written approval of Chemonics.

Section C. Ordering Procedures

C.1. Ordering – General

(a) Any services to be furnished under this indefinite quantity subcontract shall be ordered by issuance of fixed price task orders/purchase orders (orders) by Chemonics. Such orders may be issued from the effective date of this subcontract through its expiration.

(b) All orders are subject to the terms and conditions, including clauses incorporated by reference, of this indefinite quantity subcontract. In the event of conflict between terms and conditions of an order and of this subcontract, the terms and conditions of this subcontract shall control.

(c) Orders must be issued through written communication by the **Insert Name of supervisor** or his/her designee.

(d) Orders are subject to any terms, conditions, and/or limitations which may be imposed by Chemonics or UNITED STATE GOVERNMENT (USG). Any orders that include a period of performance that exceeds the estimated completion date of the IDIQ subcontract shall retain any and all appropriate subcontract terms and conditions, including revisions to FAR and AIDAR clauses that are effective after the estimated completion date but are within the authorized period of performance in the order. The indefinite quantity subcontract period is not extended unless by formal modification and new sub-task orders shall not be issued after the basic subcontract estimated completion date, as modified. Only the **Insert Name of supervisor** or his/her designee may modify the indefinite quantity subcontract.

C.2. Sub Task Orders (STOs) Contents

Each STO shall specify at a minimum the following sections:

- A.1 Background;
- A.2 Statement of Work
- A.3 Deliverables and Deliverables Schedule;
- A.4 Technical Directions;
- A.5 Term of Performance of the Sub Task Order;
- A.6 Contract Type;
- A.7 Firm Fixed Prices;
- A.8 Other Clauses as may be required for Specific Orders (e.g., Key Personnel)

C.3. Ordering Procedure

As the need for the Subcontractor's services and expertise arise in the course of the project, the Chemonics authorized representative, **Insert name of Chemonics' authorized representative here**, or his/her designee shall:

(a) Issue a Sub-Task Order at least two (2) weeks before the commencement of the services .

C.4. Performance of Orders

a) Upon award of a fixed price sub-task order, the Subcontractor shall commence the work.

b) After a fixed price sub-task order is issued, neither Chemonics nor the Subcontractor may alter it without a formal bilateral modification to the sub-task order.

c) Under no circumstance shall any adjustments authorize the Subcontractor to be paid any sum in excess of the sub-task order fixed price.

d) The Subcontractor is not authorized to delegate or assign (subcontract) full or partial performance of a sub-task order to another organization without the express consent of Chemonics contracts department.

C.5. Ordering Limitations

All orders statements of work and performance periods shall be within the scope of work and effective period of this indefinite quantity subcontract.

C.6. Changes, Termination and Stop Work

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 in Section CC herein.

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) which is incorporated by reference in Section EE herein.

Chemonics may order the Subcontractor to stop work under any order issued hereunder pursuant to the Stop Work Order Clause incorporated by reference in Section EE herein.

Section D. Reporting and Technical Direction

(a) Only the Chemonics authorized signatory may make changes to this Subcontract. All modifications must be identified as such in writing and executed by the parties.

(b) The Subcontractor shall render the services and produce the deliverables stipulated in each order, under the general technical direction of the Chemonics authorized representative, or his/her designee as indicated in each order. The Chemonics authorized representative or his/her designee will be responsible for monitoring the Subcontractor's performance under this 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 Chemonics authorized representative or his/her designee, unless otherwise specified in a purchase order 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 the Chemonics authorized representative other authorized project staff member.

Section E. Period of Performance

(a) The effective date of this subcontract is {insert start date} and the completion date is {insert end date}.

(b) In accordance with FAR Clause 52.217-9 (Option to Extend the Term of the Contract), Chemonics

may extend the term of this contract by written notice to the Subcontractor within 30 days; provided Chemonics gives a preliminary written notice of its intent to extend at least 90 days before the contract expires. The preliminary notice does not commit Chemonics to an extension.

(c) If Chemonics exercises this option, the extended contract shall be considered to include this option clause.

(d) The total duration of this contract, including the exercise of any options under this clause, will be no more than [insert years] consisting of one (1) year IQS base period, with up to [insert number of options] option years.]

(e) The Subcontractor shall conduct the services and deliver the deliverables set forth in each order in accordance with the order schedule.

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

Section F. Invoicing and Payment

Upon the GHSC-PSM authorized representative's, as identified above or in the order, acceptance of the contract deliverables described in each fixed price purchase order, the Subcontractor shall submit an original invoice to GHSC-PSM for payment. The invoice shall be sent to the attention of Chemonics authorized representative and shall include the following information: a) subcontract number, b) deliverables delivered and accepted as well as copies of all reports and required documentation c) total amount due; and d) payment information corresponding to the authorized account listed in below.

Payment Account Information

Chemonics 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 electronically wired 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)

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 valid invoice. Invoicing shall be made in (choose either US dollars or specify a local currency if this is a local subcontract), paid to the account specified above.

Section G. Branding Policy and Reporting Requirements

The Subcontractor shall comply with the requirements of the UNITED STATE GOVERNMENT (USG) "Graphic Standard Manual" available at [www.United State Government \(USG\).gov/branding](http://www.United State Government (USG).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.

Reports to be prepared under fixed price orders shall bear the name of Chemonics, the prime contract number, this subcontract number, and the sub-task order/order number, and shall be prepared in English unless otherwise specified.

Section H. Authorized geographic code [AIDAR 725.702]; 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 935.

(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 UNITED STATE GOVERNMENT (USG) 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 UNITED STATE GOVERNMENT (USG) 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 UNITED STATE GOVERNMENT (USG) through Chemonics and has received payment for such purposes, Chemonics may require the Subcontractor to refund the entire amount of the purchase.

Section I. 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 therefore, 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 J. Insurance

Prior to starting work, the Subcontractor at its own expense, shall procure and maintain in force, on all Its operations, insurance in accordance with the clause listed below.

The policies of insurance shall be in such form and shall be issued by such company or companies as may be satisfactory to Chemonics. Upon request from Chemonics, the Subcontractor shall furnish Chemonics with certificates of insurance from the insuring companies which shall specify the effective dates of the policies, the limits of liabilities there under, and contain a provision that the said insurance will not be canceled except upon thirty (30) days' notice in writing to Chemonics. The Subcontractor shall not cancel any policies of insurance required hereunder either before or after completion of the work without written consent of Chemonics.

- 1) Commercial general liability insurance with a combined bodily injury and property damage single limit of \$10,000,000 per occurrence which covers, at a minimum, premises, independent contractor, contractual liability, personal and advertising injury, and broad form property damage with no care, custody, and control exclusion, and with no copyright infringement, trade secrets or software code exclusions;
- 2) Warehouse keeper's liability insurance with limits and coverage sufficient to cover the Subcontractor's contractual liabilities under this agreement but at a minimum \$5,000,000 limit per occurrence;
- 3) Employer's liability insurance in accordance with the applicable laws of [Country];
- 4) Workers' compensation insurance in accordance with the applicable laws of [Country];

(a) FAR 52.228-3 WORKER'S COMPENSATION INSURANCE (DEFENSE BASE ACT INSURANCE) (JULY 2014) [Updated by AAPD 05-05 — 02/12/04]

The Subcontractor shall (a) provide, before commencing performance under this subcontract, such workers' compensation or security as the Defense Base Act (DBA) (42 U.S.C. 1651, et seq.) requires and

(b) continue to maintain it until performance is completed. The Subcontractor shall insert, in all lower-tier subcontracts authorized by Chemonics under this subcontract to which the Defense Base Act applies, a clause similar to this clause imposing upon those lower-tier subcontractors this requirement to comply with the Defense Base Act.

