



# Task Order 3 Annual Report Appendix D: Quality Assurance SOPs



PRESIDENT'S MALARIA INITIATIVE



**NOVEMBER 2007**

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<b>TITLE:</b> SOP Index for Task Order 3- Malaria Quality Assurance		<b>DOCUMENT No.:</b> SOP Index
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> Updated as needed	Last updated 10/18/07

## Long Lasting Insecticide Treated Nets (LLINs)- Series TO3-QA-LLINs

Document	Revision Number	Status	Title	Responsible for developing SOP
TO3-QA-LLINs-01	01	Approved - 10/9/07	<a href="#">Quality Assurance Activities with QA Costs/Risks</a>	FHI
TO3-QA-LLINs-02	01	Approved - 10/9/07	<a href="#">Pre-qualification of LLIN Suppliers</a>	JSI/CA/FHI
TO3-QA-LLINs-03	01	Approved - 10/9/07	<a href="#">Sampling, Inspection and Testing of LLINs</a>	JSI/CA/FHI
TO3-QA-LLINs-04	00	Approved - 8/8/07	<a href="#">Conducting Audits of LLIN Suppliers</a>	FHI
TO3-QA-LLINs-05	00	Approved - 8/9/07	<a href="#">Conducting Laboratory Audits for LLINs</a>	FHI
TO3-QA-LLINs-06	00	Approved - 8/9/07	<a href="#">Supplier Report Card for LLINs</a>	FHI
TO3-QA-LLINs-07	00	Approved - 8/9/07	<a href="#">Evaluating LLINs In-Country</a>	FHI

## Rapid Diagnostic Test Kits (RDTs) –Series TO3-QA-RDTs

Document	Revision Number	Status	Title	Responsible for developing SOP
TO3-QA-RDTs-20	01	Approved 10/18/07	<a href="#">Quality Assurance Activities with QA Costs/Risks</a>	FHI
TO3-QA-RDTs-21	00	Approved - 9/10/07	<a href="#">Pre-qualification of RDT Suppliers</a>	JSI/CA/FHI/WHO
TO3-QA-RDTs-22	00	Approved - 9/10/07	<a href="#">Sampling, Inspection, Testing of RDTs-Pre-shipment</a>	JSI/CA/FHI/WHO
TO3-QA-RDTs-23	01	Approved - 9/25/07	<a href="#">Sampling, Inspection, Testing of RDTs-Post-shipment</a>	JSI/CA/FHI/WHO
TO3-QA-RDTs-24	00	Approved - 9/10/07	<a href="#">Conducting Audits of RDT Suppliers</a>	FHI
TO3-QA-RDTs-25	00	Approved - 9/10/07	<a href="#">Conducting Laboratory Audits for RDTs</a>	FHI
TO3-QA-RDTs-26	00	Approved - 9/10/07	<a href="#">Supplier Report Card for RDTs</a>	FHI
TO3-QA-RDTs-27	00	Approved - 9/10/07	<a href="#">Evaluating RDTs In-Country</a>	FHI

## All Pharmaceutical Drug products (Pharm) –Series TO3-QA-Pharm

Document	Revision Number	Status	Title	Responsible for developing SOP
TO3-QA-Pharm-30	00	Approved 10/18/07	<a href="#">Quality Assurance Activities with QA Activities/Costs/Risks</a>	FHI
TO3-QA-Pharm-31	01	Approved 10/18/07	<a href="#">Pre-qualification of Pharmaceutical Suppliers</a>	FHI
TO3-QA-Pharm-32	01	Approved 10/18/07	<a href="#">Sampling and Testing of Pharmaceuticals-Pre-shipment</a>	FHI/USP
TO3-QA-Pharm-33	01	Approved 10/18/07	<a href="#">Sampling and Testing of Pharmaceuticals-Post-shipment</a>	FHI/USP
TO3-QA-Pharm-34	01	Approved 10/18/07	<a href="#">Conducting Post Market Surveillance for Pharmaceuticals</a>	FHI/USP
TO3-QA-Pharm-35	01	Approved 10/18/07	<a href="#">Conducting Audits of Pharmaceutical Suppliers</a>	FHI/USP
TO3-QA-Pharm-36	01	Approved 10/18/07	<a href="#">Conducting Audits of Pharmaceutical drug testing Labs</a>	FHI
TO3-QA-Pharm-37	01	Approved 10/18/07	<a href="#">Supplier Report Card for Pharmaceuticals</a>	FHI
TO3-QA-Pharm-38	00 Obsolete	10/18/07- Obsolete	<a href="#">Interim (Emergency) Quality Assurance strategy for the procurement of Coartem®</a>	FHI
TO3-QA-Pharm-40	00	Approved 10/18/07	<a href="#">QA Pharmaceutical testing for products obtained from other Agencies</a>	FHI/USP
TO3-QA-Pharm-41	01	Approved 10/18/07	<a href="#">Quality Assurance for AS + AQ from MissionPharma and Guilin Pharmaceuticals</a>	FHI

Others to be determined as the project progresses .....



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**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Long Lasting Insecticide Treated Nets (LLINs) Quality Assurance Activities/Risks/Estimated Costs		<b>DOCUMENT No.:</b> TO3-QA-LLINs-01
<b>DATE ISSUED:</b> 10/9/07	<b>SUPERSEDES:</b> 8/7/07-rev 00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel- Signature on File – October 9, 2007

**1.0 PURPOSE:**

1.1	To establish a document that serves as a summarized reference for quality assurance steps for procuring LLINs and is also a guide for associated risks and estimated costs.								
1.2	Risk Management is the formal process by which risk factors are systematically identified, and assessed. The methodology of Risk Management involves four steps; <table border="1" style="margin-left: 20px;"> <tr> <td>1.</td> <td>Identifying and classifying the areas of potential risk.</td> </tr> <tr> <td>2.</td> <td>Quantifying the risk by determining the probability of events and associated consequences.</td> </tr> <tr> <td>3.</td> <td>Responding to the risk by having or developing the means to handle the identified and quantified risk.</td> </tr> <tr> <td>4.</td> <td>Capturing and retaining lessons learned as knowledge to aid future decisions.</td> </tr> </table>	1.	Identifying and classifying the areas of potential risk.	2.	Quantifying the risk by determining the probability of events and associated consequences.	3.	Responding to the risk by having or developing the means to handle the identified and quantified risk.	4.	Capturing and retaining lessons learned as knowledge to aid future decisions.
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**2.0 QUALITY ASSURANCE ACTIVITIES/RISKS/ESTIMATED COSTS:**

2.1	<p>The process of employing Risk Management for procurement of commodities allows the JSI Quality Assurance Partners and procurement team the tools to make sound decisions based on program needs that include Emergency procurements and very tight schedules.</p> <p style="text-align: center;"><b>ACTIVITY and RISK DATA SHEET For LLINs</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Country:</th> <th style="width: 25%;">LLIN Description:</th> <th style="width: 15%;">Date Ordered:</th> <th style="width: 15%;">Date Inspected/Tested:</th> <th style="width: 10%;">Shipment (expected days)</th> <th style="width: 10%;">Date Requested –In-Country</th> <th style="width: 5%;">Total number of days</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <th>Activity</th> <th>Cost</th> <th>Risk-Low (1-2) a. Use 1 if good history b. use 2 if no history</th> <th>Risk-Medium (3-4) a. Use 3 if good history b. use 4 if no history</th> <th>Risk-High (5)</th> <th>Score</th> <th>Day(s)</th> </tr> <tr> <td>Select suppliers from criteria; Type of net/insecticide along with country registration and requirements</td> <td>n/a</td> <td>WHOPES-Phase II</td> <td>WHOPES-Phase I USAID pre-qualified</td> <td>No WHOPES</td> <td></td> <td></td> </tr> <tr> <td>Pre-shipment Sampling/Inspection</td> <td>Crown Agents \$350.00 per day to \$500.00 per/day</td> <td>On-site Inspection/Testing</td> <td>On-Site sampling-concurrent Inspection</td> <td>No Inspection</td> <td></td> <td></td> </tr> <tr> <td>Pre-shipment Independent physical and chemical testing</td> <td>PSB -Singapore PE-\$1,925 PET- \$2,125</td> <td>No Concurrent Testing</td> <td>Concurrent testing</td> <td>No-Testing</td> <td></td> <td></td> </tr> <tr> <td>In-Country evaluation of LLINs</td> <td>As-needed basis (complaint or audit)</td> <td>WHOPES-Phase II Field data</td> <td>WHOPES-Phase I Field data pending</td> <td>No WHOPES No field data</td> <td></td> <td></td> </tr> <tr> <td>Supplier audit</td> <td></td> <td>Audit –conducted Good Supplier history</td> <td>Audit conducted-corrective actions pending- some supplier history</td> <td>No Audit- No history</td> <td></td> <td></td> </tr> <tr> <td>Laboratory audit</td> <td></td> <td>ISO-17025 Certified</td> <td>Not ISO 17025 Certified but has Quality management system</td> <td>No quality Management system</td> <td></td> <td></td> </tr> <tr> <td colspan="5" style="text-align: right;"><b>TOTAL SCORE</b></td> <td></td> <td></td> </tr> <tr> <td colspan="2"><b>Total Expected costs</b></td> <td colspan="2"><b>Risk Associated with Quality Prevention Activities of LLINs</b></td> <td colspan="3"></td> </tr> <tr> <td colspan="2"></td> <td>Low Risk Preferred</td> <td>Low to Medium</td> <td>Medium Acceptable (risks identified)</td> <td>Medium to High</td> <td>High Risk</td> </tr> <tr> <td colspan="2"></td> <td>6</td> <td>12</td> <td>18</td> <td>24</td> <td>30</td> </tr> </tbody> </table>							Country:	LLIN Description:	Date Ordered:	Date Inspected/Tested:	Shipment (expected days)	Date Requested –In-Country	Total number of days								Activity	Cost	Risk-Low (1-2) a. Use 1 if good history b. use 2 if no history	Risk-Medium (3-4) a. Use 3 if good history b. use 4 if no history	Risk-High (5)	Score	Day(s)	Select suppliers from criteria; Type of net/insecticide along with country registration and requirements	n/a	WHOPES-Phase II	WHOPES-Phase I USAID pre-qualified	No WHOPES			Pre-shipment Sampling/Inspection	Crown Agents \$350.00 per day to \$500.00 per/day	On-site Inspection/Testing	On-Site sampling-concurrent Inspection	No Inspection			Pre-shipment Independent physical and chemical testing	PSB -Singapore PE-\$1,925 PET- \$2,125	No Concurrent Testing	Concurrent testing	No-Testing			In-Country evaluation of LLINs	As-needed basis (complaint or audit)	WHOPES-Phase II Field data	WHOPES-Phase I Field data pending	No WHOPES No field data			Supplier audit		Audit –conducted Good Supplier history	Audit conducted-corrective actions pending- some supplier history	No Audit- No history			Laboratory audit		ISO-17025 Certified	Not ISO 17025 Certified but has Quality management system	No quality Management system			<b>TOTAL SCORE</b>							<b>Total Expected costs</b>		<b>Risk Associated with Quality Prevention Activities of LLINs</b>							Low Risk Preferred	Low to Medium	Medium Acceptable (risks identified)	Medium to High	High Risk			6	12	18	24	30
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2.2	Comments from Activity sheet;
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### 3.0 RESPONSIBILITIES:

3.1	<p>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</p> <p>The procurement and quality assurance of LLINs involves an integrated specialized team of partners from various organizations. These include;</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 25%;">Quality Assurance Partners</th> <th style="width: 25%;">Major Responsibility</th> <th style="width: 45%;">Other Responsibilities</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>John Snow Inc.</td> <td>Procurement Pre-Qualification</td> <td>Audits</td> </tr> <tr> <td>2.</td> <td>PATH</td> <td>Procurement Pre-Qualification</td> <td>Audits</td> </tr> <tr> <td>3.</td> <td>Crown Agents</td> <td>Procurement Pre-Qualification</td> <td>Sampling agency Inspection of LLINs at the manufacturing site Audits</td> </tr> <tr> <td>4.</td> <td>Family Health International</td> <td>Oversight of QA- Activities Standard Operating Procedures</td> <td>Audits Monitoring suppliers Complaints</td> </tr> <tr> <td>5.</td> <td>United States Pharmacopeia</td> <td>No Major Responsibilities for LLINs at this time</td> <td></td> </tr> </tbody> </table>		Quality Assurance Partners	Major Responsibility	Other Responsibilities	1.	John Snow Inc.	Procurement Pre-Qualification	Audits	2.	PATH	Procurement Pre-Qualification	Audits	3.	Crown Agents	Procurement Pre-Qualification	Sampling agency Inspection of LLINs at the manufacturing site Audits	4.	Family Health International	Oversight of QA- Activities Standard Operating Procedures	Audits Monitoring suppliers Complaints	5.	United States Pharmacopeia	No Major Responsibilities for LLINs at this time	
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### 4.0 DOCUMENT HISTORY:

Date Issued	History	Previous issue date	Reason for change
8/7/07	00	N/A	New Issue.
10/5/07	01	8/7/07	Add Risk Management



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Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Pre-qualification of Long Lasting Insecticide Treated Net (LLINs) Suppliers		<b>DOCUMENT No.:</b> TO3-QA-LLINs-02
<b>DATE ISSUED:</b> 10/9/07	<b>SUPERSEDES:</b> 8/7/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI /Crown Agents /Path /USP/ Family Health International	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File	

## 1.0 PURPOSE:

<b>1.1</b>	<p>A pre-qualification supplier strategy is required in order to immediately begin procurement of LLINs under the USAID   DELIVER PROJECT -Task Order 3- Malaria. LLINs currently procured by agencies select suppliers based on the WHO Pesticide Evaluation Scheme (WHOPES) criteria. This has limited the availability of LLINs to countries and also has increased the unit price over the past couple of years. Only a very small number of suppliers have the complete WHOPES approval. USAID has established criteria that allows for the pre-qualification of LLIN suppliers that have not completed the entire WHOPES approval process. The USAID technical criteria will provide the opportunity for other manufacturers to supply LLINs to help meet the demands for nets around the world and to aggressively fight the battle against Malaria. However, this technical strategy will require careful evaluation of these suppliers with the added requirement of 100% inspection and testing and other quality assurance requirements as defined in TO3-QA-LLINs-03.</p>
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## 2.0 BACKGROUND:

<b>2.1</b>  Technical Standards for USAID – financed LLINs- Criteria for LLIN Prequalification	<p>The WHOPES test approval process requires three phases:</p> <ul style="list-style-type: none"> <li>• Phase I –Laboratory (regeneration of insecticide and wash resistance)</li> <li>• Phase II- Short term field trials (wash resistance, efficacy and impact on vector behavior)</li> <li>• Phase III- Long term field trials (Long lasting efficacy, community acceptance, safety observations)</li> </ul> <p>WHOPES provides an “interim recommendation” for products that pass Phase I and Phase II trials, a process that can take up to 2 years or more to complete. A “full recommendation” is not provided until the final completion of Phase III studies which requires a minimum of 3 years. Since WHOPES is not a regulatory body, approval is not required before a product is sold. USAID has maintained a policy of purchasing only LLINs that have a WHOPES recommendation (interim or full). However, the WHOPES recommendation has been given to only 3 products. This number of LLIN products has resulted in limited availability for large purchases as well as higher prices. There are several additional products that are under WHOPES review but the process can take several years and official recommendations are only given once per year.</p> <p><b>USAID will therefore consider the procurement of LLINs that have not received a WHOPES recommendation but are advanced in the WHOPES review process and considered likely to receive a formal recommendation.</b></p>
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### 3.0 REFERENCE DOCUMENTS:

<b>3.1</b>	1.	President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa
	2.	Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization
	3.	Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification
	4.	Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.
	5.	Quality Assurance and Inspection of LLINs – Crown Agents

### 4.0 RESPONSIBILITIES:

<b>4.1</b>	<b>Responsibilities - Quality Assurance-Partners USAID   DELIVER – TO3 Malaria</b>		
4..1.1	The procurement and quality assurance of LLINs involves an integrated specialized team of partners from various organizations. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement Pre-Qualification	Audits
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### 5.0 PRE-QUALIFICATION OF SUPPLIERS: USAID CRITERIA

<b>5.1</b>	<b>The pre-qualification of suppliers of LLINs for USAID will meet the WHOPES phase I approval and are into the short term field testing trials. They must also meet the criteria established by USAID as specified in the “Technical Standards for USAID –financed LLINs-Criteria for LLIN prequalification”</b>
5.1.1	For USAID LLIN suppliers to be pre-qualified they must present data from their own laboratory plus a recognized independent laboratory using WHOPES protocol (Guidelines for Laboratory and Field testing of Long Lasting Insecticidal Mosquito Nets”, Geneva 2005)

5.1.2	<p>A USAID pre-qualified LLIN supplier is also required to meet the following criteria; <b>See Appendix A.</b></p> <table border="1" data-bbox="418 289 1349 701"> <tr> <td>1.</td> <td>Has been accepted into the WHOPES program.</td> </tr> <tr> <td>2.</td> <td>Meets or exceeds the WHOPES specifications for netting material and construction.</td> </tr> <tr> <td>3.</td> <td>Uses one of the six WHOPES-recommended pyrethroid treatments.</td> </tr> <tr> <td>4.</td> <td>Clearly defines the chemical specifications of their product and how it adheres to these specifications. <ul style="list-style-type: none"> <li>• Type of chemical used</li> <li>• Dosage</li> <li>• Distribution</li> </ul> </td> </tr> <tr> <td>5.</td> <td>Provide information on the three main attributes of the LLIN. <ul style="list-style-type: none"> <li>• The net</li> <li>• The insecticide</li> <li>• The binding process by which the insecticide is affixed to the net (and is wash resistant)</li> </ul> </td> </tr> </table>	1.	Has been accepted into the WHOPES program.	2.	Meets or exceeds the WHOPES specifications for netting material and construction.	3.	Uses one of the six WHOPES-recommended pyrethroid treatments.	4.	Clearly defines the chemical specifications of their product and how it adheres to these specifications. <ul style="list-style-type: none"> <li>• Type of chemical used</li> <li>• Dosage</li> <li>• Distribution</li> </ul>	5.	Provide information on the three main attributes of the LLIN. <ul style="list-style-type: none"> <li>• The net</li> <li>• The insecticide</li> <li>• The binding process by which the insecticide is affixed to the net (and is wash resistant)</li> </ul>																																												
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5.1.4	<p><b>Insecticides:</b> The supplier must provide documentation of the type of insecticide used. WHOPES has recommended six pyrethroid insecticides for the treatment of nets.</p> <table border="1" data-bbox="418 1413 1443 1749"> <thead> <tr> <th></th> <th>Insecticide</th> <th>Application-type</th> <th>Brand Names</th> <th>Net Type</th> <th>Manufacturer</th> </tr> </thead> <tbody> <tr> <td rowspan="3">1.</td> <td rowspan="3">Deltamethrin</td> <td>LLIN</td> <td>Permanet®</td> <td>Polyester</td> <td>Vestergard</td> </tr> <tr> <td>LLIN</td> <td>DAWAplus®</td> <td>Polyester</td> <td>Tana Netting</td> </tr> <tr> <td>LLIN</td> <td>NetProtect®</td> <td>Polyethylene</td> <td>Bestnet</td> </tr> <tr> <td rowspan="2">2.</td> <td rowspan="2">Alpha-cypermethrin</td> <td>LLIN</td> <td>Interceptor®</td> <td>Polyester</td> <td>BASF</td> </tr> <tr> <td>LLIN</td> <td>DuraNet®</td> <td>Polyethylene</td> <td>Clarke</td> </tr> <tr> <td>3.</td> <td>Permethrin</td> <td>LLIN</td> <td>Olyset®</td> <td>Polyethylene</td> <td>Sumitomo</td> </tr> <tr> <td>4.</td> <td>Lambdacyhalothrin</td> <td>LLIN</td> <td>Iconet®</td> <td>Polyester</td> <td>Syngeta AG</td> </tr> <tr> <td>5.</td> <td>Cyfluthrin</td> <td>None to date</td> <td>Not applicable</td> <td></td> <td></td> </tr> <tr> <td>6.</td> <td>Etofenprox</td> <td>Spraying</td> <td>Not applicable</td> <td></td> <td></td> </tr> </tbody> </table>		Insecticide	Application-type	Brand Names	Net Type	Manufacturer	1.	Deltamethrin	LLIN	Permanet®	Polyester	Vestergard	LLIN	DAWAplus®	Polyester	Tana Netting	LLIN	NetProtect®	Polyethylene	Bestnet	2.	Alpha-cypermethrin	LLIN	Interceptor®	Polyester	BASF	LLIN	DuraNet®	Polyethylene	Clarke	3.	Permethrin	LLIN	Olyset®	Polyethylene	Sumitomo	4.	Lambdacyhalothrin	LLIN	Iconet®	Polyester	Syngeta AG	5.	Cyfluthrin	None to date	Not applicable			6.	Etofenprox	Spraying	Not applicable		
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5.1.5	<p><b>Insecticide binding process:</b> The supplier must provide documentation on the type of net along with the insecticide binding process. Presently there are two methods used for binding the insecticide to the yarn or net;</p> <table border="1" data-bbox="418 323 1240 499"> <thead> <tr> <th>Insecticide Binding Process</th> <th>Brand Names</th> <th>Insecticide Type</th> <th>Manufacturer</th> </tr> </thead> <tbody> <tr> <td>1. Polyethylene</td> <td>NetProtect®</td> <td>Deltamethrin</td> <td>Bestnet</td> </tr> <tr> <td></td> <td>Olyset®</td> <td>Permethrin</td> <td>Sumitomo</td> </tr> <tr> <td></td> <td>Duranet®</td> <td>Alpha-cypermethrin</td> <td>Clarke Mosquito Control</td> </tr> </tbody> </table> <p>The insecticide is mixed with the polymer used to create the yarn. The insecticide is therefore distributed inside of the polyethylene yarn as it is made. As the net is washed, insecticide on the surface that may wear off is replaced by fresh insecticide “seeping” from the polymer.</p> <table border="1" data-bbox="418 625 1240 781"> <thead> <tr> <th>Insecticide Binding Process</th> <th>Brand Names</th> <th>Insecticide Type</th> <th>Manufacturer</th> </tr> </thead> <tbody> <tr> <td>2. Polyester</td> <td>Permanet®</td> <td>Deltamethrin</td> <td>Vestergard</td> </tr> <tr> <td></td> <td>DAWAplus®</td> <td>Deltamethrin</td> <td>Tana Netting</td> </tr> <tr> <td></td> <td>Interceptor®</td> <td>Alpha-cypermethrin</td> <td>BASF</td> </tr> </tbody> </table> <p>For polyester nets such as Permanet®, the insecticide is bound to the manufactured netting with a chemical binder. The insecticide and binder can be applied at several stages of the net manufacturing process, including post-manufacturing in the form of long-lasting treatment kits.</p>	Insecticide Binding Process	Brand Names	Insecticide Type	Manufacturer	1. Polyethylene	NetProtect®	Deltamethrin	Bestnet		Olyset®	Permethrin	Sumitomo		Duranet®	Alpha-cypermethrin	Clarke Mosquito Control	Insecticide Binding Process	Brand Names	Insecticide Type	Manufacturer	2. Polyester	Permanet®	Deltamethrin	Vestergard		DAWAplus®	Deltamethrin	Tana Netting		Interceptor®	Alpha-cypermethrin	BASF																																						
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	<p>Based on the WHOPES phase I acceptance and information obtained through this pre-qualification scheme, <b><u>the following suppliers are pre-qualified under the USAID technical requirements:</u></b></p> <table border="1"> <thead> <tr> <th></th> <th>Manufacturer/ Insecticide-</th> <th>Brand Names</th> <th>Net Type</th> <th>WHOPES Phase I</th> <th>USAID Criteria</th> </tr> </thead> <tbody> <tr> <td colspan="6">1. Deltamethrin</td> </tr> <tr> <td>a.</td> <td><b>Vestergaard Frandsen</b></td> <td>Permanet®</td> <td>Polyester</td> <td>Passed</td> <td>Passed</td> </tr> <tr> <td>b.</td> <td><b>Tana Netting Co. Ltd.</b></td> <td>DAWAplus®</td> <td>Polyester</td> <td>Passed</td> <td>Passed</td> </tr> <tr> <td>c.</td> <td><b>Bestnet</b></td> <td>NetProtect®</td> <td>Polyethylene</td> <td>Passed</td> <td>Passed</td> </tr> <tr> <td colspan="6">2. Alpha-cypermethrin</td> </tr> <tr> <td>a.</td> <td><b>BASF</b></td> <td>Interceptor®</td> <td>Polyester</td> <td>Passed</td> <td>Passed</td> </tr> <tr> <td>b.</td> <td><b>Clarke Mosquito Control</b></td> <td>DuraNet®</td> <td>Polyethylene</td> <td>Passed</td> <td>Passed</td> </tr> <tr> <td colspan="6">3. Permethrin</td> </tr> <tr> <td>a.</td> <td><b>Sumitomo</b></td> <td>Olyset®</td> <td>Polyethylene</td> <td>Passed</td> <td>Passed</td> </tr> </tbody> </table>		Manufacturer/ Insecticide-	Brand Names	Net Type	WHOPES Phase I	USAID Criteria	1. Deltamethrin						a.	<b>Vestergaard Frandsen</b>	Permanet®	Polyester	Passed	Passed	b.	<b>Tana Netting Co. Ltd.</b>	DAWAplus®	Polyester	Passed	Passed	c.	<b>Bestnet</b>	NetProtect®	Polyethylene	Passed	Passed	2. Alpha-cypermethrin						a.	<b>BASF</b>	Interceptor®	Polyester	Passed	Passed	b.	<b>Clarke Mosquito Control</b>	DuraNet®	Polyethylene	Passed	Passed	3. Permethrin						a.	<b>Sumitomo</b>	Olyset®	Polyethylene	Passed	Passed
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5.1.9	The procurement team is responsible for collecting the pre-qualification information from the current and future suppliers and compiling into table form for quick reference. In addition, the procurement team will update the tables as necessary. See Appendix B																																																												
5.1.10	The procurement team can select LLINs from this current list of pre-qualified suppliers. LLINs procured have to meet country and/or program requirements. Note: The procurement team should consult with the government in advance and agree on the brand of LLIN.																																																												

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
8/7/07	00	N/A	New Issue.
10/9/07	01	8/7/07	Minor edits- no content change

**APPENDIX A**  
**Pre-Qualification Supplier Information Table**

SUPPLIER List all manufacturing sites		
ADDRESS		
CONTACT INFORMATION	Certified Letter of Authority indicating company contacts for Management, Quality Control, Quality Assurance and Production.	
	<b>Pre-qualification of Suppliers Requirements: "Technical Standards for USAID –financed LLINs-Criteria for LLIN prequalification"</b>	<b>Meets Prequalification Requirements / Comments</b>
1.	Has been accepted into the WHOPES program.	
2.	Meets or exceeds the WHOPES specifications for netting material and construction.	
3.	Uses one of the six WHOPES-recommended pyrethroid treatments.	
4.	Clearly defines the chemical specifications of their product and how it adheres to these specifications. Chemical; dosage; distribution	
5.	The supplier must provide information on the three main attributes of the LLIN. – NET	
6.	The supplier must provide information on the three main attributes of the LLIN. – INSECTICIDE	
7.	The supplier must provide information on the three main attributes of the LLIN. – THE BINDING PROCESS and brief description of the manufacturing process.	
8.	The supplier must present bio-assay test results equivalent to WHOPES –phase I, using the WHOPES guidelines, and conducted by a recognized independent laboratory demonstrating that the net retains its biological activity for at least 20 washes.	
9.	The supplier must provide documentation of on-site inspection of the manufacturing facility by a recognized third party organization ensuring that factory has stringent quality assurance procedures in place and is operating with proper worker safety and environmental controls.	
10.	The supplier must provide documentation of the current WHOPES status and any documentation of an unfavorable determination from WHOPES.	
11.	Other information that may affect pre-qualification:	
12.	Provide documentation on the type of Quality Management system for the facility (i.e. ISO-9000; EN)	
13.	Certification that the commodities are manufactured according to EN, ISO, WHO, GMP, FDA standards, whichever applies.	
14.	Certified copy of current license in country where primary manufacturing is conducted	
15.	Manufacturer's Quality Manual and Standard Operational Procedures in Microsoft-Word compatible CD form	
16.	Copies of company's environmental policy and any citations, infractions, fines, or legal actions the company has been involved in as a result of violations.	
Approval		

**APPENDIX B**  
**LLINs -Technical Evaluation**  
**Polyester Nets**

Supplier/ Brand	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/ Conclusion
<b>Vestergaard Frandsen</b>  <b>Permanet®</b>	Denmark India Vietnam Thailand Bangladesh China	Fabrication: 100% Polyester Yarn Mesh: 156 holes inch <sup>2</sup> minimum 25 cm <sup>2</sup> )  Dimensional stability: ± 5 %  Bursting strength: 250-350Kpa  Seam strength: 450Kpa  Fire safety: Class 16 Storage: ?	<b>Deltamethrin</b> 55mg/m <sup>2</sup> +/- 25%	Coating using resin binder	Phase I-Passed  Phase II-Passed  Phase III Recommended for large scale field studies-Jan 2004	<u>Rectangular</u> 70 x 180 x 150cm 130 x 180 x 150 cm 100 x 180 x 150cm  <u>Conical</u> 850 x 56 x 220cm 1050 x 56 x 220cm  Estimated potential capacity through December 2007 60 million	Meets USAID criteria  Nets are recommended for WHOPES Phase III testing

Supplier/ Brand	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/ Conclusion
<b>BASF</b>  <b>Interceptor®</b>	Australia  Thailand, Sunshine World Net 2003	Fabrication: 100 % polyester fibres (poly ethylene terephthalate or PET), Warp knitted Mesh: min. 156 inch <sup>2</sup> (= min. 24 holes / cm <sup>2</sup> )  Dimensional stability: ± 5 %  Bursting strength: 250Kpa  Seam strength: 250Kpa  Fire safety: Storage: <45 °C	<b>alpha-cybermin</b> 200 mg / m <sup>2</sup> ± 25 %.	co-polymeric binder by means of a padding process	Phase I-Passed  Phase II-Passed  Phase III- Recommended pending Phase III trials	<u>Rectangular</u> 160 x 180 x 150cm    Estimated potential capacity through December 2007 1.6 million	Meets USAID criteria  Acceptable based on WHOPES Phase II Interim recommendation

Supplier/ Brand	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/ Conclusion
<b>Tana Netting Co. ltd</b>  <b>DAWAplus®</b>	Bangkok 10110 Thailand, 27 Sukhumvit oi 53	Fabrication: 100 % polyester fibres (poly ethylene terephthalate or PET), Warp knitted Mesh: min. 156 inch <sup>2</sup> (= min. 25 holes / cm <sup>2</sup> )  Dimensional stability: <5 % shrinkage  Bursting strength: 405Kpa (100 denier) and 220 75 denier) Seam strength: ?  Fire safety: 16 CFR 1610 – CS191-53 Storage: <45 °C	<b>Deltamethrin</b> 40 mg / m <sup>2</sup> ± 25 %.	co-polymeric binder by means of a padding process	Phase I-Passed Phase II- Phase III-	190 x 180 x 150cm 160 x 180 x 150 cm 130 x 180 x 150cm 100 x 180 x 150cm 70 x 180 x 150cm  Estimated potential capacity through December 2007 4.0 million	Meets USAID criteria  Acceptable based on WHOPES Phase I and USAID criteria

## APPENDIX B Polyethylene Nets

Supplier	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/Conclusion
Sumitomo  Olyset®	Japan Tanzania Changzhou, China Dalian, China Vietnam	Fabrication: 100% Polyethylene warp  Mesh: 156 holes inch <sup>2</sup> minimum 25 cm <sup>2</sup> )  Dimensional stability: ≤ 10%  Bursting strength: 350Kpa  Seam strength: 350Kpa  Fire safety: Class 1 Storage: ?	Permethrin 2% w/w	In process incorporation	Phase I-Passed  Phase II-Passed  Phase III - recommended for Phase III testing	130 x 180 x 150 cm 160 x 180 x 150cm 190 x 180 x 150cm  Estimated potential capacity through December 2007 30 million-globally	Meets USAID criteria  Nets are recommended for Phase III testing  <b>Acceptable on basis of USAID and WHOPES status</b>

Supplier	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/Conclusion
Bestnet  NetProtect®  May trade under the name - Intection	India Not clearly indicated. Siva inspect by UNICEF, and failed on ISO certification, SOPs	Fabrication: 100% Polyethylene Yarn knitted/Raschel  Mesh: 136 holes inch <sup>2</sup> (21 holes / cm <sup>2</sup> ) (Independent: 156/25)  Dimensional stability: ± 10 %  Bursting strength: 375Kpa  Seam strength: 220Kpa  Fire safety: Class 1 Storage: ?	Deltamethrin	In process	Phase I-Passed Phase II-  Phase III-	<u>Rectangular</u> 160 x 180 x 150cm 12 sizes of rectangular  <u>Conical</u> 6 sizes of conical  Estimated potential capacity through December 2007 2.4 million	Meets USAID criteria  The company has WHOPES I recommendation  Company has limited experience (<2years).  Bursting strength for nets is not consistent with mesh indicated strength. UNICEF report shows its not sufficient Proof of concentration of insecticide after washing unclear

Supplier	Manufacturing site	Net Specifications	Insecticide	Binding Process	WHOPES Status	Other Info	Comments/Conclusion
Clarke Mosquito Control  Duramet®	VKA Polymers, Tamil Nadu India	Fabrication: 100% Polyethylene warp knitted  Mesh: 132 holes inch <sup>2</sup> minimum (Independent: 156/25)  Dimensional stability: ± 10 %  Bursting strength: 450Kpa  Seam strength: 450Kpa  Fire safety: Class 1 Storage: ?	Alpha-cypermethrin	In process extrusion	Phase I-Passed  Phase II-  Phase III-	Estimated potential capacity through December 2007 1 million	Meets USAID criteria  The company has WHOPES I recommendation  Nets are recommended for WHOPES Phase II testing  <b>Acceptable on basis of USAID and WHOPES status</b>



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Sampling, Inspection and Testing of Long Lasting Insecticide Treated Nets (LLINs) for Pre-shipment		<b>DOCUMENT No.:</b> TO3-QA-LLINs-03
<b>DATE ISSUED:</b> 10/9/07	<b>SUPERSEDES:</b> 8/7/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / USP/ Path/ Family Health International	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File	

## 1.0 PURPOSE:

<b>1.1</b>	To establish a quality assurance plan for the sampling, inspection and testing of long lasting insecticide treated nets (LLINs). LLIN suppliers that are qualified under the WHOPES process and also meet the USAID pre-qualification criteria outlined in the “Technical Standards for USAID financed LLINs criteria for pre-qualification” will be subject to <b><u>100% sampling, inspection, and testing</u></b> . This strategy provides added confidence that suppliers are providing a high quality net product consistent with WHO and USAID recommended requirements.
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## 2.0 BACKGROUND:

<b>2.1</b>	<p><b>Technical consultation on specifications and quality control of netting materials and mosquito nets- World Health Organization: 2005 –</b>  <a href="http://malaria.who.int/docs/Tech-ConsultNettingMaterials.pdf">http://malaria.who.int/docs/Tech-ConsultNettingMaterials.pdf</a></p> <p>Product specifications for mosquito netting material were developed by WHO in 2000. In 2000, WHO proposed minimum specifications for the physical characteristics of polyester netting material, the most commonly used material for mosquito nets. These specifications were developed primarily for institutional buyers and national malaria control programs to provide guidance for procurement as well as to facilitate control of mosquito nets. In 2005 a meeting of experts agreed to replace the 2000 material specific requirements for polyester, polyethylene, and cotton netting, and instead develop generic specifications applicable to all netting materials irrespective of fibers from which they are made. The major characteristics of good quality nets are:</p> <ul style="list-style-type: none"> <li>• Prevention of insect/vector entry</li> <li>• Dimensional stability after washing</li> <li>• Strength of netting materials and seams</li> <li>• Retention of strength over a period of time (durability and storage stability)</li> <li>• Safety for users</li> </ul> <p>After five years there was a need to update the specifications that were proposed earlier. Some of the test methods were not clearly defined, or were difficult to use reliably or had to be modified. Certain specification limits initially proposed were either too stringent or not stringent enough. Also, about this same time, a new material, high density polyethylene (HDPE) was introduced into this market.</p>
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### 3.0 **REFERENCE DOCUMENTS:**

<b>3.1</b>	1.	President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa
	2.	Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization
	3.	Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification
	4.	Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.

### 4.0 **RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</b>		
4.1.1	The procurement and quality assurance of LLINs involves an integrated specialized team of partners from various organizations. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
1.	John Snow Inc.	Procurement Pre-Qualification	Audits
2.	PATH	Procurement Pre-Qualification	Audits
3.	Crown Agents	Procurement Pre-Qualification	Sampling agency Inspection of LLINs at the manufacturing site Audits
4.	Family Health International	Oversight of QA- Activities	Standard Operating Procedures Audits Monitoring suppliers Complaints
5.	United States Pharmacopeia	No Major Responsibilities for LLINs at this time	Audits

### 5.0 **PROCEDURE FOR SAMPLING/INSPECTION and TESTING LLIN CONSIGNMENTS**

<b>5.1</b>	<b>SAMPLING OF LLINS at THE MANUFACTURING SITE</b>
5.1.1	The procurement team will select the appropriate net supplier after careful review of country/program requirements. The supplier will provide a sampling date to the procurement team. Family Health International will also be notified of the sampling date.
5.1.2	A qualified sampling agency is then selected to perform the sampling.

5.1.3	<p>For the interim period, Crown Agents will provide sampling and inspection of LLIN manufacturers. Crown Agents’ inspection division has been closely involved with the development and introduction of inspection procedures to assure the quality of nets and has many years experience with this type of sampling and inspection.</p> <p>-----</p> <p>Estimated number of days to sample/inspect/with sampling costs.</p> <table border="1" data-bbox="402 352 808 615"> <thead> <tr> <th>Country</th> <th>Estimated cost of sampling/inspection per day</th> </tr> </thead> <tbody> <tr><td>Vietnam</td><td>\$500.00</td></tr> <tr><td>Thailand</td><td>\$500.00</td></tr> <tr><td>China</td><td>\$500.00</td></tr> <tr><td>Tanzania</td><td>\$450.00</td></tr> <tr><td>Nigeria</td><td>\$450.00</td></tr> <tr><td>Kenya</td><td>\$450.00</td></tr> <tr><td>India</td><td>\$350.00</td></tr> <tr><td>South Korea</td><td>\$500.00</td></tr> </tbody> </table> <table border="1" data-bbox="1047 352 1510 520"> <thead> <tr> <th>Number of nets</th> <th>Sample size</th> <th>Number of days</th> </tr> </thead> <tbody> <tr><td>0-70,000</td><td>200</td><td>1</td></tr> <tr><td>70,001-140,000</td><td>400</td><td>2</td></tr> <tr><td>140,001-210,000</td><td>600</td><td>3</td></tr> <tr><td>210,001-280,000</td><td>800</td><td>4</td></tr> </tbody> </table> <p>-----</p>	Country	Estimated cost of sampling/inspection per day	Vietnam	\$500.00	Thailand	\$500.00	China	\$500.00	Tanzania	\$450.00	Nigeria	\$450.00	Kenya	\$450.00	India	\$350.00	South Korea	\$500.00	Number of nets	Sample size	Number of days	0-70,000	200	1	70,001-140,000	400	2	140,001-210,000	600	3	210,001-280,000	800	4								
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5.1.4	<p>After the interim period, other sampling agencies may be identified based on qualifications and experience with sampling and inspecting LLINs. It’s important to have more than one sampling/inspection agency available to conduct this service. The selection of geographical proximity of the sampling agency to the manufacturing site is critical to reduce lead times and costs. Potential sampling/inspection agencies must be able to show competency in performing the sampling/inspection of LLINs per this procedure.</p>																																									
5.1.5	<p>Currently there is no WHO standard for the number of samples required for examining a batch/consignment. WHO does recommend using a large sample size but recognizes that cost is a major factor. Smaller sample sizes increase the risk of accepting defective LLINs in a batch/consignment. WHO listed in the updated section of the “Technical Consultation on Specifications and Quality Control of Netting Materials: 2005”, the probabilities associated with finding a defective based on 90%, 95% and 99% confidence together with the number of samples tested.</p> <p>-----</p> <p>Sampling rate based on probability of detection and frequency of non-compliance; Example: A buyer aiming for 90% confidence to detect a non-compliance occurring at 10% frequency would have to collect and test 22 nets.</p> <table border="1" data-bbox="402 1268 1510 1503"> <thead> <tr> <th rowspan="2">Actual frequency of non-compliant nets in the batch</th> <th colspan="3">Minimum number of samples per batch required to detect a non-compliant net with a probability of:</th> </tr> <tr> <th>90%</th> <th>95%</th> <th>99%</th> </tr> </thead> <tbody> <tr><td>20%</td><td>11</td><td>14</td><td>21</td></tr> <tr><td>15%</td><td>15</td><td>19</td><td>29</td></tr> <tr><td>10%</td><td>22</td><td>29</td><td>44</td></tr> <tr><td>5%</td><td>45</td><td>59</td><td>90</td></tr> <tr><td>1%</td><td>231</td><td>299</td><td>459</td></tr> </tbody> </table> <p>Compare this table to one using only 8 nets sampled:</p> <table border="1" data-bbox="402 1528 1510 1713"> <thead> <tr> <th>Actual frequency of non-compliant nets in the batch</th> <th>Probability of detecting a non-compliant net by testing 8 nets</th> </tr> </thead> <tbody> <tr><td>44%</td><td>99%</td></tr> <tr><td>31%</td><td>95%</td></tr> <tr><td>25%</td><td>90%</td></tr> <tr><td>10%</td><td>57%</td></tr> <tr><td>5%</td><td>34%</td></tr> <tr><td>1%</td><td>8%</td></tr> </tbody> </table> <p>The recommended sampling scheme is based on a 95% confidence probability that defects can be detected from the typical net manufacturing process using random sampling methods. General Level I inspection sizes provides an adequate amount of nets to be sampled. The AQL (Acceptable Quality Level) at 2.5 is USAID’s risk that 2.5 defective nets (on average) out of 100</p>	Actual frequency of non-compliant nets in the batch	Minimum number of samples per batch required to detect a non-compliant net with a probability of:			90%	95%	99%	20%	11	14	21	15%	15	19	29	10%	22	29	44	5%	45	59	90	1%	231	299	459	Actual frequency of non-compliant nets in the batch	Probability of detecting a non-compliant net by testing 8 nets	44%	99%	31%	95%	25%	90%	10%	57%	5%	34%	1%	8%
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may get distributed. An acceptable manufacturing process should have a process defect level (% defective) less than ½ of the AQL or 1.25 defective nets out of 100 as the out-going quality level. There is the manufacturer’s risk that some nets could be rejected but are accepted. These are the alpha and beta rules of statistical sampling and testing.

Crown Agents will sample the batch/consignment at the manufacturing site based on ISO 2859-1: 1999 standard; General Inspection Level I-AQL 2.5

Two sampling plans can be used based on the manufacturer’s batch definition, number of bales in a batch, number of nets in a bale, and for cost considerations, the number of batches in a consignment. Producing nets is a continuous process. However, depending on the manufacturer, breaks in the process may cause smaller batches at times. The sampling agency has to use discretion and good judgment when determining the overall batch and consignment sample size to use.

**Sampling Plan #1**

# of LLINs In consignment	Sample Size	Maximum Sample extraction From each bale	Accept/Reject (Total Net Defects for Visual Inspection-5.2.2)
3,201- 10,000 – code J	80	4 nets	Acc 5/Rej 6
10,001-35,000 – code K	125	4 nets	Acc 7/Rej 8
35,001-150,000 –code L	200	4 nets	Acc 10/Rej 11
150,001- 500,000 –code M	315	(TBD)	Acc 14/Rej 15
Over 500,000-code N	500	(TBD)	Acc 21/Rej 22

Alternatively, sampling plan 2 uses the normal inspection sizes under Level I and a modified multiple or stratum sample size (using Level I). This plan can be used based on the need to adjust to differences in batch or number of bales and sub-lots.