(b) AIDAR 752.228-3 WORKERS' COMPENSATION (DEFENSE BASE ACT) [Updated by AAPD 22-01- 6-10-22]

As prescribed in AIDAR 728.308, the following supplemental coverage is to be added to the clause specified in FAR 52.228-3.

(b)(1) The Subcontractor agrees to procure DBA insurance pursuant to the terms of the contract between UNITED STATE GOVERNMENT (USG) and UNITED STATE GOVERNMENT (USG)'s DBA insurance carrier unless the Subcontractor has a DBA self-insurance program approved by the U.S. Department of Labor or has an approved retrospective rating agreement for DBA.

(b)(2) If UNITED STATE GOVERNMENT (USG) or Subcontractor has secured a waiver of DBA coverage (See AIDAR 728.305-70(a)) for Subcontractor's employees who are not citizens of, residents of, or hired in the United States, the Subcontractor agrees to provide such employees with worker's compensation benefits as required by the laws of the country in which the employees are working, or by the laws of the employee's native country, whichever offers greater benefits.

(b)(3) The Subcontractor further agrees to insert in all lower-tier subcontracts hereunder to which the DBA is applicable a clause similar to this clause, including the sentence, imposing on all lower-tier subcontractors authorized by Chemonics a like requirement to provide overseas workmen's compensation insurance coverage and obtain DBA coverage under the UNITED STATE GOVERNMENT (USG) requirements contract.

(b)(4) UNITED STATE GOVERNMENT (USG)'s DBA insurance carrier. Contractors must apply for coverage directly to Starr Indemnity & Liability Company through its agent, Marsh McLennan Agency (MMA), using any of the following methods:

1. **Website.** There is a website with the option to print a PDF application form and submit it or complete an online application. The link to the website is:

[https://www.starr.com/Insurance/Casualty/Defense-Base-Act/UNITED STATE GOVERNMENT \(USG\)---Defense-Base-Act](https://www.starr.com/Insurance/Casualty/Defense-Base-Act/UNITED STATE GOVERNMENT (USG)---Defense-Base-Act)

2. **Email.** An application form can be emailed to: [UNITED STATE GOVERNMENT \(USG\)@marshmma.com](mailto:UNITED STATE GOVERNMENT (USG)@marshmma.com)

3. **Additional Contacts.** Contacts for Starr Indemnity & Liability Company and its agent, Marsh MMA are available for guidance and question regarding the required application form and submission requirements:

- Tyler Hlawati (Starr) tyler.hlawati@Starrcompanies.com Telephone: 646-227-6556
- Bryan Cessna (Starr) bryan.cessna@starrcompanies.com Telephone: 302-249-6780
- Mike Dower (Marsh MMA) mike.dower@marshmma.com Telephone: 703-813-6513
- Diane Proctor (Marsh MMA) diane.proctor@marshmma.com Telephone: 703-813-6506

For instructions on the required application form and submission requirements, please refer to [AAPD 22-01](#). Pursuant to AIDAR 752.228-70, medical evacuation is a separate insurance requirement for overseas performance of UNITED STATE GOVERNMENT (USG) funded subcontracts; the Defense Base Act

insurance does not provide coverage for medical evacuation. The costs of DBA insurance are allowable and reimbursable as a direct cost to this Subcontract.

Before starting work, the offeror must provide Chemonics with a copy of the DBA coverage policy that covers each of its employees.

5) Professional liability in an amount of \$1,000,000 per occurrence and \$2,000,000 in the annual aggregate along with a certificate certifying that there is no security breach or unauthorized access exclusion on this policy;

6) “All risk” Property (or at least Material) Damage policy covering any equipment, premises, buildings used in providing the services and for which the Subcontractor has a liability for maintenance and/or which is owned by the Subcontractor as well as Business Interruption risk insurance based on the following basis of valuation:

§ Buildings – Cost of rebuilding

§ Equipment – Replacement costs of the equipment or parts of it

§ Business Interruption: GP for the 12 month period

7) Comprehensive automobile liability insurance with a combined bodily injury and property damage arising out of the use of all owned, leased and in accordance with the applicable laws of [Country].

The Subcontractor’s policy and certificate shall include all Indemnitees, as additional named insured. The Subcontractor will deliver a certificate(s) of insurance evidencing the coverage specified above to Chemonics **prior to signing a Subcontract and prior to providing any Services**. Such certificate(s) will stipulate that the insurance company(ies) will provide Chemonics at least thirty (30) days’ prior written notice of any cancellation of coverage. Should the Subcontractor fail to provide the requested evidence of insurance, Chemonics shall be entitled to procure such coverage on behalf of the Subcontractor and all premium costs should be borne by the Subcontractor. All coverage will include a waiver of underwriter’s rights of subrogation against Chemonics. Subcontractor will be solely responsible for any deductible or self-insurance retentions. The stipulated limits of coverage above shall not be construed as a limitation or expansion of any potential liability to Chemonics, and failure to request evidence of this insurance shall in no way be construed as a waiver of the Subcontractor’s obligation to provide the insurance coverage specified. Such insurance afforded to Chemonics shall be primary insurance and any other valid insurance existing for Chemonics’s benefit shall be in excess of such primary insurance.

The carrying of insurance as required herein by the Subcontractor, shall in no way be interpreted as relieving the Subcontractor of its other obligations under this agreement.

Section K. Liability for Lost or Damaged Commodities

a. Liability for Lost or Damaged Commodities

1. Subcontractor shall be liable for any commodities physically lost or damaged (including loss due to expiry) attributable to the fault or negligence of the Subcontractor, its employees or its contracted third parties. The Subcontractor’s liability for losses shall be based on the following valuation method: cost of commodities, plus freight and insurance plus 10% (CIF plus 10%).

Inventory Variance: The subcontractor shall manage the stock at 100% accuracy and shall be

financially liable for all positive and negative variances, netting out the positive and the negative variances per location.

2. 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.

b. Notice of Loss or Damage

1) The Subcontractor will inspect all goods upon receipt at the facilities and report and take photos of any visible or suspicion of damage with notice of receipt, and if the Subcontractor does not report damage related to inbound shipment within five working days of the goods arrival at the facilities managed by Subcontractor, then the Subcontractor shall be liable for any such 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 facilities, until the goods are transferred to Chemonics' identified transporter and/or recipient. The Subcontractor shall transfer custody of the goods when requested to Chemonics' identified transporter and/or recipient in accordance with the procedure for pick, pack and dispatch (FOT) agreed upon by the Parties. The Subcontractor may not remove or destroy any damaged cargo without written approval from Chemonics.

2) The Subcontractor will notify Chemonics in writing of any loss or damage to the goods handled by the Subcontractor promptly after discovery of same, and in no case more than forty-eight (48) after confirmation of loss or damage. Chemonics must give the Subcontractor written notice of any claim for loss or damage within sixty (60) days after discovery.

2) The Subcontractor shall accept or reject any claim filed by Chemonics within thirty (30) days of notice of the claim. If the Subcontractor is liable under this terms of this section, then the Subcontractor will pay for the lost or damaged goods within sixty (60) days.

3) Lost Goods Later Found

If any lost goods for which payment has been made to Chemonics are found or otherwise accounted for, and are also still in useable condition, Chemonics shall reimburse the Subcontractor for the amount paid.

Section L. Indemnity

Subcontractor shall defend, indemnify and hold harmless Chemonics, subsidiaries, affiliates, successors or assigns and its respective directors, officers, shareholders and employees and Chemonics/GHSC-PSM's Customers (collectively, "**Indemnitees**") against any and all loss, injury, death, damage, liability, claim, deficiency, action, judgment, interest, award, penalty, fine, cost or expense, including reasonable attorney and professional fees and costs, and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers (collectively, "**Losses**"), whether or not involving a third party claim, arising out of or related to this Subcontract, in each case whether or not caused by the negligence of Chemonics or any other Indemnified Party and whether or not the relevant Claim has merit. Subcontractor shall not enter into any settlement without Chemonics/GHSC-PSM's or Indemnitee's prior written consent.

Subcontractor shall defend and settle at its sole expense all suits or proceedings arising out of the foregoing, provided that Subcontractor has notice or is given prompt written notice of such claim or suit. Subcontractor shall not settle, compromise or discharge any pending or threatened suit, claim or litigation, arising out of, based upon, or in any way related to the subject matter of this Subcontract and to which Chemonics is or may reasonably be expected to be a party, unless and until Subcontractor has obtained a written agreement, approved by Chemonics (which shall not be unreasonably withheld) and executed by each party to such proposed settlement, compromise or discharge, releasing Chemonics from any and all liability for which Chemonics is indemnified hereunder.

Section M. 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 UNITED STATE GOVERNMENT (USG) regulations governing this subcontract, which are incorporated by reference into this subcontract, and appear in Section FF, 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 UNITED STATE GOVERNMENT (USG) 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 N. 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 UNITED STATE GOVERNMENT (USG) 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 O. Protecting Chemonics' Interests when Subcontractor is Names on the Suspected Terrorists or Blocked Individuals Lists, Ineligible to Receive UNITED STATE GOVERNMENT (USG) 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) UNITED STATE GOVERNMENT (USG) determines that the Subcontractor is ineligible to receive UNITED STATE GOVERNMENT (USG) 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 P. 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.* Neither party shall be liable to the other for any indirect, consequential, special, incidental, or punitive damages including, without limitation, loss of revenue or profits, loss of production, loss or denial of opportunity or use, loss of market, loss of goodwill, loss of reputation, or damage to credit rating.

The Subcontractor acknowledges and agrees that it has no direct action against the U.S. Government or UNITED STATE GOVERNMENT (USG) for any claims arising under this Subcontract.

Section Q. 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 R. 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 S. Organizational and 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 T. 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 U. 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 V. Restrictions on Certain Foreign Purchase (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, and North Korea 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 W. 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 X. 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:

- (a) *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
- (b) *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 Y. 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 UNITED STATE GOVERNMENT (USG)
- 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) Should Chemonics determine nonadherence to performance standards and/or contract provisions outlined herein, the Subcontractor will be notified in writing of the actions or performance measures that need improvement. Chemonics may request a formal written plan (Corrective Action Plan) to correct the contract compliance or performance issues that have impacted the provision of quality services. Failure to submit a plan within the requested timeline will be considered nonperformance and subject to paragraph (b) above.

(e) 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 against monthly key performance indicators ("KPI"). KPIs will be used as a basis for continuous improvement efforts by the Subcontractor. Regular performance reviews will be held between the Subcontractor and Chemonics/GHSC-PSM. These reviews will be used to help determine the Subcontractor's suitability for future subcontracts and to inform performance improvement. If the Subcontractor fails to meet any KPI, the timelines for addressing the deficiency as agreed within the corrective action plan will take effect. The Subcontractor will provide the Chemonics designated GHSC-PSM project representative in the timeline requested, a proposed action plan setting forth the actions the Subcontractor will take in order to promptly comply with all KPIs. The KPIs are listed in Annex 5.

"ADD KPIs INCLUDED IN THE RFP AND ANY ADDITIONAL AS REQUIRED"

Section Z. 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 AA. 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 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 purchase 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 UEI 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 BB. 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, UNITED STATE GOVERNMENT (USG), 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 CC. 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 DD. Federal Acquisition Regulation (FAR) and Agency For International Development Acquisition Regulation (AIDAR) Flowdown Provisions For Subcontracts And Task Orders Under UNITED STATE GOVERNMENT (USG) Prime Contracts

DD.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.

DD.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.
 5. "Prime Contract" means the contract between Chemonics and the U.S. Government.
 6. "Subcontract" means any contract placed by subcontractor or lower-tier subcontractors under this Contract.

DD.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 UNITED STATE GOVERNMENT (USG) 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.

DD.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.

DD.5 Provisions Incorporated by Reference

This Subcontract includes the appropriate flow-down clauses as required by the Federal Acquisition Regulations.

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.**

Clause Number	Title	Date*	Notes and Applicability
<u>52.202-1</u>	DEFINITIONS	NOV 2013	All subcontracts regardless of value
<u>52.203-3</u>	GRATUITIES	APR 1984	All subcontracts regardless of value (Note 4 applies)
<u>52.203-5</u>	COVENANT AGAINST CONTINGENT FEES	MAY 2014	All subcontracts regardless of value (Note 1 applies)
<u>52.203-6</u>	RESTRICTIONS ON SUBCONTRACTOR SALES TO THE GOVERNMENT	SEP 2006	Cost reimbursement subcontracts and cost reimbursement task orders (Note 4 applies)
<u>52.203-7</u>	ANTI-KICKBACK PROCEDURES	MAY 2014	All subcontracts regardless of value (Note 1 applies)
<u>52.203-8</u>	CANCELLATION, RECISSION, AND RECOVERY OF FUNDS FOR ILLEGAL OR IMPROPER ACTIVITY	MAY 2014	All subcontracts equal to or greater than the simplified acquisition threshold (Note 1 applies)
<u>52.203-10</u>	PRICE OR FEE ADJUSTMENT FOR ILLEGAL OR IMPROPER ACTIVITY	MAY 2014	All subcontracts equal to or greater than the simplified acquisition threshold (Note 1 applies)
<u>52.203-11</u>	CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	SEP 2007	All subcontracts equal to or greater than \$150,000 (Note 2 applies)
<u>52.203-12</u>	LIMITATIONS ON PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	OCT 2010	All subcontracts equal to or greater than \$150,000 (Note 2 applies)
<u>52.203-13</u>	CONTRACTOR CODE OF BUSINESS ETHICS AND CONDUCT	OCT 2015	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, with a copy to the Contracting officer.
<u>52.203-14</u>	DISPLAY OF HOTLINE POSTER(S)	OCT	All subcontracts that have a value in excess of