**Sampling Plan #2**

# of LLINs In consignment	Sample Size	Maximum Sample extraction From each bale	Accept/Reject (Total Net Defects for Visual Inspection-5.2.2)
0 to 10,000 – code J	80	4 nets	Acc 5/Rej 6
10,001-35,000 – code K	125	4 nets	Acc 7/Rej 8
35,001-150,000 –code L	200	4 nets	Acc 10/Rej 11
Any stratum or sub-lot over 70,000	Stratified sampling- each stratum not exceeding 70,000 and use the sampling plan above.		

5.1.6 The method of selecting bales and pulling LLINs shall be a random exercise. **APPENDIX A**

**5.2 INSPECTION OF LLINs AT THE MANUFACTURING SITE**

5.2.1 Crown Agents or other designated sampling/inspection agency will conduct a physical inspection of the LLIN’s at the manufacturing site. **Part 1**-of the inspection process is a verification of documentation, quantities, and checks of dimensions, weight and mesh size against the contract specifications.

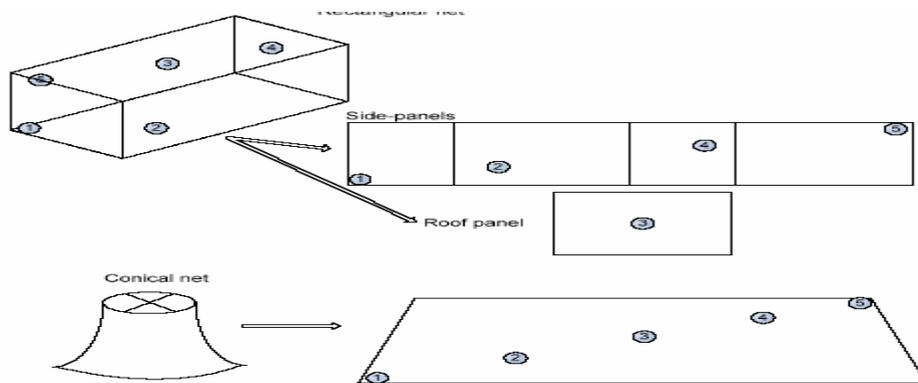
**Part 1-Verification;**

1.	Verification of contract compliance	a check of the materials to the contract specifications (type of net etc.)
2.	Verification of material compliance	dimensional check; weight; mesh size; denier; fire safety colorfastness number of filaments
3.	Verification of quantities	verify packing list and assess the quantities in the bale
4.	Verification of packing and markings	verify packing and markings with process documents
5.	Documentation and records review	i.e., Certificate of analysis, manufacturer product specification sheet, including verification of source of insecticide and polymer / fiber
The non-availability of any documents/records for verification will abort the sampling and inspection process.		

5.2.2	<p><b>Part 2</b> of the inspection is the <b>visual examination</b> of the LLINs sampled using the sampling and inspection table in section 5.1.5. <b>See Appendix A for data sheet.</b></p> <p><b>Part 2-Visual Inspection;</b></p> <table border="1" data-bbox="402 289 1425 898"> <tr> <td data-bbox="402 289 743 541">1. Visual examination-LLINs Workmanship- Critical defects</td> <td data-bbox="751 289 1133 541">           Accept 0/ Reject 1            Critical-defects            1. Hole in net            2. Hole in hood            3. Hole in border            4. Split seam            5. Incorrect dimension measurement            6. Faulty ring            7. stains         </td> <td data-bbox="1141 289 1425 541">If any one of the critical defects described in the table is found in a net, then it is rejected and counts toward the number of "net" rejects in the table listed in section 5.1.5.</td> </tr> <tr> <td data-bbox="402 552 743 730">2. Visual examination-LLINs Workmanship Non-critical defects</td> <td data-bbox="751 552 1133 730">           Accept 2/ Reject 3            Non-critical-defects            1. Discoloration            2. Trimming            3. Feel of net (handle)            4. Finish         </td> <td data-bbox="1141 552 1425 730">For non-critical defects, a total of three defects found during the inspection counts as one reject in the table listed in section 5.1.5</td> </tr> <tr> <td data-bbox="402 741 743 898">3. Visual Examination- Packaging Workmanship Critical and non-critical defects</td> <td data-bbox="751 741 1133 898">           Accept 2/ Reject 3            Non-critical-defects            1. Discoloration            2. Trimming            3. Feel of net (handle)            4. Finish         </td> <td data-bbox="1141 741 1425 898">For non-critical defects, a total of three defects found during the inspection counts as one reject in the table listed in section 5.1.5</td> </tr> </table>	1. Visual examination-LLINs Workmanship- Critical defects	Accept 0/ Reject 1 Critical-defects 1. Hole in net 2. Hole in hood 3. Hole in border 4. Split seam 5. Incorrect dimension measurement 6. Faulty ring 7. stains	If any one of the critical defects described in the table is found in a net, then it is rejected and counts toward the number of "net" rejects in the table listed in section 5.1.5.	2. Visual examination-LLINs Workmanship Non-critical defects	Accept 2/ Reject 3 Non-critical-defects 1. Discoloration 2. Trimming 3. Feel of net (handle) 4. Finish	For non-critical defects, a total of three defects found during the inspection counts as one reject in the table listed in section 5.1.5	3. Visual Examination- Packaging Workmanship Critical and non-critical defects	Accept 2/ Reject 3 Non-critical-defects 1. Discoloration 2. Trimming 3. Feel of net (handle) 4. Finish	For non-critical defects, a total of three defects found during the inspection counts as one reject in the table listed in section 5.1.5	
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5.2.3	<p>The selected LLIN manufacturer should provide a designated area so that the large number of samples can be inspected in a reasonable amount of time. The inspection area requires;</p> <table border="1" data-bbox="402 1003 1190 1129"> <tr><td>1.</td><td>A clean appropriately sized inspection table</td></tr> <tr><td>2.</td><td>Hooks/Ladder from which to hang the nets "clearing" the floor</td></tr> <tr><td>3.</td><td>The proper equipment to test the weight of the material</td></tr> <tr><td>4.</td><td>Adequate lighting</td></tr> <tr><td>5.</td><td>A minimum of two persons to assist with this process</td></tr> </table>	1.	A clean appropriately sized inspection table	2.	Hooks/Ladder from which to hang the nets "clearing" the floor	3.	The proper equipment to test the weight of the material	4.	Adequate lighting	5.	A minimum of two persons to assist with this process
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5.2.4	<p>The process of verifying the size of the LLINs involves the methods outlined in the steps below. The LLINs shall be measured using a flexible tape measure of minimum length of ten meters (~33 feet).</p> <table border="1" data-bbox="402 1287 1336 1680"> <tr> <td data-bbox="402 1287 565 1402">1. Height</td> <td data-bbox="573 1287 1271 1402">Hang the net straight without stretching, ensuring all wrinkles and/or folds that may have occurred during packaging have been removed, and measure the length vertically from the ring (for conical nets) or from the base of the hanging loop (in the case of rectangular net) to the bottom of the net along a vertical seam.</td> </tr> <tr> <td data-bbox="402 1413 565 1497">2. Length and Width</td> <td data-bbox="573 1413 1271 1497">Lay the net out flat without stretching, ensuring all wrinkles and/or folds that may have occurred during packing have been removed, and measure the length and the width of the net from the corner seam to corner seam along both the top edge and the bottom edge</td> </tr> <tr> <td data-bbox="402 1507 565 1591">3. Circumference</td> <td data-bbox="573 1507 1271 1591">Start at a given point, such as the seam, and without stretching; go around the bottom edge of the net measuring the actual circumference. Alternatively, the net can be laid double border to measure half the circumference.</td> </tr> <tr> <td data-bbox="402 1602 565 1633">4.</td> <td data-bbox="573 1602 1271 1633">Check other physical parameters as specified in the contract</td> </tr> <tr> <td data-bbox="402 1644 565 1675">5.</td> <td data-bbox="573 1644 1271 1675">Rectangular nets – check the shape and size of the top hood</td> </tr> </table>	1. Height	Hang the net straight without stretching, ensuring all wrinkles and/or folds that may have occurred during packaging have been removed, and measure the length vertically from the ring (for conical nets) or from the base of the hanging loop (in the case of rectangular net) to the bottom of the net along a vertical seam.	2. Length and Width	Lay the net out flat without stretching, ensuring all wrinkles and/or folds that may have occurred during packing have been removed, and measure the length and the width of the net from the corner seam to corner seam along both the top edge and the bottom edge	3. Circumference	Start at a given point, such as the seam, and without stretching; go around the bottom edge of the net measuring the actual circumference. Alternatively, the net can be laid double border to measure half the circumference.	4.	Check other physical parameters as specified in the contract	5.	Rectangular nets – check the shape and size of the top hood
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4.	Check other physical parameters as specified in the contract										
5.	Rectangular nets – check the shape and size of the top hood										
5.2.5	<p>If the results of the <b>verification (Part 1)</b> and/or the <b>visual inspection (Part 2)</b> do not comply, the order will be cancelled and the Inspection Agency will immediately notify the USAID   DELIVER – TO3 Malaria team.</p>										

5.2.6	<p>If the inspection results comply with the order/country requirements <b><u>the order can be shipped concurrent</u></b> with the independent physical and chemical analysis- if the manufacturer has successfully passed WHOPEs Phase II. These manufacturers are;</p> <table border="1" data-bbox="399 323 1484 674"> <thead> <tr> <th></th> <th>Manufacturer/ Insecticide-</th> <th>Brand Names</th> <th>Net Type</th> <th>WHOPEs Phase I</th> <th>WHOPEs Phase II</th> <th>WHOPEs Phase III</th> </tr> </thead> <tbody> <tr> <td colspan="7">1. Deltamethrin</td> </tr> <tr> <td>a.</td> <td><b>Vestergaard Frandsen</b></td> <td>Permanet®</td> <td>Polyester</td> <td>Passed</td> <td>Passed Jan-04'</td> <td>Recommended for large scale field studies</td> </tr> <tr> <td colspan="7">2. Alpha-cypermethrin</td> </tr> <tr> <td>a.</td> <td><b>BASF</b></td> <td>Interceptor®</td> <td>Polyester</td> <td>Passed Feb-05'</td> <td>Passed Jan-07'</td> <td>Recommended pending Phase III trials</td> </tr> <tr> <td colspan="7">3. Permethrin</td> </tr> <tr> <td>a.</td> <td><b>Sumitomo</b></td> <td>Olyset®</td> <td>Polyethylene</td> <td>Passed</td> <td>Passed Jan-01'</td> <td>Recommended pending Phase III trials</td> </tr> </tbody> </table> <p>Note: the manufacturer accepts all responsibility for shipping costs and the cost of returning the goods if the independent test results do not comply.</p>		Manufacturer/ Insecticide-	Brand Names	Net Type	WHOPEs Phase I	WHOPEs Phase II	WHOPEs Phase III	1. Deltamethrin							a.	<b>Vestergaard Frandsen</b>	Permanet®	Polyester	Passed	Passed Jan-04'	Recommended for large scale field studies	2. Alpha-cypermethrin							a.	<b>BASF</b>	Interceptor®	Polyester	Passed Feb-05'	Passed Jan-07'	Recommended pending Phase III trials	3. Permethrin							a.	<b>Sumitomo</b>	Olyset®	Polyethylene	Passed	Passed Jan-01'	Recommended pending Phase III trials
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5.2.7	<p><b>Emergency procurements of LLINs.</b> The Quality Assurance Partners and the LLIN procurement team recognize that there will be an occasional need to provide LLINs as part of an “<b>Emergency Response</b>” situation. The Emergency Response allows for the procuring and shipping of LLINs using WHOPEs Phase II approved manufacturers listed in 5.2.6. This situation requires following Release Protocol #1 listed in section 5.7.1.</p>																																																	
5.2.8	<p>For non-emergency (routine) procurement, the order <b><u>can not be shipped</u></b> until all test results from the independent laboratory have been received and accepted- Release Protocol #2.</p>																																																	
5.2.9	<p>The sampling agency will provide sampling and inspection documentation that includes, date sampled, method of sampling, number of samples taken, person(s) performing the sampling and inspection and any other relevant information. The document will be sent to JSI with a copy to FHI. <b>SEE APPENDIX B for an example of the Inspection Report</b></p>																																																	
<b>5.3</b>	<b>PHYSICAL TESTING REQUIREMENTS- INDEPENDENT LABORATORY</b>																																																	
5.3.1	<p>For the interim period, Crown Agents will coordinate and sub-contract the independent physical and chemical testing to PSB-Singapore. PSB is an accredited laboratory with experience testing LLINs.</p> <p>Samples are to be shipped to: TUV SUD PSB Corporation PTE. Ltd. Testing group No. 1 Science Park Drive Singapore 118221</p> <p>In the near future, other independent laboratories may be qualified for testing. These laboratories must demonstrate competency with physical and chemical testing of LLINs.</p>																																																	
5.3.2	<p>Five nets will be used for the independent physical testing of the batch/consignment.</p>																																																	
5.3.3	<p>Five nets will also be sent to FHI for durability and storage testing to be conducted at a later date. This is only required on a one time basis per year/ per each manufacturer.</p>																																																	

	<p>Net samples should be sent to:          Dr. David Jenkins          Family Health International          2810 Meridian Pkwy. Suite 110          Durham, NC –USA 27713</p>																														
5.3.4	<p>WHO has established Minimum General Specifications for Mosquito nets. These tests will be conducted by the independent laboratory. These include;</p> <table border="1" data-bbox="399 407 1533 772"> <thead> <tr> <th data-bbox="399 407 467 449"></th> <th data-bbox="467 407 792 449">Test</th> <th data-bbox="792 407 1117 449">WHO Specification</th> <th data-bbox="1117 407 1334 449">Test Standard</th> <th data-bbox="1334 407 1533 449">Estimated Test Cost-US Dollars</th> </tr> </thead> <tbody> <tr> <td data-bbox="399 449 467 541">1.</td> <td data-bbox="467 449 792 541">Mesh size/count</td> <td data-bbox="792 449 1117 541">156 holes/inch<sup>2</sup> (min 25/cm<sup>2</sup>) Lowest value not less than 148</td> <td data-bbox="1117 449 1334 541">Visual, Photocopying, Pick glass ISO 139</td> <td data-bbox="1334 449 1533 541">\$18.75</td> </tr> <tr> <td data-bbox="399 541 467 613">2.</td> <td data-bbox="467 541 792 613">Dimensional stability</td> <td data-bbox="792 541 1117 613">Shrinkage less than 5% For both dimensions</td> <td data-bbox="1117 541 1334 613">ISO 3759 (1994) ISO 6330 (2000) ISO 5077 (1984)</td> <td data-bbox="1334 541 1533 613">\$18.75</td> </tr> <tr> <td data-bbox="399 613 467 659">3.</td> <td data-bbox="467 613 792 659">Bursting strength</td> <td data-bbox="792 613 1117 659">&gt;250 kPa (7.3 cm<sup>2</sup> sample)</td> <td data-bbox="1117 613 1334 659">ISO 13938-1 (1999) ISO 13938-2 (1999)</td> <td data-bbox="1334 613 1533 659">\$18.75</td> </tr> <tr> <td data-bbox="399 659 467 705">4.</td> <td data-bbox="467 659 792 705">Seam strength</td> <td data-bbox="792 659 1117 705">&gt;250 kPa (7.3 cm<sup>2</sup> sample)</td> <td data-bbox="1117 659 1334 705">ISO 13938-1 (1999) ISO 13938-2 (1999)</td> <td data-bbox="1334 659 1533 705">\$18.75</td> </tr> <tr> <td data-bbox="399 705 467 772">5.</td> <td data-bbox="467 705 792 772">Durability and storage stability</td> <td data-bbox="792 705 1117 772">Not for routine analysis</td> <td data-bbox="1117 705 1334 772">Not for routine analysis</td> <td data-bbox="1334 705 1533 772">To be determined</td> </tr> </tbody> </table>		Test	WHO Specification	Test Standard	Estimated Test Cost-US Dollars	1.	Mesh size/count	156 holes/inch <sup>2</sup> (min 25/cm <sup>2</sup> ) Lowest value not less than 148	Visual, Photocopying, Pick glass ISO 139	\$18.75	2.	Dimensional stability	Shrinkage less than 5% For both dimensions	ISO 3759 (1994) ISO 6330 (2000) ISO 5077 (1984)	\$18.75	3.	Bursting strength	>250 kPa (7.3 cm <sup>2</sup> sample)	ISO 13938-1 (1999) ISO 13938-2 (1999)	\$18.75	4.	Seam strength	>250 kPa (7.3 cm <sup>2</sup> sample)	ISO 13938-1 (1999) ISO 13938-2 (1999)	\$18.75	5.	Durability and storage stability	Not for routine analysis	Not for routine analysis	To be determined
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5.4.1	<p><u>Mesh Size/count</u> – (Ref-<a href="http://malaria.who.int/docs/Tech-ConsultNettingMaterials.pdf">http://malaria.who.int/docs/Tech-ConsultNettingMaterials.pdf</a> for sections 5.3.6-5.3.13)          Background and Procedure- (Note 4- of WHO Specification - <a href="http://www.who.int/whopes/quality/permethrin_LN_July_2006.pdf">http://www.who.int/whopes/quality/permethrin_LN_July_2006.pdf</a>)</p> <p>In the absence of a simple or standard method to determine the size of holes, which may have complex shapes, in highly flexible fabrics, mesh size is determined by counting the number of holes in a square of the fabric. Counting may be done directly on the fabric or indirectly by scanning/photocopying the fabric. Indirect methods may ease counting and provide a permanent record. Before scanning/photocopying or counting directly, the fabric must be conditioned according to ISO 139:2005 at 4 hours, 20° C, 65% humidity.</p> <p>Use a template to define the square of netting, taking care not to stretch or distort the fabric. The template should be a rigid sheet, 1-2 mm thick, in/on which a calibrated (+/- 1% in each dimension) square (e.g. 1 x 1 in or 2 x 2 cm) has been accurately cut/marked. Alternatively a Pick glass may be used. If a template is not available and a ruler must be used, great care is required to ensure that the area counted is square. Where practicable, at least one edge of the square to be counted must be aligned with a row of complete holes in the fabric. Incomplete holes <math>\geq \frac{1}{2}</math> are counted as complete holes, whereas part holes <math>&lt; \frac{1}{2}</math> are not counted. Count 5 replicate squares in pieces taken according to the diagram below.</p> <p>Note: use sharp scissors or equivalent, to minimize damage to the fibers and fabric. Roll up the strips or squares and place them in labeled, new clean aluminum foil prior to testing. Samples must be kept cool, avoiding heat sources or freezing and tested with minimum delay.</p>																														



	Brand Names	Manufacturer	Net Type	Manufacturers Specification Mesh count	WHO Specification 156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> ) <b>Lowest value not less than 148</b>
1.	Permanet®	Vestergard	Polyester	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )
2.	DAWAplus®	Tana Netting	Polyester	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )
3.	NetProtect®	Bestnet	Polyethylene	136 holes/inch <sup>2</sup> (min 21cm <sup>2</sup> )	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )
4.	Interceptor®	BASF	Polyester	156 holes/inch <sup>2</sup> (min 24cm <sup>2</sup> )	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )
5.	DuraNet®	Clarke	Polyethylene	132 holes/inch <sup>2</sup>	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )
6.	Olyset®	Sumitomo	Polyethylene	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )-need to verify	156 holes/inch <sup>2</sup> (min 25cm <sup>2</sup> )-need to verify

#### 5.4.2 Dimensional stability

The tests for dimensional stability are performed with a sample of netting material treated according to ISO 3759 (1994) and ISO 6330 (2000) and the results are calculated according to ISO 5077 (1984) and expressed as percentages (shrinkage, though stretching may occur) The WHO specification state that shrinkage in either direction of the netting material must not be more than 5%. Note: Nets can be sensitive to the temperature at which they are subsequently washed.

There are 10 European washing procedures for front loading machines specified in the ISO 6330-1984 (E) standard and 11 for the United States (for top loading machines). The revised WHO specification relies on the 8A wash procedure (European norm: gentle wash at 30°C) and drying procedure C (dry flat).

	Test	WHO Specification	
2.	Dimensional stability	Shrinkage less than 5% For both dimensions	ISO 3759 (1994) ISO 6330 (2000) ISO 5077 (1984)

5.4.3	<p><b><u>Bursting Strength</u></b></p> <p>Strength of netting material can be measured as (a) its bursting strength (b) its tensile strength (c) the tear strength or (d) by the crude measurement of grasping the material in both hands and gauging the effort required to push the thumbs through it.</p> <p>Bursting strength is currently the only practicable test for which reliable data exist. Netting quality has improved over the past 5 years and WHO established the minimum bursting strength for acceptable netting materials is 250 kPa, when measured according to ISO 13938-1 (1999) or ISO 13938-2 (1999), using a 7.3 cm<sup>2</sup> sample.</p> <table border="1" data-bbox="402 457 1295 531"> <thead> <tr> <th>Test</th> <th>WHO Specification</th> </tr> </thead> <tbody> <tr> <td>3. Bursting strength</td> <td>&gt;250 kPa (7.3 cm<sup>2</sup> sample) ISO 13938-1 (1999) ISO 13938-2 (1999)</td> </tr> </tbody> </table> <table border="1" data-bbox="402 562 1466 705"> <thead> <tr> <th></th> <th>Brand Names</th> <th>Manufacturer</th> <th>Net Type</th> <th>Manufacturers Specification</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Permanet®</td> <td>Vestergard</td> <td>Polyester</td> <td>250-350 kPa</td> </tr> <tr> <td>2.</td> <td>DAWAplus®</td> <td>Tana Netting</td> <td>Polyester</td> <td>405 kPa (100 denier) / 220 kPa (75 denier)</td> </tr> <tr> <td>3.</td> <td>NetProtect®</td> <td>Bestnet</td> <td>Polyethylene</td> <td>375 kPa</td> </tr> </tbody> </table> <table border="1" data-bbox="402 726 1466 779"> <tbody> <tr> <td>4.</td> <td>Interceptor®</td> <td>BASF</td> <td>Polyester</td> <td>250 kPa</td> </tr> <tr> <td>5.</td> <td>DuraNet®</td> <td>Clarke</td> <td>Polyethylene</td> <td>450 kPa</td> </tr> </tbody> </table> <table border="1" data-bbox="402 800 1466 831"> <tbody> <tr> <td>6.</td> <td>Olyset®</td> <td>Sumitomo</td> <td>Polyethylene</td> <td>350 kPa</td> </tr> </tbody> </table>	Test	WHO Specification	3. Bursting strength	>250 kPa (7.3 cm <sup>2</sup> sample) ISO 13938-1 (1999) ISO 13938-2 (1999)		Brand Names	Manufacturer	Net Type	Manufacturers Specification	1.	Permanet®	Vestergard	Polyester	250-350 kPa	2.	DAWAplus®	Tana Netting	Polyester	405 kPa (100 denier) / 220 kPa (75 denier)	3.	NetProtect®	Bestnet	Polyethylene	375 kPa	4.	Interceptor®	BASF	Polyester	250 kPa	5.	DuraNet®	Clarke	Polyethylene	450 kPa	6.	Olyset®	Sumitomo	Polyethylene	350 kPa
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5.4.4	<p><b><u>Seam Strength</u></b></p> <p>LLINs require seams in the netting material to give the net the desired strength and to seal against mosquito entry between adjacent panels of fabric. For acceptable performance, the seams must be at least as strong as the netting. At present, there is no documented experience with standardized tension tests for seam quality control on nets.</p> <table border="1" data-bbox="402 1031 1466 1083"> <tbody> <tr> <td>4.</td> <td>Seam strength</td> <td>&gt;250 kPa (7.3 cm<sup>2</sup> sample)</td> <td>ISO 13938-1 (1999) ISO 13938-2 (1999)</td> </tr> </tbody> </table> <table border="1" data-bbox="402 1083 1466 1293"> <thead> <tr> <th></th> <th>Brand Names</th> <th>Manufacturer</th> <th>Net Type</th> <th>Manufacturers Specification</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Permanet®</td> <td>Vestergard</td> <td>Polyester</td> <td>450 kPa</td> </tr> <tr> <td>2.</td> <td>DAWAplus®</td> <td>Tana Netting</td> <td>Polyester</td> <td>Not available</td> </tr> <tr> <td>3.</td> <td>NetProtect®</td> <td>Bestnet</td> <td>Polyethylene</td> <td>220 kPa (need verifying)</td> </tr> <tr> <td>4.</td> <td>Interceptor®</td> <td>BASF</td> <td>Polyester</td> <td>250 kPa</td> </tr> <tr> <td>5.</td> <td>DuraNet®</td> <td>Clarke</td> <td>Polyethylene</td> <td>450 kPa</td> </tr> <tr> <td>6.</td> <td>Olyset®</td> <td>Sumitomo</td> <td>Polyethylene</td> <td>350 kPa</td> </tr> </tbody> </table>	4.	Seam strength	>250 kPa (7.3 cm <sup>2</sup> sample)	ISO 13938-1 (1999) ISO 13938-2 (1999)		Brand Names	Manufacturer	Net Type	Manufacturers Specification	1.	Permanet®	Vestergard	Polyester	450 kPa	2.	DAWAplus®	Tana Netting	Polyester	Not available	3.	NetProtect®	Bestnet	Polyethylene	220 kPa (need verifying)	4.	Interceptor®	BASF	Polyester	250 kPa	5.	DuraNet®	Clarke	Polyethylene	450 kPa	6.	Olyset®	Sumitomo	Polyethylene	350 kPa
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5.4.5	<p><b><u>Durability and Storage stability</u></b></p> <p>The durability of nets and netting material is a very important characteristic for the user but there is lack of simple tests which measure, or predict, resistance to the “wear and tear” arising from normal use. The most important criterion of durability is the retention of bursting strength for an acceptable time in normal storage and use. In principle, the bursting strength of all fabrics can be expected to decline over time, due to polymer degradation, and the rate of decline can be expected to be increased by handling, washing, drying, exposure to heat and light etc. In the absence of an appropriate test of “wear and tear” resistance, WHO has considered the need for a storage stability test.</p> <p>Note: Five samples from each manufacturer annually will be sent to FHI for storage. The durability and storage stability, testing the burst strength, will be conducted on an annual basis by an independent laboratory. Other tests may be conducted at any time for any investigative purposes.</p>																																							

5.5	<b>ADDITIONAL PHYSICAL TESTING DESCRIPTIONS- INDEPENDENT LABORATORY</b>																																						
5.5.1	Additional physical tests are listed in the table below and are not required for pre-shipment acceptance. The data from the manufacturer certificates of analysis must be verified against specifications. However, the independent laboratory may perform these tests on an as needed basis.																																						
	<table border="1"> <thead> <tr> <th data-bbox="402 394 472 436"></th> <th data-bbox="480 394 724 436">Test</th> <th data-bbox="740 394 1317 436">WHO Specification</th> <th data-bbox="1325 394 1529 436">Estimated Test Cost-US dollars</th> </tr> </thead> <tbody> <tr> <td data-bbox="402 441 472 575">1.</td> <td data-bbox="480 441 724 575">Number of filaments</td> <td data-bbox="740 441 1317 575">In 2000, a minimum filament count of 36 was established for the yarn to be incorporated into polyester netting. Netting made from polyester multi-filament yarn with filament counts above 30 has proven acceptable for insecticide treatment of nets at field level. Monofilament yarn is suitable for netting made of HDPE.</td> <td data-bbox="1325 441 1529 575">\$32.00</td> </tr> <tr> <td data-bbox="402 579 472 621">2.</td> <td data-bbox="480 579 724 621">Denier</td> <td data-bbox="740 579 1317 621">List denier amount</td> <td data-bbox="1325 579 1529 621">\$32.00</td> </tr> <tr> <td data-bbox="402 625 472 667">3.</td> <td data-bbox="480 625 724 667">Weight</td> <td data-bbox="740 625 1317 667">List weight</td> <td data-bbox="1325 625 1529 667">\$12.50</td> </tr> <tr> <td data-bbox="402 672 472 714">4.</td> <td data-bbox="480 672 724 714">Fire safety</td> <td data-bbox="740 672 1317 714">Meets non-flammable Class I requirement 16 CFR 1610</td> <td data-bbox="1325 672 1529 714">\$56.25</td> </tr> <tr> <td data-bbox="402 718 472 760">5.</td> <td data-bbox="480 718 724 760">Colorfastness</td> <td data-bbox="740 718 1317 760">For information only</td> <td data-bbox="1325 718 1529 760">To be determined</td> </tr> <tr> <td data-bbox="402 764 472 806">6.</td> <td data-bbox="480 764 724 806">Air permeability</td> <td data-bbox="740 764 1317 806">Not applicable (for field treated nets)</td> <td data-bbox="1325 764 1529 806">To be determined</td> </tr> <tr> <td data-bbox="402 810 472 852">7.</td> <td data-bbox="480 810 724 852">Water and insecticide uptake</td> <td data-bbox="740 810 1317 852">Not applicable (for field treated nets)</td> <td data-bbox="1325 810 1529 852">To be determined</td> </tr> <tr> <td data-bbox="402 856 472 919">8.</td> <td data-bbox="480 856 724 919">Pesticide bioavailability and retention in field – treated nets</td> <td data-bbox="740 856 1317 919">Not applicable (for field treated nets)</td> <td data-bbox="1325 856 1529 919">To be determined</td> </tr> </tbody> </table>		Test	WHO Specification	Estimated Test Cost-US dollars	1.	Number of filaments	In 2000, a minimum filament count of 36 was established for the yarn to be incorporated into polyester netting. Netting made from polyester multi-filament yarn with filament counts above 30 has proven acceptable for insecticide treatment of nets at field level. Monofilament yarn is suitable for netting made of HDPE.	\$32.00	2.	Denier	List denier amount	\$32.00	3.	Weight	List weight	\$12.50	4.	Fire safety	Meets non-flammable Class I requirement 16 CFR 1610	\$56.25	5.	Colorfastness	For information only	To be determined	6.	Air permeability	Not applicable (for field treated nets)	To be determined	7.	Water and insecticide uptake	Not applicable (for field treated nets)	To be determined	8.	Pesticide bioavailability and retention in field – treated nets	Not applicable (for field treated nets)	To be determined		
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5.5.2	<p><b>Number of Filaments</b></p> <p>Evidence indicates that texturization of multifilament polyester yarn results in slightly higher water absorption (2 to 5%) during field treatment with insecticide formulation diluted in water. Nets made from texturized yarn usually have the same range of bursting strength, slightly lower shrinkage and a softer feel than netting made of flat or round yarn. Both materials are suitable for use in mosquito nets.</p> <p>The number of filaments which the yarn is made influences physical characteristics of the netting: such as water uptake; the surface area to which insecticide can bind; and hence the final concentration of insecticide per unit area of net. The cross sectional shape and surface texture of filaments have a greater surface area than round filaments of the same cross-sectional area.</p> <p>In 2000, a minimum filament count of 36 was established for the yarn to be incorporated into polyester netting. Netting made from polyester multi-filament yarn with filament counts above 30 has proven acceptable for insecticide treatment of nets at field level. Monofilament yarn is suitable for netting made of HDPE. The WHO concluded that it was more important to ensure that the net absorbs the expected volume of insecticide formulation diluted in water, than to maintain 36 as the minimum filament count.</p>																																						
5.5.3	<p><b>Denier (Linear Density)</b></p> <p>Linear density is a characteristic of the yarn and is expressed in units of denier (grams per 9,000 meters) or decitex (grams per 10,000 meters). Denier and decitex are a description of yarn, not a minimum characteristic of the netting, although the values influence the fabric weight per unit area. Linear density is difficult to measure in any type of finished netting product and impossible to measure in warp-knitted netting. The denier/decitex of yarn is one element contributing towards the bursting strength of netting but bursting strength is a much more useful and practical overall measurement. Polyethylene nets are commonly made of higher denier yarn than polyester nets. Denier should thus be specified in procurement and included on the label but should not be part of routine quality testing.</p>																																						

5.5.4	<p><b>Weight</b> For a specific product, the weight (grams per meter square) of the final netting material is closely linked to denier of the yarn and to mesh count. Lighter netting material is cheaper. Weight is not included in the minimum specification for netting materials but it should be stated on the packaging of the net. Weight should be measured according to standard ISO 3801: 1977 with pre-conditioning according to ISO 139:2005 at 4 hours, 20° C, 65% humidity.</p>																																				
<b>5.6</b>	<b>CHEMICAL TESTING REQUIREMENTS- INDEPENDENT LABORATORY</b>																																				
5.6.1	<p>The chemical testing will be conducted by a qualified independent laboratory (i.e. PSB-Singapore). Crown Agents will coordinate (sub-contract) this testing. The chemical testing will be based on the type of net fiber and pesticide. Information is provided below for chemical testing conditions which may be applied to the testing of LLINs (5.6.2-5.6.3), however the exact testing conditions utilized by the independent laboratory need to be validated for the specific insecticide / fiber / binding system.</p>																																				
5.6.2	<p><b>Polyester nets</b>, the chemical analysis will be performed on <u>5 nets</u> per production batch/consignment using HPLC for deltamethrin and GC for alpha-cypermethrin treated nets.</p> <table border="1" data-bbox="402 798 1539 1003"> <thead> <tr> <th></th> <th>Brand Names</th> <th>Manufacturer</th> <th>Net Type</th> <th>Pesticide</th> <th>Manufacturers Specification</th> <th>USAID Specification</th> <th>Estimated Test Cost</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Permanet®</td> <td>Vestergard</td> <td>Polyester</td> <td>Deltamethrin</td> <td>55mg/m<sup>2</sup> (+/- 25%)</td> <td>55mg/m<sup>2</sup> (+/- 20%)</td> <td>\$1,040-\$2,080</td> </tr> <tr> <td>2.</td> <td>DAWAplus®</td> <td>Tana Netting</td> <td>Polyester</td> <td>Deltamethrin</td> <td>40mg/m<sup>2</sup> (+/- 25%)</td> <td>40mg/m<sup>2</sup> (+/- 20%)</td> <td>\$1,040-\$2,080</td> </tr> <tr> <td>3.</td> <td>Interceptor®</td> <td>BASF</td> <td>Polyester</td> <td>Alpha-cypermethrin</td> <td>200mg/m<sup>2</sup> (+/- 25%)</td> <td>200mg/m<sup>2</sup>(+/- 20 %)</td> <td>TBD</td> </tr> </tbody> </table> <p><b>Sample extraction;</b></p> <table border="1" data-bbox="402 1075 1367 1234"> <thead> <tr> <th>Deltamethrin</th> <th>Alpha-cypermethrin</th> </tr> </thead> <tbody> <tr> <td>sonicate the net for 1 hour in 77/23 acetonitrile/water</td> <td>sonicate the net for 1 hour sitting in approximately 0.5 inches of water in sonic bath in 20ml of xylene after the addition of an appropriate amount of deltamethrin as internal standard</td> </tr> </tbody> </table> <p><b>Deltamethrin HPLC test method parameters- polyester nets-</b> Samples of nets will be extracted with mobile phase and the extract will be analyzed by HPLC to quantify the amount of deltamethrin. The basic conditions of the extraction and HPLC analysis are provided below. <i>The conditions were obtained from a confidential source.</i></p> <p><b>Extraction Conditions:</b>  <u>Net Sample Size:</u> 30 cm x 30 cm  <u>Extraction Solution:</u> 100 mL of 77/23 Acetonitrile/Water  <u>Extraction Conditions:</u> Sonication for 1 hour followed by mixing via repeated flask inversion</p> <p><b>Targeted Deltamethrin Concentration:</b>  55 mg/m<sup>2</sup> (label claim for deltamethrin concentration on Permanet)  0.09 m<sup>2</sup> (30 cm x 30 cm) – net sample area in sq. meters  55 mg/m<sup>2</sup> x 0.09 m<sup>2</sup> = 4.95 mg of deltamethrin</p> <p>Based on the extraction conditions above, 4.95 mg of deltamethrin will be dissolved in 100 ml of mobile phase. Standard preparation can be performed by diluting 10 mg of deltamethrin to 200 mL.</p> <p><b>Chromatographic Conditions:</b>  <u>Column:</u> C18, 125 x 4 mm, 5 micron – Example – HP 7982618-564, Hypersil ODS 5 um, 125 x 4 mm, S/N – 71002  <u>Mobile Phase:</u> 77 % Acetonitrile / 23 % water  <u>Temperature:</u> Ambient  <u>Flow Rate:</u> 1 mL/min  <u>Injection Volume:</u> 20 µL</p>		Brand Names	Manufacturer	Net Type	Pesticide	Manufacturers Specification	USAID Specification	Estimated Test Cost	1.	Permanet®	Vestergard	Polyester	Deltamethrin	55mg/m <sup>2</sup> (+/- 25%)	55mg/m <sup>2</sup> (+/- 20%)	\$1,040-\$2,080	2.	DAWAplus®	Tana Netting	Polyester	Deltamethrin	40mg/m <sup>2</sup> (+/- 25%)	40mg/m <sup>2</sup> (+/- 20%)	\$1,040-\$2,080	3.	Interceptor®	BASF	Polyester	Alpha-cypermethrin	200mg/m <sup>2</sup> (+/- 25%)	200mg/m <sup>2</sup> (+/- 20 %)	TBD	Deltamethrin	Alpha-cypermethrin	sonicate the net for 1 hour in 77/23 acetonitrile/water	sonicate the net for 1 hour sitting in approximately 0.5 inches of water in sonic bath in 20ml of xylene after the addition of an appropriate amount of deltamethrin as internal standard
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5.7.3	Review of the test results and release of the shipment will be conducted through Crown Agents and the QA-Partners of the LLIN Procurement team. Overview (second review) will be conducted by FHI and the test results will be entered into a quality assurance database.
5.7.4	A Certificate of Conformance will be prepared by FHI using the format in Appendix C. The original will be sent to JSI (attention Paul Stannard or designee). A copy will be sent to USAID attention Ms. Jennifer Murphy or designee and FHI will retain a copy.
5.7.5	The test results will be monitored and a quality report card will be established to track supplier performance.
<b>5.8</b>	<b>AUDIT OF SAMPLING/INSPECTION and TESTING</b>
5.8.1	The sampling, inspection and testing processes may be audited at least annually to ensure compliance with this document.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
8/7/07	00	N/A	New Issue.
10/9/07	01	8/7/07	Add Certificate of Conformance (Appendix C) section 5.7.4 and minor edits.

**APPENDIX- A**

**INSPECTION RECORD SHEET – RANDOM SAMPLING**

Purchase order no.	
Inspection Reference:	
Item no.	
Batch Size:	
Sample Size:	
Date Sampled:	
Sampled by:	

Lot#1 / Ndola	Sample No.	CRITICAL							NON-CRITICAL				<i>Accepted/Rejected</i> Remarks
		Hole in Net	Hole in Hood	Hole in Border	Split seam	Ring defect	Stains	Measurement	Discolouration	Finish	Trimming	Feel of net	
Bale No.	1												
	2												
	3												
	4												
Bale No.	1												
	2												
	3												
	4												
Bale No.	1												
	2												
	3												
	4												
Bale No.	1												
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Bale No.	1												
	2												
	3												
	4												

**APPENDIX- B**  
**EXAMPLE INSPECTION REPORT**  
**INSPECTION REPORT**

**DESCRIPTION OF GOODS:** Blue Long Lasting Insecticidal Bed Nets (Blue)

**QUANTITY ORDERED:** 2,446,000 LLIN Bed Nets

**QUANTITY INSPECTED:** 214,000 LLIN Bed Nets

**SUPPLIER:** Sumitomo Chemical Co Ltd, Japan

**MANUFACTURER:** Changzhou Jiushi Fibre Product Co Ltd

No. 80, Renmin West Road  
Guotai Industrial Areas  
Hutang Town, Changzhou  
China

**LOCATION OF INSPECTION:** At the premises of the manufacturer in Changzhou, China

**INSPECTION:**

The inspection was carried out to assure the mosquito nets as in compliance with the order requirements. The inspection function covered examining the materials to the Contract Specification, checking the dimensions, quantity, packing and marking and verifying the manufacturer's test certificate. Samples were also sent to independent laboratories for testing.

During the inspection, the inspector had split all the goods into 4 separate lots (first lot with 70,000 pcs, second lot with 70,000 pcs, third lot with 70,000 pcs and fourth lot with 4,000 pcs). Samples of the bed nets were drawn from the each lot in accordance with ISO 2859-1:1999 General Inspection Level I, AQL 2.5.

During the visit on 9<sup>th</sup> ~ 12<sup>th</sup> Dec. 2006, all the 214,000 completed nets were available for inspection.

**LOT 1, 70,000 PCS**

Total of 50 bales were randomly drawn from this lot (the bale No: 6, 9, 27, 66, 67, 100, 119, 153, 356, 357, 383, 528, 610, 803, 811, 812, 845, 975, 999, 1001, 1212, 1291, 1292, 1307, 1323, 1356, 1357, 1405, 1406, 1446, 1447, 1500, 1503, 1516, 1517, 1518, 1562, 1580, 1583, 1598, 1599, 1601, 1607, 1612, 1717, 1725, 1726, 1733, 1734, 1735) and from each bale, 4 nets were sampled making a total of 200 nets for inspection in accordance with the sampling plan.

**Acceptance/Rejection Criteria:**

Acceptance level is based on AQL 2.5. If the number of faulty net samples exceeded 10 (ten) nets, the whole quantity of 70,000 nets is rejected.

**Quantity:**

The quantity of the offered batch was verified by counting the number of bales and the number of nets in the selected bales. Each bales consisted of 40 bed nets and, with a total of 1,750 bales, the total quantity was 70,000 bed nets.

**Visual and dimensional inspection and laboratory testing:**

The 200 samples drawn were visually and dimensionally checked. They were also compared with the pre-production net sample from CA Kenya. The findings are as summarised in the following table:

No.	Description	Requirement	Results	Compliance
1	Net shape	Rectangular	Rectangular	Comply
2	Colour	Blue	Blue	Comply
2.1	Pantone colour reference	298	-	-
2.2	Mesh size	56-holes/inch <sup>2</sup> minimum (9 holes/cm <sup>2</sup> )	60 holes/inch <sup>2</sup>	Comply
3	Method of dye application	Incorporated into polyethylene fibres	Incorporated into polyethylene fibres	Comply
4	<i>Insecticide Impregnation (Treated)</i>			
4.1	Technology	Treated with Permethrin, incorporated into the polyethylene fibres during manufacturing process	Incorporated into the polyethene resin compound. To be tested	-
4.2	Active ingredient	Permethrin 2% w/w	To be tested	-
4.3	Insecticidal effect	Net material must conserve >95% functional mortality after storage at 54°C for two weeks	-	-
5	Size of Net			
5.1	Height inclusive of border but excluding loop	150 cm (tolerance – 5%/+10%)	146 cm – 158cm	Comply
5.2	Length	180 cm (minimum)	180 cm – 190cm	Comply
5.3	Width	160 cm (minimum)	160 cm – 169cm	Comply
6	Net attachment	6 suspension loops (one at each of the four corners of the top panel and one equidistant at each of the two long sides)	6 suspension loops	Comply
7	Number of ‘gathers’	N/A	N/A	N/A
8	Number of vertical seams	One OR Four, one at each corner, (please specify the number / % of each offered)	One	Comply
9	Length of vertical seams	All vertical seams to be of equal length	-	-
10	<a href="#">Hood Panel/Hanging</a>			
10.1	Hood Material (panel, reinforcements, loops)	N/A	N/A	N/A
10.2	Hood reinforcement	N/A	N/A	N/A
10.3	Hood tie cord material	N/A	N/A	N/A
10.4	Hanging loop length	Range 50 cm (minimum) to 100 cm (maximum)	55-57 cm	Comply
10.5	Hanging loop material	Polyester material (material colour to match netting material) with stitched edges nor raw edge	Polyester material	Comply
10.6	Hanging loop ring	Not required	None	N/A

11	<b>Bottom Border</b>			
11.1	Bottom border height	N/A	N/A	N/A
11.2	Bottom border material	N/A	N/A	N/A
11.3	Bottom border fitting	Self Binding	Self binding	Comply
11.4	Bottom border edge finish	Self Binding sevedge or overlooking stitch	Self binding	Comply
12	Stitching	Single stitch using 100% polyester thread (threads must not break when pulled, seams to be tied in)	Single stitch	Comply
13	Provision of Door	None	None	Comply
14	DRAFT LABELLING REQUIREMENTS (artwork to be confirmed)	Label to be stitched into a vertical inside net where the hood panel is attached to the body of net. The label must contain the following information 1. Net brand name = “Supanet Xtra Power” \ 2. Distributed by PSI 3. Name of Manufacturer 4. Dimensions of net = 160x180x150 cms 5. Netting material = Polyethylene 6. Insecticide = Permethrin 2% w/w 7. Contract number and net batch number “...” 8. Country of Manufacture “...”	As specified	Comply
15	DRAFT CARE LABEL REQUIREMENTS (ARTWORK TO BE CONFIRMED)	Label to be stitched into a vertical seam inside the net detailing instructions for Care of the net. Instructions must include •Wash gently at 40° C maximum •No bleach •No ironing •No dry cleaning •No tumble Instructions must be pictorial(as per ISO3758) with corresponding explanatory text. Additional text “Dry in the shade” to be included.	As specified	Comply
16	Feel of Net (Handle)	Non crease	Non Crease	Comply
17	<b>Individual Packing</b>			
17.1	Individual nets	Each net to be packed in an individual, heat-sealed, pre-printed transparent plastic bag. Bag to be sufficient to prevent damage during transit.	As specified	Comply
17.2	Plastic bag	Clear polythene bag with a handle, punched, 5 cm from the top of the bag. Handle size 8.5 cm X 2 cm	Clear polythene bag with a handle, punched, 36 mm from the top of the bag. Handle size 85 mm X 20 mm	Approved by Kenya
17.3	Bag size	360 mm – 530 mm (minimum size)	360 mm – 530 mm	Comply
17.4	Bag thickness	75 microns (minimum)	-	-

17.5	Design ^details to be <i>Example of printing required is attached</i>	Design size – 185 mm x 290 mm Design to print 57 mm from bottom of punched handle +/- 5 mm Gap at edges 82.2 mm – 87.5 mm Printed in 6 colour process	Design size – 210 mm x 333 mm.  Print 103 mm from bottom of punched handle. Gap at edges 73 mm	Approved by Kenya
17.6	Instructions for use <i>Details and artwork to be confirmed</i>	General information as required by Kenya PCPB and Instructions for black on reverse of each individual bag. Printing to be in both English and Kiswahili. Date of Manufacture to be shown as either an adhesive label or ink jet printed applied directly onto reverse of the bag.	As specified	Comply
18	Bulk Packing			
18.1	Bulk packing (nets)	Waterproof compressed bales (preferred option). Alternatively LDPE bags (stitched closed) will be acceptable. Bales to be strapped with 2 strong plastic strappings, tightly bound by machine. Marks to be clearly stencilled, not handwritten, (in English) on 2 adjacent faces of each bale as follows: <ul style="list-style-type: none"> <li>• CA “CA ref No”</li> <li>• Population Services International – Kenya P.O. Box 22591, Nairobi, Kenya.</li> <li>• One bale contains: “Qty” blue rectangular bednets.</li> <li>• Supplied by: <i>Supplier name</i></li> <li>• Gross weight: “...” Kgs</li> <li>• Bale No. “...” of “...”</li> <li>• “USENOHOOKS”</li> </ul> Maximum weight of bale = 90 kgs	Marks on 2 adjacent faces. Bales to be strapped with 4 strong plastic strappings. Maximum weight of bale: 28.4kgs	Comply
18.2	Number of nets per pack	40 nets per bale packed in individual plastic bags per bale.	As specified	Comply
19		workmanship appearance	As specified	-

In addition to the above inspection, 4 samples (batch No. 0608) were sent to Singapore laboratory for testing.

In summary, the total defects were below the rejected number, so the findings were satisfactory and in compliance with the requirements of the Purchase Order.



**APPENDIX C**  
**CERTIFICATE OF CONFORMANCE**  
***Long Lasting Insecticide Treated Nets (LLINs)***  
***for***

<b>Country Designation</b>						
<b>Product</b>						
<b>Supplier</b>						
<b>Lot Number(s)</b>						
<b>Manufacturing Date of LLINs</b>						
<b>On-Site Physical Inspection Crown Agents</b>	Part I – Document verification			Complies		
	Part II - Visual Inspection Sample size n=200 -AQL 2.5 (Accept 10/Reject 11)			Description	Defectives Found: Total Complies	
	-			-		
<b>Physical Testing Independent Laboratory PSB-Singapore</b>	<b>TEST</b>	<b>SPECIFICATION</b>		<b>REQUIREMENT</b>	<b>RESULT</b>	<b>Assessment</b>
	Fibre Analysis	ISO 1833:1977	Routine	Polyester	100% Polyester	Complies
	Fabrication	ISO 8388:1998	Routine	Warp knitted	Warp knitted	Complies
	Mesh Size	ISO 7211/2:1984	Routine	24 holes/cm <sup>2</sup> -min		Complies
	Dimensional stability to washing	ISO 3759:1994 ISO 5077:1984 EN ISO 6330:2001	Routine	Nets must be heat set and show shrinkage of ≤ 5% after washing/dry		Complies
	Netting burst strength	ISO 13938-2:1999	Routine	>250 min. kpa		Complies
	Number of Filaments	ISO 8388:1998	Non-routine As requested	Multi-filament ≥34 (36) preferred		Complies
	Denier	BS 5441:1998 cl 15	Non-routine As requested	100 ± 5 (for Information Only)		For Information Only
	Mass per unit area	ISO 3801:1977	Non-routine As requested	40 ± 2		Complies
	Flammability	16-CFR 1610-CS191-53	Non-routine As requested	Class 1 (non-flammable)		Complies
	Colour Fastness	ISO 105-B02:1994	Non-routine As requested	4 or better		Complies
Colour Fastness to washing	BS EN ISO 105-C06:1997	Non-routine As requested	4 or better		Complies	
<b>Chemical Analysis of Pesticide Independent Laboratory PSB-Singapore</b>	<b>Total Deltamethrin content before wash Mean – mg/m<sup>2</sup> (Initial concentration)</b>			±20% concentration (42 to 64mg/m <sup>2</sup> )	Complies	
	<b>Total Deltamethrin content after six washings Mean – mg/m<sup>2</sup></b>			±20% concentration (42 to 64mg/m <sup>2</sup> )	Complies	
<i>Reviewed by/Date-</i> Steve Hamel-Signature on File				<b>LLINs comply with WHO and USAID   DELIVER Project –Malaria Specifications</b>		
<b>Quality Assurance Partners for USAID   DELIVER Project –Malaria</b>						

*This report shall not be reproduced except in full, without the written approval of The Quality Assurance –Partners for USAID | DELIVER Project –Malaria.  
The reported test results relate only to the items sampled and tested at pre-shipment.*



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Conducting Audits of LLIN Suppliers		<b>DOCUMENT No.:</b> TO3-QA-LLINs-04
<b>DATE ISSUED:</b> 8/8/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH Family Health International/USP	<b>APPROVED BY &amp; DATE:</b>  Steve Hamel-Signature on File	

**1.0 PURPOSE:**

<b>1.1</b>	To establish a quality assurance procedure for conducting supplier visits and audits of LLIN suppliers.
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**2.0 BACKGROUND:**

<b>2.1</b>	<p>The sampling, inspection and testing procedure described in <b>TO3-QA-LLINs-03</b> outlines a specialized program of sampling and inspecting LLINs. It's critical that an audit of the procedure at the manufacturing site be conducted.</p> <p>Auditing suppliers is a valuable quality activity that allows the customer to understand the capabilities and competency of the supplier(s). The audit creates opportunities for open dialogue to discuss potential barriers to product supply. The audit establishes a solid customer-supplier relationship that helps to create a consistent flow of product.</p>
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**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization</i>
	3.	<i>Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification</i>
	4.	<i>Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.</i>
	5.	<i>Quality Assurance and Inspection of LLINs – Crown Agents</i>
	6.	<i>TO3-QA-LLINs-03- Sampling, Inspection, and Testing of LLINs for pre-shipment</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality Assurance-Partners USAID   DELIVER – TO3 Malaria</b>		
4.1.1	These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
1.	John Snow Inc.	Procurement Pre-Qualification	Audits
2.	PATH	Procurement Pre-Qualification	Audits
3.	Crown Agents	Procurement Pre-Qualification	Sampling of LLINs Inspection of LLINs at the manufacturing site Audits
4.	Family Health International	Oversight of QA- Activities	Standard Operating Procedures Audits Monitoring suppliers Complaints
5.	United States Pharmacopeia	No Major Responsibilities for LLINs at this time	Audits

**5.0 QUALITY ASSURANCE SUPPLIER VISITS and AUDITS:**

<b>5.1</b>	<b>Supplier Site Visits and Audits</b>
5.1.1	The pre-qualification site visits are <b>waived</b> for the beginning of the procurement process for the project based on the emergency need to provide LLINs in time for the malaria season. Therefore, the desk audit conducted by JSI under the pre-qualification procedure (WHOPES approval) for the manufacturers serves as the pre-qualification audit.
5.1.2	Following this interim procurement period, site visits and audits of the LLIN suppliers will be conducted by the QA-Partners after sufficient data has been collected and reviewed. However, if any of the QA-Partners are traveling in a country where LLIN manufacturing occurs, a visit may be warranted. See Appendix A for a list of the suppliers.
5.1.3	The authorized sampling and inspection agency in consultation with the QA-Partners reserve the right to undertake a site visit/audit at any time during the manufacturing or sampling and inspection of the LLINs.
5.1.4	In the event of any reported quality problems or complaints, a visit/audit may be part of the investigation process.

5.1.5	<p>An audit checklist may be used to assist the auditor with specifics of LLIN manufacturing. The audit may consist of the following;</p> <table border="1"> <tr> <td data-bbox="467 365 532 415">1.</td> <td data-bbox="532 365 1312 415">Assessing the procedure for sampling and inspecting the LLINs (procedure TO3-QA-LLINs-03)</td> </tr> <tr> <td data-bbox="467 415 532 466">2.</td> <td data-bbox="532 415 1312 466">An assessment of the manufacturing process used for the specific net type</td> </tr> <tr> <td data-bbox="467 466 532 625">3.</td> <td data-bbox="532 466 1312 625">The manufacturing process for evidence of a consistent process (i.e., level of product intermediate testing, equipment monitoring / maintenance / calibration conducted during the course of manufacturing, and general cleanliness and organization of the process)</td> </tr> <tr> <td data-bbox="467 625 532 676">4.</td> <td data-bbox="532 625 1312 676">Reviewing evidence of an established quality system (i.e. ISO 9001)</td> </tr> <tr> <td data-bbox="467 676 532 726">5.</td> <td data-bbox="532 676 1312 726">Reviewing documentation of employee training and safety</td> </tr> <tr> <td data-bbox="467 726 532 886">6.</td> <td data-bbox="532 726 1312 886">Understanding how lot size is determined and how the manufacturer tracks product intermediates during the course of manufacturing (i.e., labeling and storage of yarn packages, warp beams, warp knitted rolls, knitted fabric before / after insecticide application, during cut and sew, finished nets before packaging).</td> </tr> <tr> <td data-bbox="467 886 532 982">7.</td> <td data-bbox="532 886 1312 982">Reviewing the manufacturer's supply of raw materials (polymer, insecticide, stabilizers...) and QA checks conducted on that raw material before nets are manufactured.</td> </tr> <tr> <td data-bbox="467 982 532 1033">8.</td> <td data-bbox="532 982 1312 1033">Investigating the establishment of a product stability (weathering) testing program.</td> </tr> <tr> <td data-bbox="467 1033 532 1129">9.</td> <td data-bbox="532 1033 1312 1129">Reviewing documentation on how the manufacturer handles product complaints.</td> </tr> <tr> <td data-bbox="467 1129 532 1255">10.</td> <td data-bbox="532 1129 1312 1255">Understanding what all of the components of the nets are (polymer, stabilizer (i.e., UV protection of polymer), spin finishes, insecticide, binders)</td> </tr> </table>	1.	Assessing the procedure for sampling and inspecting the LLINs (procedure TO3-QA-LLINs-03)	2.	An assessment of the manufacturing process used for the specific net type	3.	The manufacturing process for evidence of a consistent process (i.e., level of product intermediate testing, equipment monitoring / maintenance / calibration conducted during the course of manufacturing, and general cleanliness and organization of the process)	4.	Reviewing evidence of an established quality system (i.e. ISO 9001)	5.	Reviewing documentation of employee training and safety	6.	Understanding how lot size is determined and how the manufacturer tracks product intermediates during the course of manufacturing (i.e., labeling and storage of yarn packages, warp beams, warp knitted rolls, knitted fabric before / after insecticide application, during cut and sew, finished nets before packaging).	7.	Reviewing the manufacturer's supply of raw materials (polymer, insecticide, stabilizers...) and QA checks conducted on that raw material before nets are manufactured.	8.	Investigating the establishment of a product stability (weathering) testing program.	9.	Reviewing documentation on how the manufacturer handles product complaints.	10.	Understanding what all of the components of the nets are (polymer, stabilizer (i.e., UV protection of polymer), spin finishes, insecticide, binders)
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4.	Reviewing evidence of an established quality system (i.e. ISO 9001)																				
5.	Reviewing documentation of employee training and safety																				
6.	Understanding how lot size is determined and how the manufacturer tracks product intermediates during the course of manufacturing (i.e., labeling and storage of yarn packages, warp beams, warp knitted rolls, knitted fabric before / after insecticide application, during cut and sew, finished nets before packaging).																				
7.	Reviewing the manufacturer's supply of raw materials (polymer, insecticide, stabilizers...) and QA checks conducted on that raw material before nets are manufactured.																				
8.	Investigating the establishment of a product stability (weathering) testing program.																				
9.	Reviewing documentation on how the manufacturer handles product complaints.																				
10.	Understanding what all of the components of the nets are (polymer, stabilizer (i.e., UV protection of polymer), spin finishes, insecticide, binders)																				

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
8/8/07	00	N/A	New Issue.

## ATTACHMENT A

### List of LLIN Suppliers

	Manufacturer / Insecticide-	Brand Names	Net Type	WHOPES Phase I	WHOPES Phase II	WHOPES Phase III	Production Facility Location
<b>1. Deltamethrin</b>							
a.	<b>Vestergaard Frandsen</b>	Permanet®	Polyester	Passed	Passed Jan-04'	Recommended for large scale field studies	Denmark India Vietnam Thailand Bangladesh China
b.	<b>Tana Netting Co. Ltd.</b>	DAWAplus®	Polyester	Passed Sep-06'	Interim expected Jan-08'	-----	Bangkok 10110 Thailand, 27 Sukhumvit oi 53
c.	<b>Bestnet</b>	NetProtect®	Polyethylene	Passed Sep-06'	Interim expected Jan-08'	-----	India Not clearly indicated.
<b>2. Alpha-cypermethrin</b>							
a.	<b>BASF</b>	Interceptor®	Polyester	Passed Feb-05'	Passed Jan-07'	Recommended pending Phase III trials	Australia  Thailand, Sunshine World Net 2003
b.	<b>Clarke Mosquito Control</b>	DuraNet®	Polyethylene	Passed Nov-06'	Interim expected Jan-08'	-----	1 <sup>st</sup> stage of process in France 2 <sup>nd</sup> stage of process VKA Polymers, Tamil Nadu India
<b>3. Permethrin</b>							
a.	<b>Sumitomo</b>	Olyset®	Polyethylene	Passed	Passed Jan-01'	Recommended pending Phase III trials	Japan Tanzania Changzhou, China Dalian, China Vietnam



# USAID | DELIVER PROJECT

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## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Conducting Laboratory Audits for LLINs		<b>DOCUMENT No.:</b> TO3-QA-LLINs-05
<b>DATE ISSUED:</b> 8/9/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH Family Health International/USP	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File	

### 1.0 PURPOSE:

<b>1.1</b>	To describe the procedure for conducting an audit of laboratories that perform physical and chemical testing of long lasting insecticide treated nets (LLINs).
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### 2.0 BACKGROUND:

<b>2.1</b>	Reliable test results are vital to monitoring the quality of the LLINs. Laboratories must be competent with adequately trained personnel, proper test equipment, document control, etc. The audit process also creates opportunities for open dialogue and continuous improvement.
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### 3.0 REFERENCE DOCUMENTS:

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization</i>
	3.	<i>Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification</i>
	4.	<i>Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.</i>
	6.	<i>TO3-QA-LLINs-03- Sampling, Inspection, and Testing of LLINs for pre-shipment</i>
	7.	<i>ISO/IEC-17025:2005General Requirements for the Competence of Testing and Calibration Laboratories</i>



**4.0 RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality Assurance-Partners USAID   DELIVER – TO3 Malaria</b>		
4.1.1			
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement	
	2. PATH	Procurement	Lab audits for LLINs
	3. Crown Agents	Procurement/Sampling/ Inspection	Supplier Audits
	4. Family Health International	QA-Oversight	Supplier Audits Lab audits for LLINs
	5. United States Pharmacopeia	No major responsibility	

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Laboratory Audits</b>
5.1.1	The laboratory audit should be performed by one of the QA-Partners that have laboratory audit experience and specifically LLIN testing experience.
5.1.2	The audit should be performed using the requirements outlined in; <i>ISO/IEC-17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories</i> . See Appendix A.
<b>5.2</b>	<b>Audit Report</b>
5.2.1	The audit report including any non-conformances will be reported to the USAID   DELIVER Project TO3-Malaria team.
5.2.2	Any corrective actions will be monitored by the QA-Partners.
<b>5.3</b>	<b>Frequency of Laboratory Audits</b>
5.3.1	Laboratory audits should be conducted on a 2-year basis unless corrective action follow-up is required.
5.3.2	Any new laboratory identified to provide testing of LLINs may require an audit prior to submission of samples in-order to verify compliance with <i>ISO/IEC-17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories</i> .

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
8/9/07	00	N/A	New Issue.



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## APPENDIX A

Assessor Instructions: Review the laboratory's documented management system to verify compliance with the applicable 17025 documentation requirements. Assess to verify that the documented management system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. Please note that the N/A block has been removed for those clauses that are always applicable for all types of laboratories, both commercial and captive. Record comments related to any requirement on the space provided. All deficiencies must be identified and explained in the assessor deficiency report.

Laboratory Name: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Personnel Information (Names, Titles, and Responsibilities):

Technical Management: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Quality Manager (QM):

\_\_\_\_\_

Deputy QM:

\_\_\_\_\_

**General Requirements for Accreditation of Laboratories Checklist**

**Type of Assessment (please indicate):**

**Full Assessment**

**Surveillance Assessment**

To the best of my knowledge, all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of ISO/IEC 17025. I hereby attest that all 'Yes' marked compliance clauses, whether initialed or not, meet the aforementioned requirements. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

Assessor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<b>4. MANAGEMENT REQUIREMENTS</b>					
<b>4.1 Organization</b>					
4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.					
4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the <i>customer</i> , the regulatory authorities or organizations providing recognition.					
4.1.3 The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.					
4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.					

Requirement	Reference	{ RESERVED FOR ASSESSORS ONLY }			
		Compliance			Comments
		Y	N	NA	
4.1.5 The laboratory shall					
a) have managerial and technical personnel <i>who, irrespective of other responsibilities, have</i> the authority and resources needed to carry out their duties, <i>including the implementation, maintenance and improvement of the management system</i> , and to identify the occurrence of departures from the <i>management</i> system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);					
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;					
c) have policies and procedures to ensure the protection of its <i>customers'</i> confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;					
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;					
e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;					
f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;					
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;					
h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;					
i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the <i>management system related to quality</i> is implemented and followed at all times;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;					
j) appoint deputies for key managerial personnel (see note).					
k) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.					
4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.					
<b>4.2 Management system</b>					
4.2.1 The laboratory shall establish, implement and maintain a <b>management</b> system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.					
The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.					
4.2.2 The laboratory's <b>management</b> system policies <b>related to quality, including a quality policy statement</b> , shall be defined in a quality manual (however named).					
The overall objectives shall be <b>established, and reviewed during management review</b> . The quality policy statement shall be issued under the authority of <b>top management</b> . It shall include at least the following:					
a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its <b>customers</b> ;					
b) the management's statement of the laboratory's standard of service;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
c) <i>the purpose of the management system related to quality;</i>					
d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and					
e) the laboratory management's commitment to <i>comply</i> with this International Standard <i>and to continually improve the effectiveness of management system.</i>					
4.2.3 <i>Top management shall provide evidence of commitment to the development and implementation of the management system and continually improving its effectiveness.</i>					
4.2.4 <i>Top management shall communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.</i>					
4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the <i>management</i> system.					
4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.					
4.2.7 <i>Top management shall ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.</i>					
<b>4.3 Document control</b>					
4.3.1 General  The laboratory shall establish and maintain procedures to control all documents that form part of its <i>management</i> system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.					
4.3.2 Document approval and issue					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.3.2.1 All documents issued to personnel in the laboratory as part of the <b>management</b> system shall be reviewed and approved for use by authorized personnel prior to issue.					
A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the <b>management</b> system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.					
4.3.2.2 The procedure(s) adopted shall ensure that:					
a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;					
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;					
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;					
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.					
4.3.2.3 <b>Management</b> system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).					
4.3.3 Document changes					
4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.					
4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.3.3.3 If the laboratory's <b>document</b> control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined.					
Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.					
4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.					
<b>4.4 Review of requests, tenders and contracts</b>					
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:					
a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);					
b) the laboratory has the capability and resources to meet the requirements;					
c) the appropriate test and/or calibration method is selected and capable of meeting the <b>customers'</b> requirements (see 5.4.2).					
Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the <b>customer</b> .					
4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a <b>customer</b> relating to the <b>customer's</b> requirements or the results of the work during the period of execution of the contract.					
4.4.3 The review shall also cover any work that is subcontracted by the laboratory.					
4.4.4 The <b>customer</b> shall be informed of any deviation from the contract.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.					
<b>4.5 Subcontracting of tests and calibrations</b>					
4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.					
4.5.2 The laboratory shall advise the <i>customer</i> of the arrangement in writing and, when appropriate, gain the approval of the <i>customer</i> , preferably in writing.					
4.5.3 The laboratory is responsible to the <i>customer</i> for the subcontractor's work, except in the case where the <i>customer</i> or a regulatory authority specifies which subcontractor is to be used.					
4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.					
<b>4.6 Purchasing services and supplies</b>					
4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.					
Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.					
4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements.					
Records of actions taken to check compliance shall be maintained.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.					
4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.					
<b>4.7 Service to the customer</b>					
4.7.1 The laboratory shall <i>be willing to cooperate with customers</i> or their representatives <i>in clarifying</i> the <i>customer's</i> request and <i>in monitoring</i> the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other <i>customers</i> .					
4.7.2 <i>The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service.</i>					
<b>4.8 Complaints</b>					
The laboratory shall have a policy and procedure for the resolution of complaints received from <i>customers</i> or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also <b>4.11</b> ).					
<b>4.9 Control of nonconforming testing and/or calibration work</b>					
4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the <i>customer</i> . The policy and procedures shall ensure that:					
a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;					
b) an evaluation of the significance of the nonconforming work is made;					
c) <i>correction is</i> taken immediately, together with any decision about the acceptability of the nonconforming work;					
d) where necessary, the <i>customer</i> is notified and work is recalled;					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
e) the responsibility for authorizing the resumption of work is defined.					
4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.					
<b>4.10 Improvement</b> <i>The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</i>					
<b>4.11 Corrective action</b>					
<b>4.11.1 General</b> The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the <b>management</b> system or technical operations have been identified.					
<b>4.11.2 Cause analysis</b> The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.					
<b>4.11.3 Selection and implementation of corrective actions</b> Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.					
Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.					
The laboratory shall document and implement any required changes resulting from corrective action investigations.					
<b>4.11.4 Monitoring of corrective actions</b> The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.					
<b>4.11.5 Additional audits</b> Where the identification of <b>nonconformities</b> or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.					
<b>4.12 Preventive action</b>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.12.1 Needed improvements and potential sources of <b>nonconformities</b> , either technical or concerning the <b>management</b> system, shall be identified.					
<b>When improvement opportunities are identified</b> or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such <b>nonconformities</b> and to take advantage of the opportunities for improvement.					
4.12.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.					
<b>4.13 Control of records</b>					
<b>4.13.1 General</b>					
4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.					
4.13.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.					
Retention times of records shall be established.					
4.13.1.3 All records shall be held secure and in confidence.					
4.13.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.					
<b>4.13.2 Technical records</b>					
4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.					
The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.					
<b>4.13.2.2</b> Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.					
<b>4.13.2.3</b> When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.					
In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.					
<b>4.14 Internal audits</b>					
<b>4.14.1</b> The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the <b>management</b> system and this International Standard.					
The internal audit program shall address all elements of the <b>management</b> system, including the testing and/or calibration activities.					
It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.					
Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.					
<b>4.14.2</b> When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify <b>customers</b> in writing if investigations show that the laboratory results may have been affected.					
<b>4.14.3</b> The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.					
<b>4.15 Management review</b>					
4.15.1 In accordance with a predetermined schedule and procedure, the laboratory's <b>top</b> management shall periodically conduct a review of the laboratory's <b>management</b> system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:					
the suitability of policies and procedures;					
reports from managerial and supervisory personnel;					
the outcome of recent internal audits;					
corrective and preventive actions;					
assessments by external bodies;					
the results of interlaboratory comparisons or proficiency tests;					
changes in the volume and type of the work;					
<b>customer</b> feedback;					
complaints;					
<b>recommendations for improvement</b> ;					
other relevant factors, such as quality control activities, resources and staff training.					
4.15.2 Findings from management reviews and the actions that arise from them shall be recorded.					
The management shall ensure that those actions are carried out within an appropriate and agreed timescale.					
5 Technical requirements					
5.1 General					

Requirement	Reference	{ RESERVED FOR ASSESSORS ONLY }			
		Compliance			Comments
		Y	N	NA	
5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: <ul style="list-style-type: none"> <li>- human factors (5.2);</li> <li>- accommodation and environmental conditions (5.3);</li> <li>- test and calibration methods and method validation (5.4);</li> <li>- equipment (5.5);</li> <li>- measurement traceability (5.6);</li> <li>- sampling (5.7);</li> <li>- the handling of test and calibration items (5.8).</li> </ul>					
5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.					
<b>5.2 Personnel</b>					
5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.					
When using staff who are undergoing training, appropriate supervision shall be provided.					
Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.					
5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel.					
The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.					
<i>The effectiveness of the training actions taken shall be evaluated.</i>					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's <i>management</i> system.					
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.					
5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.					
The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.					
<b>5.3 Accommodation and environmental conditions</b>					
5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.					
The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.					
The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.					
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.					
5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.					
5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.					
5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.					
<b>5.4 Test and calibration methods and method validation</b>					
5.4.1 General The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.					
The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.					
All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).					
Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the <i>customer</i> .					
5.4.2 Selection of methods The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the <i>customer</i> and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used.					

Requirement	Reference	{ RESERVED FOR ASSESSORS ONLY }			
		Compliance			Comments
		Y	N	NA	
The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.					
When the <i>customer</i> does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated.					
The <i>customer</i> shall be informed as to the method chosen.					
The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.					
The laboratory shall inform the <i>customer</i> when the method proposed by the <i>customer</i> is considered to be inappropriate or out of date.					
5.4.3 Laboratory-developed methods  The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.					
Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.					
5.4.4 Non-standard methods  When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the <i>customer</i> and shall include a clear specification of the <i>customer's</i> requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.					
5.4.5 Validation of methods					
5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.					
5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the <i>customer's</i> needs.					
5.4.6 Estimation of uncertainty of measurement					
5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.					
5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.					
5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.					
5.4.7 Control of data					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.					
5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:					
a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;					
b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;					
c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.					
<b>5.5 Equipment</b>					
5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).					
In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.					
5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.					
Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.					

Requirement	Reference	{ RESERVED FOR ASSESSORS ONLY }			
		Compliance			Comments
		Y	N	NA	
Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).					
5.5.3 Equipment shall be operated by authorized personnel.					
Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.					
5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.					
5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:					
a) the identity of the item of equipment and its software;					
b) the manufacturer's name, type identification, and serial number or other unique identification;					
c) checks that equipment complies with the specification (see 5.5.2);					
d) the current location, where appropriate;					
e) the manufacturer's instructions, if available, or reference to their location;					
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;					
g) the maintenance plan, where appropriate, and maintenance carried out to date;					
h) any damage, malfunction, modification or repair to the equipment.					
5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.					
The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9).					
5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.					
5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.					
5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.					
5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.					
5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.					
<b>5.6 Measurement traceability</b>					
5.6.1 General  All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
The laboratory shall have an established program and procedure for the calibration of its equipment.					
5.6.2 Specific requirements					
5.6.2.1 Calibration					
5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) ( <i>Système international d'unités</i> ).					
A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.					
When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.					
The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).					
5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:					
- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;					
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Participation in a suitable program of interlaboratory comparisons is required where possible.					
5.6.2.2 Testing					
5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.					
5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).					
5.6.3 Reference standards and reference materials					
5.6.3.1 Reference standards The laboratory shall have a program and procedure for the calibration of its reference standards.					
Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.					
Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.					
Reference standards shall be calibrated before and after any adjustment.					
5.6.3.2 Reference materials Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.6.3.3 Intermediate checks  Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.					
5.6.3.4 Transport and storage  The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.					
5.7 Sampling					
5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.					
The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken.					
Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.					
5.7.2 Where the <i>customer</i> requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.					
5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken.					
These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.					
5.8 Handling of test and calibration items					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the <i>customer</i> .					
5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.					
5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.					
When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the <i>customer</i> for further instructions before proceeding and shall record the discussion.					
5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed.					
When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.					
Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.					
<b>5.9 Assuring the quality of test and calibration results</b>					
5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.					
This monitoring shall be planned and reviewed and may include, but not be limited to, the following:					
a) regular use of certified reference materials and/or internal quality control using secondary reference materials;					
b) participation in interlaboratory comparison or proficiency-testing programs;					
c) replicate tests or calibrations using the same or different methods;					
d) retesting or recalibration of retained items;					
e) correlation of results for different characteristics of an item.					
<b>5.9.2</b> <i>Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from being reported.</i>					
<b>5.10 Reporting the results</b>					
5.10.1 General  The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.					
The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the <b>customer</b> and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.					
In the case of tests or calibrations performed for internal <b>customers</b> , or in the case of a written agreement with the <b>customer</b> , the results may be reported in a simplified way.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
Any information listed in 5.10.2 to 5.10.4 which is not reported to the <b>customer</b> shall be readily available in the laboratory which carried out the tests and/or calibrations.					
5.10.2 Test reports and calibration certificates Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:					
a) a title (e.g. "Test Report" or "Calibration Certificate");					
b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;					
c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;					
d) the name and address of the <b>customer</b> ;					
e) identification of the method used;					
f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;					
g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;					
h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;					
i) the test or calibration results with, where appropriate, the units of measurement;					
j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;					
k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.10.3 Test reports					
5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:					
a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;					
b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;					
c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a <i>customer's</i> instruction so requires, or when the uncertainty affects compliance to a specification limit;					
d) where appropriate and needed, opinions and interpretations (see 5.10.5);					
e) additional information which may be required by specific methods, <i>customers</i> or groups of <i>customers</i> .					
5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:					
a) the date of sampling;					
b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);					
c) the location of sampling, including any diagrams, sketches or photographs;					
d) a reference to the sampling plan and procedures used;					
e) details of any environmental conditions during sampling that may affect the interpretation of the test results;					
f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
5.10.4 Calibration certificates					
5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:					
a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;					
b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;					
c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).					
5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.					
When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.					
When statements of compliance are made, the uncertainty of measurement shall be taken into account.					
5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.					
5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the <i>customer</i> . This requirement may be superseded by legal regulations.					
5.10.5 Opinions and interpretations  When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.					

Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
<p>5.10.6 Testing and calibration results obtained from subcontractors</p> <p>When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.</p>					
<p>When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.</p>					
<p>5.10.7 Electronic transmission of results</p> <p>In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).</p>					
<p>5.10.8 Format of reports and certificates</p> <p>The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.</p>					
<p>5.10.9 Amendments to test reports and calibration certificates</p> <p>Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:  "Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]",  or an equivalent form of wording.</p> <p>Such amendments shall meet all the requirements of this International Standard.</p>					
<p>When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.</p>					
<p>8.1 Accredited organizations may incorporate statements concerning their accreditation in publicity and/or advertising materials, including brochures and organization publications, technical literature, business reports, web sites and quotations or proposals for work.</p>					

<p>9.1 Every circumstance where the principle of accurate representation applies cannot be anticipated and dealt with in this document. Therefore, it is the responsibility of the accredited and applicant organization representatives not to misrepresent their accredited status under any circumstances.</p>					
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<p>a) The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall be retained for an appropriate, prescribed time;</p>					
<p>b) The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;</p>					
<p>c) The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute;</p>					
<p>d) The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated for each type of calibration and records of these calculations shall be maintained. (NOTE: Records of these calculations must be maintained for calibrations done as of 8/1/06.) Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;</p>					*
<p>e) Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior of the reference standard.</p>					



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Supplier Report Card for LLINs		<b>DOCUMENT No.:</b> TO3-QA-LLINs-06
<b>DATE ISSUED:</b> 8/9/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH Family Health International/USP	<b>APPROVED BY &amp; DATE:</b>  <i>Steve Hamel-Signature on File</i>	

### 1.0 PURPOSE:

<b>1.1</b>	To describe the procedure for preparing and reporting supplier performance information.
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### 2.0 BACKGROUND:

<b>2.1</b>	Monitoring supplier performance via a scorecard (or report card) is a valuable quality management and communication tool between the supplier and customer (USAID   DELIVER Project TO3-Malaria).
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### 3.0 REFERENCE DOCUMENTS:

<b>3.1</b>	<table border="1" style="width: 100%;"> <tr> <td style="width: 5%; text-align: center;">1.</td> <td><i>Standard operating procedure TO3-QA-LLINs-03 Sampling, Inspection and Testing of LLINs</i></td> </tr> <tr> <td style="text-align: center;">2.</td> <td><i>The Supplier Management Handbook, Sixth Edition- American Society for Quality</i></td> </tr> </table>	1.	<i>Standard operating procedure TO3-QA-LLINs-03 Sampling, Inspection and Testing of LLINs</i>	2.	<i>The Supplier Management Handbook, Sixth Edition- American Society for Quality</i>
1.	<i>Standard operating procedure TO3-QA-LLINs-03 Sampling, Inspection and Testing of LLINs</i>				
2.	<i>The Supplier Management Handbook, Sixth Edition- American Society for Quality</i>				

### 4.0 RESPONSIBILITIES:

<b>4.1</b>	Responsibilities - Quality Assurance- Partners; USAID   DELIVER – TO3 Malaria										
4.1.1	<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 30%;">Quality Assurance Partners</th> <th style="width: 65%;">Major Responsibility</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1.</td> <td>Family Health International</td> <td>Collect information on suppliers and generate scorecards</td> </tr> <tr> <td style="text-align: center;">2.</td> <td>John Snow Inc.</td> <td>Provide additional information related to supplier(s)</td> </tr> </tbody> </table>			Quality Assurance Partners	Major Responsibility	1.	Family Health International	Collect information on suppliers and generate scorecards	2.	John Snow Inc.	Provide additional information related to supplier(s)
	Quality Assurance Partners	Major Responsibility									
1.	Family Health International	Collect information on suppliers and generate scorecards									
2.	John Snow Inc.	Provide additional information related to supplier(s)									

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Components of a Scorecard</b>				
5.1.1	There are generally three to five components of a supplier scorecard. These can be ranked based on the degree of importance by the customer or they can have equal weight. There is no standard scorecard that is used across industry or in supplier quality. The most important factor is that the customer and supplier agree to the rating and that the scorecard is the same for all suppliers of that product.				
5.1.2	<p>The scorecard for LLINs will focus on;</p> <table border="1" data-bbox="467 667 776 806"> <tr><td>"On-time deliveries"</td></tr> <tr><td>Test data (CpK)</td></tr> <tr><td>Complaints/Product audit (In-Country evaluations)</td></tr> <tr><td>Supplier Audits</td></tr> </table> <p>The ranking of importance is "to be determined".</p>	"On-time deliveries"	Test data (CpK)	Complaints/Product audit (In-Country evaluations)	Supplier Audits
"On-time deliveries"					
Test data (CpK)					
Complaints/Product audit (In-Country evaluations)					
Supplier Audits					
<b>5.2</b>	<b>"On-Time" Deliveries</b>				
5.2.1	<p>An important aspect of supplier performance is monitoring "on-time" deliveries. The information is obtained from John Snow Inc on a monthly basis through the database. The information monitored is;</p> <table border="1" data-bbox="467 1075 776 1184"> <tr><td>Order date</td></tr> <tr><td>Actual ship date</td></tr> <tr><td>Desired delivery date</td></tr> <tr><td>Actual delivery date</td></tr> </table> <p>Note: There is a "window" that can be established that is determined by the customer.</p>	Order date	Actual ship date	Desired delivery date	Actual delivery date
Order date					
Actual ship date					
Desired delivery date					
Actual delivery date					
<b>5.3</b>	<b>LLIN Test Data</b>				
5.3.1	Copies of the LLIN inspection and chemical test reports are sent to Family Health International for input into an Excel database.				
5.3.2	The data are statistically evaluated against the existing specification (for each test) in order to observe trends in the manufacturing process. (Process capability index CpK)				
5.3.3	Other statistical methods may also be used depending on the nature of the reported data. Any rejections are also included.				
<b>5.4</b>	<b>Complaints/Product audit (In-Country Evaluations)</b>				
5.4.1	If the USAID   DELIVER Project TO3-Malaria team receives any complaint regarding the LLIN, that information is investigated and corrective actions are evaluated and monitored. In-Country product audit testing is also included.				

<b>5.5</b>	<b>Supplier Audits</b>
5.5.1	If any non-conformances are found during an audit, the corrective actions are monitored. Audit reports may also be part of the supplier scorecard.
<b>5.6</b>	<b>Scorecard Reports</b>
5.6.1	Scorecard reports will be disseminated to the USAID   DELIVER Project TO3-Malaria team on a periodic basis. The frequency will depend on the amount of information collected in a specific time period, generally 6 or 12 months.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
8/9/07	00	N/A	New Issue.



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Evaluating LLINs In-Country		<b>DOCUMENT No.:</b> TO3-QA-LLINs-07
<b>DATE ISSUED:</b> 8/9/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH Family Health International/USP	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File	

**1.0 PURPOSE:**

<b>1.1</b>	To establish a procedure for the evaluation of LLINs In-Country.
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**2.0 BACKGROUND:**

<b>2.1</b>	<p>Under routine use, LLINs will be subject to normal “wear and tear” including as many as twenty washings. The durability and insecticide amount may need to be determined at some interval(s) of the product life-cycle. Auditing of the physical and chemical properties of the LLIN In-Country, helps provide additional information of the quality compared to initial test results.</p> <p>In addition, there may be a need to conduct an investigation of a particular LLIN because of a concern raised by the USAID Mission or end-user.</p>
------------	--

**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	<table border="1"> <tr> <td>1.</td> <td>President’s Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</td> </tr> <tr> <td>2.</td> <td>Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization</td> </tr> <tr> <td>3.</td> <td>Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification</td> </tr> <tr> <td>4.</td> <td>Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.</td> </tr> </table>	1.	President’s Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa	2.	Technical consultation on specifications and quality control of netting materials and mosquito nets-World Health Organization	3.	Technical Standards for USAID –financed LLINs-Criteria for LLIN Prequalification	4.	Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.
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4.	Guidelines for Laboratory and Field Testing of Long-Lasting Insecticidal Mosquito Nets World Health Organization WHO/CDS/WHOPES/GCDPP/2005.								

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	Responsibilities - Quality Assurance-Partners for USAID   DELIVER – TO3 Malaria		
4.1.1	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement /Pre-Qualification	Audits
	2. PATH	Procurement /Pre-Qualification	Audits
	3. Crown Agents	Procurement Pre-Qualification	Sampling agency Inspection of LLINs at the manufacturing site Audits
	4. Family Health International	Oversight of QA-Activities	Standard Operating Procedures, Audits Monitoring suppliers, Complaints
	5. United States Pharmacopeia		Audits

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Collecting LLINs In-Country</b>
5.1.1	It may be necessary to collect LLINs In-Country based on a concern raised by the end user, the USAID Mission, or others. In addition, the QA-Partners may request LLINs as part of an audit exercise.
5.1.2	Determine if any of the LLINs can be collected by a USAID Mission representative or other designee. The number of available LLINs for collection will depend on the specific situation. LLINs should be shipped to;  Family Health International 2810 Meridian Pkwy- Suite 110 Durham, NC 27713 USA Attention: Dr. David Jenkins/Steve Hamel
<b>5.2</b>	<b>Investigation/Audit Report-Initial</b>
5.2.1	An investigation/audit report is started upon receipt of information regarding a concern or complaint. Use Appendix A to begin to collect the information. It is necessary to gather as much information regarding the procurement and distribution of the LLIN including the original test results, etc.
<b>5.3</b>	<b>Testing</b>
5.3.1	Testing of the LLIN for durability (burst strength) and insecticide amount is required. Other tests can be added as determined through the investigation process. (Reference TO3-QA-LLINs-03)
<b>5.4</b>	<b>Investigation/Audit Report-Final</b>
5.4.1	The Investigation/audit report is completed and findings are reported to USAID   DELIVER Project TO3-Malaria and the Country Mission office or others as designated.
5.4.2	Any recommended corrective actions are reviewed with the manufacturer and follow-up is required to properly complete the investigation/audit report.
5.4.3	The findings are included in the supplier’s scorecard information.

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
8/9/07	00	N/A	New Issue.

APPENDIX A

**INVESTIGATION/AUDIT REPORT  
LLINs-In-Country  
2007**

Checklist	
Complaint or Audit:	
Date Complaint /Audit reported:	
Complaint reported by:	
Manufactured by:	
Amount of product involved:	
Action:	
Management – the responsibilities and authority for the management of non-conforming work are designated and actions are defined and taken when non-conforming product is identified	
An evaluation of the significance of the non-conforming product is made- Conclusion	
Corrective actions are taken immediately.	
USAID   DELIVER Project notified	
Responsibility for authorizing the use of the product;	
Review of Records	
Corrective Actions- actions most likely to eliminate the problem and to prevent recurrence And the corrective action(s) shall be appropriate to the magnitude and risk of the problem	



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Rapid Diagnostic Test Kits (RDTs) Quality Assurance Activities/Risks/Estimated Costs		<b>DOCUMENT No.:</b> TO3-QA-RDTs-20
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> 8/7/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel- Signature on File –

### 1.0 PURPOSE:

1.1	To establish a document that serves as a summarized reference for quality assurance steps for procuring RDTs and is also a guide for associated risks and estimated costs.								
1.2	Risk Management is the formal process by which risk factors are systematically identified, and assessed. The methodology of Risk Management involves four steps; <table border="1" style="margin-left: 20px;"> <tr> <td>1.</td> <td>Identifying and classifying the areas of potential risk.</td> </tr> <tr> <td>2.</td> <td>Quantifying the risk by determining the probability of events and associated consequences.</td> </tr> <tr> <td>3.</td> <td>Responding to the risk by having or developing the means to handle the identified and quantified risk.</td> </tr> <tr> <td>4.</td> <td>Capturing and retaining lessons learned as knowledge to aid future decisions.</td> </tr> </table>	1.	Identifying and classifying the areas of potential risk.	2.	Quantifying the risk by determining the probability of events and associated consequences.	3.	Responding to the risk by having or developing the means to handle the identified and quantified risk.	4.	Capturing and retaining lessons learned as knowledge to aid future decisions.
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4.	Capturing and retaining lessons learned as knowledge to aid future decisions.								