Clause Number	Title	Date*	Notes and Applicability
		2015	\$5.5 million except those performed entirely outside of the U.S. (Note 8 applies)
<u>52.203-17</u>	CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENTS TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS	APR 2014	All Subcontracts equal to or greater than the simplified acquisition threshold
<u>52.203-19</u>	PROHIBITION ON REQUIRING CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS OR STATEMENTS	JAN 2017	Applies to all Subcontracts regardless of value or type
<u>52.204-06</u>	Unique Entity Identifier	OCT 2016	All Subcontracts equal to or greater than \$30,000
<u>52.204-10</u>	REPORTING EXECUTIVE COMPENSATION AND FIRST TIER SUBCONTRACT AWARDS (Subparagraph (d)(2) does not apply.)	OCT 2018	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.
<u>52.204-23</u>	PROHIBITION ON CONTRACTING FOR HARDWARE, SOFTWARE AND SERVICES DEVELOPED BY KASPERSKY LAB AND OTHER COVERED ENTITIES	JUL 2018	Applies to all subcontracts, regardless of value or type. "Contractor" and "Contractor Employee" refer to "Subcontractor" and "Subcontractor Employee."
<u>52.204-25</u>	PROHIBITION ON CONTRACTING FOR CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT	AUG 2020	All subcontracts regardless of value (Note 1 applies)
<u>52.204-27</u>	PROHIBITION ON A BYTEDANCE COVERED APPLICATION	JUNE 2023	All subcontracts regardless of value (Note 1 applies)
<u>52.204-30</u>	FEDERAL ACQUISITION SUPPLY CHAIN SECURITY ACT ORDERS – PROHIBITION	DEC 2023	All subcontracts regardless of value (Note 1 applies)
<u>52.209-2</u>	PROHIBITION ON CONTRACTING WITH INVERTED DOMESTIC CORPORATIONS - REPRESENTATION	NOV 2015	All subcontracts regardless of value (Note 1 applies)
<u>52.209-6</u>	PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT	AUG 2013	All Subcontracts > \$35,000. (Note 2 applies)
<u>52.209-10</u>	PROHIBITION ON CONTRACTING WITH INVERTED DOMESTIC CORPORATIONS	DEC 2014	All subcontracts regardless of value (Note 1 applies)
<u>52.215-2</u>	AUDITS AND RECORDS - NEGOTIATION	OCT 2010	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.)
<u>52.215-10</u>	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.	AUG 2011	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 "Chemomics" in paragraph (d)(1).)
<u>52.215-11</u>	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.	AUG 2011	Applies if submission of certified cost or pricing data is required for modifications. (Notes 1, 2 and 4 apply.)
<u>52.215-12</u>	SUBCONTRACTOR CERTIFIED COST OR PRICING DATA	OCT 2010	Applies if Subcontract > \$750,000 and is not otherwise exempt under FAR 15.403.
<u>52.215-13</u>	SUBCONTRACTOR CERTIFIED COST OR PRICING DATA—MODIFICATIONS	OCT 2010	Applies if Subcontract > \$750,000 and is not otherwise exempt under FAR 15.403.

Clause Number	Title	Date*	Notes and Applicability
<u>52.215-14</u>	INTEGRITY OF UNIT PRICES	OCT 2010	Applies if Subcontract is above the simplified acquisition threshold. Delete paragraph (b) of the clause.
<u>52.215-15</u>	PENSION ADJUSTMENTS AND ASSET REVERSIONS	OCT 2010	Applies if Subcontract meets the applicability requirements of FAR 15.408(g). (Note 5 applies.)
<u>52.215-16</u>	FACILITIES CAPITAL COST OF MONEY	JUN 2003	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.
<u>52.215-17</u>	WAIVER OF FACILITIES CAPITAL COST OF MONEY	OCT 1997	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.
<u>52.215-18</u>	REVERSION OR ADJUSTMENT OF PLANS FOR POST-RETIREMENT BENEFITS (PRB) OTHER THAN PENSIONS	JUL 2005	Applicable if this Subcontract meets the applicability requirements of FAR 15.408(j). (Note 5 applies.)
<u>52.215-19</u>	NOTIFICATION OF OWNERSHIP CHANGES	OCT 1997	Applies if this Subcontract meets the applicability requirements of FAR 15.408(k). (Note 5 applies.)
<u>52.215-20</u>	REQUIREMENTS FOR CERTIFIED COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA.	OCT 2010	(Note 2 applies.)
<u>52.215-21</u>	REQUIREMENTS FOR CERTIFIED COST OR PRICING DATA OR INFORMATION OTHER THAN CERTIFIED COST OR PRICING DATA - MODIFICATIONS	OCT 2010	(Note 2 applies)
<u>52.215-23</u>	LIMITATION ON PASS-THROUGH CHARGES	OCT 2009	Applies for cost-reimbursement subcontracts which exceed the simplified acquisition threshold. (Notes 1, 2 and 4 apply.)
<u>52.216-7</u>	ALLOWABLE COST AND PAYMENT Alt II applies to educational institutions. Alt IV applies to non-profit organizations.	AUG 2018	Applies to Cost Reimbursement Subcontracts, and to the materials portion of Time & Materials (T&M) Subcontracts, and Sub-task Orders. (Note 1 applies except in paragraphs (a)(3) and (b)(1)(ii)(F) where note 3 applies. Note 2 applies except in paragraph (g) where note 7 applies. The blank in paragraph (a)(3) is completed with "the 30th" unless otherwise specified in this Subcontract. Paragraphs (a)(2), (b)(4), and (d)(4) are deleted. In paragraph (h) "six years" is changed to "5 years." The references to government entities in paragraph (d) are unchanged.)
<u>52.216-8</u>	FIXED FEE	JUN 2011	Applies only if this Subcontract includes a fixed fee. Delete the last two sentences of the clause. Does not apply if this is a T&M Subcontract or Task Order. (Notes 1 and 2 apply.)
<u>52.216-10</u>	INCENTIVE FEE	JUN 2011	Applies only if this Subcontract includes an incentive fee. Does not apply if this is a T&M Subcontract or Task Order. (Notes 1 and 2 apply, except in paragraphs (e)(4)(v) and (e)(4)(vi) where "Government" is unchanged. Subparagraph (e)(4)(iv) and the last two sentences of paragraph (c)(2) are deleted. The amounts in paragraph (e) are set forth in the Subcontract.)
<u>52.216-11</u>	COST CONTRACT - NO FEE	APR 1984	Applies only to Cost Reimbursement-No Fee Subcontracts. Does not apply if this is a T&M

Clause Number	Title	Date*	Notes and Applicability
			Subcontract or Task Order. (Notes 1 and 2 apply.)
<u>52.216-18</u>	ORDERING	OCT 1995	Applies to Indefinite Quantity Subcontracts (IQS) Or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.
<u>52.216-19</u>	ORDER LIMITATIONS	OCT 1995	Applies to Indefinite Quantity Subcontracts (IQS) Or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.
<u>52.216-22</u>	INDEFINITE QUANTITY	OCT 1995	Applies to Indefinite Quantity Subcontracts (IQS) Or Indefinite Delivery Indefinite Quantity (IDIQ) Subcontracts only.
<u>52.217-8</u>	OPTION TO EXTEND SERVICES	NOV 1999	Insert "30 days" as <i>the period of time within which Chemonics may exercise the option.</i> (Notes 1 and 2 apply.)
<u>52.217-9</u>	OPTION TO EXTEND THE TERM OF THE CONTRACT	MAR 2000	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.)
<u>52.219-8</u>	UTILIZATION OF SMALL BUSINESS CONCERNS	OCT 2018	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.)
<u>52.219-9</u>	SMALL BUSINESS SUBCONTRACTING PLAN (If a subcontracting plan was required by the RFP, the plan is incorporated herein by reference.)	AUG 2018	Applies if this Subcontract > \$700,000 and if the Subcontract offers lower-tier subcontracting opportunities. The clause <i>does not</i> apply at any value if the Subcontractor is U.S. small business concern. Note 2 is applicable to paragraph (c) only. (Note 8 applies.)
<u>52.222-2</u>	PAYMENT FOR OVERTIME PREMIUMS	JUL 1990	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.)
<u>52.222-3</u>	CONVICT LABOR	JUN 2003	Applies to all Subcontracts >\$3,000 involving some or all performance in the U.S.
<u>52.222-21</u>	PROHIBITION OF SEGREGATED FACILITIES	APR 2015	(Note 8 applies.) Does not apply to work performed outside the United States by Subcontractor employees who were not recruited within the United States.
<u>52.222-22</u>	PREVIOUS CONTRACTS AND COMPLIANCE REPORT	FEB 1999	Applies if clause 52.222-26 applies.
<u>52.222-26</u>	EQUAL OPPORTUNITY	SEP 2016	Does not apply to work performed outside the United States by Subcontractor employees who were not recruited within the United States.
<u>52.222-29</u>	NOTIFICATION OF VISA DENIAL	APR 2015	Applies to all Subcontracts regardless of type or value.
<u>52.222-35</u>	EQUAL OPPORTUNITY FOR VETERANS	SEP 2010	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.
<u>52.222-36</u>	EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES	JUL 2014	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. (Note 8 applies.)

Clause Number	Title	Date*	Notes and Applicability
<u>52.222-37</u>	EMPLOYMENT REPORTS ON VETERANS	FEB 2016	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 employees recruited outside the United States
<u>52.222-40</u>	NOTIFICATION OF EMPLOYEE RIGHTS UNDER THE NATIONAL LABOR RELATIONS ACT	DEC 2010	Applies to Subcontracts 000above the simplified acquisition threshold. <i>Does not</i> apply to Subcontracts performed <i>entirely</i> outside the U.S. <i>Does not</i> 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;
<u>52.222-50</u>	COMBATING TRAFFICKING IN PERSONS (Alternate 1 applies when work is performed outside the U.S. and it is included in the Prime Contract)	OCT 2020	Applies to all Subcontracts, regardless of type, value. (Note 2 applies starting in paragraph c. In paragraph (h) Note 1 applies.)
<u>52.222-54</u>	EMPLOYMENT ELIGIBILITY VERIFICATION	OCT 2015	Applies to Subcontracts which exceed the simplified acquisition threshold <i>except for</i> 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 < 120 days.
<u>52.223-6</u>	DRUG-FREE WORKPLACE	MAY 2001	Applies to all Subcontracts regardless of value or type. (Notes 2 and 4 apply)
<u>52.223-18</u>	ENCOURAGING CONTRACTOR POLICIES TO BAN TEXT MESSAGING WHILE DRIVING	AUG 2011	Applies to all subcontracts regardless of value.
<u>52.225-1</u>	BUY AMERICAN ACT -- SUPPLIES	MAY 2014	Applies if the Statement of Work contains other than domestic components. (Note 2 applies.)
<u>52.225-13</u>	RESTRICTIONS ON CERTAIN FOREIGN PURCHASES	JUN 2008	Applies to all Subcontracts regardless of value or type
<u>52.225-14</u>	INCONSISTENCY BETWEEN ENGLISH VERSION AND TRANSLATION OF CONTRACT	FEB 2000	Applies to all Subcontracts regardless of value or type
<u>52.227-1</u>	AUTHORIZATION AND CONSENT	DEC 2007	Applies if the Subcontract is above the simplified acquisition threshold. (Notes 4 and 7 apply.)
<u>52.227-2</u>	NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT	DEC 2007	Applies if this Subcontract is above the simplified acquisition threshold. (Notes 2 and 4 apply.)
<u>52.227-9</u>	REFUND OF ROYALTIES	APR 1984	Applies if this Subcontract includes royalties
<u>52.227-14</u>	RIGHTS IN DATA - GENERAL	MAY 2014	Applies to all subcontracts regardless of type or value. Delete paragraph (d) which is replaced by AIDAR 752.227-14.
<u>52.228-3</u>	WORKER'S COMPENSATION INSURANCE (DEFENSE BASE ACT)	JUL 2014	Applies to all Subcontracts, regardless of type or value. See also AIDAR 752.228-3.
<u>52.228-4</u>	WORKER'S COMPENSATION AND WAR-HAZARD INSURANCE OVERSEAS	APR 1984	Applies to all Subcontracts, regardless of type or value, only if the Prime Contracts includes this clause.
<u>52.228-7</u>	INSURANCE—LIABILITY TO THIRD PERSONS	MAR 1996	Applicable to Cost Reimbursement Subcontracts and Task Orders of any value. (Notes 4 and 7 apply)

Clause Number	Title	Date*	Notes and Applicability
<u>52.228-9</u>	CARGO INSURANCE	MAY 1999	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)
<u>52.229-6</u>	TAXES – FOREIGN FIXED PRICE CONTRACTS	FEB 2013	Applies to Fixed Price Subcontracts of any value.
<u>52.229-8</u>	TAXES—FOREIGN COST-REIMBURSEMENT CONTRACTS	MAR 1990	Applicable to Cost Reimbursement and T&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.
<u>52.230-2</u>	COST ACCOUNTING STANDARDS	OCT 2015	Applies only when referenced in this Subcontract that full CAS coverage applies. "United States" means "United States or Chemonics." Delete paragraph (b) of the clause.
<u>52.230-3</u>	DISCLOSURE AND CONSISTENCY OF COST ACCOUNTING PRACTICES	OCT 2015	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.
<u>52.230-4</u>	DISCLOSURE AND CONSISTENCY OF COST ACCOUNTING PRACTICES FOR CONTRACTS AWARDED TO FOREIGN CONCERNS	MAY 2012	Applies only when referenced in this Subcontract, modified CAS coverage applies. Note 3 applies in the second and third sentences.
<u>52.230-5</u>	COST ACCOUNTING STANDARDS -- EDUCATIONAL INSTITUTIONS	AUG 2016	"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.
<u>52.230-6</u>	ADMINISTRATION OF COST ACCOUNTING STANDARDS	JUN 2010	Applies if FAR 52.230-2, FAR 52.230-3, FAR 52.230-4 or FAR 52.230-5 applies.
<u>52.232-20</u>	LIMITATION OF COST	APR 1984	Applies if this Subcontract is a fully funded Cost Reimbursement or T&M Subcontract or Task Order. (Notes 1 and 2 apply.)
<u>52.232-22</u>	LIMITATION OF FUNDS	APR 1984	Applies if this Subcontract is an incrementally funded Cost Reimbursement or T&M Subcontract or Task Order. (Notes 1 and 2 apply.)
<u>52.232-40</u>	PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS	DEC 2013	Applies if the Subcontractor is a U.S. small business and Chemonics receives accelerated payments under the prime contract. (Note 1 applies.)
<u>52.233-3</u>	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 called for by this Subcontract.	AUG 1996	"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".
<u>52.237-8</u>	RESTRICTION ON SEVERANCE PAYMENTS TO FOREIGN NATIONALS	AUG 2003	Applies to Subcontracts--regardless of type and value--that include provision of host country national personnel.
<u>52.237-9</u>	INSTRUCTIONS: INCLUDE THIS ONLY IF IT APPEARS IN THE PRIME CONTRACT.	MAY 2014	Applies to Subcontracts—regardless of type and value--that include provision of host country national personnel ONLY if the Prime Contracts