### 2.0 QUALITY ASSURANCE ACTIVITIES/RISKS/ESTIMATED COSTS:

2.1	<p>The process of employing Risk Management for procurement of commodities allows the JSI Quality Assurance Partners and procurement team the tools to make sound decisions based on program needs that include Emergency procurements and very tight schedules.</p> <p style="text-align: center;"><b>ACTIVITY and RISK DATA SHEET</b> For RDTs</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">Country:</th> <th style="width: 25%;">RDT Description:</th> <th style="width: 15%;">Date Ordered:</th> <th style="width: 15%;">Date Inspected/Tested:</th> <th style="width: 10%;">Shipment (expected days)</th> <th style="width: 10%;">Date Requested –In-Country</th> <th style="width: 10%;">Total number of days</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: center;"><b>Activity</b></td> <td style="text-align: center;"><b>Cost</b></td> <td style="text-align: center;"><b>Risk-Low (1-2)</b> a. Use 1 if good history b. use 2 if no history</td> <td style="text-align: center;"><b>Risk-Medium (3-4)</b> a. Use 3 if good history b. use 4 if no history</td> <td style="text-align: center;"><b>Risk-High (5)</b></td> <td style="text-align: center;"><b>Score</b></td> <td style="text-align: center;"><b>Day(s)</b></td> </tr> <tr> <td>Select suppliers from criteria; Type of RDT with country registration and requirements</td> <td style="text-align: center;">n/a</td> <td>USAID pre-qualified, WHO list of RDTs or SRA approved</td> <td>WHO list of RDTs or SRA approved</td> <td>Not found on WHO list of RDTs or not SRA approved</td> <td></td> <td></td> </tr> <tr> <td>Pre-shipment Inspection</td> <td style="text-align: center;">n/a</td> <td>No Concurrent Inspection</td> <td>Concurrent Inspection</td> <td>No Inspection</td> <td></td> <td></td> </tr> <tr> <td>Post-shipment Inspection / testing</td> <td>Currently no charge for QA testing</td> <td>No Concurrent Inspection / Testing</td> <td>Concurrent Inspection / Testing</td> <td>No Inspection No Testing</td> <td></td> <td></td> </tr> <tr> <td>In-Country evaluation of RDTs</td> <td>As-needed basis (complaint or audit)</td> <td>Stability data on file through Exp. Date</td> <td>Stability data incomplete through Exp. Date</td> <td>No Stability data available</td> <td></td> <td></td> </tr> <tr> <td>Supplier audit</td> <td></td> <td>Audit –conducted -found compliant</td> <td>Audit conducted- corrective actions pending- some supplier history</td> <td>No Audit- No history</td> <td></td> <td></td> </tr> <tr> <td>Laboratory audit</td> <td></td> <td>Compliant with WHO Checklist</td> <td>Not evaluated against WHO checklist but has Quality management system</td> <td>No quality Management system</td> <td></td> <td></td> </tr> <tr> <td colspan="6" style="text-align: right;"><b>TOTAL SCORE</b></td> <td></td> </tr> <tr> <td style="text-align: center;">Total Expected costs</td> <td></td> <td colspan="4" style="text-align: center;"><b>Risk Associated with Quality Prevention Activities of LLINs</b></td> <td></td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">Low Risk Preferred 6</td> <td style="text-align: center;">Low to Medium 12</td> <td style="text-align: center;">Medium Acceptable (risks identified) 18</td> <td style="text-align: center;">Medium to High 24</td> <td style="text-align: center;">High Risk 30</td> </tr> </tbody> </table>						Country:	RDT Description:	Date Ordered:	Date Inspected/Tested:	Shipment (expected days)	Date Requested –In-Country	Total number of days								<b>Activity</b>	<b>Cost</b>	<b>Risk-Low (1-2)</b> a. Use 1 if good history b. use 2 if no history	<b>Risk-Medium (3-4)</b> a. Use 3 if good history b. use 4 if no history	<b>Risk-High (5)</b>	<b>Score</b>	<b>Day(s)</b>	Select suppliers from criteria; Type of RDT with country registration and requirements	n/a	USAID pre-qualified, WHO list of RDTs or SRA approved	WHO list of RDTs or SRA approved	Not found on WHO list of RDTs or not SRA approved			Pre-shipment Inspection	n/a	No Concurrent Inspection	Concurrent Inspection	No Inspection			Post-shipment Inspection / testing	Currently no charge for QA testing	No Concurrent Inspection / Testing	Concurrent Inspection / Testing	No Inspection No Testing			In-Country evaluation of RDTs	As-needed basis (complaint or audit)	Stability data on file through Exp. Date	Stability data incomplete through Exp. Date	No Stability data available			Supplier audit		Audit –conducted -found compliant	Audit conducted- corrective actions pending- some supplier history	No Audit- No history			Laboratory audit		Compliant with WHO Checklist	Not evaluated against WHO checklist but has Quality management system	No quality Management system			<b>TOTAL SCORE</b>							Total Expected costs		<b>Risk Associated with Quality Prevention Activities of LLINs</b>							Low Risk Preferred 6	Low to Medium 12	Medium Acceptable (risks identified) 18	Medium to High 24	High Risk 30
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2.2	Comments from Activity sheet;
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### 3.0 RESPONSIBILITIES:

3.1	<p>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</p> <p>The procurement and quality assurance of RDTs involves an integrated specialized team of partners from various organizations. These include;</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 25%;">Quality Assurance Partners</th> <th style="width: 25%;">Major Responsibility</th> <th style="width: 45%;">Other Responsibilities</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>John Snow Inc.</td> <td>Procurement Pre-Qualification</td> <td>Audits</td> </tr> <tr> <td>2.</td> <td>PATH</td> <td>Procurement Pre-Qualification</td> <td>Audits</td> </tr> <tr> <td>3.</td> <td>Crown Agents</td> <td>Procurement Pre-Qualification</td> <td>Sampling agency Inspection of RDTs at the manufacturing site Audits</td> </tr> <tr> <td>4.</td> <td>Family Health International</td> <td>Oversight of QA- Activities Standard Operating Procedures</td> <td>Audits Monitoring suppliers Complaints</td> </tr> <tr> <td>5.</td> <td>United States Pharmacopeia</td> <td>No Major Responsibilities for RDTs at this time</td> <td></td> </tr> </tbody> </table>		Quality Assurance Partners	Major Responsibility	Other Responsibilities	1.	John Snow Inc.	Procurement Pre-Qualification	Audits	2.	PATH	Procurement Pre-Qualification	Audits	3.	Crown Agents	Procurement Pre-Qualification	Sampling agency Inspection of RDTs at the manufacturing site Audits	4.	Family Health International	Oversight of QA- Activities Standard Operating Procedures	Audits Monitoring suppliers Complaints	5.	United States Pharmacopeia	No Major Responsibilities for RDTs at this time	
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### 4.0 DOCUMENT HISTORY:

Date Issued	History	Previous issue date	Reason for change
8/7/07	00	N/A	New Issue.
10/18/07	01	8/7/07	Add Risk Management



# USAID | DELIVER PROJECT

## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Pre-qualification of Rapid Diagnostic Test Kit (RDT) Suppliers		<b>DOCUMENT No.:</b> TO3-QA-RDTs-21
<b>DATE ISSUED:</b> 11/1/07	<b>SUPERSEDES:</b> 9/10/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel- Signature on File

### 1.0 PURPOSE:

1.1	To establish a document that provides the procedure for pre-qualification of RDT suppliers.
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### 2.0 BACKGROUND:

2.1	<p>The global procurement of Malaria Rapid Diagnostic Test Kits (RDTs) has increased rapidly as has the range of commercially available products. The USAID pre-qualified list of RDT suppliers aims to secure Malaria RDTs of a consistent quality with regards to both sensitivity and stability in malaria endemic countries. Methods to accurately monitor the quality of these tests are required. There are no WHO specifications with a standardized evaluation and testing scheme (such as WHOPES for LLIN insecticides).</p> <p>Currently, the WHO lists commercially available RDTs from a variety of suppliers. Although the suppliers and products are not officially recommended by WHO, the list is based on evidence of quality manufacturing, through documentary evidence of independent certification of compliance with ISO 13485:2003 (or US FDA 21 CFR 820) and a stability testing protocol provided by companies to the WHO. When the WHO list of pre-qualified suppliers becomes available, this will be the primary reference list.</p> <p>Speed of response to field office demands is likely to be critical. To enable this, the establishment of a list of “pre-qualified” vendors is necessary. The pre-qualification process will also help set up a common standard for manufacturers and their products. USAID   Deliver Project (the buyer) and the QA-Partners have established a pre-qualification procedure. Included in this procedure is a list of the suppliers that meet the criteria.</p> <p>The prequalification criteria outlined in the document will be employed until the QAP group for the USAID-Deliver Project is aware of a WHO pre-qualified list of RDT suppliers / products.</p>
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### 3.0 **DOCUMENT REFERENCES:**

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004
	3.	<i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006
	4.	Malaria Rapid Diagnosis- <i>Making it Work-Meeting Report</i> ; World Health Organization; 2003
	5.	<a href="http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf">http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf</a>
	6.	<a href="http://www.wpro.who.int/sites/rdt/purchasing_rdts.htm">http://www.wpro.who.int/sites/rdt/purchasing_rdts.htm</a>

### 4.0 **RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</b>		
4.1.1	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement Pre-Qualification	Audits
	2. PATH	Procurement Pre-Qualification	Audits/ Field evaluations
	3. Crown Agents	Procurement Pre-Qualification	Sampling agency Audits Field Technical Assistance
	4. Family Health International	Oversight of QA- Activities	Standard Operating Procedures Audits Monitoring suppliers Complaints
	5. United States Pharmacopeia	Field Technical assistance	Audits

### 5.0 **PRE-QUALIFICATION OF SUPPLIERS: USAID CRITERIA**

<b>5.1</b>	<b>Pre-Qualification Criteria (See Appendix A)</b>
5.1.0	Suppliers wishing to become pre-qualified for the USAID Deliver Project must meet the technical and administrative requirements as follows:
5.1.1	The supplier must provide evidence of product registration with malaria endemic country's relevant authority, or supporting documentation that product is being provided to National Malaria Control Programmes as part of standard malaria diagnosis guidelines.
5.1.2	The supplier must provide evidence of third party field data testing including stability data. Demonstrate evidence of real time stability testing data for a minimum period of twenty four (24) months is required. Testing conditions for stability of temperature and humidity should be comparable to those found in typical malaria endemic countries.
5.1.3	The supplier must provide specificity testing results of at least 90% and sensitivity greater than 90% from a reputable testing laboratory i.e., RITM Philippines or Institut Pasteur (Cambodia)  Ref: <a href="http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO_field_QA_guide.pdf">http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO_field_QA_guide.pdf</a>
5.1.4	The supplier must provide evidence of Good Manufacturing Practices in the form of ISO 13485:2003 or USFDA 21 CFR 820 covering quality management systems for the

	manufacturing of medical devices.																																																																																																																																							
5.1.5	The supplier must provide evidence of production capacity such as current customers with delivered orders over 50,000 test kits, complete with customer contact information.																																																																																																																																							
5.1.6	The supplier must provide evidence of support in-country for the product, including names of personnel or agents, statement of capacity and nature of relationship with manufacturer.																																																																																																																																							
5.1.7	Guaranteed product shelf life shall be a minimum of 18 months (15 months remaining after delivery in-country). The supplier must provide real time data to support storage temperature.																																																																																																																																							
5.1.8	The purchased test kits will be in cassette format and include lancets, swabs, blood transfer device and buffer solution.																																																																																																																																							
5.1.9	The supplier must provide an "Instruction Booklet" in the appropriate language. Also, any major limitations of the test which may lead to misdiagnosis should be acknowledged.																																																																																																																																							
5.1.10	The supplier must provide a "Statement of willingness to accept pre-shipment QC/QA inspection and testing by an independent testing agency designated by Buyer".																																																																																																																																							
5.1.11	As it becomes available, documentation should be kept on file with regard to the legal status of patent infringement suits for the RDT suppliers. No RDTs should be procured from suppliers that have legal suits filed against them for patent related issues.																																																																																																																																							
5.1.12	Based on this exercise, <b><u>the following suppliers are pre-qualified under the USAID technical requirements:</u></b>																																																																																																																																							
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5.1.13	The USAID   Deliver Project procurement team is responsible for collecting the pre-qualification information from the current and future suppliers and compiling into table form for quick reference. In addition, the procurement team will update the tables as necessary. Appendix A should be completed for each manufacturer where signature approval is obtained from FHI and JSI representatives. Original signature copies (along with supporting documentation for appendix A) should be kept on file at both locations.
5.1.14	The procurement team can select RDTs from this current list of pre-qualified suppliers. RDTs procured must meet country registration and/or program requirements.

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/10/07	00	N/A	New Issue.
11/1/07	01	9/10/07	Updated appendix A. Add more detail on signature approval (5.1.13).

**APPENDIX A**  
**Pre-Qualification Supplier Information Table**

<b>SUPPLIER</b> List all manufacturing sites		
<b>ADDRESS</b>		
<b>CONTACT INFORMATION</b>	Certified Letter of Authority indicating company contacts for Management, Quality Control, Quality Assurance and Production.	
	<b>Pre-qualification of Suppliers Requirements</b>	<b>Meets Prequalification Requirements / Comments</b>
1.	Proof of product registration with malaria endemic country's relevant authority, or proof that product is being provided to National Malaria Control Programmes as part of standard malaria diagnosis guidelines.	
2.	Evidence of third party field data testing including stability data. Demonstrate evidence of real time stability testing data of a minimum period of twenty four (24) months. Testing conditions for stability of temperature and humidity should be comparable to those found in typical malaria endemic countries.	
3.	Provide specificity testing results of at least 90% and sensitivity greater than 90%	
4.	Provide evidence of Good Manufacturing Practices in the form of ISO 13485:2003 or USFDA 21 CFR 820 covering quality management systems for the manufacturing of medical devices.	
5.	Provide evidence of production capacity such as current customers with delivered orders over 50,000 test kits, complete with customer contact information.	
6.	Demonstrated evidence of representation in-country providing product support, including names of personnel or agents, statement of capacity and nature of relationship with manufacturer.	
7.	Required product shelf life shall be a minimum of 18 months (15 months remaining after delivery in-country). Provide real time data to support storage temperature.	
8.	Test will be required to be in cassette format and include lancets, swabs, blood transfer device and buffer solution.	
9.	Instruction booklet shall be provided in the appropriate language.	
10.	Statement of willingness to accept pre-shipment QC/QA inspection and testing by an independent testing agency designated by Buyer.	
11.	Other information that may affect pre-qualification:	
a.	Provide documentation on the type of Quality Management system for the facility (i.e. ISO-9000; EN)	
b.	Certification that the commodities are manufactured according to EN, ISO, WHO, GMP, FDA standards, whichever applies.	
c.	Certified copy of current license in country where primary manufacturing is conducted	
d.	Manufacturer's Quality Manual and Standard Operational Procedures in Microsoft-Word compatible CD form	
e.	Copies of company's environmental policy and any citations, infractions, fines, or legal actions the company has been involved in as a result of violations.	
Approval	<b>FHI</b> _____ <b>Date</b> _____ <b>JSI</b> _____ <b>Date</b> _____	



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Sampling and Inspection of Rapid Diagnostic Test Kits (RDTs) for Pre-shipment		<b>DOCUMENT No.:</b> TO3-QA-RDTs-22
<b>DATE ISSUED:</b> 11/1/ 2007	<b>SUPERSEDES:</b> 9/10/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

## 1.0 PURPOSE:

1.1	To establish a document that outlines the required steps for pre-shipment sampling and inspection of Rapid Diagnostic Kits for Malaria treatment.
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## 2.0 BACKGROUND:

2.1	<p>The World Health Organization lists commercially available RDTs from a variety of suppliers. Although the RDT suppliers and products are not officially recommended by WHO, the list is based on evidence of quality manufacturing, through documentary evidence of independent certification of compliance with ISO 13485:2003 (or US FDA 21 CFR 820) and a stability testing protocol provided by companies to the WHO. A system for assessing the quality and performance of RDTs is required, but formal WHO recommended specifications with a standardized evaluation and testing scheme (such as WHOPES for LLIN insecticides) does not currently exist.</p> <p>Historically donor organizations have not placed emphasis on pre-shipment testing but have focused on post-shipment quality assessments. This is due mainly to possible extreme temperature and humidity exposure of the kits during transporting and warehousing. The QA-Partners for Malaria have devised a sampling/inspection plan that addresses the need for quality checks prior to shipping the RDTs and outlines the need for pre-shipment testing on as-needed basis. This plan helps to minimize the risk of receiving non-conforming kits in-country.</p>
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## 3.0 DOCUMENT REFERENCES:

3.1	<table border="1"> <tr> <td style="width: 5%;">1.</td> <td><i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i></td> </tr> <tr> <td>2.</td> <td><i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004</td> </tr> <tr> <td>3.</td> <td><i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006</td> </tr> <tr> <td>4.</td> <td><i>Malaria Rapid Diagnosis- Making it Work-Meeting Report;</i> World Health Organization; 2003</td> </tr> </table>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>	2.	<i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004	3.	<i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006	4.	<i>Malaria Rapid Diagnosis- Making it Work-Meeting Report;</i> World Health Organization; 2003
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**4.0 RESPONSIBILITIES:**

4.1	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;			
	Quality Assurance Partners	Major Responsibility	Other Responsibilities	
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits / Field Evaluations
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities	Standard Operating Procedures Audits/Monitoring suppliers Complaints
5.	United States Pharmacopeia	Technical assistance for chemical testing	Audits	

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Pre-Shipment Sampling/Inspection Protocols</b>										
5.1.1	<p><b>Pre-Shipment sampling/inspection Protocol #1- <u>Emergency shipments of RDTs.</u></b>            The Quality Assurance Partners and the RDT procurement team recognize that there will be an occasional need to provide RDTs as part of an “<u>Emergency Response</u>” situation. Only USAID/Washington can classify a shipment as an “Emergency”. The <u>Emergency Response</u> allows for the procuring and shipping of RDTs without pre-shipment inspection. The verification of documents to the order is required and is conducted <b>concurrent to shipping</b>. The Emergency RDTs should only be procured from suppliers with a solid history of providing a consistent quality product.</p> <p>The verification of documents includes; See Appendix A</p> <table border="1"> <tr><td>1.</td><td>certificate of analysis</td></tr> <tr><td>2.</td><td>information that outlines RDT kit components / storage conditions</td></tr> <tr><td>3.</td><td>packing list (providing RDT quantity for each lot)</td></tr> <tr><td>4.</td><td>example package labeling</td></tr> <tr><td>5.</td><td>other relevant documentation specifically required for the consignment</td></tr> </table> <p>The document verification will be conducted by a QA-Partner specializing in RDTs (ie. Crown Agents, PATH, or other designated partner). A second review will be conducted by FHI and the results of the verification will be entered into the QA database.</p>	1.	certificate of analysis	2.	information that outlines RDT kit components / storage conditions	3.	packing list (providing RDT quantity for each lot)	4.	example package labeling	5.	other relevant documentation specifically required for the consignment
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5.1.2	<p><b>Pre-Shipment sampling/inspection protocol #2- <u>All RDT Suppliers.</u></b>            All RDT suppliers require quality document verification that is <u>not performed</u> concurrent to shipping but must be complete and reviewed prior to release of the shipment. A QA-Partner will conduct the review and issue a statement of “Release for Shipment”.</p> <p>The document verification includes; See Appendix A</p> <table border="1"> <tr><td>1.</td><td>certificate of analysis</td></tr> <tr><td>2.</td><td>information that outlines RDT kit components / storage conditions</td></tr> <tr><td>3.</td><td>packing list (providing RDT quantity for each lot)</td></tr> <tr><td>4.</td><td>example package labeling</td></tr> <tr><td>5.</td><td>other relevant documentation specifically required in the consignment</td></tr> </table> <p>A copy of the documents and signed QA review will be sent to FHI for a cursory second review (that does not impact the “Release for Shipment”). The results of the document verification will be entered into the QA database.</p>	1.	certificate of analysis	2.	information that outlines RDT kit components / storage conditions	3.	packing list (providing RDT quantity for each lot)	4.	example package labeling	5.	other relevant documentation specifically required in the consignment
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5.1.3	<p><b>Pre-Shipment sampling/inspection protocol #3 – This protocol is designed for the Pre-shipment inspections by an Independent Inspection Agency on an as-needed basis.</b> The as-needed is determined by the QAP’s or USAID based on the need for the information or as part of an audit of the manufacturer, or as a step in a quality investigation. The Independent inspection consists of the following;</p> <p><b>Part 1- Document verification</b></p> <table border="1" data-bbox="386 401 1437 537"> <tr><td>1.</td><td>certificate of analysis</td></tr> <tr><td>2.</td><td>information that outlines RDT kit components / storage conditions</td></tr> <tr><td>3.</td><td>packing list (providing RDT quantity for each lot)</td></tr> <tr><td>4.</td><td>example package labeling</td></tr> <tr><td>5.</td><td>other relevant documentation specifically required in the consignment</td></tr> </table> <p><b>Part 2- On site Inspection</b></p> <table border="1" data-bbox="386 604 1437 957"> <tr><td>a.</td><td>Conformity to the PO specification/standards</td></tr> <tr><td>b.</td><td>The quality of individual packing against the PO</td></tr> <tr><td>c.</td><td>If any product damage occurred during packing and preparation for shipment (If possible make photographs of pallets and cases)</td></tr> <tr><td>d.</td><td>Check labeling against mission/end-user requirements and artwork proofs</td></tr> <tr><td>e.</td><td>Verify batch number identification by carton/pallet to certificates;</td></tr> <tr><td>f.</td><td>Verify quantity in each batch;</td></tr> <tr><td>g.</td><td>Verify manufacturing and expiry dates for each batch (with labeled storage conditions);</td></tr> <tr><td>h.</td><td>Verify total number of units in the consignment;</td></tr> <tr><td>i.</td><td>Verify Conformity of marking on the outer carton against PO specifications.</td></tr> <tr><td>j.</td><td>Check Certificate of Analysis or other Quality Certificates that describe internal test results.</td></tr> <tr><td>k.</td><td>Evaluation of the kit components including the presence of package inserts / instructions</td></tr> </table>	1.	certificate of analysis	2.	information that outlines RDT kit components / storage conditions	3.	packing list (providing RDT quantity for each lot)	4.	example package labeling	5.	other relevant documentation specifically required in the consignment	a.	Conformity to the PO specification/standards	b.	The quality of individual packing against the PO	c.	If any product damage occurred during packing and preparation for shipment (If possible make photographs of pallets and cases)	d.	Check labeling against mission/end-user requirements and artwork proofs	e.	Verify batch number identification by carton/pallet to certificates;	f.	Verify quantity in each batch;	g.	Verify manufacturing and expiry dates for each batch (with labeled storage conditions);	h.	Verify total number of units in the consignment;	i.	Verify Conformity of marking on the outer carton against PO specifications.	j.	Check Certificate of Analysis or other Quality Certificates that describe internal test results.	k.	Evaluation of the kit components including the presence of package inserts / instructions
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i.	Verify Conformity of marking on the outer carton against PO specifications.																																
j.	Check Certificate of Analysis or other Quality Certificates that describe internal test results.																																
k.	Evaluation of the kit components including the presence of package inserts / instructions																																
5.1.4	The required sampling plan (number of samples, Acceptable Quality Level, critical or non-critical characteristics etc.) for the Independent on-site inspection will be determined based on the specific situation and the circumstances regarding any investigation or audit.																																
<b>5.2</b>	<b>Testing of RDTs-Pre-Shipment</b>																																
	Any pre-shipment samples designated for testing (as-needed) situation will follow the protocol(s) in Standard Operating Procedure TO3-QA-RDTs-23. Specific tests will be determined based on the situation and circumstances.																																
<b>5.3</b>	<b>RELEASE of SHIPMENT and REVIEW OF TEST RESULTS</b>																																
5.3.1	Review of the test results and release of the shipment will be conducted through the QA-Partners of the RDT Procurement team. Overview (second review) will be conducted by FHI and the test results will be entered into a quality assurance database.																																
5.3.2	The test results will be monitored and a quality report card will be established to track supplier performance.																																
5.3.3	<p>In the case of any kits not complying with the pre-shipment sampling/inspection protocols outlined in sections 5.1.1-5.1.3, the following steps are to be taken;</p> <table border="1" data-bbox="386 1766 1437 1927"> <tr> <td data-bbox="386 1766 443 1871">1.</td> <td data-bbox="451 1766 1437 1871">The QA-Partners inform both the supplier and the USAID   DELIVER PROJECT procurement unit that the consignment <b>does not comply</b> and details the reasons for non-compliance.</td> </tr> <tr> <td data-bbox="386 1877 443 1927">2.</td> <td data-bbox="451 1877 1437 1927">The RDTs remain in supplier’s custody until a determination/agreement is reached by all parties on the next course of action.</td> </tr> </table>	1.	The QA-Partners inform both the supplier and the USAID   DELIVER PROJECT procurement unit that the consignment <b>does not comply</b> and details the reasons for non-compliance.	2.	The RDTs remain in supplier’s custody until a determination/agreement is reached by all parties on the next course of action.																												
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	4.	If the RDTs are not urgently required, the procurement unit initiates action with the supplier for replacement of consignment.
	5.	In the case that goods can be replaced by the supplier, the QA-Partners follow up with the supplier in co-ordination with the USAID   DELIVER PROJECT procurement unit until the replacement is received. Any replaced/rectified goods will be made available for re-inspection by an Independent Inspection Agency or QA-Partners at the vendor's expense including the cost of the inspection fees.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/10/07	00	N/A	New Issue.
11/1/07	01	9/10/07	Updated PATH responsibilities

**APPENDIX A**  
**Pre-Inspection/Document Verification Checklist**  
**Rapid Diagnostic Test Kits**

Type of Shipment	Indicate	Designated country
Emergency Shipment		
Non-Emergency Shipment		

Supplier		
ADDRESS		
CONTACT INFORMATION		
Type of Test Kit (Species)		
	<b>Pre-inspection/Document verification checklist</b>	<b>Meets Requirements / Comments</b>
1.	certificate of analysis	
2.	information that outlines RDT kit components / storage conditions	
3.	packing list (providing RDT quantity for each lot)	
4.	example package labeling (Attach)	
5.	other relevant documentation specifically required in the consignment	
Performed by: QA-Partner or other designee		
Reviewed by: QA-Partner FHI		



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Sampling, Inspection, and Testing of Rapid Diagnostic Kits (RDTs) Post-Shipment		<b>DOCUMENT No.:</b> TO3-QA-RDTs-23
<b>DATE ISSUED:</b> 11/1/2007	<b>SUPERSEDES:</b> 9/25/07 rev01	<b>Revision:</b> 02
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

## 1.0 PURPOSE:

<b>1.1</b>	<b>To establish a procedure that defines the sampling, inspection, and testing of Rapid Diagnostic Test Kits (RDTs) at Post-shipment.</b>
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## 2.0 BACKGROUND:

<b>2.1</b>	Historically, the quality testing of RDTs has occurred at post-shipment. This is due to the sensitivity of the kits to exposure of extreme temperatures during transport. RDTs have a short shelf-life of 18-24 months and can easily lose effectiveness if not stored properly and are exposed to temperature and humidity outside the recommended range suggested by the manufacturer(s).
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## 3.0 DOCUMENT REFERENCES:

<b>3.1</b>	<table border="1"> <tr> <td style="width: 5%; text-align: center;">1.</td> <td><i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i></td> </tr> <tr> <td style="text-align: center;">2.</td> <td><i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004</td> </tr> <tr> <td style="text-align: center;">3.</td> <td><i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006</td> </tr> <tr> <td style="text-align: center;">4.</td> <td><i>Malaria Rapid Diagnosis- Making it Work-Meeting Report;</i> World Health Organization; 2003</td> </tr> </table>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>	2.	<i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004	3.	<i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006	4.	<i>Malaria Rapid Diagnosis- Making it Work-Meeting Report;</i> World Health Organization; 2003
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**4.0 RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits / Field Evaluations
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities	Standard Operating Procedures Audits/Monitoring suppliers Complaints
5.	United States Pharmacopeia	Technical assistance for chemical testing	Audits	

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Post-Shipment Inspection of RDTs (Emergency and Non-emergency shipments)</b>												
5.1.1	<p>Emphasis of inspecting and testing RDTs occurs at post-shipment. The <b>goal</b> is to test every consignment of RDTs. This testing includes a post-shipment inspection and sensitivity (stability) testing for each lot.</p> <p>However, the USAID   DELIVER PROJECT Task order 3 team recognizes the need for two testing protocols. These include Emergency and Non-emergency (routine) shipments.</p> <table border="1" data-bbox="479 1144 1458 1306"> <thead> <tr> <th>Protocol Number</th> <th>Description</th> <th>Inspection</th> <th>Sensitivity</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Emergency Shipments</td> <td>Concurrent inspection</td> <td>Concurrent testing</td> </tr> <tr> <td>2</td> <td>Non-Emergency Shipments</td> <td>Required-prior to distribution</td> <td>Initial testing required – prior to distribution</td> </tr> </tbody> </table>	Protocol Number	Description	Inspection	Sensitivity	1	Emergency Shipments	Concurrent inspection	Concurrent testing	2	Non-Emergency Shipments	Required-prior to distribution	Initial testing required – prior to distribution
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1	Emergency Shipments	Concurrent inspection	Concurrent testing										
2	Non-Emergency Shipments	Required-prior to distribution	Initial testing required – prior to distribution										
<b>5.2</b>	<b>Post-Shipment Inspection –Emergency Shipments</b>												
5.2.1	<p>The QA-Partners and the RDT procurement team recognize that there will be a need to provide RDTs under “Emergency” situations. Only USAID/Washington can classify a shipment as an “Emergency”.</p> <p>The Emergency RDTs should only be procured from suppliers with a solid history of providing a consistent quality product.</p> <p>Emergency RDTs will require Post-shipment inspection with the inspection being performed <b>concurrently with distribution</b>. See Appendix A.</p> <p>The concurrent inspection is conducted by a USAID Mission representative or other designee.</p>												
<b>5.3</b>	<b>Post-Shipment Inspection –Non-Emergency Shipments (Routine)</b>												
5.3.1	Non-emergency (routine) shipments of RDTs require a post-shipment inspection be performed <b>prior to distribution</b> . See Appendix A.												

	The post-shipment inspection verifies the contents of the consignment and looks for obvious damage during transporting.																						
5.3.2	At the time of shipment, the Freight Forwarder (FF) and the Malaria procurement team shall provide documents to the recipient country program office that the RDT (Emergency or routine) shipment will be arriving by (date) and prepare to conduct a post-shipment inspection.																						
5.3.3	<p>A USAID Mission representative or other designee is requested to conduct the Post-shipment inspection of thirteen units for each individual lot of the consignment. The sampling of the (13) units/lot shall be conducted randomly.</p> <p>=====</p> <p>Note: Thirteen samples were determined based on ISO-2859 Sampling and Inspection Plan. S-2 (special sampling plan up to 500,000) AQL – 0.1 =Accept 0/Reject 1</p> <p>=====</p>																						
5.3.4	<p>The Post-shipment inspection of RDTs includes the following;</p> <table border="1"> <tr> <td colspan="2"><b>I. Inspection of RDT shipment</b></td> </tr> <tr> <td>1.</td> <td><b>Check conformity to the Purchase order and country requirements/specification</b> Inspect the PO list to the country requirements.</td> </tr> <tr> <td>2.</td> <td><b>Inspect the Integrity of packaging for consignment at arrival.</b> Inspect the entire consignment (or lots) if identified and look for obvious damage to cases and packages of RDTs. If any damage is present, isolate the cases (packages) and determine quantity.</td> </tr> <tr> <td>3.</td> <td><b>Determine if any product damage was caused by transporting</b> ie. Cases on top (double stacked) or cases on end of pallets were damaged during transport</td> </tr> <tr> <td colspan="2"><b>II. Sample thirteen units from each lot (or consignment) and perform the inspection in steps 4,5,6</b></td> </tr> <tr> <td>4.</td> <td> <table border="1"> <tr> <td>Inspect the</td> <td rowspan="3">All thirteen units must comply</td> </tr> <tr> <td>a. kit labeling</td> </tr> <tr> <td>b. kit components</td> </tr> <tr> <td>c. presence of package inserts</td> <td></td> </tr> </table> </td> </tr> <tr> <td>5.</td> <td>Check batch number identification All thirteen units must comply</td> </tr> <tr> <td>6.</td> <td>Check manufacture and expiry dates All thirteen units must comply</td> </tr> </table>	<b>I. Inspection of RDT shipment</b>		1.	<b>Check conformity to the Purchase order and country requirements/specification</b> Inspect the PO list to the country requirements.	2.	<b>Inspect the Integrity of packaging for consignment at arrival.</b> Inspect the entire consignment (or lots) if identified and look for obvious damage to cases and packages of RDTs. If any damage is present, isolate the cases (packages) and determine quantity.	3.	<b>Determine if any product damage was caused by transporting</b> ie. Cases on top (double stacked) or cases on end of pallets were damaged during transport	<b>II. Sample thirteen units from each lot (or consignment) and perform the inspection in steps 4,5,6</b>		4.	<table border="1"> <tr> <td>Inspect the</td> <td rowspan="3">All thirteen units must comply</td> </tr> <tr> <td>a. kit labeling</td> </tr> <tr> <td>b. kit components</td> </tr> <tr> <td>c. presence of package inserts</td> <td></td> </tr> </table>	Inspect the	All thirteen units must comply	a. kit labeling	b. kit components	c. presence of package inserts		5.	Check batch number identification All thirteen units must comply	6.	Check manufacture and expiry dates All thirteen units must comply
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5.3.5	<p>The country representative will submit, via e-mail, the results of the Post-shipment inspection to the following;</p> <table border="1"> <tr> <td>1.</td> <td>John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a></td> </tr> <tr> <td>2.</td> <td>Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a></td> </tr> </table> <p>If any one of the inspection criteria does not comply, USAID, the QA-Partners, and the procurement team must be notified immediately to assess the proper next steps.</p>	1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>	2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>																		
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<b>5.4</b>	<b>Post-Shipment Sensitivity Testing–Emergency and Non-emergency Shipments</b>						
5.4.1	<p>Samples of RDTs for <b>Emergency and Non-emergency</b> shipments require sensitivity testing. The proper number of samples to be pulled is outlined below. See Appendix A.</p> <table border="1" data-bbox="457 373 1416 491"> <thead> <tr> <th data-bbox="457 373 756 466">Sampling Need</th> <th data-bbox="756 373 1039 466"><i>P-falciparum</i> Species RDTs Sampled / Lot –</th> <th data-bbox="1039 373 1416 466">Combination <i>Plasmodium</i> (<i>Pv</i> or <i>P. vivax</i>) Species RDTs Sampled / Lot –</th> </tr> </thead> <tbody> <tr> <td data-bbox="457 466 756 491">Sensitivity testing</td> <td data-bbox="756 466 1039 491">150 units</td> <td data-bbox="1039 466 1416 491">200 units</td> </tr> </tbody> </table> <p>The full cycle of sensitivity testing takes 18 months to complete per lot tested, where initial results are collected followed by testing every three months.</p>	Sampling Need	<i>P-falciparum</i> Species RDTs Sampled / Lot –	Combination <i>Plasmodium</i> ( <i>Pv</i> or <i>P. vivax</i> ) Species RDTs Sampled / Lot –	Sensitivity testing	150 units	200 units
Sampling Need	<i>P-falciparum</i> Species RDTs Sampled / Lot –	Combination <i>Plasmodium</i> ( <i>Pv</i> or <i>P. vivax</i> ) Species RDTs Sampled / Lot –					
Sensitivity testing	150 units	200 units					
5.4.2	<p>The WPRO office should be contacted (by FHI) regarding the need for RDT testing (contact information shown below).</p> <p>Malaria, other Vector-borne and Parasitic Diseases Unit Western Pacific Regional Office World Health Organization P.O. Box 2932 Manila, Philippines. Ph: +63 2 5288001 FAX: +63 2 5211036 <a href="mailto:mal-rdt@wpro.who.int">mal-rdt@wpro.who.int</a></p> <p><b>The WPRO office will arrange for the testing to be conducted at one of the following laboratories (Ref: <a href="http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO field QA guide.pdf">http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO field QA guide.pdf</a>)</b></p> <table border="1" data-bbox="386 1150 870 1255"> <tbody> <tr> <td data-bbox="386 1150 441 1205">1.</td> <td data-bbox="441 1150 870 1205">RITM Philippines</td> </tr> <tr> <td data-bbox="386 1205 441 1255">2.</td> <td data-bbox="441 1205 870 1255">Institut Pasteur (Cambodia)</td> </tr> </tbody> </table> <p>RITM may be used as the primary lab for testing. If confirmatory testing is required, then the Institut Pasteur may be utilized. The CDC in the US (and possibly various laboratories in Africa) may be used for future testing, as well. <u>FHI will inform the country office which lab to send the RDTs.</u></p>	1.	RITM Philippines	2.	Institut Pasteur (Cambodia)		
1.	RITM Philippines						
2.	Institut Pasteur (Cambodia)						

5.4.3	<p>WHO will test the samples according to the procedure outlined in <b>Appendix B- WHO 2.2 RDT Quality Control Procedure</b>.  Ref - <a href="http://www.wpro.who.int/NR/rdonlyres/B5446BF5-BCFA-427D-B9FE-CEA57D36B92B/0/RDTQCMethodsManualV4final3.pdf">http://www.wpro.who.int/NR/rdonlyres/B5446BF5-BCFA-427D-B9FE-CEA57D36B92B/0/RDTQCMethodsManualV4final3.pdf</a></p> <p><b>Emergency RDTs</b> –Sensitivity Testing follows protocol #1. Distribution of RDTs can begin without initial test results.</p> <p><b>Non-emergency RDTs</b>- protocol #2- The distribution of RDTs can not begin until the initial testing interval has been completed.</p> <table border="1" data-bbox="480 575 1455 737"> <thead> <tr> <th>Protocol Number</th> <th>Description</th> <th>Inspection</th> <th>Sensitivity</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Emergency Shipments</td> <td>Concurrent inspection</td> <td>Concurrent testing</td> </tr> <tr> <td>2</td> <td>Non-Emergency Shipments</td> <td>Required- prior to distribution</td> <td>Initial testing required – prior to distribution</td> </tr> </tbody> </table>	Protocol Number	Description	Inspection	Sensitivity	1	Emergency Shipments	Concurrent inspection	Concurrent testing	2	Non-Emergency Shipments	Required- prior to distribution	Initial testing required – prior to distribution
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1	Emergency Shipments	Concurrent inspection	Concurrent testing										
2	Non-Emergency Shipments	Required- prior to distribution	Initial testing required – prior to distribution										
5.4.4	<p>In the event of a non-compliant sensitivity result, the QA-Partners and USAID will investigate in conjunction with WHO (testing laboratory) to develop a suitable action plan.</p>												
<b>5.5 Reporting of Test Results</b>													
5.5.1	<p>The WHO Malaria Disease Unit will provide initial and subsequent test results via e-mail to the USAID   DELIVER Project Malaria QA-Partners at;</p> <table border="1" data-bbox="386 989 870 1304"> <tbody> <tr> <td>1.</td> <td>John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a></td> </tr> <tr> <td>2.</td> <td>Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a></td> </tr> <tr> <td>3.</td> <td>Designated Country Contact</td> </tr> </tbody> </table> <p>For reference, an example template of a Quality Control Report for RDTs is provided in Appendix C.</p>	1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>	2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>	3.	Designated Country Contact						
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3.	Designated Country Contact												
5.5.2	<p>A Certificate of Conformance will be prepared by FHI using the format in Appendix D. The original will be sent to JSI (attention Paul Stannard or designee). A copy will be sent to USAID attention Ms. Jennifer Murphy or designee and FHI will retain a copy.</p>												

## 6.0 DOCUMENT HISTORY:

Date Issued	History	Previous issue date	Reason for change
9/10/07	00	N/A	New Issue.
9/25/07	01	9/10/07	Update Appendix A to include Cambodia address and shipping instructions
11/1/07	02	9/25/07	Updated PATH responsibilities

**APPENDIX A**  
**Post-Shipment Inspection/Document Verification Checklist**  
**Rapid Diagnostic Test Kits**

<b>I. Type of Shipment</b>		<b>Indicate</b>	<b>Designated country</b>
Emergency Shipment			
Non-Emergency Shipment			
Supplier			
Quantity of RDTs			
Number of Lots in consignment			
Type of Test Kit(Species)			
<b>II. Inspection of RDT shipment</b>			<b>Accept/Reject</b>
1.	<b>Check conformity to the Purchase order and country requirements/specification</b> Inspect the PO list to the country requirements.		
2.	<b>Inspect the Integrity of packaging for consignment at arrival.</b> Inspect the entire consignment (or lots) if identified and look for obvious damage to cases and packages of RDTs. If any damage is present, isolate the cases (packages) and determine quantity.		
3.	<b>Determine if any product damage was caused by transporting</b> ie. Cases on top (double stacked) or cases on end of pallets were damaged during transport		
<b>III. Sample thirteen units from each lot (or consignment) and perform the inspection in steps 4,5,6</b>			
4.	Inspect the a. kit labeling b. kit components c. presence of package inserts	All thirteen units must comply	<b>Accept/Reject</b> a. b. c.
5.	Check batch number identification	All thirteen units must comply	
6.	Check manufacture and expiry dates	All thirteen units must comply	
<b>IV. Sample the appropriate number of RDTs from each lot per consignment</b>			
7.	If – P-falciparum Species RDTs Sampled / Lot –	150	<b>Sampled by/date;</b>
8.	If - Combination Plasmodium Species RDTs Sampled / Lot –	200	<b>Sampled by/date;</b>
Boxes should be marked clearly: "Keep cool, <25C. Do not freeze" and packed in a protective courier package.			
<b>V. Send Sensitivity samples to: Philippines or Cambodia; Please identify where samples sent.</b>			
Malaria, other Vector-borne and Parasitic Diseases Unit Western Pacific Regional Office World Health Organization P.O. Box 2932 Manila, Philippines. Ph: +63 2 5288001 FAX: +63 2 5211036 <a href="mailto:mal-rdt@wpro.who.int">mal-rdt@wpro.who.int</a>		Mr Heng Borom World Health Organization No. 177-179 corner Streets Pasteur(51) and 254 Sangkat Chak Tomouk Khan Daun Penh Phnom Penh, Cambodia  Phone +855 23-216610 Fax (855) 23-216211 <a href="mailto:Hengb@cam.wpro.who.int">Hengb@cam.wpro.who.int</a>	
<b>VI. Submit a copy of Appendix A with the Sensitivity samples</b>			
<b>VII. Submit via e-mail- Copy of Appendix A to:</b>			
1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>		
2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>		
<b>Performed by/Date;</b>			<b>Reviewed by/Date (if applicable);</b>

# Appendix B

Document:	SOP 2.2	Malaria RDT QC Methods Manual			
Subject:	RDT QC Procedure			Revision Date:	August 2006
Section:	RDT QC	Version:	4	Page:	Page 17 of 178
WHO Regional Office for the Western Pacific & Special Programme for Research and Training in Tropical Diseases (TDR)					
WORLD HEALTH ORGANIZATION			ORGANISATION MONDIALE DE LA SANTE		

## SOP 2.2: RDT Quality Control Procedure

### AIM

To provide guidelines for the testing of RDTs using quality control samples to assess if the sensitivity of the RDT batch is acceptable for use in the field.

### BACKGROUND

Published trials and experience in various countries has demonstrated a wide variability in the sensitivity of malaria RDTs, both within and between products trials [1-10]. Sensitivity is particularly variable at lower parasite densities. The WHO expert consultations of 1999 and 2003 recommended 95% sensitivity at 100 parasites/ $\mu$ L as a reasonable target for RDT performance [11-12]. False negative results have also occurred at higher parasite densities [1, 6-8].

Reliance on RDTs to guide malaria case management is expected to increase. Therefore a quality assurance (QA) system for RDTs is needed to ensure there are good practices related to manufacturing, purchase, transport, storage, and technical use by health workers. A method of monitoring these practices is to implement quality control (QC) procedures at a number of different stages:

- a. Prior deployment to the field (initial testing)
- b. By health workers prior to use in the field.

This document specifically relates to quality control testing prior to deployment to the field (initial testing). An integral component of the initial QC testing is the development and use of quality control samples to test the threshold sensitivity of RDTs to determine if deterioration has occurred. To ensure that acceptable sensitivity is maintained on the lot that passed the initial QC testing RDTs should be tested on receipt from a manufacturer prior to use in the field (immediate testing) and further testing be performed at a later date on withheld RDTs (long term QC).

This initial QC of RDTs will provide some confidence about the quality of RDTs used as a basis for determining malaria therapy.

For the purposes of this document, RDTs detecting only *P. falciparum* are designated 'Pf', and the pan-specific line on combination RDTs is designated 'Pv' for *P. vivax*, as this is the non-*P. falciparum* species most likely to be included in parasite panels. The methods may be adapted to RDTs with other parasite-specific test lines.

### PURPOSE

This Standard Operating Procedure (SOP) describes the process of initial QC testing (immediate and long term) of malaria RDTs.

### SCOPE

This procedure applies to the WHO malaria rapid diagnostic test quality assurance initiative. The SOP is only to be modified with agreement of the Designated WHO Officer.

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## REAGENTS, EQUIPMENT

Reagent/Equipment	Quantity Required
PLDH and HRP2 ELISA	1
If ELISA is unavailable – reliable RDTs	100
RDTs for QC testing	106 (Pf) or 162 (combo)
1-20 µL Pipette	1
Minus 70°C freezer	1
Refrigerator thermometer (range: -20°C to 50 °C)	1
Incubator thermometer (range: 0°C to 100°C)	3
4°C refrigerator	4
Incubator (range: 20°C to 80°C)	1
Pipette tips (1-20 µL capacity)	
Quality Control samples; 0, 200, 5000 parasites/µL	

## PROCEDURE

### A. Number of RDTs (per lot) required for QC

#### For Pf-only RDTs:

- 13 RDTs are required at initial testing and 7 RDTs at each subsequent (3 month) test
- At least 40 extra RDTs should be retained in case of repeat testing or if extra RDTs are required to be sent to a confirmatory laboratory
- Therefore, a total quantity of **100 RDTs** will be required for the complete 18 months of QC testing (Figure 1)

Immediate QC: 13 RDTs	=13
Long term QC): +5 intervals x 7 RDTs	=35
Spare	=52
Total	=100

#### For Pf and Pv (combo) RDTs:

- 25 RDTs are required at initial testing, and 13 at each subsequent (3 month) test
- At least 50 extra RDTs should be retained in case of repeat testing or if extra RDTs are required to be sent to a confirmatory laboratory (Figure 2)
- Therefore, a total quantity of **150 RDTs** will be required for the complete 18 months of QC testing (Figure 2)

Immediate QC: 25 RDTs	=25
Long term QC): 5 intervals x 13 RDTs	=65
Spare	=60
Total	=150

### B. Immediate QC Testing

- Follow the procedure for receipt of RDTs (SOP 2.1)
- For **Pf only RDTs**:
  - Total tested = 13 RDTs (Figure 1).
  - Select QC samples from 4 *P. falciparum* cases; testing 2 RDTs against 200 parasite/µL samples and 1 against high (5000 parasites /µL) from each case. Test 1 RDT against a negative sample (Figure 1).
- For **Pf and Pv (combo) RDTs**:
  - Total tested = 25 RDTs (Figure 2).
  - Select QC samples from 4 *P. falciparum* and 4 *P. vivax* cases; testing 2 RDTs against 200 parasite/µL samples and 1 against high (e.g. 2000 - 5000 parasites /µL) from each case. Test 1 RDT against a negative sample (Figure 2).

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4. One hour before RDT testing, thaw the selected QC aliquots. Refer to SOP 3.3 for thawing procedure.
5. For **Pf RDTs**, remove a total of 13 RDTs from the RDT lot; from at least 2 different boxes. See Figure 1.
6. For **Pf and Pv (combo) RDTs**, remove a total of 25 RDTs from the RDT lot; from at least 2 different boxes. See Figure 2.
7. RDTs should be brought to room temperature BEFORE OPENING the package for testing.
8. Check integrity of RDT packaging when opening, ensure no signs of moisture (e.g. desiccant, if present, should be the original colour). If signs of moisture are present, DO NOT use the RDT.
9. Test the RDTs with the above QC samples.
10. Perform RDT testing as per manufacturer instructions. Transfer the blood to the RDT by pipette (See SOP 3.4).
11. Record the results on the QC result sheet (Form 007).
12. Note: Do not re-use frozen aliquots of QC samples – ONE USE ONLY.

#### C. Long term QC Testing

1. Enough stock should be retained to enable testing of the RDTs every 3 months
2. Note the expiry date i.e. 18 months and calculate the number of times the stock will be tested i.e. 3, 6, 9, 12, 15 = 5 intervals, and adequate reserve RDTs (Figure 3)
3. RDTs reserved for QC testing should be stored at 28°C
4. For **Pf RDTs**
  - (a) 7 RDTs are tested at each interval
  - (b) Select QC samples from 2 *P. falciparum* cases (same cases as previous at testing interval); testing 2 RDTs against 200 parasite/ $\mu$ L samples and 1 against high (e.g. 2000 - 5000 parasites / $\mu$ L) from each case. Test 1 RDT against a negative sample (Figure 1).
5. For **Pf and Pv (combo) RDTs**
  - (a) 13 RDTs are tested at each interval
  - (b) Select QC samples from 2 *P. falciparum* and 4 *P. vivax* cases (same cases as previous at testing interval); testing 2 RDTs against 200 parasite/ $\mu$ L samples and 1 against high (5000 parasites / $\mu$ L) from each case. Test 1 RDT against a negative sample (Figure 2).
6. If a 28°C incubator is unavailable, store RDTs in non-air conditioned area at room temperature and record minimum and maximum temperature daily.

#### D. RESULTS

For a lot of RDTs to pass the QC assessment, all quality control dilutions must be positive (100%) and the negative control must be negative i.e.:

QC Dilutions (parasites/ $\mu$ L)	Desired number positive/number tested	
	Initial	Subsequent
200 ( <i>P. falciparum</i> )	8/8	4/4
High ( <i>P. falciparum</i> )	4/4	2/2
200 ( <i>P. vivax</i> )	8/8	4/4
High ( <i>P. vivax</i> )	4/4	2/2
0	1/1	1/1

**If the above criteria are not met on immediate testing, then further procedures should be undertaken, see algorithm below (Figure 4 and 5).**

#### E. REPORTING

For immediate QC, a report should be prepared using a QC RDT Report (Form 008) and within five working days of receipt of the RDTs. The report should be emailed to the responsible officer. The responsible officer will send results to the referring centre by email and hard copy. For long term QC report should be issued every 3 months within the expiry date. Use the same report format as above.

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If an error is detected in a report and the report has already been sent to the referring centre, the original report should NOT be amended but a new report generated (with a new date) with the original results enclosed and a supplementary section detailing the correct information and explanation regarding the error that occurred.

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Figure 1: Flow Diagram of Initial QC procedure for Pf-only RDTs  
(High parasite density (5000 p/μL) may be varied).

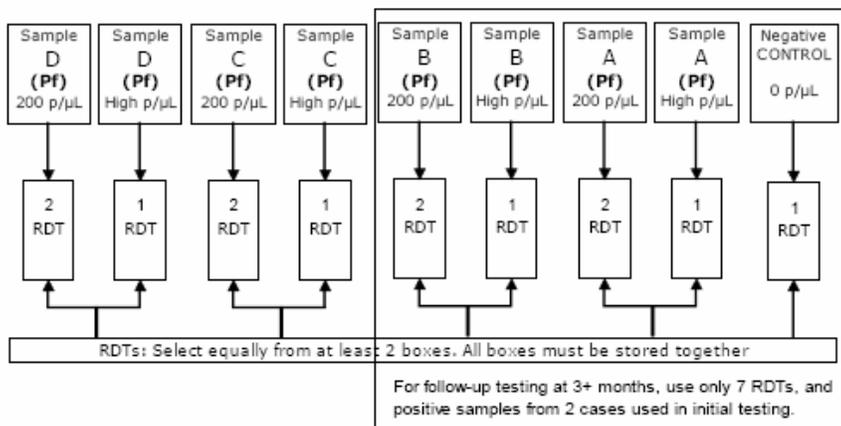
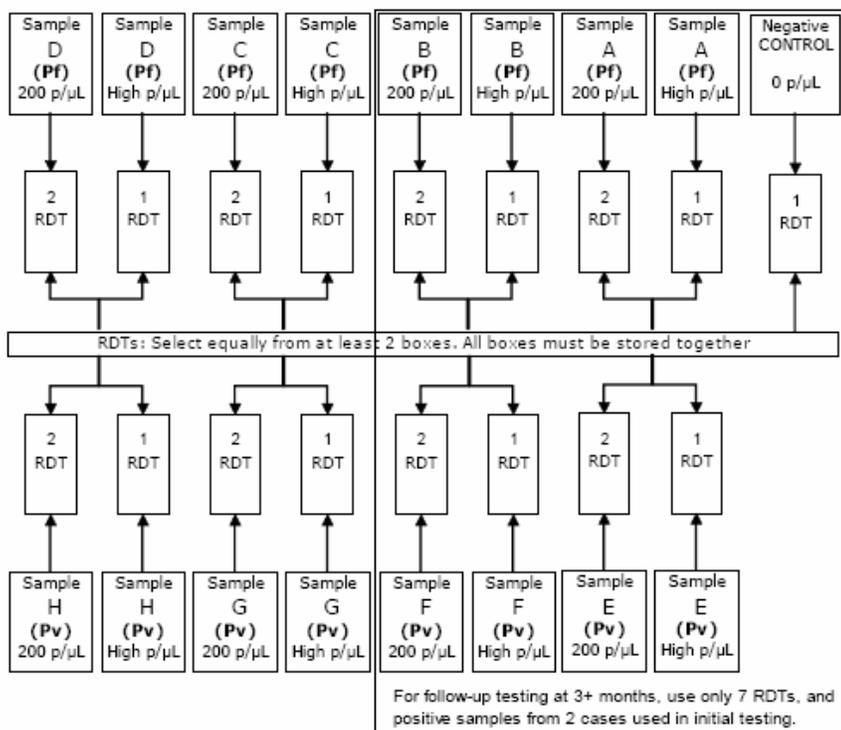


Figure 2: Flow Diagram of Initial QC procedure for Pf and Pv (combo) RDTs  
(High parasite density (5000 p/μL) may be varied).



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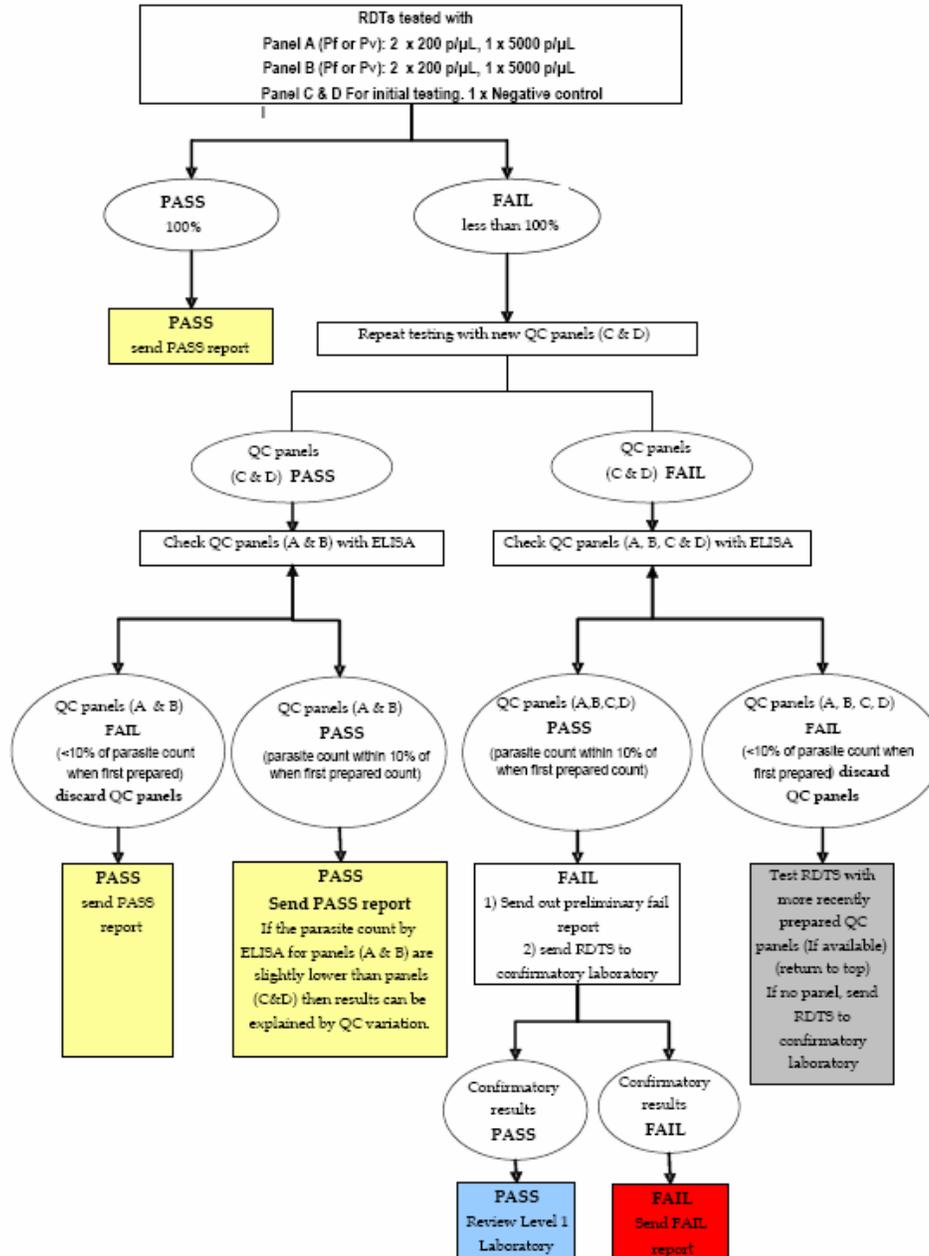
Figure 3: RDTs required for immediate and long term QC for RDTs with 18 month expiry date

	<b>Pf RDTs</b>	<b>Pf &amp; Pv RDTs</b>
<b>Immediate QC</b>	13 RDTs	25 RDTs
<b>28°C Incubator</b>		
<b>3 months</b>	7 RDTs	13 RDTs
<b>6 months</b>	7 RDTs	13 RDTs
<b>9 months</b>	7 RDTs	13 RDTs
<b>12 months</b>	7 RDTs	13 RDTs
<b>15 months</b>	7 RDTs	13 RDTs
<b>spare</b>	52 RDTs	60 RDTs
<b>Total</b>	100 RDTs	150 RDTs



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Figure 5: Algorithm for QC testing of RDTs (ELISA available)



\*\* If testing fails (i.e. not 100%), and is repeated using the same or different panels, the previous history of failure is not included in the pass assessment.

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#### NOTES:

1. The 1999 WHO expert consultation Malaria Diagnosis: new perspectives recommended 95% sensitivity at 100 parasites/ $\mu$ L as a reasonable target for RDT performance [11]. However for quality assurance of RDTs, quality control samples of 200 p/ $\mu$ L were chosen to test the lower limit of detection. At 100 p/ $\mu$ L, sufficient antigen concentration could not be guaranteed for a fair evaluation of RDTs as:  
Dilutions were prepared based on an initial parasite count (see SOP 3.2), and therefore some variability in malaria microscopy is unavoidable, and exact parasite densities will vary around the designated value.  
There may also be variation in expression and structure of antigens, and wide variation between the relationship between parasite density and antigen concentration due to sequestration and antigen persistence.
2. Although 5000 parasites/ $\mu$ L is recommended, a lower parasite density may need to be used i.e. 2000 parasites/ $\mu$ L due to the inability to obtain a sufficiently high initial malaria parasite density in sample preparation
3. If ELISA (HRP2 and/or pLDH) is not available, the integrity of the QC samples can be checked with stock RDT i.e. RDTs stored in the laboratory that is considered to have good sensitivity and are of high quality.
4. QC dilutions were prepared based on an initial parasite count (see SOP 3.2). Some variability in malaria microscopy is unavoidable, and exact parasite densities will vary around the designated value. The relationship between parasite density and antigen concentration will also vary. Consequently, RDT lots that do not pass immediate testing should be checked at a second facility before rejection. This should be arranged through the designated WHO officer.
5. For long term QC, the RDTs are stored at 28°C rather than 4°C as RDTs are supposed to be below 30°C and in the field RDTs are likely to be kept closer to 28°C than 4°C.

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**APPENDIX C  
MALARIA RDT LOT-TEST REPORT**

<p><b><i>Malaria RAPID DIAGNOSTIC TEST</i></b>  <b>Quality Control Report</b>          (Lot testing)</p> <p><b>Research Institute for Tropical Medicine</b>  <i>Filinvest Corporate City Cpd., Alabang, Muntinlupa City 1781, Philippines</i></p>
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<b>Report prepared by:</b>	Christine Joy C. Dureza/Jennifer S. Luchavez
<b>of (Institute):</b> in cooperation with the World Health Organization,	Research Institute for Tropical Medicine
<b>for the attention of:</b> <i>(name and institution)</i>	

<b>Date report prepared:</b> <div style="text-align: center; margin-top: 10px;">dd/mm/yyyy</div>
---

Summary of results

Testing Interval	Date tested dd/mm/yyyy	<i>Product (lot;expiry): ICT Malaria Cassette Test, ICT Diagnostics, South Africa (31257; 03/2009)</i>	
		Result	Other Observations
			•
			•
			•
			•
			•
			•
<i>0 months</i>	03/08/2007		•

Details of RDTs tested

<b>Name of RDT:</b>	
<b>Manufacturer:</b>	
<b>Lot no:</b>	
<b>Expiry:</b> dd/mm/yyyy	
<b>Previous storage conditions:</b>	
<b>Condition of RDTs on receipt:</b>	

Initial RDT receipt details:

<b>Sent from:</b>	WHO, WPRO
<b>Transport method / condition to testing institute:</b>	
<b>Quantity received:</b>	
<b>Place received:</b>	
<b>Date received:</b> dd/mm/yyyy	

Method:

1. QC testing Method:

RDTs were tested with frozen QC samples based on the algorithm described in SOP 4.3 of the WHO Quality Control Methods Manual for Malaria RDTs. For a lot of RDTs to pass the QC assessment, all quality control dilutions must be positive (100%) and the negative control must be negative. RDTs that do not meet these criteria will be forwarded to a second laboratory for confirmation.

The RDT lots will be retained in this laboratory for long term Quality Control. A further report will be issued after the next QC assessment.

2. Samples used for QC testing:

**Quality control (QC) samples of dilutions from wild-parasites prepared according to SOP 5.2 of the WHO Quality Assurance Methods Manual for Malaria RDTs. Samples are stored at -80°C.**

**Samples used include:**

- a) **Negative control:** 0 parasites/ $\mu$ l of *Plasmodium falciparum*
- b) **Low Positive Control:** 200 parasites/ $\mu$ l of *Plasmodium falciparum*
- c) **High Positive Control:** 2000 or 5000 parasites/ $\mu$ l of *Plasmodium falciparum*
- d) **Low Positive Control:** 200 parasites/ $\mu$ l of *Plasmodium vivax*\*
- e) **High Positive Control:** 2000 or 5000 parasites/ $\mu$ l of *Plasmodium vivax*\*

\* *delete as necessary*

3. RDT preparation method:

**RDTs were tested as per manufacturer instructions, using micropipette for blood transfer.**

Details of RDT QC testing results: month  testing

Table 1: First Testing

Quality control dilutions		Product (lot;expiry):		
Sample ID	(parasites/ $\mu$ l)	RDTs Tested	RDTs Positive	% Positive
	200	2		
	2000	1		
	200	2		
	2000	1		
	200	2		
	2000	1		
	200	2		
	2000	1		
	200	2		
	2000	1		
	200	2		
	2000	1		
		RDTs Tested	RDTs negative	% negative
Negative control	0	1	0	0

Table added here for repeat testing

### Interpretation of results:

For a lot of RDTs to pass the QC assessment, all quality control dilutions must be positive (100%) and the negative control must be negative.

Interpretation of results:

• **PASS:** This RDT lot passed the quality control test and the sample assessed is **SUFFICIENTLY SENSITIVE FOR USE in the field.**

• **DEFERRED:** This RDT lot failed this assessment, and has been sent to another institution for confirmation. A final report will be issued on receipt of the confirmatory results. It is recommended that the lot is **RETAINED** until a final report is received.

• **FAIL:** This RDT lot failed the initial QC assessment and also failed confirmatory testing at another institution. It is recommended that this lot should **NOT BE USED** in the field as it has been assessed as lacking sufficient sensitivity. It is recommended that the manufacturer be contacted and advised of the results.

Note:

This assessment is performed in collaboration with the World Health Organization, Regional Office for the Western Pacific. The report is prepared for the confidential information of the institution that submitted the rapid diagnostic tests (RDT) for assessment. **The results are for use of the institution that submitted the RDTs for assessment as evidence that the stored samples of the particular lot of RDTs tested performed with sufficient sensitivity for use. They must not be used for purposes of advertising or otherwise promoting a product, or as evidence of formal approval or recommendation of a product, without the written permission of the testing institution and World Health Organization. Other than confirmation of sufficient sensitivity of the sample of the tested lot, the results listed here do not indicate endorsement of the RDT product by the World Health Organization or the testing institution.** While the results indicate that the RDTs tested are sufficiently sensitive against the QC parasite samples used for testing, they do not necessarily reflect actual sensitivity in the field where local storage conditions, variation in parasite antigen, and host factors may affect operation. Recommendations on use and storage of RDTs in the field can be obtained from the WHO website [www.wpro.who.int/rdt](http://www.wpro.who.int/rdt), or by email from [mal-rdt@wpro.who.int](mailto:mal-rdt@wpro.who.int)

*Signed:*

**Christine Joy C. Dureza**

Technician

**Jennifer S. Luchavez**

Laboratory Head

**Copies of report:**

Include email copy to:

Procurer.

WHO ([mal-rdt@wpro.who.int](mailto:mal-rdt@wpro.who.int) or [belld@wpro.who.int](mailto:belld@wpro.who.int))

Hard copy to be retained by testing institute.



**APPENDIX D**  
**CERTIFICATE OF CONFORMANCE**  
***Rapid Diagnostic Test Kits (RDTs)***  
***for***

<b>Country Designation</b>					
<b>Product</b>					
<b>Supplier</b>					
<b>Lot Number(s)</b>					
<b>MFD of RDTs</b>		<b>EXP of RDTs</b>			
<b>Compliant / Non-Compliant</b>					
<b>Shipment Inspections</b>	<b>Pre-shipment Inspection Summary</b> (Ref. Doc. – TO3-QA-RDTs-22-Appendix A)		<b>Compliant</b>		
	Notes –				
	<b>Post-shipment Inspection Summary</b> (Ref. Doc. – TO3-QA-RDTs-23-Appendix A)		<b>Compliant</b>		
	Notes -				
<b>QC Testing</b>  <b>(WHO-WPRO)</b>  <b>Testing Site –</b>  _____  _____	<b>TEST</b>	<b>SPECIFICATION</b>	<b>REQUIREMENT</b>	<b>RESULT</b>	<b>Assessment</b>
	<b>Initial</b>	WHO – Methods Manual for Lab. QC Testing of Malaria RDTs	Pass / Fail		Complies
	Test Date -		Observations -		
	<b>3 month</b>		Pass / Fail		Complies
	Test Date -		Observations -		
	<b>6 month</b>		Pass / Fail		Complies
	Test Date -		Observations -		
	<b>9 month</b>		Pass / Fail		Complies
	Test Date -		Observations -		
	<b>12 month</b>		Pass / Fail		Complies
	Test Date -		Observations -		
	<b>15 month</b>		Pass / Fail		Complies
	Test Date -		Observations -		
	<b>18 month</b>		Pass / Fail		Complies
Test Date -	Observations -				
<b>Reviewed by/Date-</b> Steve Hamel-Signature on File			<b>RDTs comply with WHO and USAID   DELIVER Project – Malaria Specifications</b>		
<b>Quality Assurance Partners for USAID   DELIVER Project –Malaria</b>					

*This report shall not be reproduced except in full, without the written approval of The Quality Assurance –Partners for USAID | DELIVER Project –Malaria.  
The reported test results relate only to the items sampled and tested at pre-shipment.*



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Conducting Audits of RDT Suppliers		<b>DOCUMENT No.:</b> TO3-QA-RDTs-24
<b>DATE ISSUED:</b> 11/1/07	<b>SUPERSEDES:</b> 9/10/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

## 1.0 PURPOSE:

1.1	To establish a document that provides a procedure for conducting audits of RDT Suppliers with respect to USAID contract requirements and adherence to GMP (21CFR820) or ISO 13485:2003.
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## 2.0 BACKGROUND:

2.1	Although documentation is provided to the WHO by RDT suppliers for inclusion on the WHO WebBuy List (Ref 3.2), QAP should be proactive in auditing the manufacturers of RDTs in order to provide additional assurance that the RDTs are being prepared under good manufacturing practices.
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## 3.0 REFERENCE DOCUMENTS:

3.1	Current contract between USAID and manufacturer.
3.2	<a href="http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf">http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf</a>
3.3	ISO 13485:2003 - Medical devices -- Quality management systems -- Requirements for regulatory purposes
3.4	Audit Checklist (ISO 13485:2003)– Medical Devices – <a href="#">ISO 13485-2003 Generic Checklist.doc</a> (Appendix A)
3.5	Code for Federal Regulations Title 21 Part 820 Good Manufacturing Practices for Medical Devices: general.
3.6	PQC 161 – Production Surveillance Audit
3.7	Audit Checklist (GMP)– Pharmaceutical / Medical Devices – <a href="#">..\100-series\100series Forms\PQC161-Audit Checklist.DOC</a> (Appendix B)

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits / Field Evaluations
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities	Standard Operating Procedures Audits/Monitoring suppliers Complaints
5.	United States Pharmacopeia	Technical assistance for chemical testing	Audits	

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Scheduling</b>				
5.1.1	Manufacturers will be audited on-site and evaluated for compliance with ISO 13485:2003 or 21 CFR 820. Audits will be conducted by the Quality Assurance Partners (QAP) team.				
5.1.2	For recently pre-qualified manufacturers, an audit should be conducted within the first year of pre-qualification with subsequent audits being conducted every two years.				
<b>5.2</b>	<b>Conducting Audit</b>				
5.2.1	Depending on the information submitted by the manufacturer during the pre-qualification step (Ref-TO3-QA-RDTs-21), the audit will be conducted based on ISO 13485:2003 (Ref. Doc. – 3.4) or GMP (21 CFR 820) criteria (Ref. Doc. – 3.7), where the appropriate checklist is utilized to guide and document the findings of the audit.				
5.2.2	The checklist utilized for GMP (21 CFR 820) contains subparts A-K which are applicable for medical devices with the following exceptions: <table border="1" style="margin-left: 20px;"> <tr> <td><b>Subpart I</b></td> <td>Laboratory Controls shall be replaced with Device Evaluation</td> </tr> <tr> <td><b>Subpart K</b></td> <td>Omit for medical devices</td> </tr> </table>	<b>Subpart I</b>	Laboratory Controls shall be replaced with Device Evaluation	<b>Subpart K</b>	Omit for medical devices
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<b>Subpart K</b>	Omit for medical devices				

5.3	Audit Report
5.3.1	An internal memo shall be prepared listing the conclusions of the audit, including informational items that may impact future operational audits.
5.3.2	An external report shall be provided to the vendor and QAP listing the observations, and where appropriate, suggested guidelines. The accompanying letter shall request a corrective action plan, if needed, and estimated dates of completion.
5.3.3	If observations are significant, and the facility is out of compliance in critical areas, a follow-up visit may be scheduled prior to the next scheduled audit.
5.3.4	Follow - up on suggested corrective measures will be performed on subsequent audits.
5.3.5	Depending on the severity of the non-compliant issue, the auditor may suggest that the manufacturer be removed from the pre-qualified list (even after only the first audit) until the follow-up audit has been completed to evaluate the status of the corrective actions.

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/10/07	00	N/A	New Issue.
11/1/07	01	00	Update PATH responsibilities and appendix A

**Appendix A**  
**Audit Checklist – USAID Deliver Project**

Auditor \_\_\_\_\_ Date \_\_\_\_\_

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
<b>4 Quality management system</b>			
<b>4.1 General requirements</b>			
4.1q1	The organization shall establish, document, implement and maintain a quality management system and <b>maintain (continually improve)</b> its effectiveness in accordance with the requirements of this International Standard.	Has Organization established, documented, implemented and maintained a QMS and <b>maintained (continually improved)</b> its effectiveness in accordance with ISO 9001/13485? (Questions in section 4.1 are verified throughout the audit)	
4.1q2a	The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),	Where has Organization identified the processes needed for the QMS and their application throughout the organization? (See 4.2.2)	
4.1q2b	The organization shall b) determine the sequence and interaction of these processes,	Were has Organization determined the sequence and interaction of QMS processes? (See 4.2.2)	
4.1q2c	The organization shall c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,	What are the criteria and methods Organization uses to ensure that the operation and control of QMS processes are effective?	
4.1q2d	The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,	Has Organization provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6)	
4.1q2e	The organization shall e) monitor, measure and analyse these processes, and	How does Organization monitor, measure and analyze QMS processes? (See section 8)	
4.1q2f	The organization shall f) implement actions necessary to achieve planned results and <b>maintain the effectiveness (continual improvement)</b> of these processes.	How has Organization implemented actions necessary to achieve planned results and <b>maintain the effectiveness (continual improvement)</b> of processes needed for the QMS?	
4.1q3	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 9001:2000?	
4.1q4	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	When Organization outsources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4)	
4.1q5	Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).	Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4)	
NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.			
<b>4.2 Documentation requirements</b>			
<b>4.2.1 General</b>			

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
4.2.1q1a	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). f) any other documentation specified by national or regional regulations.	Does Organization have documented statements of a quality policy and quality objectives? (See 5.3, 5.4.1) Does Organization have a quality manual? Does Organization have the documented procedures required by ISO 9001:2000/13485:2003? Are adequate documents in place to ensure the effective planning, operation and control of Organization's processes? Does documentation include the records required by ISO 9001:2000? Are there any documents required by regulations?	
	Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.	(Verify throughout audit)	
	For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3).	Can you show me a file for each type or model of medical device containing or identifying documents with product specifications and QMS requirements?	
	These documents shall define the complete manufacturing process and, if applicable, installation and servicing.	(Review documents to verify they define the complete manufacturing process, installation and servicing)	
	<b>NOTE 1</b> Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.		
	<b>NOTE 2/1</b> The extent of the quality management system documentation can differ from one organization to another due to a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel.		
	<b>NOTE 3</b> The documentation can be in any form or type of medium.		
	<b>4.2.2 Quality manual</b>		
4.2.2q1a	The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions and/or non-application (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.	Where in the quality manual is the scope of the QMS identified, including details of and justification for exclusions and/or requirements that don't apply? Where does the quality manual contain or reference the documented procedures established for the QMS? Where does the quality manual include a description of the interaction between the processes of the QMS?	
	The quality manual shall outline the structure of the documentation used in the quality management system.	Where does the quality manual outline the documentation structure of the QMS?	
	<b>4.2.3 Control of documents</b>		
4.2.3q1	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.	How are the documents required by the QMS controlled? (Documents to be reviewed throughout the audit)	

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
4.2.3q2	<p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> <li>a) to review and approve documents for adequacy prior to issue,</li> <li>b) to review and update as necessary and re-approve documents?</li> <li>c) to ensure that changes and the current revision status of documents are identified?</li> <li>d) to ensure that relevant versions of applicable documents are available at points of use?</li> <li>e) to ensure that documents remain legible and readily identifiable?</li> <li>f) to ensure that documents of external origin are identified and their distribution controlled?</li> <li>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</li> </ul>	<p>Can you show me a <b>documented procedure</b> that defines the controls needed for <u>each</u> of the following?</p> <ul style="list-style-type: none"> <li>a) review and approve documents for adequacy prior to issue?</li> <li>b) review and update as necessary and re-approve documents?</li> <li>c) ensure that changes and the current revision status of documents are identified?</li> <li>d) ensure that relevant versions of applicable documents are available at points of use?</li> <li>e) ensure that documents remain legible and readily identifiable?</li> <li>f) ensure that documents of external origin are identified and their distribution controlled?</li> <li>g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</li> </ul>	
	<p>The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.</p>		
	<p>The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained.</p>		
	<p>This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.</p>		
<b>4.2.4 Control of records</b>			
4.2.4q1	<p>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.</p>	<p>What records exist that provide evidence of conformity to requirements and of the effective operation of the QMS? (Should be reviewed throughout the audit)</p>	
4.2.4q2	<p>Records shall remain legible, readily identifiable and retrievable.</p>	<p>Are records legible, readily identifiable and retrievable? (Should be reviewed throughout the audit)</p>	
4.2.4q3	<p>A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p>	<p>Does Organization have a <b>documented procedure</b> defining the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?</p>	
	<p>The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years</p>		

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	from the date of product release by the organization or as specified by relevant regulatory requirements.		
<b>5 Management responsibility</b>			
<b>5.1 Management commitment</b>			
5.1q1a	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and <b>maintaining (continually improving)</b> its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	How does top management communicate the importance of meeting customer and legal requirements to the organization? Has a company quality policy been established? (See 5.3) What are the quality objectives established by top management? (See 5.4.1) Does top management conduct management reviews? (See 5.6) How does top management ensure the availability of resources to support and continually improve the QMS?	
<b>NOTE For the purposes of this International Standard, statutory requirements are limited to the safety and performance of the medical device only.</b>			
<b>5.2 Customer focus</b>			
5.2q1	Top management shall ensure that customer requirements are determined and are met <b>with the aim of enhancing customer satisfaction</b> (see 7.2.1 & 8.2.1).	How does top management ensure that customer requirements are determined and met?	
<b>5.3 Quality policy</b>			
5.3q1a	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and <b>to maintain (continually improve)</b> the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	How does top management ensure that the quality policy is appropriate to the purpose of the organization? Does the quality policy include a commitment to comply with requirements and <b>to maintain (continually improve)</b> QMS effectiveness? Are the contents of the quality policy relevant to Organization, and measurable? Is the quality policy communicated and understood within the organization? Is there an established process to review the quality policy for continuing suitability?	
<b>5.4 Planning</b>			
<b>5.4.1 Quality objectives</b>			
5.4.1q1	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	Has top management established quality objectives (including those needed to meet requirements for product) at relevant functions and levels within the organization?	
5.4.1q2	The quality objectives shall be measurable and consistent with the quality policy.	Are the quality objectives consistent with the quality policy? What are the measurements?	
<b>5.4.2 Quality management system planning</b>			

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
5.4.2q1	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	How do you ensure that the planning of the QMS is carried out in order to meet the requirements given in ISO 9001:2000 section 4.1, as well as the quality objectives? How do you ensure that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?	
<b>5.5 Responsibility, authority and communication</b>			
<b>5.5.1 Responsibility and authority</b>			
5.5.1q1	Top management shall ensure that responsibilities and authorities are defined, <b>documented</b> and communicated within the organization.	How are responsibilities and authorities defined, <b>documented</b> and communicated within the organization? (Verify throughout audit)	
	Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.		
<b>NOTE National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).</b>			
<b>5.5.2 Management representative</b>			
5.5.2q1a	Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement (see 8.5), and c) ensuring the promotion of awareness of <b>regulatory and</b> customer requirements throughout the organization.	Who is your ISO 9001:2000 management representative? Does the management representative have responsibility and authority to a) ensure that processes needed for the QMS are established, implemented and maintained? b) report to top management on the performance of the QMS and any need for improvement? c) ensure the promotion of awareness of <b>regulatory and</b> customer requirements throughout the organization?	
<b>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</b>			
<b>5.5.3 Internal communication</b>			
5.5.3q1	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	How is information regarding the effectiveness of the QMS communicated within the organization?	
<b>5.6 Management review</b>			
<b>5.6.1 General</b>			

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
5.6.1q1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.	What is the frequency that top management reviews the organization's QMS?	
5.6.1q2	This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	What kinds of information are reviewed in management reviews? (must include suitability, adequacy and effectiveness of QMS; improvement; & changes to the QMS, quality policy and objectives)	
5.6.1q3	Records from management reviews shall be maintained (see 4.2.4).	Can you show me <b>records</b> from recent management reviews?	
<b>5.6.2 Review input</b>			
5.6.2q1	The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, <b>and</b> g) recommendations for improvement, <b>and</b> h) <b>new or revised regulatory requirements.</b>	Can you show me that <u>each</u> of the following were included in review(s)? a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, <b>and</b> g) recommendations for improvement, <b>and</b> h) <b>new or revised regulatory requirements.</b>	
<b>5.6.3 Review output</b>			
5.6.3q1	The output from the management review shall include any decisions and actions related to a) improvement <b>needed to maintain</b> the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	What decisions or actions have resulted from management reviews for <u>each</u> of the following? a) improvement <b>needed to maintain</b> the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	
<b>6 Resource management</b>			
<b>6.1 Provision of resources</b>			
6.1q1	The organization shall determine and provide the resources needed a) to implement ( <b>and maintain</b> ) the quality management system and <b>maintain (continually improve)</b> its effectiveness, and b) to <b>meet regulatory and (enhance customer satisfaction by meeting)</b> customer requirements.	What resources has Organization provided to implement and maintain the QMS <b>and continually improve its</b> effectiveness? What resources has Organization provided to ensure that customer <b>and regulatory</b> requirements are met? (See 6.2, 6.3, 6.4)	
<b>6.2 Human resources</b>			
<b>6.2.1 General</b>			
6.2.1q1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	What are the education, training, skills and experience required by this job/task? How does this person meet those qualifications?	
<b>6.2.2 Competence, awareness and training</b>			
6.2.2q1	The organization shall a) determine the necessary competence for	How do you determine the necessary education, training, skills and experience	

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	<p>personnel performing work affecting product quality,  b) provide training or take other actions to satisfy these needs,  c) evaluate the effectiveness of the actions taken,  d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and  e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>	<p>for people performing work affecting product quality?  What training or other actions do you provide to satisfy the needs of personnel?  When you provide training or other actions to satisfy competence needs, how do you evaluate the effectiveness of those actions? (records)  (Sample throughout organization)  How do your activities contribute to the achievement of quality objectives?  Where do you maintain <b>records</b> of education, training, skills and experience?</p>	
	<p><b>NOTE</b> National or regional regulations might require the organization to establish documented procedures for identifying training needs.</p>		
	<p><b>6.3 Infrastructure</b></p>		
6.3q1	<p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable  a) buildings, workspace and associated utilities,  b) process equipment (both hardware and software), and  c) supporting services (such as transport or communication).</p>	<p>Are the buildings, workspace, and utilities appropriate to meet product requirements? How are they maintained?  What kind of process equipment (both hardware and software) is necessary to conform to product requirements? How is the equipment maintained?  What supporting services (such as transport or communication) are needed to ensure that product meets requirements? How are they maintained?</p>	
	<p>The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.</p>	<p><b>documented requirements</b></p>	
	<p>Records of such maintenance shall be maintained (see 4.2.4).</p>	<p><b>Records</b></p>	
	<p><b>6.4 Work environment</b></p>		
6.4q1	<p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>	<p>What kind of work environment is required to achieve conformity to product requirements? How is this environment managed and maintained?</p>	
	<p>The following requirements shall apply.  a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1).  b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1).  c) The organization shall ensure that all personnel who are required to work</p>	<p><b>Documented requirements and work instructions</b></p>	

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)].  d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).		
<b>7 Product realization</b>			
<b>7.1 Planning of product realization</b>			
7.1q1	The organization shall plan and develop the processes needed for product realization.	Where are the processes needed for product realization identified?	
7.1q2	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	Is the planning of product realization consistent with the requirements of the other processes of the QMS? (Verify there are no inconsistencies or conflicts between quality system procedures)	
7.1q3	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).	Where in the product realization process do you determine the quality objectives and requirements for products? When planning for product realization, how do you establish processes, documents, and provide resources specific to the product How do you determine verification, validation, monitoring, inspection and test activities specific to the product, and the criteria for product acceptance? What <b>records</b> exist showing that both the realization processes and the product meet requirements?	
7.1q4	The output of this planning shall be in a form suitable for the organization's method of operations.	What are the outputs of product realization planning? Are they in a form suitable for Organization?	
	The organization shall establish documented requirements for risk management throughout product realization.	<b>documented requirements</b> for risk management	
	Records arising from risk management shall be maintained (see 4.2.4).	<b>records</b>	
NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.			
NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.			
NOTE 3 See ISO 14971 for guidance related to risk management.			

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	<b>7.2 Customer-related processes</b>		
	<b>7.2.1 Determination of requirements related to the product</b>		
7.2.1q1a	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	How does Organization determine <u>each</u> of the following requirements? a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	
	<b>7.2.2 Review of requirements related to the product</b>		
7.2.2q1	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined and documented, b) contract or order requirements c) the organization has the ability to meet the defined requirements.	What kind of review is done to ensure that the organization has the ability to meet requirements before committing to supply product? How do you ensure that product requirements are defined, <b>documented</b> , and reviewed before committing to supply product? How do you ensure that contract or order requirements differing from those previously expressed are resolved before committing to supply product?	
7.2.2q2	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Can you show me records of the product requirement review results and actions resulting from them?	
7.2.2q3	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	When customers don't have documented requirements, how do you confirm their requirements before accepting orders?	
7.2.2q4	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	When product requirements are changed, how do you ensure that relevant documents are changed and that relevant personnel are made aware of the changes?	
	NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.		
	<b>7.2.3 Customer communication</b>		
7.2.3q1	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order c) customer feedback, including customer complaints (see 8.2.1), and d) advisory notices (see 8.5.1).	What method(s) are used to communicate with customers regarding - product information? - enquiries, contracts, or order handling, including amendments? - feedback, including customer complaints? - advisory notices?	
	<b>7.3 Design and development</b>		
	<b>7.3.1 Design and development planning</b>		
	The organization shall establish	<b>documented procedures</b>	

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	documented procedures for design and development.		
7.3.1q1	The organization shall plan and control the design and development of product.	Can you explain to me the process used by Organization to plan and control the design and development of product?	
7.3.1q2	During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification, validation and design transfer activities (see Note) that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	What are the stages in the design and development process? How do you determine the review, verification, validation, and design transfer activities appropriate to each design and development stage? How/where are design and development responsibilities and authorities defined?	
7.3.1q3	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	How does Organization ensure effective communication and clear assignment of responsibility between different groups involved in design and development?	
7.3.1q4	Planning output shall be documented, and updated as appropriate, as the design and development progresses (see 4.2.3).	As product design and development progresses, how are the planning outputs documented and updated?	
<b>NOTE Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.</b>			
<b>7.3.2 Design and development inputs</b>			
7.3.2q1a	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional, performance and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development, and e) output(s) of risk management (see 7.1).	What are the design inputs relating to each of the following product requirements? a) functional, performance and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and f) other requirements essential for design and development, and d) output(s) of risk management. Where are they recorded?	
7.3.2q2	These inputs shall be reviewed for adequacy and approved.	How & when are the design and development inputs reviewed and approved for adequacy?	
7.3.2q3	Requirements shall be complete, unambiguous and not in conflict with each other.	How does Organization ensure that requirements are complete, unambiguous and don't conflict with each other?	
<b>7.3.3 Design and development outputs</b>			
7.3.3q1	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.	How can design and development outputs be verified against the inputs? (see 7.3.5q1) Are these outputs approved prior to release?	
7.3.3q2	Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance	Can you show me examples of design and development outputs and how they meet the input requirements? What outputs include information for purchasing, production and service? Where are product acceptance criteria specified?	