Clause Number	Title	Date*	Notes and Applicability
	WAIVER OF LIMITATION ON SEVERANCE PAYMENTS TO FOREIGN NATIONALS		includes this clause.
<u>52.242-1</u>	NOTICE OF INTENT TO DISALLOW COSTS	APR 1984	Applies to Cost Reimbursement and T&M Subcontracts and Task Orders of any value.
<u>52.242-3</u>	PENALTIES FOR UNALLOWABLE COSTS	MAY 2014	Applies to all subcontracts > \$700,000, regardless of subcontract type.
<u>52.242-4</u>	CERTIFICATION OF FINAL INDIRECT COSTS	JAN 1997	Applies to Cost Reimbursement and T&M Subcontracts and Task Orders that provide for reimbursement of Subcontractor indirect cost rates, regardless of subcontract value.
<u>52.242-13</u>	BANKRUPTCY	JUL 1995	Notes 1 and 2 apply.
<u>52.242-15</u>	STOP-WORK ORDER Alternate I (APR 1984) applies if this is a cost-reimbursement Subcontract.	AUG 1989	Notes 1 and 2 apply.
<u>52.243-1</u>	CHANGES-FIXED PRICE (Alt III)	AUG 1987	Applies to Fixed Price Subcontracts of any value.
<u>52.243-2</u>	CHANGES - COST REIMBURSEMENT	AUG 1987	Notes 1 and 2 apply. Applies if this is a Cost Reimbursement Subcontract or Task Order.
<u>52.243-3</u>	CHANGES - TIME-AND-MATERIALS OR LABOR-HOUR	SEP 2000	Notes 1 and 2 apply. Applies if this is a T&M Subcontract or Task Order.
<u>52.244-6</u>	SUBCONTRACTS FOR COMMERCIAL ITEMS	JAN 2019	Applies to Subcontracts for commercial items only.
<u>52.245-1</u>	GOVERNMENT PROPERTY (APR 2012) (ALT I)	JAN 2017	"Contracting Officer" means "Chemonics" 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. "Government" is unchanged in the phrases "Government property" and "Government furnished property" and where elsewhere used except in paragraph (d)(1) where it means "Chemonics" and except in paragraphs (d)(2) and (g) where the term includes Chemonics.
<u>52.246-3</u>	INSPECTION OF SUPPLIES - COST REIMBURSEMENT Applies to Cost Reimbursement Subcontracts and Task Orders.	MAY 2001	Note 1 applies, except in paragraphs (b), (c), and (d) where Note 3 applies, and in paragraph (k) where the term is unchanged. In paragraph (e), change "60 days" to "120 days", and in paragraph (f) change "6 months" to "12 months"
<u>52.246-4</u>	INSPECTION OF SERVICES – FIXED PRICE	AUG 1996	Applies to Fixed Priced Subcontracts of any value.
<u>52.246-5</u>	INSPECTION OF SERVICES—COST REIMBURSEMENT	MAY 2001	Applies to Cost Reimbursement Subcontracts of any value. (Note 3 applies in paragraphs (b) and (c). Note 1 applies in paragraphs (d) and (e).)
<u>52.246-6</u>	INSPECTION—TIME-AND-MATERIAL AND LABOR-HOUR	MAY 2001	Applies to T&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.)
<u>52.246-25</u>	LIMITATION OF LIABILITY - SERVICES	FEB 1997	Applies to Subcontracts at or below the simplified acquisition threshold or more.
<u>52.247-63</u>	PREFERENCE FOR U.S.-FLAG AIR CARRIERS	JUN 2003	Applies to all Subcontracts that include international air travel.

Clause Number	Title	Date*	Notes and Applicability
<u>52.247-64</u>	PREFERENCE FOR PRIVATELY OWNED U.S. FLAG COMMERCIAL VESSELS	FEB 2006	Applies for Subcontracts that include provision of freight services.
<u>52.247-67</u>	SUBMISSION OF TRANSPORTATION DOCUMENTS FOR AUDIT	FEB 2006	Applies to Subcontracts that include provision of freight services.
<u>52.249-1</u>	TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED-PRICE) (SHORT FORM)	APR 1984	Applies to all Fixed Price Subcontracts.
<u>52.249-6</u>	TERMINATION (COST-REIMBURSEMENT) Alternate IV (SEP 1996) applies if this is a time and materials Subcontract.)	MAY 2004	Notes 1 and 2 apply. Substitute "90 days" for "120 days" and "90-day" for "120-day" in paragraph (d). Substitute "180 days" for "1 year" in paragraph (f). In paragraph (j) "right of appeal", "timely appeal" and "on an appeal" shall mean the right to proceed under the "Disputes" clause of this Contract. Settlements and payments under this clause may be subject to the approval of the Contracting Officer.
<u>52.249-8</u>	DEFAULT FIXED PRICE SUPPLY & SERVICE	APR 1984	Applies to all Fixed Price Subcontracts.
<u>52.249-14</u>	EXCUSABLE DELAYS	APR 1984	(Note 2 applies; Note 1 applies to (c). In (a)(2) delete "or contractual".)

The following Agency For International Development Acquisition Regulations (AIDAR) clauses apply to this Contract:

Clause Number	Title	Date*	Notes and Applicability
752.202-1	DEFINITIONS (ALT 70 AND ALT 72)	JAN 1990	Applies to all Subcontracts, regardless of value or type. "Contractor" and "Contractor Employee" refer to "Subcontractor" and "Subcontractor Employee".
752.211-70	LANGUAGE AND MEASUREMENT	JUN 1992	Applies to all Subcontracts, regardless of type or value
752.225-70	SOURCE AND NATIONALITY REQUIREMENTS	FEB 2012	Applies to all Subcontracts, regardless of type or value. (Notes 4, 5 and 7 apply)
752.227-14	RIGHTS IN DATA – GENERAL	OCT 2007	Applies to all Subcontracts regardless of type or value. This clause replaces paragraph (d) of FAR 52.227-14 Rights in Data—General.
752.228-3	WORKER'S COMPENSATION INSURANCE (DEFENSE BASE ACT)	DEC 1991	The supplemental coverage described in this clause is required in addition to the coverage specified in FAR 52.228-3.
752.228-7	INSURANCE – LIABILITY TO THIRD PERSONS	JULY 1997	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)
752.228-9	CARGO INSURANCE	DEC 1998	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.