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	criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.	Where are product characteristics needed for safe and proper use specified?	
	Records of the design and development outputs shall be maintained (see 4.2.4).	Where are <b>records</b> of design and development maintained?	
	NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.		
	<b>7.3.4 Design and development review</b>		
7.3.4q1a	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions.	At what stages of design and development do you perform reviews to evaluate if the results meet requirements? (See 7.3.1q2b)  Can you show me some problems that have been identified and actions proposed at these reviews?	
7.3.4q2	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, <b>as well as other specialist personnel (see 5.5.1 and 6.2.1).</b>	What functions ( <b>including specialists</b> ) are represented at these reviews? At each stage, are all functions concerned with that stage represented?	
7.3.4q3	Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the results of the reviews and any necessary actions taken?	
	<b>7.3.5 Design and development verification</b>		
7.3.5q1	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.	What verification activities are performed to ensure that the design and development outputs have met the input requirements? (See 7.3.3q1)	
7.3.5q2	Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the results of the verification activities <u>and</u> resulting actions?	
	<b>7.3.6 Design and development validation</b>		
7.3.6q1	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, ( <b>where known</b> ).	What design and development validation activities are performed to ensure that the product is capable of meeting the requirements for the intended use?	
7.3.6q2	<b>(Wherever practicable,)</b> validation shall be completed prior to the delivery or implementation of the product ( <b>see Note 1</b> ).	Do records show that validation is done before product shipment? <b>If not, is the justification recorded?</b>	
7.3.6q3	Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the validation activity results <u>and</u> any follow-up actions?	
	As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations ( <b>see Note 2</b> ).		
	NOTE 1 If a medical device can only be validated following assembly and installation at		

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	point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.		
	NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.		
	<b>7.3.7 Control of design and development changes</b>		
7.3.7q1	Design and development changes shall be identified and records maintained.	How are design and development changes identified? Where are the <b>records</b> kept?	
7.3.7q2	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.	Are changes reviewed, verified, validated, and approved before implementation?	
7.3.7q3	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.	Can you show me evidence that the review of design and development changes includes evaluation of the effect on component parts and products in the field?	
7.3.7q4	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the results of change reviews and any necessary actions?	
	<b>7.4 Purchasing</b>		
	<b>7.4.1 Purchasing process</b>		
7.4.1q1	The organization shall <b>establish documented procedures</b> to ensure that purchased product conforms to specified purchase requirements.	How do you ensure that purchased product conforms to specified requirements? <b>Can you show me a documented procedure for this?</b>	
7.4.1q2	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.	How do you determine the type and extent of control applied to the supplier and the purchased product?	
7.4.1q3	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.	How do you evaluate and select suppliers? (based on their ability to supply product in accordance with Organization's requirements)	
7.4.1q4	Criteria for selection, evaluation and re-evaluation shall be established.	Can you show me the criteria for selection, evaluation and re-evaluation of suppliers?	
7.4.1q5	Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the results of supplier evaluations and any necessary actions? (verify that criteria have been met)	
	<b>7.4.2 Purchasing information</b>		
7.4.2q1	Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.	Do orders/contracts include requirements for approval of product, procedures, processes and equipment? Do require any qualification of supplier personnel? If so, can you show where the requirement is documented? Do you have any QMS requirements of your suppliers? If so, can you show me where they are required?	
7.4.2q2	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	How does Organization ensure the adequacy of purchasing requirements before communicating them to the supplier?	
	To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).	<b>documents and records</b>	

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<b>7.4.3 Verification of purchased product</b>			
7.4.3q1	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	What inspection or other activities are used to ensure that purchased product meets your purchasing requirements?	
7.4.3q2	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	Do you ever perform product verification at the supplier's site? If so, where are the verification arrangements and method of product release identified?	
Records of the verification shall be maintained (see 4.2.4).		Can you show me records of onsite verification?	
<b>7.5 Production and service provision</b>			
<b>7.5.1 Control of production and service provision</b>			
<b>7.5.1.1 General requirements</b>			
7.5.1q1	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities, and g) the implementation of defined operations for labelling and packaging.	When carrying out production (or service) are all of the following controlled conditions in place? a) Is information that describes the characteristics of the product available? b) Are appropriate documented procedures, documented requirements, work instructions, reference materials and reference measurement procedures available (if needed)? c) Is suitable equipment used for carrying out production (or service)? d) Are appropriate gages, etc. used in production (or service)? (See 7.6) e) Are appropriate kinds of monitoring and measurement done? (See 8.2.4) f) Are proper release, delivery and post-delivery activities in place? g) Are packaging and labeling operations defined and implemented?	
The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution.		record	
The batch record shall be verified and approved.			
NOTE A batch can be a single medical device.			
<b>7.5.1.2 Control of production and service provision — Specific requirements</b>			
<b>7.5.1.2.1 Cleanliness of product and contamination control</b>			
The organization shall establish documented requirements for cleanliness of product if a) product is cleaned by the organization prior to sterilization and/or its use, or b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or c) product is supplied to be used non-sterile and its cleanliness is of significance in use, or d) process agents are to be removed from		documented requirements for cleanliness of product	

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	product during manufacture.		
	If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.		
	<b>7.5.1.2.2 Installation activities</b>		
	If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.	<b>documented requirements</b> with acceptance criteria for installing and verifying the installation	
	If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification.	<b>documented requirements</b> for installation and verification if installation is performed by outside org.	
	Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4).	<b>Records</b> of installation and verification	
	<b>7.5.1.2.3 Servicing activities</b>		
	If servicing is a specified requirement, the organization shall establish documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.	<b>documented procedures, work instructions and reference materials and reference measurement procedures</b>	
	Records of servicing activities carried out by the organization shall be maintained (see 4.2.4).	<b>Records</b> of servicing activities	
	NOTE Servicing can include, for example, repair and maintenance.		
	<b>7.5.1.3 Particular requirements for sterile medical devices</b>		
	The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4).	<b>records</b> of the process parameters for the sterilization process	
	Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).	Sterilization traceability <b>records</b>	
	<b>7.5.2 Validation of processes for production and service provision</b>		
	<b>7.5.2.1 General requirements</b>		
7.5.2q1	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.	Do you have any production or service processes where the resulting output cannot be verified later? If so, how to you validate them?	
7.5.2q2	Validation shall demonstrate the ability of these processes to achieve planned results.	Can you show me records that demonstrate that the validation done has met the requirements?	
7.5.2q3a	The organization shall establish arrangements for these processes including, as applicable	How are these special processes reviewed and approved? Can you show me records of personnel and	

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	a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures d) requirements for records (see 4.2.4), and e) revalidation.	equipment qualification? Where are specific methods and procedures defined? Can you show me <b>records</b> for these processes? When changes are made to processes, how do you revalidate them?	
	The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements.	<b>documented procedures</b> for validation of computer software	
	Such software applications shall be validated prior to initial use.		
	Records of validation shall be maintained (see 4.2.4).	<b>Records</b> of validation	
<b>7.5.2.2 Particular requirements for sterile medical devices</b>			
	The organization shall establish documented procedures for the validation of sterilization processes.	<b>documented procedures</b> for the validation of sterilization processes	
	Sterilization processes shall be validated prior to initial use.		
	Records of validation of each sterilization process shall be maintained (see 4.2.4).	<b>Records</b> of validation of each sterilization process	
<b>7.5.3 Identification and traceability</b>		<b>7.5.3 Identification and traceability</b>	
<b>7.5.3.1 Identification</b>			
7.5.3q1	(Where appropriate,) the organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.	How do you identify product throughout your processes? (Verify in production, storage, segregation areas, etc.) Can you show me <b>documented procedures</b> for this?	
	The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].	<b>documented procedures</b>	
<b>7.5.3.2 Traceability</b>			
<b>7.5.3.2.1 General</b>			
	The organization shall establish documented procedures for traceability.	<b>documented procedures</b> for traceability	
	Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).		
7.5.3q3	Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	Can you show me unique identification <b>records</b> for products requiring traceability?	
NOTE In some industry sectors, configuration management is a means by which identification and traceability (are) can be maintained.			
<b>7.5.3.2.2 Particular requirements for active implantable medical devices and</b>			

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<b>implantable medical devices</b>			
	In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.	<b>records</b> of all components, materials and work environment conditions	
	The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection.		
	Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).	<b>Records</b> of the name and address of consignee	
<b>7.5.3.3 Status identification</b>			
7.5.3q2	The organization shall identify the product status with respect to monitoring and measurement requirements.	How is product inspection status identified? (Verify in production, storage, segregation areas, etc.)	
	The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.		
<b>7.5.4 Customer property</b>			
7.5.4q1	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.	Do you use any customer-owned property? (Product, packaging, drawings, tooling, gages...) (If so, ask questions below)	
7.5.4q2	The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product.	How do you ensure that customer-owned property is identified, verified, protected, and safeguarded?	
7.5.4q3	If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	If any customer property is lost, damaged etc., how is it reported to the customer? Can you show me <b>records</b> regarding this?	
NOTE Customer property can include intellectual property or confidential health information.			
<b>7.5.5 Preservation of product</b>			
7.5.5q1	The organization shall <b>establish documented procedures or documented work instructions for preserving (preserve)</b> the conformity of product during internal processing and delivery to the intended destination.	How do you preserve the conformity of product during internal processing and delivery? (Verify product throughout audit) <b>Can you show me documented work instructions or procedures for this?</b>	
7.5.5q2	This preservation shall include identification, handling, packaging, storage and protection.	How do identification, handling, packaging, storage and protection address the preservation of product?	
7.5.5q3	Preservation shall also apply to the constituent parts of a product.	Does this also apply to component parts?	
	The organization shall establish documented procedures or documented work instructions for the control of product		

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	with a limited shelf-life or requiring special storage conditions.		
	Such special storage conditions shall be controlled and recorded (see 4.2.4).		
<b>7.6 Control of monitoring and measuring devices</b>			
7.6q1	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	How do you determine the measurements to be taken and the measuring equipment needed to demonstrate conformity with requirements?	
7.6q2	The organization shall establish <b>documented procedures (processes)</b> to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	What process is in place to ensure that measurements are taken per the requirements? <b>Can you show me documented procedures for this?</b>	
7.6q3a	Where necessary ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage.	a) How do you ensure that measuring and test equipment is calibrated or verified proper frequencies with NIST traceable standards? If no such standards exist, where do you <b>record</b> the basis used for calibration or verification? b) What process is used to adjust or re-adjust measuring and test equipment when needed? c) How are measuring tools identified to enable the calibration status to be determined? d) How do you safeguard measuring equipment from adjustments that would invalidate the measurement results? e) How do you ensure that measuring its test equipment is protected from damage and deterioration during handling, maintenance and storage?	
7.6q4	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.	When equipment is found to be out of calibration, how do you assess and record the validity of the previous measuring results?	
7.6q5	The organization shall take appropriate action on the equipment and any product affected.	What actions do you take on the equipment and any product affected?	
7.6q6	Records of the results of calibration and verification shall be maintained (see 4.2.4).	Can I see your <b>records</b> of the results of calibration and verification?	
7.6q7	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	Do you use computer software for monitoring and measurement? If so, is its ability to perform that function confirmed prior to initial use and reconfirmed as necessary?	
NOTE See ISO 10012-1 and ISO 10012-2 for guidance <b>related to measurement management systems.</b>			
<b>8 Measurement, analysis and improvement</b>			

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<b>8.1 General</b>			
8.1q1	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to (continually improve) maintain the effectiveness of the quality management system.	How do you plan and implement measurement, analysis and improvement processes needed a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system? c) to (continually improve) maintain the effectiveness of the quality management system?	
8.1q2	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	How do you determine what monitoring measurement, and analysis methods to use, including statistical techniques? How do you determine the extent of their use?	
NOTE National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.			
<b>8.2 Monitoring and measurement</b>			
<b>8.2.1 (Customer satisfaction) Feedback</b>			
8.2.1q1	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to (customer perception as to) whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	How do you obtain information about (customer perception as to) whether Organization has met customer requirements? How is this information used?	
	The organization shall establish a documented procedure for a feedback system [see 7.2.3 c)] to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).		
	If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).		
<b>8.2.2 Internal audit</b>			
8.2.2q1	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.	Are internal audits being conducted at planned intervals? Do they determine whether the QMS conforms to the requirements of ISO 9001 and to the other requirements established by Organization? (Review records to demonstrate conformance) Do they determine whether the QMS is effectively implemented and maintained? (Review records)	
8.2.2q2	An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.	Can you show me an audit plan that takes into consideration the importance of the processes and areas to be audited, and the results of previous audits?	
8.2.2q3	The audit criteria, scope, frequency and methods shall be defined.	Where are the audit criteria, scope, frequency and methods defined?	

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8.2.2q4	Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	Can you demonstrate that selection of auditors and the conduct of audits are objective and impartial, and that auditors don't audit their own work?	
8.2.2q5	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.	Can you show me your internal audit <b>procedure</b> ? Can you show me the <b>records</b> of internal QMS audits?	
8.2.2q6	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.	Who ensures that actions are taken to eliminate detected nonconformities and their causes? Are they being taken care of in a timely manner? (verify with records)	
8.2.2q7	Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).	What activities are done to verify the actions taken, and how are the verification results reported?	
	NOTE See ISO (10011-1, ISO 10011-2 and ISO 10011-3) 19011 for guidance related to quality auditing.		
<b>8.2.3 Monitoring and measurement of processes</b>			
8.2.3q1	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.	What methods are used to monitor and measure the QMS processes?	
8.2.3q2	These methods shall demonstrate the ability of the processes to achieve planned results.	Can you show that they have achieved the desired results?	
8.2.3q3	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	When the desired results are not achieved, what actions are taken to ensure that the product meets requirements?	
<b>8.2.4 Monitoring and measurement of product</b>			
<b>8.2.4.1 General requirements</b>			
8.2.4q1	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.	What characteristics are checked to verify that product requirements have been met?	
8.2.4q2	This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).	At what stages of the product realization process do monitoring and measuring activities take place? Can you show me <b>documented procedures</b> for monitoring and measurement of product?	
8.2.4q3	Evidence of conformity with the acceptance criteria shall be maintained.	How is evidence of conformity with acceptance criteria maintained?	
8.2.4q4	Records shall indicate the person(s) authorizing release of product (see 4.2.4).	Can you show me <b>records</b> that indicate who has authorized release of product to the next stage of the process?	
8.2.4q5	Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed	How do you ensure that product is not released until the all requirements have been met?	

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	(unless otherwise approved by a relevant authority and, where applicable, by the customer).	If product must be released prior to this, how is it approved?	
	<b>8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices</b>		
	The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.	Can you show me <b>records</b> showing the identity of personnel performing inspection or testing?	
	<b>8.3 Control of nonconforming product</b>		
8.3q1	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.	How do you ensure that nonconforming products are identified and controlled to prevent unintended use or delivery? (Verify product throughout audit)	
8.3q2	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.	Can you show me a <b>documented procedure</b> defining the controls for dealing with nonconforming product? Does it show responsibilities/authorities?	
8.3q3	The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession (by a relevant authority and, where applicable, by the customer); c) by taking action to preclude its original intended use or application.	When you have nonconforming product, what methods do you use to deal with it?	
	The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met.		
	Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).	Can you show me <b>records</b> of the identity of personnel authorizing concessions?	
8.3q4	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Can you show me <b>records</b> of NC material and any actions taken? Are there any <b>records</b> of concessions obtained?	
8.3q5	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	When nonconforming product is corrected, can you demonstrate that it is re-verified to ensure it conforms to requirements?	
8.3q6	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	When nonconforming product is detected after shipment, what actions are taken, such as containment? (Verify corrective action records)	
	If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the	Can you show me rework <b>work instructions</b> approved by same authority as the original work instruction?	

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	original work instruction.		
	Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).	Can you show me <b>records</b> of determination of adverse effects of rework? Was the determination made prior to authorization of the work instruction?	
<b>8.4 Analysis of data</b>			
8.4q1	The organization shall <b>establish documented procedures</b> to determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.	What data is collected and analyzed to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of its effectiveness can be made? <b>Can you show me documented procedures that describe this activity?</b>	
8.4q2a	The analysis of data shall provide information relating to a) <b>(customer satisfaction) feedback</b> (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.	What information does this analysis provide relating to: - <b>(customer satisfaction) feedback?</b> (5.6) - conformity to product requirements? (See 5.6) - characteristics and trends of processes and products? (See 5.6) - suppliers? (See 7.4.1)	
	<b>Records of the results of the analysis of data shall be maintained (see 4.2.4).</b>		
<b>8.5 Improvement</b>			
<b>8.5.1 (Continual improvement) General</b>			
8.5.1q1	The organization shall <b>(continually improve the) identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness</b> of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	<b>Can you demonstrate that Organization's QMS effectiveness continually improves?</b> <b>Can you demonstrate that Organization identifies and implements changes to ensure continued QMS effectiveness?</b> What tools do you use? (See 5.6, 8.2.2, 8.4, 8.5.2, 8.5.3)	
	The organization shall establish <b>documented procedures for the issue and implementation of advisory notices.</b>	<b>documented procedures</b>	
	<b>These procedures shall be capable of being implemented at any time.</b>		
	<b>Records of all customer complaint investigations shall be maintained (4.2.4).</b>	<b>records</b>	
	If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).		
	If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).	<b>Record</b>	
	If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.	<b>documented procedures</b>	
<b>8.5.2 Corrective action</b>			
8.5.2q1	The organization shall take action to eliminate the cause of nonconformities in	Do corrective actions records identify and address root cause(s)?	

Q#	ISO 9001:2000 and/or ISO 13485:2003 Clause Text	Sample Audit Question	Evidence
	order to prevent recurrence.	(Do root causes match actions?)	
8.5.2q2	Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Are actions taken appropriate to the severity of the problem?	
8.5.2q3	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), e) (records) recording of the results of any investigation and of action taken (see 4.2.4), and f) reviewing the corrective action taken and its effectiveness.	Can you show me a <b>documented procedure</b> defining requirements for each of the following? a) reviewing nonconformities (including customer complaints) b) determining the causes of nonconformities c) evaluating the need for action to ensure that nonconformities do not recur d) determining and implementing action needed e) records of the results of any investigation and of action taken f) reviewing the corrective action taken and its effectiveness	
8.5.2q4	e) (records) recording of the results of any investigation and of action taken (see 4.2.4), and	Can you show me <b>records</b> of investigation and corrective actions taken?	
	<b>8.5.3 Preventive action</b>	<b>8.5.3 Preventive action</b>	
8.5.3q1	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.	How do you determine potential nonconformities to take action on? Do preventive action records identify and address root cause(s)?	
8.5.3q2	Preventive actions shall be appropriate to the effects of the potential problems.	Are actions taken appropriate to the severity of the problem?	
8.5.3q3	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) (records) recording of the results of any investigation and of action taken (see 4.2.4), and e) reviewing preventive action taken and its effectiveness.	Can you show me a <b>documented procedure</b> defining requirements for each of the following? a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, f) (records) recording of the results of any investigation and of action taken (see 4.2.4), and d) reviewing preventive action taken and its effectiveness.	
8.5.3q4	d) (records) recording of the results of any investigation and of action taken (see 4.2.4), and	Can you show me <b>records</b> of preventive actions taken?	



<b>ORGANIZATION and PERSONNEL - SUBPART B</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.22 Responsibilities of Quality Control Unit</b>	
Define the Quality Assurance Program	
QC unit	
QA unit	
Regulatory	
Supplier certification program	
<b>Has the FDA Inspected the facility?</b>	
Date of Last Inspection	
Results of Last Inspection	
Adequate testing Facilities?	
In-Process checks performed by QA?	
QA records signed dated and reviewed by a second person?	
Do records indicate the final disposition of materials manufactured at the facility?	
Are inspection and test procedures written?	
<b>211.25 Personnel Qualifications</b>	
Training records up-to-date?	
Annual GMP training?	
On-going training program?	
Any Certification training?	
Is there an adequate number of qualified personnel to supervise?	
<b>211.28 Personnel responsibilities</b>	
Is personnel wearing proper attire?	
Is personnel practicing good sanitation and health habits?	
Are persons with a medical condition excluded from product contact?	
<b>211.34 Consultants</b>	
Are there records of consultants on file?	

NOTES:	
<b>BUILDINGS AND FACILITIES - SUBPART C</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.42 Design and Construction Features</b>	
Are the buildings of suitable size and construction to facilitate cleaning and other operations?	
Building should have adequate space to prevent mix-ups?	
Operations shall be performed within specifically designed areas to prevent contamination?	
Receipt, storage and handling shall be controlled.	
Holding items before release.	
Holding of rejected items.	
Storage of released components.	
Storage of in-process materials.	
Control and Laboratory operations.	
Temperature and Humidity controls	
Aseptic processing-floors, walls and ceilings easily cleaned.	
Air supply filtered through high efficiency particulate air filters under positive pressure.	
A system for monitoring environmental conditions.	
A system for cleaning and disinfecting the room and equipment.	
Separate facility for the manufacture of penicillin	
<b>211.44 Lighting</b>	
Adequate Lighting shall be provided in all areas.	
<b>211.46 Ventilation, air filtration, air heating and cooling</b>	
Adequate ventilation shall be provided.	
Control over air pressure shall be provided	
Control over dust particles	
<b>211.48 Plumbing</b>	
Potable water shall meet EPA water regulations 40 CFR 141	
<b>211.50 Sewage and Refuse</b>	
Waste shall be disposed in a safe manner.	
<b>211.52 Washing and toilet facilities</b>	
Adequate washing and toilet facilities shall be provided including hot and cold water, soap	
<b>211.56 Sanitation</b>	

Building shall be free of rodents, insects.	
Waste and trash shall be disposed in a timely manner	
Are there written procedures assigning responsibility for sanitation and describing cleaning schedules?	
Are sanitation procedures required by contractors and temporary employees?	
<b>211.58 Maintenance</b>	
Is there good building maintenance?	
NOTES:	

<b>EQUIPMENT - SUBPART D</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.63 Equipment Design, size, and location</b>	
Equipment of appropriate size, design and location.	
<b>211.65 Equipment construction</b>	
Surfaces that contact components are not reactive, additive or adsorptive	
Lubricants or coolants do not come into contact	
<b>211.67 Equipment cleaning and maintenance</b>	
Is equipment and utensils cleaned and maintained?	
Are there written procedures for cleaning?	
Who is responsible for cleaning and maintaining equipment?	
Cleaning schedules?	
Procedures for assembling and disassembling equipment?	
Obliteration of previous batch number?	
Protection of clean equipment prior to use?	
Inspection of cleanliness prior to use?	
Records shall be kept of cleanliness sanitizing and inspection?	
<b>211.68 Automatic , mechanical and electronic equipment</b>	
Is equipment calibrated, inspected?	
Are written records maintained?	
Are master records properly controlled?	
Are computer outputs checked for accuracy?	
<b>211.72 Filters</b>	
Filters for liquid filtration for manufacture, processing shall not release fibers in the product.	
NOTES:	



<b>containers and closures</b>	
Is the oldest approved stock used first?	
<b>211.87 Re-testing of approved components,,,,</b>	
Are components, drug products re-tested after long periods of storage?	
<b>211.89 Rejected Components, drug products and closures</b>	
Are rejected products controlled under a quarantine system?	
<b>211.94 Drug Product containers and closures</b>	
Are there written procedures for pyrogenic properties?	
NOTES:	

<b>PRODUCTION AND PROCESS CONTROLS - SUBPART F</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.100 Written Procedures- Deviations</b>	
Are written procedures approved by the QC unit?	
Are deviations from the written procedure documented?	
<b>211.101 Charge in of components</b>	
Batch records must have 100% of label claim	
Weighings observed and signed by a second person	
Containers are properly identified	
<b>211.103 Calculation of Yield</b>	
Are yields calculated and verified by a second person?	
<b>211.105 Equipment Identification</b>	
Are equipment and phases of production properly identified?	
Is the equipment identified on the batch record?	
<b>211.110 Sampling and testing of in-process materials and drug products</b>	
Are there procedures that describe the in-process controls?	
Are rejected in-process materials segregated and properly identified?	
<b>211.111 Time Limitations on Production</b>	
Are there time limitations on the production?	
Are deviations from this time limit justified and documented?	
<b>211.113 Control of Microbiological contamination</b>	



Is returned labeling maintained and stored in a manner to prevent mix-ups?	
<b>211.130 Packaging and Labeling operations</b>	
Are packaging lines and materials separated physically?	
Is the packaging line identified?	
Are the labels examined before packaging?	
Is there written documentation of line clearance?	
Is the line clearance documentation in the batch record?	
<b>211.132 Tamper resistant packaging requirements for OTC drug products</b>	
Not applicable	
<b>211.134 Drug Product Inspection</b>	
Packages and labeled products shall be examined during finishing operations that they have the correct label.	
Is a representative sample taken and examined?	
Are these data in the batch record?	
<b>211.137 Expiration Dating</b>	
Expiration dating based on appropriate stability studies.	
Associated with storage conditions on the container	
NOTES:	
<b>HOLDING AND DISTRIBUTION - SUBPART H</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.142 Warehousing procedures</b>	
Do warehouse procedures include quarantine before release?	
Does the storage affect the product?	
<b>211.150 Distribution Records</b>	
Is there written procedures for distribution of drug products?	
Is the oldest stock used first?	
Is the system so recall can be facilitated?	
<b>LABORATORY CONTROLS - SUBPART I</b>	
<b>211.160 General Requirements</b>	
Are documents approved by the QC unit?	
Are sampling documents in place?	

How are samples received in the QC lab?	
Are solutions properly labeled?	
Is there a LIMS system?	
Are written specifications in place?	
Are samples and documents properly identified?	
Is there a good calibration program?	
Who performs the calibrations?	
Are instruments properly tagged?	
Are instruments that do not require calibration properly tagged?	
Do some instruments that have a daily calibration have a log book?	
<b>211.165 Testing and release for distribution</b>	
Test records for analytical?	
Test records for microbiological?	
Test records for in-process?	
Any investigations?	
Have deviations been investigated?	
Any re-sampling and re-testing?	
Are there method validation documents?	
<b>211.166 Stability Testing</b>	
Is there a stability program?	
What are the storage conditions?	
Are test methods stability indicating?	
<b>211.167 Special Testing Requirements</b>	
Is there sterility testing?	
<b>211.170 Reserve Samples</b>	
Are samples from each lot retained?	
Are retains kept 1 year past the expiration date?	
<b>211.173 Laboratory Animals</b>	
Use of animal testing?	
Are records kept?	
<b>211.176 Penicillin contamination</b>	
Non-penicillin drug products are contaminated by penicillin products must be tested.	
<b>RECORDS AND REPORTS - SUBPART J</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.180 General Requirements</b>	
Are production records retained 1 year past the expiration date?	
Are records easily attainable?	
Written records shall be maintained for evaluating each batch at least annually to determine the need for changes in manufacturing.	

Does the annual review cover complaints, recalls, returned drug products and investigations?	
<b>211.182 Equipment cleaning and use log</b>	
Are there equipment cleaning logs?	
Is there dedicated equipment?	
<b>211.184 Component, drug product container, closure and labeling records</b>	
Refer to 211.80	
<b>211.186 Master production and control records.</b>	
Who is the keeper of the records?	
Are records controlled?	
<b>211.188 Batch production and control records</b>	
Do batch records explain all of the necessary steps in manufacturing?	
weights and measures of components?	
verified by a second individual?	
yield calculations?	
packaging labels?	
reconciliation?	
test releases?	
any investigations?	
<b>211.192 Production record review</b>	
Are records reviewed and approved by the quality control unit?	
<b>211.194 Laboratory records</b>	
Do lab records include all of the data?	
Is the sample clearly identified?	
Is the method used clearly identified?	
sample and standard weights used?	
graphs, spectra included?	
Any investigations?	
Are tests signed and reviewed by a second individual?	
Is there reference standard used?	
Is there a reference standard program?	
<b>211.198 Complaint Files</b>	
Are there written procedures covering complaints?	
Complaint files up to 1 year after the expiration date?	
Is there follow up information?	
<b>RETURNED AND SALVAGED DRUG PRODUCTS - PART K</b>	
<b>211.204 Returned drug products</b>	
Are returned products identified and quarantined?	
Are returned products re-processed?	
Any returned product exposed to adverse conditions?	

Document Reference	Procedure Requirements to be evaluated	Document Review Comments	Assessment Findings

NONCONFORMITY REPORT

Area/Activity Audited:		Standard Reference:
Category:	Major**	Minor**
Findings:		
Observation report:		
Auditor:		



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

## Task Order 3- MALAR IA Quality Assurance Procedures

<b>TITLE:</b> Conducting Laboratory Audits for Rapid Diagnostic Kits (RDTs)		<b>DOCUMENT No.:</b> TO3-QA-RDTs-25
<b>DATE ISSUED:</b> 11/1/2007	<b>SUPERSEDES:</b> 9/10/07 Rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

### 1.0 PURPOSE:

1.1	To establish a document that provides a format for conducting audits of laboratories which evaluate the quality of RDTs with respect to USAID contract requirements.
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### 2.0 BACKGROUND:

2.1	<p>Through cooperation with the WHO Western Pacific Regional Office (WHO-WPRO), laboratories that may be considered for testing are;</p> <table border="1" style="margin-left: 40px;"> <tr> <td>1.</td> <td>RITM Philippines</td> </tr> <tr> <td>2.</td> <td>Institut Pasteur (Cambodia)</td> </tr> <tr> <td>3.</td> <td>Centers for Disease Control- US</td> </tr> </table> <p>Ref: <a href="http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO_field_QA_guide.pdf">http://www.wpro.who.int/NR/rdonlyres/5A639481-535D-4F1C-B86A-A577FC2DE854/0/RDTWPRO_field_QA_guide.pdf</a></p>	1.	RITM Philippines	2.	Institut Pasteur (Cambodia)	3.	Centers for Disease Control- US
1.	RITM Philippines						
2.	Institut Pasteur (Cambodia)						
3.	Centers for Disease Control- US						
2.2	Although the candidate laboratories listed above are collaborating with the WHO, the facilities used for testing RDTs should be visited by members of the QAP team (Family Health International) to ensure that the laboratories are operating properly.						

### 3.0 REFERENCE DOCUMENTS:

3.1	Current contract between USAID and manufacturer.
3.2	<a href="http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf">http://www.wpro.who.int/NR/rdonlyres/E59BDEC7-C5C1-4374-B76B-C303E97BB925/0/MD_table22_ISO131485criteriarev130407.pdf</a>
3.3	<p><a href="#">Form 001 - On-Site Evaluation Checklist.doc</a> (Appendix A) taken directly from the website below: <a href="http://www.wpro.who.int/NR/rdonlyres/B5446BF5-BCFA-427D-B9FE-CEA57D36B92B/0/RDTQCMETHODSMANUALV4FINAL3.PDF">http://www.wpro.who.int/NR/rdonlyres/B5446BF5-BCFA-427D-B9FE-CEA57D36B92B/0/RDTQCMETHODSMANUALV4FINAL3.PDF</a></p>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits / Field Evaluations
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities	Standard Operating Procedures Audits/Monitoring suppliers Complaints
5.	United States Pharmacopeia	Technical assistance for chemical testing	Audits	

**5.0 PROCEDURE:**

5.1	Laboratories will be visited on-site by staff from the Quality Assurance-Partners and evaluated for compliance to <b>Appendix A- Form 001 - On-Site Evaluation Checklist</b> (Ref. Doc. 3.3). Effort should be made to schedule the audit so that all pertinent laboratory staff are present.
5.2	Audits will be conducted every 1-2 years.
5.3	An internal memo shall be prepared listing the highlights of the audit, including informational items that may impact future operational audits.
5.4	An external report shall be provided to the laboratory and QA-Partners listing observations, and where appropriate, suggested guidelines for improvement. The report shall request a corrective action plan, if needed, and estimated dates of completion.
5.5	If observations are significant, and the facility is out of compliance in critical areas, a follow-up visit may be scheduled prior to the next scheduled audit. If the corrective action plan is found not to have been completed prior to the follow-up visit, the laboratory will not be utilized for QA testing of RDTs until additional audits indicate compliance.

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/10/07	00	N/A	New Issue.
11/1/07	01	9/10/07	Updated PATH responsibilities

## APPENDIX A

Checklist from <http://www.wpro.who.int/NR/rdonlyres/B5446BF5-BCFA-427D-B9FE-CEA57D36B92B/0/RDTQCMETHODSManualV4final3.pdf>

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### On-site Evaluation Checklist (Form 001)

Institution:	
Scientist/Technician/s:	
Assessor:	Date

<b>Section 1: Administration</b>		
Sub-Section	Checks	Assessor's Comments
Workplace	<ul style="list-style-type: none"> <li>• Dedicated work area?</li> <li>• Security, restricted access?</li> <li>• Efficient workflow?</li> <li>• Housekeeping (cleanliness and tidiness)</li> <li>• Referral arrangements satisfactory, including records of the dispatch of specimens and the return of results?</li> <li>• Out of hours arrangements adequate?</li> <li>• Are the following satisfactory: lighting, ventilation, water, temperature, noise, bench space/covering, storage space, facilities for staff (office space, bench area, etc), power (emergency, voltage stabilisers, outlets, etc)?</li> </ul>	
Supervision	<ul style="list-style-type: none"> <li>• Is there adequate supervision by the Head of the laboratory?</li> <li>• Are there adequate arrangements for supervision in the absence of the Head of the laboratory?</li> </ul>	

**On-site Evaluation Checklist (Form 001)**

Sub-Section	Checks	Assessor's Comments
Staffing	<ul style="list-style-type: none"> <li>• Appropriate training for all staff, with records on file?</li> <li>• Duties and responsibilities documented?</li> <li>• Arrangements adequate for staff absences?</li> <li>• Adequate provision for in-house continuing education?</li> <li>• Staff encouraged and supported to attend external continuing education including professional society meetings, conferences?</li> <li>• Regular staff meetings, with minutes kept?</li> </ul>	
Standard Operating Procedures	<ul style="list-style-type: none"> <li>• Procedure Manual in laboratory (all methods included)?</li> <li>• Staff aware of location of Procedure Manual?</li> <li>• Methods reviewed at least annually, and review documented?</li> <li>• Manual reflects current practice?</li> <li>• References included in Procedure Manual?</li> <li>• Specimens and results/records archived according to government and other regulations/requirements?</li> <li>• Appropriate staff involved in method review?</li> <li>• Staff demonstrate adequate expertise/understanding of methods?</li> <li>• Procedures in place to ensure that amendments are made to all copies of the Procedure Manual and brought to the attention of all staff?</li> </ul>	

**On-site Evaluation Checklist (Form 001)**

Sub-Section	Checks	Assessor's Comments
Quality Assurance	<ul style="list-style-type: none"> <li>• Are appropriate internal QC procedures performed, documented and reviewed?</li> <li>• Do the records show what corrective action has been taken where necessary?</li> <li>• Does the laboratory have a Quality Manual that includes a Quality Policy, SOP describing how QA (internal QC and external QAP) functions, all quality related SOPs and forms, corrective action SOP?</li> <li>• Does the laboratory participate in external QA programs (QAPs) covering its full range of testing?</li> <li>• Are the QAP results satisfactory, reviewed, recorded, and corrective action taken?</li> </ul>	
Laboratory Results Register	<ul style="list-style-type: none"> <li>• Results register located in laboratory?</li> <li>• Register neat and legible?</li> </ul>	
Equipment	<ul style="list-style-type: none"> <li>• Calibration, maintenance and service records kept in the laboratory?</li> <li>• Are SOPs written for equipment maintenance and calibration?</li> <li>• Equipment (including pipettes, thermometers and timers) calibrated?</li> <li>• Laboratory records must show supplier, date of purchase, serial number and cost of each piece of equipment</li> <li>• Temperature checks performed daily, records kept?</li> <li>• -80°C freezer alarm operating?</li> </ul>	
Computer	<ul style="list-style-type: none"> <li>• Check there is sufficient back-up and security of documents</li> <li>• Password protected?</li> </ul>	

**On-site Evaluation Checklist (Form 001)**

Sub-Section	Checks	Assessor's Comments
Supplies	<ul style="list-style-type: none"> <li>• Adequate supplies for 3 months?</li> <li>• Detail any recent delivery problems</li> </ul>	
Laboratory Safety	<ul style="list-style-type: none"> <li>• Does the laboratory have relevant written safety procedures?</li> <li>• All staff instructed in safety procedures and this training recorded?</li> <li>• Personal protective equipment (gowns, gloves, shields, etc) used in the laboratory?</li> <li>• Enclosed footwear only?</li> <li>• Fresh disinfectant (antibacterial and antiviral) readily available?</li> <li>• Work bench of suitable height and design</li> <li>• Stools with back supports?</li> <li>• Appropriate biohazard waste disposal?</li> <li>• Sufficient sharps bins?</li> <li>• Are emergency exits conspicuously marked and free of obstructions?</li> <li>• Staff offered appropriate immunisation?</li> <li>• Appropriate safety equipment (including shower, eyewash, fire extinguisher, fire blanket, etc) available?</li> <li>• Fire and evacuation orders displayed prominently?</li> </ul>	
Other issues?	<ul style="list-style-type: none"> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> <li>•</li> </ul>	

**On-site Evaluation Checklist (Form 001)**

<b>Section 2: QC panel preparation</b>		
<b>Sub-Section</b>	<b>Checks</b>	<b>Assessor's Comments</b>
ALL	<ul style="list-style-type: none"> <li>• Check field work documentation</li> <li>• Check pipetting technique</li> </ul>	

\* It is unlikely that panel preparation can be observed during an on-site assessment.

<b>Section 3: RDT QA procedure</b>		
<b>Sub-Section</b>	<b>Checks</b>	<b>Assessor's Comments</b>
QC Panel use	<ul style="list-style-type: none"> <li>• Completely thawed prior to use?</li> <li>• Only used once?</li> <li>• Appropriately labelled?</li> <li>• The ID number recorded on worksheet?</li> </ul>	
RDT register storage	<ul style="list-style-type: none"> <li>• Details of RDTs received recorded in the laboratory register?</li> <li>• RDTs inspected on arrival?</li> <li>• RDTs kept at 4°C?</li> <li>• Check RDT register</li> </ul>	
RDT transport	<ul style="list-style-type: none"> <li>• Check RDT Movement Register</li> </ul>	
Panel transport	<ul style="list-style-type: none"> <li>• Check QC panel transport register</li> </ul>	
RDT QA	<ul style="list-style-type: none"> <li>• RDT testing technique correct?</li> <li>• QA method followed exactly as documented?</li> <li>• Any negative QA results are repeated and confirmed?</li> <li>• Check previous QA worksheets</li> <li>• Check RDT package inserts are accessible</li> </ul>	
Reporting	<ul style="list-style-type: none"> <li>• All reports are in standard format?</li> <li>• Results reported within 5 days?</li> </ul>	



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Supplier Report Card for Rapid Diagnostic Test Kits (RDTs)		<b>DOCUMENT No.:</b> TO3-QA-RDTs-26
<b>DATE ISSUED:</b> 9/10/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

**1.0 PURPOSE:**

<b>1.1</b>	To describe the procedure for preparing and reporting supplier performance information.
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**2.0 BACKGROUND:**

<b>2.1</b>	Monitoring supplier performance via a scorecard (or report card) is a valuable quality management and communication tool between the supplier and customer (USAID   DELIVER Project TO3-Malaria).
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**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	1. <i>Standard operating procedure TO3-QA-RDTs-23 Sampling, Inspection and Testing of RDTs-Post Shipment</i>
	2. <i>The Supplier Management Handbook, Sixth Edition- American Society for Quality</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	Responsibilities - Quality Assurance- Partners; USAID   DELIVER – TO3 Malaria													
4.1.1	<table border="1"> <thead> <tr> <th></th> <th>Quality Assurance Partners</th> <th>Major Responsibility</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Family Health International</td> <td>Collect information on suppliers and generate scorecards</td> </tr> <tr> <td>2.</td> <td>John Snow Inc.</td> <td>Provide additional information related to supplier(s)</td> </tr> <tr> <td>3.</td> <td>PATH</td> <td>Audits / Field Evaluations</td> </tr> </tbody> </table>			Quality Assurance Partners	Major Responsibility	1.	Family Health International	Collect information on suppliers and generate scorecards	2.	John Snow Inc.	Provide additional information related to supplier(s)	3.	PATH	Audits / Field Evaluations
	Quality Assurance Partners	Major Responsibility												
1.	Family Health International	Collect information on suppliers and generate scorecards												
2.	John Snow Inc.	Provide additional information related to supplier(s)												
3.	PATH	Audits / Field Evaluations												

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Components of a Scorecard</b>				
5.1.1	There are generally three to five components of a supplier scorecard. These can be ranked based on the degree of importance by the customer or they can have equal weight. There is no standard scorecard that is used across industry or in supplier quality. The most important factor is that the customer and supplier agree to the rating and that the scorecard is the same for all suppliers of that product.				
5.1.2	<p>The scorecard for RDTs will focus on;</p> <table border="1" data-bbox="467 667 776 806"> <tr><td>"On-time deliveries"</td></tr> <tr><td>Test data (CpK)</td></tr> <tr><td>Complaints/Product audit (In-Country evaluations)</td></tr> <tr><td>Supplier Audits</td></tr> </table> <p>The ranking of importance is "to be determined".</p>	"On-time deliveries"	Test data (CpK)	Complaints/Product audit (In-Country evaluations)	Supplier Audits
"On-time deliveries"					
Test data (CpK)					
Complaints/Product audit (In-Country evaluations)					
Supplier Audits					
<b>5.2</b>	<b>"On-Time" Deliveries</b>				
5.2.1	<p>An important aspect of supplier performance is monitoring "on-time" deliveries. The information is obtained from John Snow Inc on a monthly basis through the database. The information monitored is;</p> <table border="1" data-bbox="467 1077 776 1186"> <tr><td>Order date</td></tr> <tr><td>Actual ship date</td></tr> <tr><td>Desired delivery date</td></tr> <tr><td>Actual delivery date</td></tr> </table> <p>Note: There is a "window" that can be established that is determined by the customer.</p>	Order date	Actual ship date	Desired delivery date	Actual delivery date
Order date					
Actual ship date					
Desired delivery date					
Actual delivery date					
<b>5.3</b>	<b>RDT Test Data</b>				
5.3.1	Copies of the RDT post-shipment initial test data reports are sent to Family Health International for input into an Excel database. Subsequent three-month sensitivity data is also added to look for trends.				
5.3.2	The data are statistically evaluated against the existing specification (for each test) in order to observe trends in the manufacturing process. (Process capability index CpK)				
5.3.3	Other statistical methods may also be used depending on the nature of the reported data. Any rejections are also included.				
<b>5.4</b>	<b>Complaints/Product audit (In-Country Evaluations)</b>				
5.4.1	If the USAID   DELIVER Project TO3-Malaria team receives any complaint regarding the RDTs, that information is investigated and corrective actions are evaluated and monitored. In-Country product audit testing is also included.				

<b>5.5</b>	<b>Supplier Audits</b>
5.5.1	If any non-conformances are found during an audit, the corrective actions are monitored. Audit reports may also be part of the supplier scorecard.
<b>5.6</b>	<b>Scorecard Reports</b>
5.6.1	Scorecard reports will be disseminated to the USAID   DELIVER Project TO3-Malaria team on a periodic basis. The frequency will depend on the amount of information collected in a specific time period, generally 6 or 12 months.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/10/07	00	N/A	New Issue.



# USAID | DELIVER PROJECT

Task Order 3- MALARIA		Quality Assurance Procedures
<b>TITLE:</b> Evaluating RDTs In-Country		<b>DOCUMENT No.:</b> TO3-QA-RDTs-27
<b>DATE ISSUED:</b> 9/10/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File	

## 1.0 PURPOSE:

<b>1.1</b>	<b>To establish a procedure for evaluating RDTs In-Country.</b>
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## 2.0 BACKGROUND:

<b>2.1</b>	Historically, the quality testing of RDTs has occurred at post-shipment. This is due to the sensitivity of the kits to exposure of extreme temperatures during transport and storage. RDTs have a short shelf-life of 18-24 months and can easily lose effectiveness if not stored properly and are exposed to temperature and humidity outside the recommended range suggested by the manufacturer(s).
<b>2.2</b>	Once RDTs have reached the final destination within country, storage conditions (temperature, humidity, care of handling) may not meet the manufacturer's recommended requirements, thus potentially compromising the RDT quality and shelf life. In addition to the post-shipment testing conducted for as-received RDTs, it is recommended that field sampling, inspection, and testing of RDTs be conducted when problems are suspected during field use with regard to adverse storage conditions or suspected RDT performance problems.