Clause Number	Title	Date*	Notes and Applicability
752.228-70	MEDICAL EVACUATION (MEDEVAC) SERVICES	JUL 2007	Applies to all Subcontracts requiring performance outside the U.S.
752.231-71	SALARY SUPPLEMENTS FOR HG EMPLOYEES (THE SUBCONTRACTOR SHALL FLOW DOWN THIS CLAUSE TO LOWER-TIER SUBCONTRACTS, IF LOWER-TIER SUBCONTRACTING IS AUTHORIZED.)	MAR 2015	Applies to all Subcontracts, regardless of value or type, with a possible need for services of a Host Government employee. (Note 5 applies)
752.245-71	TITLE TO AND CARE OF PROPERTY	APR 1984	Applies to Subcontracts where the Subcontractor is authorized by Chemonics to purchase property under the Subcontract for use outside the U.S. (Note 5 applies)
752.247-70	PREFERENCE FOR PRIVATELY OWNED U.S.-FLAG COMMERCIAL VESSELS	OCT 1996	(Note 5 applies)
752.7001	BIOGRAPHICAL DATA	JUL 1997	Applies to all Cost Reimbursement Subcontracts and Task Orders, and T&M Subcontracts and Task Orders utilizing a multiplier, regardless of value. (Note 3 applies)
752.7002	TRAVEL AND TRANSPORTATION	JAN 1990	Applies to all Cost Reimbursement and T&M Subcontracts and Task Orders performed in whole or in part outside the U.S., regardless of value. (Note 5 applies)
752.7004	EMERGENCY LOCATOR INFORMATION	JUL 1997	Applies to all Subcontracts performed in whole or in part outside the U.S., regardless of value. (Note 5 applies)
752.7005	SUBMISSION REQUIREMENTS FOR DEVELOPMENT EXPERIENCE DOCUMENTS	SEP 2013	Applies to all Subcontracts. (Note 5 applies)
752.7007	PERSONNEL COMPENSATION	JUL 2007	Applies to all Cost Reimbursement Subcontracts and Task Orders and T&M Subcontracts and Task Orders with a multiplier, regardless of value.
752.7008	USE OF GOVERNMENT FACILITIES OR PERSONNEL	APR 1984	Applies to all Subcontracts regardless of value or type. (Note 5 applies)
752.7009	MARKING	JAN 1993	Applies to all Subcontracts. (Note 5 applies)
752.7010	CONVERSION OF U.S. DOLLARS TO LOCAL CURRENCY	APR 1984	Applies to all Subcontracts, regardless of value or type, involving performance outside the U.S. (Note 5 applies)
752.7011	ORIENTATION AND LANGUAGE TRAINING	APR 1984	Applies to Cost Reimbursement Subcontracts and Task Orders, regardless of value, involving performance outside the U.S. (Note 5 applies)
752.7012	PROTECTION OF THE INDIVIDUAL AS A RESEARCH SUBJECT	AUG 1995	Applies to any Subcontract, regardless of value or type, which involves research using human subjects. (Note 5 applies)
752.7013	CONTRACTOR-MISSION RELATIONSHIPS	JUN 2018	Applies to all subcontracts, regardless of value or type. "Contractor" and "Contractor Employee" refer to "Subcontractor" and "Subcontractor Employee."
752.7014	NOTICE OF CHANGES IN TRAVEL REGULATIONS	JAN 1990	Applies to Cost Reimbursement and T&M Subcontracts of any value involving work outside the U.S. (Note 2 applies)
752.7025	APPROVALS	APR 1984	Applies to all Subcontracts. (Note 5 applies)

Clause Number	Title	Date*	Notes and Applicability
752.7027	PERSONNEL	DEC 1990	Applies to all Cost Reimbursement and T&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&M contracts. (Note 5 applies)
752.7028	DIFFERENTIALS AND ALLOWANCES APPLIES TO ALL COST REIMBURSEMENT AND T&M SUBCONTRACTS OF ANY VALUE INVOLVING WORK PERFORMED IN WHOLE OR IN PART OVERSEAS.	JUL 1996	This clause does not apply to TCN and CCN employees. TCN and CCN employees are not eligible for differentials and allowances, unless specifically authorized by the cognizant Assistant Administrator or Mission Director. A copy of such authorization shall be retained and made available as part of the contractor's records which are required to be preserved and made available by the "Examination of Records by the Comptroller General" and "Audit" clauses of this contract.) (Note 5 applies)
752.7029	POST PRIVILEGES	JUL 1993	For use in all non-commercial subcontracts involving performance overseas.
752.7031	LEAVE AND HOLIDAYS	OCT 1989	For use in all cost-reimbursement and T&M subcontracts for technical or professional services. (Note 5 applies)
752.7032	INTERNATIONAL TRAVEL APPROVAL AND NOTIFICATION REQUIREMENTS	APR 2014	Applies to all subcontracts requiring international travel. (Note 5 applies)
752.7033	PHYSICAL FITNESS (JULY 1997)	JUL 1997, PARTI ALLY REVIS ED AUG 2014	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)
752.7034	ACKNOWLEDGMENT AND DISCLAIMER	DEC 1991	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)
752.7101	VOLUNTARY POPULATION PLANNING ACTIVITIES	JUN 2008	If a subcontract with family planning activities is contemplated, add "Alternate 1 (6/2008)" to the clause name.

Section EE. Sub-Task Order Template

The following template (Sections A.1 through A.8) shall be used to order warehousing services and related deliverables under the IQS. Chemonics reserves the right to modify this template as needed to accommodate pricing and other considerations as may be needed.

1. Issued by:	2. Issued to:
Chemonics International Inc. (Insert Chemonics' address) (Insert City, State Zip code)	[Insert Name of Subcontractor]
3. Indefinite Quantity Subcontract (IQS) Number:	[Insert IQS No.]
4. Sub-Task Order Number:	[Insert Sub-TO No]
5. Prime Contract and Task Order Number:	[Insert Prime TO No.]
6. Sub-Task Order Contents	
A.1 BACKGROUND A.2 STATEMENT OF WORK A.3 DELIVERABLES AND DELIVERABLES SCHEDULE A.4 TECHNICAL DIRECTIONS A.5 TERM OF PERFORMANCE A.6 CONTRACT TYPE A.7 FIRM FIXED PRICES A.8 ADDITIONAL CLAUSES	
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 subcontract shall be subject to and governed by the following documents: (a) the Subcontract referenced in Block 3 above; (b) this Sub-Task Order; and (c) such provisions and specifications as are attached or incorporated by reference herein.	
Name:	Name:
Title:	Title:
[Insert name of Subcontractor]	Chemonics International Inc.
By (signature)	By (signature)
Date:	Date:

[Instructions: When the STO below is released in an RFP, the “instructions” under Sections A.1 through A.8 should be removed and replaced with “TBD” because this STO is for public consumption – i.e. it is not necessary for offerors to see our instructions (to ourselves).