## 3.0 DOCUMENT REFERENCES:

<b>3.1</b>	<table border="1"> <tr> <td style="width: 5%;">1.</td> <td><i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i></td> </tr> <tr> <td>2.</td> <td><i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004</td> </tr> <tr> <td>3.</td> <td><i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006</td> </tr> <tr> <td>4.</td> <td>Malaria Rapid Diagnosis- <i>Making it Work-Meeting Report</i>; World Health Organization; 2003</td> </tr> </table>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>	2.	<i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004	3.	<i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006	4.	Malaria Rapid Diagnosis- <i>Making it Work-Meeting Report</i> ; World Health Organization; 2003
1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>								
2.	<i>The Use of Malaria Rapid Diagnostic Tests-</i> World Health Organization (Roll Back Malaria)- 2004								
3.	<i>Methods Manual for Laboratory Quality Control Testing of Malaria Rapid Diagnostic Tests-</i> World Health Organization- Version Four-2006								
4.	Malaria Rapid Diagnosis- <i>Making it Work-Meeting Report</i> ; World Health Organization; 2003								

#### 4.0 **RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of RDTs involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Field Evaluations	Audits
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities	Standard Operating Procedures Audits/Monitoring suppliers Complaints
5.	United States Pharmacopeia	Technical assistance for chemical testing	Audits	

#### 5.0 **PROCEDURE:**

<b>5.1</b>	<b>Collecting RDTs In-Country</b>
5.1.1	It may be necessary to collect RDTs In-Country based on any concern raised by the user, USAID Mission staff, or others. Furthermore, QA-Partners may request RDTs as part of an audit exercise.
5.1.2	Determine if any of the RDTs can be collected by a USAID Mission representative or other designee. The number of available RDTs for collection will depend on the specific situation. Also, designated members of QAP may visit the site in order to assist in the investigation depending on the severity of the situation.
<b>5.2</b>	<b>Investigation/Audit Report-Initial</b>
5.2.1	Upon receipt of the concern (or audit) of RDTs, an investigation/audit report is started by QAP staff (i.e. Family Health International). It is necessary to gather as much information regarding the procurement and distribution of the RDT lots including the original test results, etc. See Appendix A.
<b>5.3</b>	<b>RDT Visual Inspection</b>
5.3.1	At the location where RDTs have been collected, the USAID Mission representative (or designee) conducts a visual inspection of the RDTs as guided by Appendix B. All information outlined in Appendix B should be provided as much as possible. For additional background information on inspections, SOP TO3-QA-RDTs-23 (Sampling, Inspection, and Testing for Post-Shipment) should be consulted.
<b>5.4</b>	<b>Testing</b>
5.4.1	In order to arrange for testing, WHO-WPRO should be contacted and informed of the test kit type (i.e., RDT product name, plasmodium species, number of samples on hand) – See Appendix B for additional instructions.

	<p><u>WHO-WPRO Contact Information</u>  Malaria, other Vector-borne and Parasitic Diseases Unit  Western Pacific Regional Office  World Health Organization  P.O. Box 2932  Manila, Philippines.  Ph: +63 2 5288001  FAX: +63 2 5211036  <a href="mailto:mal-rdt@wpro.who.int">mal-rdt@wpro.who.int</a></p> <p>Testing of the RDTs for sensitivity (both initial and long term for stability) is required to the extent possible based on sample availability. (Reference TO3-QA-RDTs-23-Sampling, Inspection, and Testing for Post-Shipment) Results will be compared to original test results (if available) for the lot under investigation.</p>
<b>5.5</b>	<b>Investigation/Audit Report-Final</b>
5.5.1	The Investigation/audit report is completed and findings are reported to USAID   DELIVER Project TO3-Malaria and the Country Mission office or others as designated.
5.5.2	Any recommended corrective actions are reviewed with the manufacturer and follow-up is required to properly complete the investigation/audit report.
5.5.3	The findings are included in the supplier's scorecard information.

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/10/07	00	N/A	New Issue.

**APPENDIX A**

**INVESTIGATION/AUDIT REPORT  
RDTs-In-Country**

<b>Checklist</b>	
Complaint or Audit:	
Date Complaint /Audit reported:	
Complaint reported by:	
Manufactured by:	
Amount of product involved:	
Action:	
Management – the responsibilities and authority for the management of non-conforming work are designated and actions are defined and taken when non-conforming product is identified	
An evaluation of the significance of the non-conforming product is made- Conclusion	
Corrective actions are taken immediately.	
USAID   DELIVER Project notified	
Responsibility for authorizing the use of the product;	
Review of Records	
Corrective Actions- actions most likely to eliminate the problem and to prevent recurrence And the corrective action(s) shall be appropriate to the magnitude and risk of the problem	

**APPENDIX B**

**Field Sampling Inspection Checklist**

**Rapid Diagnostic Test Kits**

<b>I. Background Information</b>			
<b>Field Sampling Location</b>			
<b>Sampling Date</b>			
<b>Supplier</b>			
<b>Product Name</b>			
<b>Lot Numbers</b>			
<b>Quantity of RDTs available for sampling for each lot</b>			
<b>Type of Test Kit(Species)</b>			
<b>II. Inspection of RDT shipment</b>			<b>Accept/Reject</b>
1.	<b>Inspect the Integrity of RDT packaging at arrival.</b> Inspect the entire consignment (or lots) if identified and look for obvious damage to cases and packages of RDTs. If any damage is present, isolate the cases (packages) and determine quantity.		
2.	<b>Determine if any product damage was caused by transporting</b> ie. Cases on top (double stacked) or cases on end of pallets were damaged during transport		
<b>III. Sample a maximum of thirteen units from each lot and perform the inspection in steps 3,4,5</b>			
3.	Inspect the a. kit labeling b. kit components c. presence of package inserts	All units must comply	<b>Accept/Reject</b> a. b. c.
4.	Check batch number identification	All units must comply	
5.	Check manufacture and expiry dates	All units must comply	
<b>IV. For sensitivity testing of field samples, sample as many RDTs as possible not to exceed the amounts indicate in 6 and 7</b>			
6.	If – P-falciparum Species RDTs Sampled / Lot –	150	<b>Sampled by/date;</b>
7.	If - Combination Plasmodium Species RDTs Sampled / Lot –	200	<b>Sampled by/date;</b>
<b>V. Contact the WHO-WPRO to arrange for testing:</b>			
<p>Malaria, other Vector-borne and Parasitic Diseases Unit                  Western Pacific Regional Office                  World Health Organization                  P.O. Box 2932                  Manila, Philippines.                  Ph: +63 2 5288001                  FAX: +63 2 5211036  <a href="mailto:mal-rdt@wpro.who.int">mal-rdt@wpro.who.int</a></p>			
<b>VI. Submit a copy of Appendix B with the Sensitivity samples for testing</b>			
<b>VII. Submit via e-mail- Copy of Appendix B to:</b>			
1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>		
2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>		
<b>Performed by/Date;</b>			
<b>Reviewed by/Date;</b>			



## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Pharmaceutical(s) -Quality Assurance Activities, QA Costs, and Risks		<b>DOCUMENT No.:</b> TO3-QA-Pharm-30
<b>DATE ISSUED:</b> 10/10/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

### 1.0 PURPOSE:

1.1	To establish a document that serves as a summarized reference for quality assurance steps for Pharmaceuticals and is also a guide for sampling, testing, quality costs and associated risks.								
1.2	Risk Management is the formal process by which risk factors are systematically identified, and assessed. The methodology of Risk Management involves four steps; <table border="1" style="margin-left: 20px;"> <tr> <td>1.</td> <td>Identifying and classifying the areas of potential risk.</td> </tr> <tr> <td>2.</td> <td>Quantifying the risk by determining the probability of events and associated consequences.</td> </tr> <tr> <td>3.</td> <td>Responding to the risk by having or developing the means to handle the identified and quantified risk.</td> </tr> <tr> <td>4.</td> <td>Capturing and retaining lessons learned as knowledge to aid future decisions.</td> </tr> </table>	1.	Identifying and classifying the areas of potential risk.	2.	Quantifying the risk by determining the probability of events and associated consequences.	3.	Responding to the risk by having or developing the means to handle the identified and quantified risk.	4.	Capturing and retaining lessons learned as knowledge to aid future decisions.
1.	Identifying and classifying the areas of potential risk.								
2.	Quantifying the risk by determining the probability of events and associated consequences.								
3.	Responding to the risk by having or developing the means to handle the identified and quantified risk.								
4.	Capturing and retaining lessons learned as knowledge to aid future decisions.								

### 2.0 QUALITY ASSURANCE ACTIVITIES/RISKS/ESTIMATED COSTS:

2.1	<b>ACTIVITY and RISK DATA SHEET For Pharmaceuticals</b>							
	<b>Country:</b>	<b>Pharmaceutical Description:</b>		<b>Date Ordered:</b>	<b>Date Inspected/Tested:</b>	<b>Shipment (expected days)</b>	<b>Date Requested – In-Country</b>	<b>Total number of days</b>
	<b>Activity</b>	<b>Cost</b>		<b>Risk-Low (1-2)</b> a. Use 1 if good history b. use 2 if no history	<b>Risk-Medium (3-4)</b> a. Use 3 if good history b. use 4 if no history	<b>Risk-High (5)</b>	<b>Score</b>	<b>Day(s)</b>
	Select suppliers from criteria; Type of drug along with country registration and requirements	n/a		US Supplier(s) FDA approved Facility- Coartem®-FDA approved facility Fansidar®-FDA approved drug/ facility	WHO pre-qualified list or FDA/SRA approved facility in country other than US or Global Fund Compliance QA list	No WHO, FDA, or SRA		
	Pre-shipment Sampling/Testing	Crown Agents \$500-\$1,500 per/day	USP or SA \$1,000-\$5,000 Per batch	100% –pre shipment Testing	Concurrent Testing or specified audit testing	No Testing		
	Post-shipment chemical testing			Post-shipment Testing before distribution	Concurrent testing With distribution	No-Testing		
	Post Market Surveillance			Each drug/country has a post market plan	Case-by-case basis depending on the country and the drug	No-Post Market testing		
	Supplier audit			Audit –conducted with good supplier history	Audit conducted- corrective actions pending- some supplier history	No Audit- No history		
	Laboratory audit			ISO-17025 Certified	Not ISO 17025 Certified but has Quality management system	No quality Management system		
	<b>TOTAL SCORE</b>							
<b>Total Expected costs</b>				<b>Risk Associated with Quality Activities of Pharmaceuticals</b>				
				Low Risk Preferred	Low to Medium	Medium Acceptable	Medium to High (risks identified)	High Risk
				6	12	18	24	30

2.2	Comments
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### 3.0 **RESPONSIBILITIES:**

3.1	The procurement and quality assurance of Pharmaceuticals involves a team of partners from various organizations. These include;			
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>	
	1. John Snow Inc.	Procurement Pre-Qualification		
	2. PATH	Procurement Pre-Qualification	Audits	
	3. Crown Agents	Procurement Pre-Shipment Sampling		
	4. Family Health International	Oversight of QA-Activities Standard Operating Procedures	Audits/Monitoring suppliers Complaints Chemical analysis	
	5. United States Pharmacopeia	Chemical analysis Technical Assistance Post Market Surveillance	Audits	

### 4.0 **DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
10/10/07	00	N/A	New Issue.



# USAID | DELIVER PROJECT

## Task Order 3- MALARIA

## Quality Assurance Procedures

TITLE: Pre-qualification of Pharmaceutical Suppliers		DOCUMENT No.: TO3-QA-Pharm-31
DATE ISSUED: 10/10/07	SUPERSEDES: 9/27/07rev00	Revision: 01
WRITTEN BY & DATE: JSI / Crown Agents / PATH / FHI / USP		APPROVED BY & DATE: Steve Hamel-Signature on File

### 1.0 PURPOSE:

1.1	To establish a document that provides the procedure for pre-qualification of pharmaceutical suppliers.
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### 2.0 BACKGROUND:

2.1	<p>The increasing rate of malaria related deaths is partially attributed to the resistance of <i>Plasmodium falciparum</i> to the more traditional medications, such as sulfadoxine-pyrimethamine, chloroquine, and amodiaquine. This resistance is evident in parts of South America, Asia, and Africa. During the past several years, artemisinin-based combination therapies have been used on an increasing scale world-wide. These medications have a quick response to <i>Plasmodium falciparum</i> and seem to be easily tolerated by patients.</p> <p>There are two anti-malarial drugs manufactured in the United States in FDA approved facilities. These two drugs, Coartem® produced by Novartis in New York, and Fansidar® produced by Roche in New Jersey are <u>waived</u> from the pre-qualification process.</p> <p>WHO has prepared a list of other pre-qualified suppliers of ACTs from WHO- GMP inspections. Due to the immediate procurement needs of USAID’s malaria program, this list should serve as the <b>primary reference</b> of product pre-qualification. In addition, the <i>Global Fund Compliance List of Malaria Drugs Quality Assurance Policy</i> serves as a supplemental source of supplier status with WHO and Stringent Regulatory Authorities (SRA’s).</p> <p>As more resources can be devoted to pharmaceutical supplier pre-qualifications, additional activities can be added to the supplier evaluations, such as audits and product testing at pre-shipment.</p>
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### 3.0 **DOCUMENT REFERENCES:**

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<a href="http://www.rbm.who.int/cmcc_upload/0/000/015/364/RBMInfosheet_9.htm">http://www.rbm.who.int/cmcc_upload/0/000/015/364/RBMInfosheet_9.htm</a>
	3.	<a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a>
	4.	<a href="http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf">http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf</a>
	5.	<a href="http://www.theglobalfund.org/en/about/procurement/compliance/">http://www.theglobalfund.org/en/about/procurement/compliance/</a>

### 4.0 **RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</b>		
4.1.1	The procurement and quality assurance of pharmaceuticals and other anti-malarial drugs involves a team of partners from various organizations. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
1.	John Snow Inc.	Procurement Pre-Qualification	
2.	PATH	Procurement Pre-Qualification	Audits/ Field evaluations
3.	Crown Agents	Procurement Pre-Qualification	Sampling agency Field Technical Assistance
4.	Family Health International	Oversight of QA- Activities Standard Operating Procedures	Audits Monitoring suppliers Complaints
5.	United States Pharmacopeia	Drug testing Technical assistance	Audits

### 5.0 **PRE-QUALIFICATION OF SUPPLIERS: USAID CRITERIA**

<b>5.1</b>	<b>Pre-Qualification Criteria</b>	
5.1.1	The current WHO pre-qualified list for ACT suppliers is provided in Appendix A. This list was generated based on the following activities through the WHO.	
	1.	Evaluation of Product Dossiers (including product data and information for innovator and generic products).
	2.	Presence of Regulatory Approval for Product Manufacturing.
	3.	Product is manufactured under GMP with National Regulatory Authority or qualified GMP inspector certification.
	4.	Product has certification with WHO certification scheme for pharmaceutical product quality for international commerce.
	5.	On-site inspection of manufacturing site by WHO approved inspector.
5.1.2	During the early stages of USAID's Malaria Program, this list (Appendix A) will serve as the primary reference of product pre-qualification. Updates to Appendix A should be made as the WHO pre-qualified list is changed. The Global Fund Compliance List provides additional information on SRA and WHO pre-qualified status and also lists other anti-malaria drugs <a href="http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf">http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf</a> .	

5.1.3	<p>Additional criteria for product pre-qualification are listed in the table below.</p> <table border="1" data-bbox="418 201 1477 751"> <tr> <td data-bbox="427 201 488 352">1.</td> <td data-bbox="496 201 1469 352">An evaluation should be conducted on the product's regulatory status in each of USAID's focus countries. Each manufacturer should be contacted for this information. For products found not to be registered in the appropriate focus countries and depending on the need for product, the manufacturer will be asked to register the product in order to meet the needs of USAID's malaria program.</td> </tr> <tr> <td data-bbox="427 359 488 457">2.</td> <td data-bbox="496 359 1469 457">The manufacturer should provide evidence of production capacity such as current customers or past orders (with quantities delivered) accompanied by complete customer contact information.</td> </tr> <tr> <td data-bbox="427 464 488 562">3.</td> <td data-bbox="496 464 1469 562">The manufacturer should provide evidence of in-country support for the product including staff contact information, statement of capacity, and the nature of the relationship with the manufacturer.</td> </tr> <tr> <td data-bbox="427 569 488 604">4.</td> <td data-bbox="496 569 1469 604">Information on product shelf-life should be provided.</td> </tr> <tr> <td data-bbox="427 611 488 688">5.</td> <td data-bbox="496 611 1469 688">The manufacturer must provide package inserts in appropriate languages (designated by USAID)</td> </tr> <tr> <td data-bbox="427 695 488 751">6.</td> <td data-bbox="496 695 1469 751">The Manufacturer must provide a "Statement of willingness to accept pre-shipment QC/QA inspection and testing by independent testing agency designated by the Buyer."</td> </tr> </table>	1.	An evaluation should be conducted on the product's regulatory status in each of USAID's focus countries. Each manufacturer should be contacted for this information. For products found not to be registered in the appropriate focus countries and depending on the need for product, the manufacturer will be asked to register the product in order to meet the needs of USAID's malaria program.	2.	The manufacturer should provide evidence of production capacity such as current customers or past orders (with quantities delivered) accompanied by complete customer contact information.	3.	The manufacturer should provide evidence of in-country support for the product including staff contact information, statement of capacity, and the nature of the relationship with the manufacturer.	4.	Information on product shelf-life should be provided.	5.	The manufacturer must provide package inserts in appropriate languages (designated by USAID)	6.	The Manufacturer must provide a "Statement of willingness to accept pre-shipment QC/QA inspection and testing by independent testing agency designated by the Buyer."
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6.	The Manufacturer must provide a "Statement of willingness to accept pre-shipment QC/QA inspection and testing by independent testing agency designated by the Buyer."												
<b>5.2 Additional Pre-Qualification Criteria</b>													
5.2.1	As more USAID resources, products, and suppliers become available for use, members of QA-Partners may conduct manufacturing site audits for compliance to cGMP standards and request that independent testing of product be conducted on an established frequency.												
<b>5.3 Documentation for Product Pre-Qualification</b>													
5.3.1	The JSI procurement team is responsible for collecting the pre-qualification information from the current and future suppliers and compiling into table form for quick reference. In addition, the procurement team will update the tables as necessary. Appendix B should be used to document the pre-qualification activities for a given product / manufacturer.												
5.3.2	The procurement team can select pharmaceutical drug products from this current list of pre-qualified suppliers. Drugs procured have to meet country and/or program requirements.												

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/27/07	00	N/A	New Issue.
10/10/07	01	9/27/07	Change from "ACTs" to Pharm

**APPENDIX A**  
**USAID | DELIVER Project**

**WHO Pre-qualified List of Anti-Malarial Drugs**

Information below taken directly from the following website: <http://mednet3.who.int/prequal/>

Procurement, Quality and Sourcing Project: Access to Artemisinin-based Combination Antimalarial Drugs, Version:6th Edition of acceptable quality. Suppliers whose Artemisinin-based Combination Antimalarial products have been found acceptable, in principle, for procurement by UN Agencies- 30 August 2007-Please refer to the website above to obtain the latest version.

International Non-Proprietary Name	Strength	Dosage form	Supplier	Manufacturing site		Packaging material and pack	
Artesunate	50mg	Tablets	Sanofi-Synthelabo, Gentilly, France	Guilin Pharmaceutical Co. Ltd, Guangxi	P. R. China	Blister	25 blister of 12
Artemether / Lumefantrine	20mg / 120mg	Tablets	Novartis Pharma, Basel, Switzerland	Beijing Novartis Pharma, Beijing Novartis Pharmaceuticals Corporation Suffern	P. R. China USA	Blister	30 blisters of 6, 12, 18 or 24
Artemotil	50mg/ml	sol inj	ARTECEF BV Zeewolde The Netherlands	Rotexmedica GmbH Trittau	Germany	Ampoules	10 or 100 ampoules each of 1ml
Artemotil	150mg/ml	sol inj	ARTECEF BV Zeewolde The Netherlands	Rotexmedica GmbH Trittau	Germany	Ampoules	10 or 100 ampoules each of 1ml
Artesunate	50mg	Tablets	Ipca Laboratories Ltd.	Dadra and Nagar Haveli (U.T.)	India	PVdC/Alu	12
Artesunate	50mg	Tablets	Guilin Pharmaceutical Co Ltd	Guilin, Guangxi	P. R. China	PVC/Al Blister	12
Amodiaquine	150mg	Film-coated Tablets	Guilin Pharmaceutical Co., Ltd	Guilin, Guangxi	P. R. China	PVC/Al Blister Cardboard Box	6 2 x 6
Artesunate + Amodiaquine	50mg + 150mg	Tablets	Guilin Pharmaceutical Co., Ltd	Guilin, Guangxi	P. R. China	PVC blisters sealed with an aluminum foil lid Cardboard box	4 + 4 3 x (4 + 4)

**APPENDIX B**  
**USAID | DELIVER Project**

**Pre-Qualification –  
Pharmaceutical Drug Supplier Information Table**

<b>SUPPLIER</b> List all manufacturing sites		
<b>ADDRESS</b>		
<b>CONTACT INFORMATION</b>	Certified Letter of Authority indicating company contacts for Management, Quality Control, Quality Assurance and Production.	
	<b>Pre-qualification of Suppliers Requirements</b>	<b>Meets Prequalification Requirements / Comments</b>
1.	Currently a member of the WHO pre-qualified list for ACT suppliers.	
2.	Product's registration status in focus countries for USAID's Malaria Program – List all countries.	
3.	The manufacturer should provide evidence of production capacity such as current customers or past orders (with quantities delivered) accompanied by complete customer contact information.	
4.	The manufacturer should provide evidence of in-country support for the product, including staff contact information, statement of capacity, and the nature of the relationship with the manufacturer.	
5.	Information on product shelf-life should be provided.	
6.	The manufacturer must provide package inserts in appropriate languages (designated by USAID)	
7.	The Manufacturer must provide a "Statement of willingness to accept pre-shipment QC/QA inspection and testing by independent testing agency designated by the Buyer."	
8.	Other information that may be conducted for pre-qualification depending on availability of resources:	
a.	Outcome of manufacturing site audits for compliance to GMP criteria	
b.	Outcome of independent product testing	
c.	Provide documentation on the type of Quality Management system for the facility (i.e. ISO-9000; EN)	
d.	Certification that the commodities are manufactured according to EN, ISO, WHO, GMP, FDA standards, whichever applies.	
e.	Certified copy of current license in country where primary manufacturing is conducted	
f.	Manufacturer's Quality Manual and Standard Operational Procedures in Microsoft-Word compatible CD form	
g.	Copies of company's environmental policy and any citations, infractions, fines, or legal actions the company has been involved in as a result of violations.	
Approval		

### **Pre-Qualification- Desk Audit**

Suppliers are required to provide documentation of their manufacturing capabilities, technical and specifications standards of the processes used to manufacture the medical device or pharmaceutical product being audited. If any process or service directly related to the manufacturing of the product(s) is subcontracted, a separate documentation packet must be submitted for the subcontractor. Documents in languages other than English must include a translation and should be submitted in addition with the original non-translated document. Below is a list of documents requested for Pre-Qualification;

- Certified copy of current license in country where primary manufacturing is conducted.
- A copy of Drug Master File (DMF) **or** a brief description of the manufacturing procedure for the product(s) being subject to this questionnaire (only if DMF is not applicable or available)
- Certified Letter of Authority indicating company contacts for Management, Quality Control, Quality Assurance and Production.
- Manufacturer's Quality Manual and applicable Standard Operational Procedures in Microsoft-Word compatible CD form
- Certification that the commodities are manufactured according to EN, ISO, WHO, GMP, FDA standards, whichever applies.
- Any laboratory certification that contains the scope of tests directly related to the manufacturing of medical devices or pharmaceuticals of interest on this audit.
- Copies of company's environmental policy and any citations, infractions, fines, or legal actions the company has been involved in as a result of violations.

**Pharmaceutical and Medical Products Supplier Questionnaire**

Date \_\_\_\_\_ Product(s) \_\_\_\_\_

---

**1. General Information:**

Pharmaceutical or Medical Supplier Name: \_\_\_\_\_

Parent Company (Full Legal Name) : \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone #: \_\_\_\_\_ Fax #: \_\_\_\_\_ e-mail: \_\_\_\_\_

Management Contact Name, Tel # and e-mail: \_\_\_\_\_

---

Quality Control Contact Name, Tel. and e-mail: \_\_\_\_\_

---

Quality Assurance Contact Name, Tel. and e-mail: \_\_\_\_\_

---

Production Contact Name, Tel. and e-mail: \_\_\_\_\_

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**2. Organization and Personnel**

2.1 Attach Organizational Chart

2.2 Number of employees:

Total:	_____
Production Dept. only	_____
QC Dept. only	_____
QA Dept. only	_____
Sales/Marketing Dept. only	_____

2.3 Employee training file:

Is there documentation of personnel training and education	Yes	No
Frequency of training;	SOPs _____	
	GMP _____	
	Safety _____	
	GLP _____	

List any special training for QC and QA personnel; \_\_\_\_\_

### 3. Quality Control/Quality Assurance

3.1 Is your company certified to any of the following? Check box for all applicable and write certificate number;

DIN EN ISO	Certificate No.:	_____
DIN ISO 14000 or latest version	Certificate No.:	_____
GMP	Certificate No.:	_____
Other	Certificate No.:	_____

3.2 Does your company hold a Manufacturing Authorization according to the drug law of your country?

Yes Issuing Authority: \_\_\_\_\_ No  
 Date of issue: \_\_\_\_\_

If Yes: List product groups for which Manufacturing Authorization has been issued:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

3.3 Has your company been inspected by the FDA?

Yes date of last inspection: \_\_\_\_\_ No

Please provide inspection report.

3.4 Are your manufacturing facilities subject to any other type(s) of inspection?

Yes No  
 If yes, please state type of inspection and inspection level.

Area Inspected	Product	Authority	Date

3.5 Does your facility have a formal system by which engineering changes are evaluated for process, product, regulatory, and environmental impact prior to implementation? Yes No  
 Briefly describe system, include approval responsibilities.

3.6 Does your company have a Quality Control laboratory on site Yes No  
 Is it accredited? Yes No ,  
 If yes, by whom \_\_\_\_\_  
 Is any quality control testing subcontracted? Yes No  
 If yes, write their names, accreditation credentials and accredited scope\_\_\_\_\_

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3.7 Is microbiological monitoring performed on a regular basis for:

Raw materials	Yes	No
Product	Yes	No
Air, floor, walls, machines/equipment	Yes	No
Water	Yes	No
Personnel	Yes	No

Please provide records for review

3.8 Does your company perform internal audits on a regular basis? Yes No  
Are these audits recorded? Yes No  
Are corrective and preventive actions addressed and recorded? Yes No  
Are there any reoccurring problems Yes No , if yes describe

3.9 a) Do you have a DMF for the API of interest? Yes No  
b) What is that DMF #? or #'s? \_\_\_\_\_

c) Has the FDA or appropriate agency reviewed this DMF? Yes No  
d) What is the notification process for DMF changes?

e) Are customers notified of changes to the DMF?

3.10 Is there a formal procedure for qualifying and monitoring subcontractors? Yes No ,  
If so what services are subcontracted

3.11 Does your facility have procedures to protect the integrity, confidentiality and safety of records?  
Yes No ,  
If yes, briefly describe

3.12 Do you prepare Annual Quality Review Reports for each API? Yes No

3.13 Briefly describe document control system (SOP, batch records, specifications, methods) in terms of hierarchy, revisions, approval authority and control.

3.14 Describe formal investigation procedures for non-conforming lots or discrepancies occurring during all stages of manufacturing. Please provide examples of investigations.

#### 4. Receiving Control

- 4.1 Are quarantined raw materials and rejected raw materials clearly identified, segregated and documented?  
Yes No ,  
if yes describe how this  
is accomplished
- 4.2 a) Are conditions for raw materials storage areas controlled and monitored? Yes No  
b) Are these systems alarmed? Yes No  
c) Do you use the same warehouse for the storage of incoming components and final APIs?  
Yes No
- 4.3 Do you have written internal specifications or acceptance criteria for each lot of raw material and/or  
packaging component received? Yes No
- 4.4 a) Is a supplier Certificate of Analysis(COA) required for each lot of raw material and/or packaging  
component received? Yes No  
b) Is an identity test performed on each lot? Yes No
- 4.5 Is each lot of raw materials assigned a unique lot number on receipt even if the vendor batch number is  
the same? Yes No  
Explain lot numbering system.

---

#### 5. Manufacturing Facility

- 5.1 Are there adequate and up-to-date facility drawings for critical systems such as  
HVAC , water purification systems, etc. available for the facility? Yes No
- 5.2 a) Is there a system to identify each major piece of equipment?  
Describe the system Yes No  
b) Are qualification, maintenance and calibration records maintained for each piece of equipment?  
Yes No  
c) Describe preventative maintenance at the facility.
- 5.3 Does the facility have adequate lighting, ventilation, dust control, vector control,

	and proper physical barriers to prevent cross contamination?	Yes	No
5.4	Is a Certificate of Suitability available for inspection? Please provide for review	Yes	No
5.5	Are API synthesis operations performed in a segregated closed area with its own air handling system?	Yes	No
5.6	Do you have a documented validation program for manufacturing processes? If so, describe the key components of this program.  Please provide documentation examples of validation program.	Yes	No
5.7	a) What grade of water is used during synthesis or formulation of APIs?		
	b) Are there maintenance records for water purification equipment? Provide example of records.	Yes	No
	c) What is the overall testing protocol, including parameters and frequency of testing? Please provide sample of reports.		
	d) Are all points of use and sampling clearly identified?	Yes	No
5.8	Is any raw material reused? If so, what quality controls are in place to assure quality?	Yes	No
5.9	Is manufacturing facility dedicated exclusively to the product(s) being subject to this questionnaire? If no, list other products and describe what measures are in place for preventing cross-contamination in terms of mixing ingredients, records and labels.	Yes	No
5.10	Have support systems (e.g. vacuum, air, water, steam) been validated?	Yes	No
5.11	Are time, temperature and pressure-monitored processes documented and retained with batch records? Yes No		
5.12	Are there positive pressure differentials with all doors leading into less clean areas?	Yes	No
5.13	Do pipes indicate contents and direction of flow?	Yes	No
5.14	Are records maintained for tracing use of raw materials, intermediates and finished APIs?	Yes	No

- |      |  |     |    |
|------|--|-----|----|
| 5.15 | Is product(s) being subject to this questionnaire re-packed or re-labeled after it leaves manufacturer?  | Yes | No |
| 5.16 | Is there a formal stability program for key intermediates and API?   | Yes | No |
| 5.17 | Is there a procedure for customer notification of manufacturing processes?   | Yes | No |
| 5.18 | a) Is there a written procedure for cleaning methods?  | Yes | No |
|      | b) Was cleaning procedure validated?   | Yes | No |
|      | c) Are cleaning procedures documented?   | Yes | No |
|      | d) Are there written cleaning schedules and procedures for the holding tanks, transfer lines and other equipment, which may be in contact with the intermediates and APIs? | Yes | No |
|      | Provide documentation for review.  |     |    |
| 5.19 | a) Are manufacturing areas for controlled substances clearly defined and limited in access?  |     |    |
|      | Yes  | No  |    |
|      | b) Are limited access areas under surveillance?  | Yes | No |
| 5.20 | a) Is there a written procedure to monitor the handling of controlled substances?  |     |    |
|      | Yes  | No  |    |
|      | b) Are non-controlled and controlled drugs stored together?  | Yes | No |
|      | c) Does your facility have license for handling controlled substances?   | Yes | No |

---

**6. Computer systems**

- |     |  |     |    |
|-----|--|-----|----|
| 6.1 | Have computer systems and programs been validated?<br>If yes, to what specifications? Please provide documentation | Yes | No |
| 6.2 | Are computer systems backed up?  | Yes | No |
| 6.3 | Are computer systems secured against unauthorized access and changes?  | Yes | No |
| 6.4 | Do you use electronic batch records or electronic signatures?  | Yes | No |
| 6.5 | Please explain how computers are used within QA/QC?  |     |    |
-

## 7. Components, containers and closures

- |     |  |     |    |
|-----|--|-----|----|
| 7.1 | Are there written specifications for all components and closures for products being subjected to this questionnaire?<br>Please provide documentation | Yes | No |
| 7.2 | Is there a written procedure to QC components and closures?<br>Please provide documentation  | Yes | No |
| 7.3 | Are there written specifications for product packaging procedures?   | Yes | No |
| 7.4 | Is container closure information part of DMF, ANDA or NDA?<br>Please provide documentation   | Yes | No |
- 

## 8. Labeling and Packaging

- |     |   |     |    |
|-----|---|-----|----|
| 8.1 | Are there written procedures for printing labels, label issuance, label storage, label disposal and product labeling?<br>Please provide documentation | Yes | No |
| 8.2 | a) Is there a Master label file for all labels?<br>Please provide documentation   | Yes | No |
|     | b) Is there a procedure and follow-up documentation to confirm label compliance?  | Yes | No |
| 8.3 | a) Are cut or roll labels used?   | Yes | No |
|     | b) Is 'gang-printing' permitted?  | Yes | No |
| 8.4 | Is an area clearance performed between production lots?   | Yes | No |
| 8.5 | Is accountability and variance verified?<br>Describe this procedure.  | Yes | No |
| 8.6 | If additional processing is performed, how is it identified on the label?   |     |    |
| 8.7 | Are there written procedures that detail packaging specifications?<br>Please provide documentation  | Yes | No |
| 8.8 | Is there a Master packaging list?<br>Please provide documentation   | Yes | No |
| 8.9 | Are package lines validated?  | Yes | No |
- 

## 9.0 Complaints

- |     |  |     |    |
|-----|--|-----|----|
| 9.1 | Write name of person(s) or department responsible for investigating and documenting complaints.<br>_____ |     |    |
| 9.2 | Is there a written procedure for investigating complaints?   | Yes | No |
| 9.3 | Are complaints analyzed for trends and CAPA implemented?<br>Please provide documentation.                | Yes | No |





**Task Order 3 - MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Sampling and Testing of Pharmaceutical drugs for Pre-shipment		<b>DOCUMENT No.:</b> TO3-QA-Pharm-32
<b>DATE ISSUED:</b> 10/31/07	<b>SUPERSEDES:</b> 10/15/07 rev01	<b>Revision:</b> 02
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File -

**1.0 PURPOSE:**

1.1	To establish a procedure that outlines the steps for pre-shipment sampling and testing of pharmaceutical drugs for malaria treatment.
-----	---

**2.0 BACKGROUND:**

2.1	WHO has recommended specific ACTs for which there is evidence of efficacy and safety in the treatment of malaria. <i>The Global Fund Quality Assurance Compliance Policy</i> also lists ACTs and other drugs that have been pre-qualified by WHO and also those with stringent regulatory authority (SRA) status. In addition, two antimalarial drugs are approved and regulated by the US Food and Drug Administration. To ensure that all pharmaceuticals procured through the DELIVER mechanism are of an assured quality and meet established standards, a procedure that addresses pre-shipment activities is required.
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**3.0 DOCUMENT REFERENCES:**

3.1	<table border="1"> <tr> <td>1.</td> <td><i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i></td> </tr> <tr> <td>2.</td> <td><i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i></td> </tr> <tr> <td>3.</td> <td><i>WHO malaria treatment guidelines</i></td> </tr> <tr> <td>4.</td> <td><a href="http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm">http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm</a></td> </tr> <tr> <td>5.</td> <td><a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a></td> </tr> <tr> <td>6.</td> <td><a href="http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf">http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf</a></td> </tr> <tr> <td>7.</td> <td><a href="http://www.theglobalfund.org/en/about/procurement/compliance/">http://www.theglobalfund.org/en/about/procurement/compliance/</a></td> </tr> </table>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>	2.	<i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i>	3.	<i>WHO malaria treatment guidelines</i>	4.	<a href="http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm">http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm</a>	5.	<a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a>	6.	<a href="http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf">http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf</a>	7.	<a href="http://www.theglobalfund.org/en/about/procurement/compliance/">http://www.theglobalfund.org/en/about/procurement/compliance/</a>
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5.	<a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a>														
6.	<a href="http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf">http://www.theglobalfund.org/pdf/guidelines/Compliance_list_MALARIA.pdf</a>														
7.	<a href="http://www.theglobalfund.org/en/about/procurement/compliance/">http://www.theglobalfund.org/en/about/procurement/compliance/</a>														

**4.0 RESPONSIBILITIES:**

4.1	The procurement and quality assurance of pharmaceuticals involves a team of partners from various organizations. These include:		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement /Pre-Qualification	Audits
	2. PATH	Procurement /Pre-Qualification	Audits
	3. Crown Agents	Procurement	Pre-shipment sampling/inspection
	4. Family Health International	Oversight of QA-activities Standard Operating Procedures	Audits/Monitoring Suppliers/Complaints
	5. United States Pharmacopeia	Pre- and post-shipment testing, Post-market surveillance	Audits

5.0 **PROCEDURE:**

<b>5.1</b>	<b>Pre-qualified supplier(s)</b>						
5.1.1	Only pharmaceutical products specified on the WHO pre-qualified list, the Global Fund Quality Assurance Policy list, and/or US manufactured, FDA-approved Coartem <sup>®</sup> and Fansidar <sup>®</sup> products can be procured for implementation in PMI programs.						
<b>5.2</b>	<b>Pre-shipment sampling and testing of antimalarial drugs manufactured in the United States: Coartem<sup>®</sup> and Fansidar<sup>®</sup></b>						
5.2.1	The pre-shipment sampling and testing requirements for antimalarial drugs manufactured in the United States from an FDA approved facilities do not require routine testing. These facilities in New York (Coartem <sup>®</sup> by Novartis) and New Jersey (Fansidar <sup>®</sup> by Roche) are regulated by the US Food and Drug Administration. However, an audit testing plan consisting of a minimum of three lots per year will be tested to ensure compliance. Any audit testing will be performed concurrent to shipping or distribution depending on availability of samples at pre- or post-shipment. <table border="1" data-bbox="328 613 1196 701"> <tr> <td>1.</td> <td>Coartem<sup>®</sup> - USP test method in draft form. Reference standards not available until 2008. Testing of three lots in 2008 required.</td> </tr> <tr> <td>2.</td> <td>Fansidar<sup>®</sup> - minimum of three lots tested per year, dependent upon quantities procured.</td> </tr> </table>	1.	Coartem <sup>®</sup> - USP test method in draft form. Reference standards not available until 2008. Testing of three lots in 2008 required.	2.	Fansidar <sup>®</sup> - minimum of three lots tested per year, dependent upon quantities procured.		
1.	Coartem <sup>®</sup> - USP test method in draft form. Reference standards not available until 2008. Testing of three lots in 2008 required.						
2.	Fansidar <sup>®</sup> - minimum of three lots tested per year, dependent upon quantities procured.						
5.2.2	Certificates of Analyses are required for each lot of <b>Coartem<sup>®</sup></b> and <b>Fansidar<sup>®</sup></b> for each shipment. The Certificate of Analysis (COA) will be reviewed by Family Health International (JSI's Quality Assurance Partner) with copies filed at FHI, JSI and USAID.						
<b>5.3</b>	<b>Pre-Shipment sampling and testing of antimalarial drugs from the WHO pre-qualified list and Global Fund Quality Assurance Compliance Policy list</b>						
5.3.1	Antimalarial drugs procured from suppliers listed on the WHO and the Global Fund Quality Assurance Compliance lists require <b>100% pre-shipment sampling and testing.</b>						
5.3.2	Sampling of pharmaceutical products will be conducted by an independent sampling agency, chosen based on qualifications, proximity to the supplier and availability.						
5.3.3	There may be instances whereby the supplier is requested to submit samples to the testing laboratory. A sampling plan designed by the Quality Assurance Partners will be provided to the supplier.						
5.3.4	The sampling agency will collect the samples using statistical models listed in the table below; <table border="1" data-bbox="328 1165 1148 1524"> <tr> <td>1.</td> <td>The number of samples chosen are representative of the number of batches or lots in the shipment.</td> </tr> <tr> <td>2.</td> <td>All samples are selected randomly from throughout each lot in the shipment. Random sampling is predicated on the theory that each unit within a lot has an equal chance of being selected.</td> </tr> <tr> <td>3.</td> <td>The method for selecting samples varies depending on the organization of materials presented for inspection. Three common methods of sampling include: <ol style="list-style-type: none"> <li>1) <b>Square-root N + 1:</b> Randomly select the number of cases to sample by using the equation <math>\sqrt{N} + 1</math>. Pull the required number of individual units from the selected cases.</li> <li>2) <b>Systematic Random Sampling:</b> Select one unit at random. Then select the remainder using a fixed scheme (every 5th or 10th unit)</li> <li>3) <b>Stratified Random Sampling:</b> Select a random sample of containers which holds the individual units. Draw another sample from each container.</li> </ol> </td> </tr> </table>	1.	The number of samples chosen are representative of the number of batches or lots in the shipment.	2.	All samples are selected randomly from throughout each lot in the shipment. Random sampling is predicated on the theory that each unit within a lot has an equal chance of being selected.	3.	The method for selecting samples varies depending on the organization of materials presented for inspection. Three common methods of sampling include: <ol style="list-style-type: none"> <li>1) <b>Square-root N + 1:</b> Randomly select the number of cases to sample by using the equation <math>\sqrt{N} + 1</math>. Pull the required number of individual units from the selected cases.</li> <li>2) <b>Systematic Random Sampling:</b> Select one unit at random. Then select the remainder using a fixed scheme (every 5th or 10th unit)</li> <li>3) <b>Stratified Random Sampling:</b> Select a random sample of containers which holds the individual units. Draw another sample from each container.</li> </ol>
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	Approximately 200 tablets/per lot are selected and shipped in the appropriate container to the designated testing laboratory.
5.3.5	Samples for testing will be sent via a global courier, for example, DHL, with COA documentation (and other required documents) to the specified testing laboratory. Samples should be packaged in appropriate containers and consistently labeled per the certificate of analysis. The tracking number of the package is provided to the designated testing laboratory for confirmation upon receipt. The sample package must be labeled “ <i>Samples for Analytical testing Purposes Only - Not for Distribution.</i> ”
5.3.6	<p>Testing will be conducted by a primary designated laboratory (USP, India or North-West University, South Africa). In the event that testing schedules indicate a significant delay in confirmatory reporting, upon which subsequent shipping is dependent, two alternate laboratories, USP, Rockville and FHI, NC may be used. All laboratory facilities are ISO-17025 accredited.</p> <p><u>Primary Drug Testing Laboratories</u></p> <p>1) USP-India Pvt. Ltd.  ICICI Knowledge Park, Genome Valley  Turkapally, Shamirpet  Ranga Reddy District, Hyderabad 500 078, A.P. India  Phone: +91 40 2348 0088  Attn Dr. Koduru Surendranath</p> <p>2) NORTH-WEST UNIVERSITY  Private Bag X6001 Potchefstroom;  2520 South Africa  Attn: Prof Banie Boneschans-Head - Pharmaceutical &amp;  Biomedical Services School of Pharmacy  E-Mail: Banie.Boneschans@nwu.ac.za  Tel (all hours) +27 82 568 4414  Tel (w) +27 18 2992280  Tel (h) +27 18 2973577  Fax +27 18 2992284</p> <p><u>Secondary Drug Testing Laboratories</u></p> <p>1) USP-Rockville, MD.  c/o Steve Lane  United States Pharmacopeia  12601 Twinbrook Parkway  Rockville, MD 20852</p> <p>2) Family Health International  2810 Meridian Pkwy, Suite 110  Durham, NC- USA 27713  Attn. Dr. David Jenkins  djenkins@fhi.org</p>

**Comment [JCM1]:** What if capsules? Injections? Other formulations? Blister packs?

**Comment [JCM2]:** Do they also state something to the effect that they are not intended for human consumption? ??

**Comment [JCM3]:** Can you explain briefly why that is important, ISO-17025.

5.3.7	<p>The Pre-shipment testing plan will fall under two scenarios:</p> <table border="1" data-bbox="329 163 1013 289"> <tr> <td data-bbox="329 163 386 205">1.</td> <td data-bbox="386 163 1013 205">Full compendial testing if the product is listed in the US, BP, International or Japanese monographs.</td> </tr> <tr> <td data-bbox="329 205 386 289">2.</td> <td data-bbox="386 205 1013 289">If the product does not have an approved monograph, then the manufacturer's test methods are acceptable to use by the independent laboratory. However, method verification/validation may be required, which would add additional analyses time.</td> </tr> </table>	1.	Full compendial testing if the product is listed in the US, BP, International or Japanese monographs.	2.	If the product does not have an approved monograph, then the manufacturer's test methods are acceptable to use by the independent laboratory. However, method verification/validation may be required, which would add additional analyses time.
1.	Full compendial testing if the product is listed in the US, BP, International or Japanese monographs.				
2.	If the product does not have an approved monograph, then the manufacturer's test methods are acceptable to use by the independent laboratory. However, method verification/validation may be required, which would add additional analyses time.				
5.3.8	<p>The analytical test report is sent to JSI's Quality Assurance Partner-Family Health International for independent review and approval at the following location:</p> <p>Primary contact:  Steve Hamel, Deputy Director Product Quality and Compliance  Family Health International  2810 Meridian Pkwy, Suite 133  Durham, NC 27713</p>				
5.3.9	<p>Drug products cannot be shipped from their point of origin until pre-shipment testing has been completed and results accepted by JSI's Quality Assurance Partners.</p> <p>Note- The testing laboratory is required to perform the initial review of the test results. FHI will perform a second independent review.</p>				
5.3.10	<p>A Certificate of Conformance will be prepared by FHI and issued on behalf of the USAID   DELIVER Project. The original document will be sent to JSI with a copy to USAID. A copy will also be retained by FHI. JSI will notify the supplier that the test results have been accepted and the drug product can ship.</p>				

Comment [JCM4]: Issued to whom?