A.1 BACKGROUND

(Insert background/contextual information on the project making sure to tailor information to what the sub needs to know to perform work. This section should describe the overarching goals of the prime contract and/or component or program)

A.2 STATEMENT OF WORK

(Insert statement of work for the Subcontractor specifically, and show how the subcontractor's work ties back to the prime contract's objectives)

A.3 DELIVERABLES AND DELIVERABLES SCHEDULE

a) The Subcontractor shall deliver to Chemonics the following deliverables, in accordance with the schedule set forth below. Deliverables shall be submitted electronically and in hard copy to the individual specified in Section A.4 and shall insert any language, page, or formatting requirements if applicable.

Deliverable No. 1: Deliverable Name **TBD**

(Complete description of deliverable No. 1. Focus on the end state, result, report, or product the Subcontractor must achieve in order to be paid, but do not describe processes for achieving it. This description must be complete. Chemonics cannot withhold payment based upon a requirement that is not specified here.)

Deliverable No. 2: Deliverable Name **TBD**

(Complete description of deliverable No. 1. Focus on the end state, result, report, or product the Subcontractor must achieve in order to be paid, but do not describe processes for achieving it. This description must be complete. Chemonics cannot withhold payment based upon a requirement that is not specified here.)

b) Deliverables Schedule

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

<u>Deliverable No.*</u>	<u>Deliverable Name*</u>	<u>Due Date</u>
1	TBD	TBD
2	TBD	TBD

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

Chemonics reserves the unilateral right to terminate this fixed price sub-task order 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).

Chemonics may order changes in the scope of work above pursuant to the Federal Acquisition Regulation (FAR) Clause 52.243-1, Changes—Fixed Price.

A.4 TECHNICAL DIRECTIONS

The Subcontractor shall render the services and produce the deliverables stipulated in Sections A.2 and A.3, above, under the general technical direction of the (specify name and title -- usually COP or other project technical leader), or his/her designee. The (specify name and title -- usually COP or other project technical leader), or his/her designee will be responsible for monitoring the Subcontractor's performance under this fixed price sub-task order. The Subcontractor shall not communicate directly with UNITED STATE GOVERNMENT (USG) during the performance of this fixed price sub-task order.

A.5 TERM OF PERFORMANCE

- a) The period of performance for this sub-task order is from (insert start date) to (insert end date). The Subcontractor shall deliver the deliverables set forth in Section A.3 in accordance with the Statement of Work in Section A.2 to the (designate receiving person) in accordance with the schedule stipulated therein.
- b) In the event that the Subcontractor fails to make progress so as to endanger performance of this fixed price sub-task order, or is unable to fulfill the terms of this fixed price sub-task order by the approved completion date, the Subcontractor shall notify Chemonics forthwith and Chemonics shall have the right to summary termination of this fixed price sub-task order upon written notice to the Subcontractor in accordance with the incorporated FAR Clause 52.249-8, Default (Fixed-Price Supply and Service)

A.6 CONTRACT TYPE

This is a firm fixed price (FFP) type sub-task order.

A.7 FIRM FIXED PRICE

- a) As consideration for the delivery of all of the products and/or services stipulated in Section A.2 and A. 3, Chemonics will pay the Subcontractor a total of [Insert STO total price. If the governing IQS is denominated in local currency, be sure to use local currency here as well]. This figure represents the total price of this sub-task order and is fixed for the period of performance outlined in Section A.5, Period of Performance. (Include the following language only if Chemonics will make more than one payment.) Chemonics will pay the total price through a series of installment payments. Chemonics will pay the total price of each deliverable upon the Subcontractor's successful completion and delivery of each deliverable. Chemonics will make each payment subject to Section A.7(c), below, after Subcontractor's completion of the corresponding deliverable indicated in the following table:

Installment Number and Amount	Corresponding Deliverable Number(s) and Name(s)*
1. \$XX,XXX	1. (Deliverable No. 1 Name)
2. \$YY,YYY	2. (Deliverable No. 1 Name)

*Deliverable Line items above refer to those fully described in Section A.3 a. and b., above.

- b) Upon [Insert name of responsible person on your project who is tasked with inspecting and accepting the subcontractor’s deliverables] acceptance of the contract deliverables described in Section A.2 Statement of Work, and A.3 Deliverables and Deliverables Schedule, the Subcontractor shall submit an original invoice to Global Health Supply Chain Program—Procurement and Supply Management project for payment. The invoice shall be sent to the attention of [Insert name and title of person who will receive invoices] and shall include the following information: a) subcontract number, b) deliverables delivered and accepted, c) total amount due, per Section A.7(a) above; and d) payment information corresponding to the authorized account listed in A.7(c), below. Payment will be made according to the terms described in the ordering Subcontract.
- c) Chemonics shall remit payment according to the term specified in the ordering Subcontract and corresponding to approved, complete invoices payable to the Subcontractor via check sent to the Subcontractor’s official address or to the following authorized account:
1. Account name: (INSERT Account name provided by the Subcontractor)
 2. Bank name: (INSERT Subcontractor's bank name)
 3. Bank address or branch location: (INSERT Subcontractor's bank address or branch location)
 4. Account number: (INSERT Subcontractor's bank account SWIFT and IBAN reference as applicable)

A.8 ADDITIONAL CLAUSES

Section FF. Federal Funding Accountability and Transparency Act (FFATA) Subaward Reporting Questionnaire and Certification For Subcontracts and Orders Under Indefinite Delivery/Indefinite Quantity Subcontracts

- Subcontractor Name:**
Subcontract or Sub-Task Order Number:
Subcontract or Sub-Task Order Start Date:
Subcontract or Sub-Task Order 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.

(i) **Subcontractor UEI Number:**

(ii) In your business or organization's preceding completed fiscal year, did your business or organization (the legal entity to which the UEI 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

(iii) Does the public have access to information about the compensation of the executives in your business or organization (the legal entity to which the UEI 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

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

Yes No

(v) 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.

1. Name: _____
Amount: _____
2. Name: _____
Amount: _____
3. Name: _____
Amount: _____
4. Name: _____
Amount: _____
5. Name: _____
Amount: _____

The information provided above is true and accurate as of the date of execution of the referenced Subcontract or Purchase 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

Section GG. 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 2

Guidance for Loading of a Truck

Distribution space

<https://us001.blueworkslive.com/scr/processes/20000559d2966fd>

Last modified on Jun 23, 2016 5:15 PM

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 5

Key Performance Indicators

Please work with HSS to finalize the core list of KPIs. If you need to add additional KPIs beyond mandatory KPIs please refer to the KPI guide linked [here](#).

Financial and KPI Liability Summary	Party Responsible
Stock accuracy: The subcontractor shall be liable for 100% financial responsibility	Subcontractor to financially reimburse the project (subcontractor is responsible for positive and negative variances, netting out the positive and the negative variances per location)
Product loss due to theft, damage, or expiry	Chemonics to measure percentage of products damaged, stolen, or expired while in the Subcontractor's custody when compared to system records and physical count and good inventory management/warehousing practices.