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
9/27/07	00	N/A	New Issue.
10/15/07	01	9/27/07	General re-write of section 5



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Sampling and Testing of Pharmaceutical drugs for Post-shipment		<b>DOCUMENT No.:</b> TO3-QA-Pharm-33
<b>DATE ISSUED:</b> 10/16/07	<b>SUPERSEDES:</b> 9/28/07rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File –

**1.0 PURPOSE:**

<b>1.1</b>	<b>To establish a procedure that defines the sampling and testing of pharmaceutical drugs at Post-shipment as required.</b>
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**2.0 BACKGROUND:**

<b>2.1</b>	Post-Shipment testing <i>may be performed</i> to verify identity and specifications of the shipped drug product. Post-shipment testing <i>is not required</i> on a routine basis but may be necessary in certain circumstances. Quality drug testing will routinely occur at pre-shipment.
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**3.0 DOCUMENT REFERENCES:**

<b>3.1</b>	<table border="1"> <tr> <td>1.</td> <td><i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i></td> </tr> <tr> <td>2.</td> <td><i>Post Market Surveillance (TO3-QA-Pharm-34)</i></td> </tr> <tr> <td>3.</td> <td><i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i></td> </tr> <tr> <td>4.</td> <td><i>WHO malaria treatment guidelines</i></td> </tr> </table>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>	2.	<i>Post Market Surveillance (TO3-QA-Pharm-34)</i>	3.	<i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i>	4.	<i>WHO malaria treatment guidelines</i>
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3.	<i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i>								
4.	<i>WHO malaria treatment guidelines</i>								

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of Pharmaceutical drug products involves a team of partners from various organizations. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement /Pre-Qualification	Audits
	2. PATH	Procurement /Pre-Qualification	Audits
	3. Crown Agents	Procurement /Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4. Family Health International	Oversight of QA-Activities Standard Operating Procedures	Audits/Monitoring suppliers Complaints
	5. United States Pharmacopeia	Pre and post shipment testing Post market Surveillance	Audits

5.0 **PROCEDURE:**

<b>5.1</b>	<b>Post-Shipment testing-Case-by-case basis</b>						
5.1.1	Any testing at Post-shipment will be determined on a case-by-case basis. In situations where the uncertainty of product security, counterfeiting, product stability, questionable storage conditions, or lack of quality information for the drug are not known, the post-shipment testing may be conducted to supplement the pre-shipment testing.						
5.1.2	JSI's Quality Assurance Partners with consultation from USAID will determine if Post shipment testing will occur.						
<b>5.2</b>	<b>Sampling</b>						
5.2.1	If sampling of the drug product is required, then sampling should be performed immediately upon arrival in-country.						
5.2.2	The number of samples per shipment should be a minimum of 200 tablets/per lot.						
5.2.3	There are three sampling plans available for use depending on access to the entire lot, presentation, and time involved executing the sampling process. <table border="1" data-bbox="402 919 1497 1171"> <tr> <td>1.</td> <td>Samples chosen are representative of the batches or lots in the shipment.</td> </tr> <tr> <td>2.</td> <td>All samples are selected randomly from throughout the lot. Random sampling is based on the theory that each unit within the lot has the same chance of being selected.</td> </tr> <tr> <td>3.</td> <td>The method for selecting samples varies depending on the organization of materials presented for inspection. Three common methods of sampling are: <ol style="list-style-type: none"> <li>1) <b>Square-root N + 1:</b> Select the number of units based on a total count of cases etc. and Calculate <math>\sqrt{N} + 1</math>. This number is then the number of cases selected at random to sample.</li> <li>2) <b>Systematic Random Sampling:</b> Select one unit at random. Then select the remainder using a fixed scheme (every 5th or 10th unit)</li> <li>3) <b>Stratified Random Sampling:</b> Select a random sample of containers which holds the individual units. Draw another sample from each container.</li> </ol> </td> </tr> </table>	1.	Samples chosen are representative of the batches or lots in the shipment.	2.	All samples are selected randomly from throughout the lot. Random sampling is based on the theory that each unit within the lot has the same chance of being selected.	3.	The method for selecting samples varies depending on the organization of materials presented for inspection. Three common methods of sampling are: <ol style="list-style-type: none"> <li>1) <b>Square-root N + 1:</b> Select the number of units based on a total count of cases etc. and Calculate <math>\sqrt{N} + 1</math>. This number is then the number of cases selected at random to sample.</li> <li>2) <b>Systematic Random Sampling:</b> Select one unit at random. Then select the remainder using a fixed scheme (every 5th or 10th unit)</li> <li>3) <b>Stratified Random Sampling:</b> Select a random sample of containers which holds the individual units. Draw another sample from each container.</li> </ol>
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5.2.4	Use Appendix A for the sampling process. This appendix can be used as a sampling record that documents important information relative to the sample and person(s) performing the sampling.						
5.2.5	All samples collected are to be stored and transported according to specific storage requirements provided on the label. Storage and transportation of samples is conducted in a manner to prevent deterioration, contamination and adulteration of the samples.  Samples for testing should be sent via global courier i.e. DHL to the specified USP testing laboratory. The tracking number of the package is provided to the designated testing lab. The sample package must be labeled " <i>Samples for Analytical testing Purposes Only- Not for Distribution</i> ".						

<b>5.3</b>	<b>Testing</b>
5.3.1	<p>Testing will be conducted by a primary designated laboratory (USP-India or North-West University- South Africa). In the event that testing schedules indicate a significant delay in shipping the drug, two secondary laboratories, USP-Rockville and FHI-NC may be used. All labs are ISO-17025 accredited.</p> <p><u>Primary Drug Testing Laboratories</u>  1) USP-India Pvt. Ltd.  ICICI Knowledge Park, Genome Valley  Turkapally, Shamirpet  Ranga Reddy District, Hyderabad 500 078, A.P. India  Phone: +91 40 2348 0088  Attn Dr. Koduru Surendranath</p> <p>2) NORTH-WEST UNIVERSITY  Private Bag X6001 Potchefstroom; 2520 South Africa  Tel (w) +27 18 2992280 Tel (h) +27 18 2973577 Fax +27 18 2992284  Prof Banie Boneschans-Head: Pharmaceutical &amp; Biomedical Services School of Pharmacy  E-Mail: Banie.Boneschans@nwu.ac.za  Tel (all hours) +27 82 568 4414</p> <p><u>Secondary Drug Testing Laboratories</u>  1) USP-Rockville, MD.  c/o Steve Lane  United States Pharmacopeia  12601 Twinbrook Parkway  Rockville, MD 20852</p> <p>2) Family Health International  2810 Meridian Pkwy Suite 110  Durham, NC- USA 27713  Attn. Dr. David Jenkins  djenkins@fhi.org</p>
5.3.2	Post-shipment testing will include at minimum, a visual examination and the identification test listed in the compendia method. There may be situations where other tests may be required i.e. dissolution, impurities, etc.
<b>5.4</b>	<b>Concurrent testing with distribution of product</b>
5.4.1	It's anticipated that most situations requiring post-shipment testing would be conducted concurrently with distribution of the drug. It's critical that drug distribution occur upon arrival in-country. However, there may be a few isolated instances where the product would require quarantine and post-shipment testing results approved before distribution. These situations will be coordinated on a case-by-case basis.
<b>5.5</b>	<b>Review and Approval of Post-shipment testing</b>
5.2.8	<p>The primary testing laboratory is required to perform the initial review of the test results. FHI will perform a second independent review. The test report will be sent to:</p> <p>Primary contact;  Steve Hamel-Deputy Director Product Quality and Compliance  Family Health International  2810 Meridian Pkwy, Suite 133  Durham, NC 27713</p>
5.2.9	A <i>Post –Shipment Certificate of Conformance</i> will be prepared (by FHI) and issued on behalf of the USAID   DELIVER Project. The original will be sent to JSI with a copy to USAID.

	A copy will also be retained by FHI. JSI will notify the country/program that the test results have been accepted.
5.2.10	In the event, that non-conforming results have been obtained from the post-shipment samples, an investigation will be conducted by the testing laboratory and the QA-Partner, Family Health International. SEE APPENDIX B

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/28/07	00	N/A	New Issue.
10/16/07	01	9/28/07	Change SOP name to "Pharm", add North-West Laboratory

**Appendix A**  
**Post-Shipment Sampling**  
**Drugs**

<b>I. Type of Shipment</b>		<b>Indicate</b>	<b>Designated country</b>
Emergency Shipment			
Non-Emergency Shipment			
Supplier			
Quantity of Drug Product			
Number of Lots in consignment			
Type/Brand of Drug Product			
Date, time and exact location of sampling			
Lot number			
Visual Examination Observations			
Printed name and title of officials and representatives present during sampling			
<b>II. Inspection of Drug shipment</b>			<b>Accept/Reject</b>
1.	<b>Check conformity to the Purchase order and country requirements/specification</b> Inspect the PO list to the country requirements.		
2.	<b>Inspect the Integrity of packaging for consignment at arrival.</b> Inspect the entire consignment (or lots) if identified and look for obvious damage to cases and packages of Drugs. If any damage is present, isolate the cases (packages) and determine quantity.		
3.	<b>Determine if any product damage was caused by transporting</b> i.e. Cases on top (double stacked) or cases on end of pallets were damaged during transport		
<b>III. Sampling Drugs (per lot) – indicate method of sampling</b>			
4.	<b>Square-root N + 1:</b> Select the number of units based on a total count of cases etc. and calculate $\sqrt{N} + 1$ . This number is then the number of cases selected at random to sample.		<b>Sampled by/date;</b>
5.	<b>Systematic Random Sampling:</b> Select one unit at random. Then select the remainder using a fixed scheme (every 5th or 10th unit)		<b>Sampled by/date;</b>
6.	<b>Stratified Random Sampling:</b> Select a random sample of containers which holds the individual units. Draw another sample from each container.		<b>Sampled by/date;</b>
<b>IV. Send samples to: USP-India or North-West University South Africa</b>			
7.	USP-India Pvt. Ltd. ICICI Knowledge Park, Genome Valley Turkapally, Shamirpet Ranga Reddy District, Hyderabad 500 078, A.P. India Phone: +91 40 2348 0088 Attn Dr. Koduru Surendranath	NORTH-WEST UNIVERSITY Private Bag X6001 Potchefstroom; 2520 South Africa Tel (w) +27 18 2992280 Tel (h) +27 18 2973577 Fax +27 18 2992284 Prof Banie Boneschans-Head: Pharmaceutical & Biomedical Services School of Pharmacy E-Mail: Banie.Boneschans@nwu.ac.za Tel (all hours) +27 82 568 4414	<b>Airway bill/Tracking Number</b>
<b>V. Submit a copy of Appendix A with the samples</b>			
<b>VI. Submit via e-mail- Copy of Appendix A to:</b>			
1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>		
2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>		
<b>Reviewed by/Date;</b>			

**APPENDIX B**

**INVESTIGATION REPORT  
Pharmaceutical Drugs  
In-Country**

<b>Checklist</b>	
Complaint or Audit:	
Date Complaint /Audit reported:	
Complaint reported by:	
Manufactured by:	
Amount of product involved:	
Action:	
Management – the responsibilities and authority for the management of non-conforming work are designated and actions are defined and taken when non-conforming product is identified	
An evaluation of the significance of the non-conforming product is made- Conclusion	
Corrective actions are taken immediately.	
USAID   DELIVER Project notified	
Responsibility for authorizing the use of the product;	
Review of Records	
Corrective actions- Actions most likely to eliminate the problem and to prevent recurrence And the corrective action(s) shall be appropriate to the magnitude and risk of the problem	



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Conducting Post Market Surveillance for Pharmaceutical drug products		<b>DOCUMENT No.:</b> TO3-QA-Pharm-34
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> 9/28/07rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI/USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File –

**1.0 PURPOSE:**

<b>1.1</b>	The purpose is to establish a procedure for carrying out post market surveillance on drugs as required.
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**2.0 BACKGROUND:**

<b>2.1</b>	It is important to periodically perform an evaluation of the product post market to ensure continuous conformance to specifications. If during the surveillance it is determined that a hazard or other critical deficiency is present, appropriate action will be taken.
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**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>Sampling, Testing of Pharmaceutical drugs at Pre-Shipment (TO3-QA-Pharm-32)</i>
	3.	<i>Sampling, Testing of Pharmaceutical drugs at Post-Shipment (TO3-QA-Pharm-33)</i>
	4.	<i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i>
	5.	<i>WHO malaria treatment guidelines</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</b>		
<b>4.1.1</b>	These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement /Pre-Qualification	Audits
	2. PATH	Procurement /Pre-Qualification	Audits
	3. Crown Agents	Procurement /Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4. Family Health International	Oversight of QA-Activities Standard Operating Procedures	Audits/Monitoring suppliers Complaints
	5. United States Pharmacopeia	Pre and post shipment analysis Post Market Surveillance testing	Audits

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Where to conduct Post Market Surveillance – Countries</b>																																				
5.1.1	<p>The Post –Market Surveillance activity will be conducted in the countries listed in the table below;</p> <table border="1" data-bbox="467 499 812 934"> <tr><td>1.</td><td>Benin</td></tr> <tr><td>2.</td><td>DR Congo</td></tr> <tr><td>3.</td><td>Ethiopia</td></tr> <tr><td>4.</td><td>Ghana</td></tr> <tr><td>5.</td><td>Kenya</td></tr> <tr><td>6.</td><td>Madagascar</td></tr> <tr><td>7.</td><td>Malawi</td></tr> <tr><td>8.</td><td>Mozambique</td></tr> <tr><td>9.</td><td>Nigeria</td></tr> <tr><td>10.</td><td>Rwanda</td></tr> <tr><td>11.</td><td>Senegal</td></tr> <tr><td>12.</td><td>Sudan</td></tr> <tr><td>13.</td><td>Zambia</td></tr> <tr><td>14.</td><td>Liberia</td></tr> <tr><td>15.</td><td>Cambodia</td></tr> <tr><td>16.</td><td>Tanzania</td></tr> <tr><td>17.</td><td>Angola</td></tr> <tr><td>18.</td><td>Uganda</td></tr> </table>	1.	Benin	2.	DR Congo	3.	Ethiopia	4.	Ghana	5.	Kenya	6.	Madagascar	7.	Malawi	8.	Mozambique	9.	Nigeria	10.	Rwanda	11.	Senegal	12.	Sudan	13.	Zambia	14.	Liberia	15.	Cambodia	16.	Tanzania	17.	Angola	18.	Uganda
1.	Benin																																				
2.	DR Congo																																				
3.	Ethiopia																																				
4.	Ghana																																				
5.	Kenya																																				
6.	Madagascar																																				
7.	Malawi																																				
8.	Mozambique																																				
9.	Nigeria																																				
10.	Rwanda																																				
11.	Senegal																																				
12.	Sudan																																				
13.	Zambia																																				
14.	Liberia																																				
15.	Cambodia																																				
16.	Tanzania																																				
17.	Angola																																				
18.	Uganda																																				
5.1.2	A list of the drugs that have been shipped to the particular country is obtained from JSI’s logistics database.																																				
5.1.3	A second list is obtained from JSI’s database that includes the lot numbers and quantity for each drug type shipped into the country.																																				
5.1.4	The DELIVER country representative is contacted to determine if any drug remains in the warehouse.																																				
<b>5.2</b>	<b>Sampling</b>																																				
5.2.1	The DELIVER country representative may be asked to provide samples of drug products at the warehouse, medical center, or other point of drug distribution. If the DELIVER representative can not conduct the sampling, a sampling agency may be used to collect and send samples to the testing laboratory.																																				
5.2.2	The sampling of drug products for Post-Market Surveillance can be unpredictable in terms of available amounts, number of lots, and storage conditions in medical centers/pharmacies. This will directly affect the testing that may be required. It’s important to document the circumstances and observations with regards to sampling.																																				
5.2.3	Use <b>Appendix A</b> for the sample collection process. This appendix can be used as a sampling record that documents important information relative to the sample and person(s) performing the sampling.																																				
5.2.4	All samples collected are to be stored and transported according to specific storage requirements provided on the label. Storage and transportation of samples is conducted in a manner to prevent deterioration, contamination and adulteration																																				

	<p>of the samples.</p> <p>Samples for testing should be sent via global courier i.e. DHL to the specified testing laboratory. The tracking number of the package is provided to the designated testing lab. The sample package must be labeled “<i>Samples for Analytical testing Purposes Only- Not for Distribution</i>”.</p>										
<b>5.3</b>	<b>Post-Market Surveillance Testing</b>										
5.3.1	<p>Testing will be conducted by a primary designated laboratory (USP-India or North-West University- South Africa). In the event that testing schedules indicate a significant delay in shipping the drug, two secondary laboratories, USP-Rockville and FHI-NC may be used. All labs are ISO-17025 accredited.</p> <p><u>Primary Drug Testing Laboratories</u></p> <p>1) USP-India Pvt. Ltd.  ICICI Knowledge Park, Genome Valley  Turkapally, Shamirpet  Ranga Reddy District, Hyderabad 500 078, A.P. India  Phone: +91 40 2348 0088  Attn Dr. Koduru Surendranath</p> <p>2) NORTH-WEST UNIVERSITY  Private Bag X6001 Potchefstroom; 2520 South Africa  Tel (w) +27 18 2992280 Tel (h) +27 18 2973577 Fax +27 18 2992284  Prof Banie Boneschans-Head: Pharmaceutical &amp; Biomedical Services School of Pharmacy  E-Mail: Banie.Boneschans@nwu.ac.za  Tel (all hours) +27 82 568 4414</p> <p><u>Secondary Drug Testing Laboratories</u></p> <p>1) USP-Rockville, MD.  c/o Steve Lane  United States Pharmacopeia  12601 Twinbrook Parkway  Rockville, MD 20852</p> <p>2) Family Health International  2810 Meridian Pkwy Suite 110  Durham, NC- USA 27713  Attn. Dr. David Jenkins  djenkins@fhi.org</p>										
5.3.2	<p>The required tests to be conducted will depend on the number of tablet samples collected. Tests should be prioritized by the following;</p> <table border="1"> <tr> <td>1.</td> <td>Identification</td> </tr> <tr> <td>2.</td> <td>Drug impurities</td> </tr> <tr> <td>3.</td> <td>Dissolution</td> </tr> <tr> <td>4.</td> <td>Content uniformity</td> </tr> <tr> <td>5.</td> <td>Physical tests</td> </tr> </table> <p>All samples/lots should be examined for damage, leakage to the blister pack or container.</p>	1.	Identification	2.	Drug impurities	3.	Dissolution	4.	Content uniformity	5.	Physical tests
1.	Identification										
2.	Drug impurities										
3.	Dissolution										
4.	Content uniformity										
5.	Physical tests										
5.3.3	<p>If the samples/lots meet the requirements in the specification, then the supplier maintains approval. The Post-Market test results are added to the supplier report card.</p>										

5.3.4	If the lots do not comply with stated requirements, then the JSI Quality Assurance Partners will investigate using Appendix B.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/28/07	00	N/A	New Issue.
10/18/07	01	9/28/07	Change name of SOP ACTs to Pharm; add North-West University

**Appendix A**  
**USAID | DELIVER Project**  
**Post-Market Surveillance Sampling**  
**Pharmaceuticals**

<b>I. Post-Market Surveillance Sampling</b>		<b>COMMENTS/OBSERVATIONS</b>	
<b>Country</b>			
1. Date, time and exact location of sampling			
2. Describe circumstances related to sampling and indicate sample selection process			
Product name lot number MFD date Expiry Date			
Visual Examination Observations			
Printed name and title of officials and representatives present during sampling			
<b>II. Send samples to: USP-India or North-West University South Africa</b>			
7.	USP-India Pvt. Ltd. ICICI Knowledge Park, Genome Valley Turkapally, Shamirpet Ranga Reddy District, Hyderabad 500 078, A.P. India Phone: +91 40 2348 0088 Attn Dr. Koduru Surendranath	NORTH-WEST UNIVERSITY Private Bag X6001 Potchefstroom; 2520 South Africa Prof Banie Boneschans-Head: Pharmaceutical & Biomedical Services School of Pharmacy E-Mail: Banie.Boneschans@nwu.ac.za Tel (all hours) +27 82 568 4414	<b>Airway bill/Tracking Number</b>
<b>III. Submit a copy of Appendix A with the samples</b>			
<b>IV. Submit via e-mail- Copy of Appendix A to:</b>			
1.	John Snow Inc. <a href="mailto:ralph_rack@jsi.com">ralph_rack@jsi.com</a> <a href="mailto:marlon_banda@jsi.com">marlon_banda@jsi.com</a> <a href="mailto:paul_stannard@jsi.com">paul_stannard@jsi.com</a> <a href="mailto:miguel_jaureguizar@jsi.com">miguel_jaureguizar@jsi.com</a>		
2.	Family Health International <a href="mailto:shamel@fhi.org">shamel@fhi.org</a> <a href="mailto:djenkins@fhi.org">djenkins@fhi.org</a>		
<b>Reviewed by/Date;</b>			

**APPENDIX B  
USAID | DELIVER Project**

**INVESTIGATION REPORT  
Pharmaceutical Drug Products  
Post-Market Surveillance  
2007**

**Checklist**

<b>Complaint or Audit:</b>	
<b>Date Complaint /Audit reported:</b>	
<b>Complaint reported by:</b>	
<b>Manufactured by:</b>	
<b>Amount of product involved:</b>	
<b>Action:</b>	
<b>Management – the responsibilities and authority for the management of non-conforming work are designated and actions are defined and taken when non-conforming product is identified</b>	
<b>An evaluation of the significance of the non-conforming product is made- Conclusion</b>	
<b>Corrective actions are taken immediately.</b>	
<b>USAID   DELIVER Project notified</b>	
<b>Responsibility for authorizing the use of the product;</b>	
<b>Review of Records</b>	
<b>Corrective Actions- actions most likely to eliminate the problem and to prevent recurrence And the corrective action(s) shall be appropriate to the magnitude and risk of the problem</b>	



# USAID | DELIVER PROJECT

## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Conducting Audits of Pharmaceutical drug suppliers		<b>DOCUMENT No.:</b> TO3-QA-Pharm-35
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> 9/28/07rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File –

### 1.0 PURPOSE:

1.1	To establish a document that provides a procedure for conducting audits of Pharmaceutical Suppliers with respect to USAID contract requirements and adherence to Good Manufacturing Practices (21 CFR 211).
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### 2.0 BACKGROUND:

2.1	<p>The increasing rate of malaria related deaths is partially attributed to the resistance of <i>Plasmodium falciparum</i> to the more traditional medications, such as sulfadoxine-pyrimethamine, chloroquine, and amodiaquine. This resistance is evident in parts of South America, Asia, and Africa.</p> <p>During the past several years, artemisinin-based combination therapies have been used on an increasing scale world-wide. These medications have a quick response to <i>Plasmodium falciparum</i> and seem to be easily tolerated by patients. Thus far, no major reports of drug resistance to ACTs have been reported.</p> <p>The WHO has prepared a list of pre-qualified suppliers of ACTs (Ref. 3.4), which will serve to help meet the immediate procurement needs of USAID’s malaria program.</p> <p>Although the ACT suppliers have been pre-qualified by the WHO, the QA-Partners should be proactive in auditing the manufacturers of ACTs in order to provide additional assurance that the ACTs are being prepared under good manufacturing practices (Ref. 3.5) and meet the required specifications.</p>
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### 3.0 REFERENCE DOCUMENTS:

3.1	Current contract between USAID and manufacturer.
3.2	<i>President’s Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
3.3	<a href="http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMinfosheet_9.htm">http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMinfosheet_9.htm</a>
3.4	<a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a>
3.5	Code for Federal Regulations Title 21 Part 211 Good Manufacturing Practice for Finished Pharmaceuticals.

3.6	PQC 161 – Production Surveillance Audit
3.7	Audit Checklist (GMP)– Pharmaceutical Products / Medical Devices –Appendix A
3.8	TO3-QA-Pharm-31
3.9	TO3-QA-Pharm-37

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of Pharmaceutical drugs involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities Standard Operating Procedures	Audits/Monitoring suppliers Complaints
	5.	United States Pharmacopeia	chemical testing Post Market Surveillance	Audits

**5.0 PROCEDURE:**

<b>5.1</b>	<b>Scheduling</b>
5.1.1	Manufacturers will be audited on-site and evaluated for compliance with 21 CFR 211. Audits will be conducted by the QA-Partners (QAP) team.
5.1.2	For recently pre-qualified manufacturers, an audit should be conducted within the first year of pre-qualification with subsequent audits being conducted every two years at a minimum based on supplier performance.
<b>5.2</b>	<b>Conducting Audit</b>
5.2.1	The audit will be conducted based on GMP (21 CFR 211) criteria, where the GMP checklist (Ref. 3.7) is utilized to guide and document the findings of the audit. See Appendix A.
<b>5.3</b>	<b>Audit Report</b>
5.3.1	An internal memo shall be prepared listing the highlights of the audit, including informational items that may impact future operational audits.
5.3.2	An external report shall be provided to the vendor and the Quality Assurance Partners listing any observations. The accompanying letter shall request a corrective action plan, if needed, and estimated dates of completion.
5.3.3	If observations are significant, and the facility is out of compliance in critical areas, a follow-up visit may be scheduled prior to the next scheduled audit.

5.3.4	Follow - up on suggested corrective measures will be performed on subsequent audits.
5.3.5	Depending on the severity of the non-compliant issue, the auditor may suggest that the manufacturer be removed from the pre-qualified list (even after only the first audit) until the follow-up audit has been completed to evaluate the status of the corrective actions.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/28/07	00	N/A	New Issue.
10/18/07	01	9/28/07	Change SOP name from ACTs to Pharm

**APPENDIX A  
cGMP AUDIT CHECKLIST - 21 CFR 211/21 CFR 820**

Auditor (s)	Date (s)
<b>General Information</b>	<b>A-All aspects examined</b> <b>P-Procedure reviewed</b> <b>D-Documentation reviewed</b> <b>N/A- Not Applicable</b>
Company	
Division of:	
Plant audited	
Address	
Telephone	
Fax	
Product Manufactured	
Company Contacts	
Date of Last Audit	
Observations/Comments from previous audit	
Number of employees- Manufacturing	
Number of employees-Quality	
Average tenure of employees	
Is there a union organization	
Date of Last USAID contract	
ISO Certified	
Is there an Organization Chart available?	
NOTES:	
Adequate testing Facilities?	
In-Process checks performed by QA?	

OA records signed dated and reviewed by a second person?	
Do records indicate the final disposition of materials manufactured at the facility?	
Are inspection and test procedures written?	
<b>211.25 Personnel Qualifications</b>	
Training records up-to-date?	
Annual GMP training?	
On-going training program?	
Any Certification training?	
Is there an adequate number of qualified personnel to supervise?	
<b>211.28 Personnel responsibilities</b>	
Do personnel wear proper attire?	
Do personnel practice good sanitation and health habits?	
Are persons with a medical condition excluded from product contact?	
<b>211.34 Consultants</b>	
Are there records of consultant qualifications on file?	
NOTES:	
<b>BUILDINGS AND FACILITIES - SUBPART C</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.42 Design and Construction Features</b>	
Are the buildings of suitable size and construction to facilitate cleaning and other operations?	
Building should have adequate space to prevent mix-ups?	
Operations shall be performed within specifically designed areas to prevent contamination?	
Receipt, storage and handling shall be controlled.	
Holding items before release.	
Holding of rejected items.	
Storage of released components.	
Storage of in-process materials.	
Control and Laboratory operations.	
Temperature and Humidity controls	
Aseptic processing-floors, walls and ceilings easily cleaned.	
Air supply filtered through high efficiency particulate air filters.	
A system for monitoring environmental conditions.	
A system for cleaning and disinfecting the room and equipment.	
Separate facility for the manufacture of penicillin	
<b>211.44 Lighting</b>	
Adequate Lighting shall be provided in all areas.	
<b>211.46 Ventilation, air filtration, air heating and cooling</b>	
Adequate ventilation shall be provided.	
Control over air pressure shall be provided	
Control over dust particles	
<b>211.48 Plumbing</b>	
Potable water shall meet EPA water regulations 40 CFR 141	
<b>211.50 Sewage and Refuse</b>	
Waste shall be disposed in a safe manner.	
<b>211.52 Washing and toilet facilities</b>	
Adequate washing and toilet facilities shall be provided including hot and cold water, soap	
<b>211.56 Sanitation</b>	
Building shall be free of rodents, insects.	
Waste and trash shall be disposed properly in a timely manner	



<b>CONTROL of COMPONENTS and Drug Product Containers and Closures - SUBPART E</b>	A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable
<b>211.80 General Requirements</b>	
Are there written procedures for receipt, identification handling, sampling of components?	
Are components and drug closures free from contamination?	
Components properly identified?	
<b>211.82 Receipt and storage of untested components, drug containers and closures?</b>	
Are containers and components examined visually for labeling or damage?	
Are components stored under quarantine status?	
<b>211.84 Testing and approval or rejection of components, drug product container and closures</b>	
Lots shall be withheld from use until it has been sampled or examined and released by the QC unit.	
Representative samples shall be taken.	
Sampling	
containers shall be cleaned by appropriate means	
containers shall be opened sampled and resealed in a manner to prevent contamination	
sterile equipment and sampling techniques shall be used	
sample ID is required	
sample containers shall be marked	
samples - require an ID test	
sample testing - is supplier certification used?	
<b>211.86 Use of approved components, drug product containers and closures</b>	
Is the oldest approved stock used first?	
<b>211.87 Re-testing of approved components,,,,</b>	
Are components, drug products re-tested after long periods of storage?	
<b>211.89 Rejected Components, drug products and closures</b>	
Are rejected products controlled under a quarantine system?	
<b>211.94 Drug Product containers and closures</b>	
Are there written procedures for pyrogenic properties?	
NOTES:	

<b>PRODUCTION AND PROCESS CONTROLS - SUBPART F</b>	A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable
<b>211.100 Written Procedures- Deviations</b>	
Are written procedures approved by the QC unit?	
Are deviations from the written procedure documented?	
<b>211.101 Charge in of components</b>	
Batch records must have 100% of label claim	
Are weighings observed and signed by a second person	
Containers are properly identified	



Are the labels examined before packaging?	
Is there written documentation of line clearance?	
Is the line clearance documentation in the batch record?	
<b>211.132 Tamper resistant packaging requirements for OTC drug products</b>	
Not applicable	
<b>211.134 Drug Product Inspection</b>	
Packages and labeled products shall be examined during finishing operations that they have the correct label.	
Is a representative sample taken and examined?	
Are these data in the batch record?	
<b>211.137 Expiration Dating</b>	
Expiration dating based on appropriate stability studies.	
Associated with storage conditions on the container	
NOTES:	
<b>HOLDING AND DISTRIBUTION - SUBPART H</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.142 Warehousing procedures</b>	
Do warehouse procedures include quarantine before release?	
Does the storage affect the product?	
<b>211.150 Distribution Records</b>	
Are there written procedures for distribution of drug products?	
Is the oldest stock used first?	
Is the system suitable so a recall can be facilitated?	
<b>LABORATORY CONTROLS - SUBPART I</b>	
<b>211.160 General Requirements</b>	
Are documents approved by the QC unit?	
Are sampling documents in place?	
How are samples received in the QC lab?	
Are solutions properly labeled?	
Is there a LIMS system?	
Are written specifications in place?	
Are samples and documents properly identified?	
Is there an appropriate calibration program?	
Who performs the calibrations?	
Are instruments properly tagged?	
Are instruments that do not require calibration properly tagged?	
Do some instruments that have a daily calibration have a log book?	
<b>211.165 Testing and release for distribution</b>	
Test records for analytical?	
Test records for microbiological?	
Test records for in-process?	
Any investigations?	
Have deviations been investigated?	
Any re-sampling and re-testing?	
Are there method validation documents?	
<b>211.166 Stability Testing</b>	
Is there a stability program?	
What are the storage conditions?	

Are test methods stability indicating?	
<b>211.167 Special Testing Requirements</b>	
Is there sterility testing?	
<b>211.170 Reserve Samples</b>	
Are samples from each lot retained?	
Are retains kept 1 year past the expiration date?	
<b>211.173 Laboratory Animals</b>	
Use of animal testing?	
Are records kept?	
<b>211.176 Penicillin contamination</b>	
Non-penicillin drug products which may have been contaminated by penicillin products must be tested.	
<b>RECORDS AND REPORTS - SUBPART J</b>	<b>A-All aspects examined P-Procedure reviewed D-Documentation reviewed N/A- Not Applicable</b>
<b>211.180 General Requirements</b>	
Are production records retained 1 year past the expiration date?	
Are records easily attainable?	
Written records shall be maintained for evaluating each batch at least annually to determine the need for changes in manufacturing.	
Does the annual review cover complaints, recalls, returned drug products and investigations?	
<b>211.182 Equipment cleaning and use log</b>	
Are there equipment cleaning logs?	
Is there dedicated equipment?	
<b>211.184 Component, drug product container, closure and labeling records</b>	
Refer to 211.80	
<b>211.186 Master production and control records.</b>	
Who is the keeper of the records?	
Are records controlled?	
<b>211.188 Batch production and control records</b>	
Do batch records explain all of the necessary steps in manufacturing?	
weights and measures of components?	
verified by a second individual?	
yield calculations?	
packaging labels?	
reconciliation?	
test releases?	
any investigations?	
<b>211.192 Production record review</b>	
Are records reviewed and approved by the quality control unit?	
<b>211.194 Laboratory records</b>	
Do lab records include all of the data?	
Is the sample clearly identified?	
Is the method used clearly identified?	
sample and standard weights used?	
graphs, spectra included?	
Any investigations?	
Are tests signed and reviewed by a second individual?	
Is there reference standard used?	
Is there a reference standard program?	
<b>211.198 Complaint Files</b>	
Are there written procedures covering complaints?	
Complaint files up to 1 year after the expiration date?	
Is there follow up information?	
<b>RETURNED AND SALVAGED DRUG PRODUCTS -PART K</b>	
<b>211.204 Returned drug products</b>	
Are returned products identified and quarantined?	
Are returned products re-processed?	
Any returned product exposed to adverse conditions?	

QUALITY SYSTEMS DOCUMENTATION REVIEW/INITIAL ASSESSMENT WORKSHEET

Document Reference	Procedure Requirements to be evaluated	Document Review Comments	Assessment Findings

NONCONFORMITY REPORT

Area/Activity Audited:		Standard Reference:
Category:	Major**	Minor**
Findings:		
Observation report:		
Auditor:		



# USAID | DELIVER PROJECT

## Task Order 3- MALAR IA Quality Assurance Procedures

<b>TITLE:</b> Conducting Audits of pharmaceutical drug testing laboratories		<b>DOCUMENT No.:</b> TO3-QA-Pharm-36
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> 9/28/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File-

### 1.0 PURPOSE:

1.1	To establish a document that provides a format for conducting audits of laboratories which evaluate the quality of pharmaceutical drug products.
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### 2.0 BACKGROUND:

2.1	The WHO has prepared a list of quality control laboratories (Ref. 5) which have been pre-qualified based on Annex 3 of WHO Technical Report Series 902 (Ref. 6). These laboratories, along with other qualified laboratories (to be determined), may be used to conduct quality assurance testing of pharmaceutical drug products. Although these laboratories have been evaluated by the WHO, the Quality Assurance Partners of the malaria task order should periodically audit the laboratories for compliance to WHO TRS 902.
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### 3.0 REFERENCE DOCUMENTS:

3.1	1.	Current contract between USAID and manufacturer.
	2.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	3.	<a href="http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm">http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm</a>
	4.	<a href="http://mednet3.who.int/prequal/lists/mal_suppliers.pdf">http://mednet3.who.int/prequal/lists/mal_suppliers.pdf</a>
	5.	<a href="http://mednet3.who.int/prequal/lists/PQ_OCLabsList.pdf">http://mednet3.who.int/prequal/lists/PQ_OCLabsList.pdf</a>
	6.	WHO Technical Report Series 902, 2002 – “WHO Expert Committee on Specifications for Pharmaceutical Preparations” <a href="http://whqlibdoc.who.int/trs/WHO_TRS_902.pdf">http://whqlibdoc.who.int/trs/WHO_TRS_902.pdf</a>
	7.	<a href="#">Annex 3 - WHO Technical Report Series, no. 902, 2002 - Compliance-checklist.doc</a>

#### 4.0 **RESPONSIBILITIES:**

<b>4.1</b>	The procurement and quality assurance of pharmaceuticals involves a team of partners from various organizations. These include;			
		<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1.	John Snow Inc.	Procurement Pre-Qualification	Audits
	2.	PATH	Procurement Pre-Qualification	Audits
	3.	Crown Agents	Procurement Pre-Qualification Pre-Shipment Inspection	Post-Inspection/Audits
	4.	Family Health International	Oversight of QA-Activities Standard Operating Procedures	Audits/Monitoring suppliers Complaints
	5.	United States Pharmacopela	Technical assistance chemical testing Post market surveillance	Audits

#### 5.0 **PROCEDURE:**

5.1	Laboratories will be visited on-site by staff from the QA-Partners and evaluated for compliance to <b>Ref. 6</b> - Annex 3 of WHO Technical Report Series 902. Effort should be made to schedule the audit so that all pertinent laboratory staff are present. An audit checklist ( <b>Ref 7.</b> ) has been generated based on Annex 3 of WHO TRS 902 and should be used as a tool to assist in the documentation of the audit. The ISO 17025:2005 standard should also be consulted as a guide for conducting laboratory audits.
5.2	Audits will be conducted every 1-2 years, or sooner depending on laboratory performance.
5.3	An internal memo shall be prepared listing the highlights of the audit, including informational items that may impact future operational audits.
5.4	An external report shall be provided to the laboratory and QA-Partners listing observations, and where appropriate, suggested guidelines for improvement. The report shall request a corrective action plan, if needed, and estimated dates of completion.
5.5	If observations are significant, and the facility is out of compliance in critical areas, a follow-up visit may be scheduled prior to the next scheduled audit. If the corrective action plan is found not to have been completed prior to the follow-up visit, the laboratory will not be utilized for QA testing of pharmaceutical drugs until additional audits indicate compliance.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/28/07	00	N/A	New Issue.
10/18/07	01	9/28/07	Change name from ACTs to Pharm



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> Supplier Report Card for Pharmaceutical Drug products		<b>DOCUMENT No.:</b> TO3-QA-Pharm-37
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> 9/28/07 rev00	<b>Revision:</b> 01
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

**1.0 PURPOSE:**

<b>1.1</b>	To describe the procedure for preparing and reporting supplier performance information.
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**2.0 BACKGROUND:**

<b>2.1</b>	Monitoring supplier performance via a scorecard (or report card) is a valuable quality management and communication tool between the supplier and customer (USAID   DELIVER Project TO3-Malaria).
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**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	1. <i>Standard operating procedure TO3-QA-Pharm-32 Sampling, Inspection and Testing of Pharmaceutical drugs –Pre-Shipment</i>
	2. <i>The Supplier Management Handbook, Sixth Edition- American Society for Quality</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	Responsibilities - Quality Assurance- Partners; USAID   DELIVER – TO3 Malaria																		
4.1.1	<table border="1"> <thead> <tr> <th></th> <th>Quality Assurance Partners</th> <th>Major Responsibility</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td>Family Health International</td> <td>Collect information on suppliers and generate scorecards</td> </tr> <tr> <td>2.</td> <td>John Snow Inc.</td> <td>Provide additional information related to supplier(s)</td> </tr> <tr> <td>3.</td> <td>PATH</td> <td>Technical assistance-Information</td> </tr> <tr> <td>4.</td> <td>Crown Agents</td> <td>Technical assistance-Information</td> </tr> <tr> <td>5.</td> <td>USP</td> <td>Technical assistance-Information</td> </tr> </tbody> </table>		Quality Assurance Partners	Major Responsibility	1.	Family Health International	Collect information on suppliers and generate scorecards	2.	John Snow Inc.	Provide additional information related to supplier(s)	3.	PATH	Technical assistance-Information	4.	Crown Agents	Technical assistance-Information	5.	USP	Technical assistance-Information
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**5.0 PROCEDURE:**

<b>5.1</b>	<b>Components of a Scorecard</b>				
5.1.1	There are generally three to five components of a supplier scorecard. These can be ranked based on the degree of importance by the customer or they can have equal weight. There is no standard scorecard that is used across industry or in supplier quality. The most important factor is that the rating is objective and that the scorecard is the same for all suppliers of that product.				
5.1.2	<p>The general scorecard for pharmaceutical drugs will focus on;</p> <table border="1"> <tr> <td>"On-time deliveries"</td> </tr> <tr> <td>Test data (CpK)</td> </tr> <tr> <td>Complaints/Product audit (In-Country evaluations)</td> </tr> <tr> <td>Supplier Audits</td> </tr> </table> <p>The ranking of importance is "to be determined".</p>	"On-time deliveries"	Test data (CpK)	Complaints/Product audit (In-Country evaluations)	Supplier Audits
"On-time deliveries"					
Test data (CpK)					
Complaints/Product audit (In-Country evaluations)					
Supplier Audits					
<b>5.2</b>	<b>"On-Time" Deliveries</b>				
5.2.1	<p>An important aspect of supplier performance is monitoring "on-time" deliveries. The information is obtained from John Snow Inc. on a monthly basis through the database. The information monitored is;</p> <table border="1"> <tr> <td>Order date</td> </tr> <tr> <td>Actual ship date</td> </tr> <tr> <td>Desired delivery date</td> </tr> <tr> <td>Actual delivery date</td> </tr> </table> <p>Note: There is a "window" that can be established that is determined by the customer.</p>	Order date	Actual ship date	Desired delivery date	Actual delivery date
Order date					
Actual ship date					
Desired delivery date					
Actual delivery date					
<b>5.3</b>	<b>Pharmaceutical Drug Test Data</b>				
5.3.1	Copies of the particular drug Certificate of Analysis or independent test data reports are sent to Family Health International.				
5.3.2	The data are statistically evaluated against the existing specification (for each test) in order to observe trends in the manufacturing process. (Process capability index CpK)				
5.3.3	Other statistical methods may also be used depending on the nature of the reported data. Any rejections are also included.				
<b>5.4</b>	<b>Complaints/Product audit (In-Country Evaluations)</b>				
5.4.1	If the USAID   DELIVER Project TO3-Malaria team receives any complaint regarding a drug, that information is investigated and corrective actions are evaluated and monitored. In-Country product audit testing or post market surveillance may also be included.				

<b>5.5</b>	<b>Supplier Audits</b>
5.5.1	If any non-conformances are found during an audit, the corrective actions are monitored. Audit reports may also be part of the supplier scorecard.
<b>5.6</b>	<b>Scorecard Reports</b>
5.6.1	Scorecard reports will be disseminated to the USAID   DELIVER Project TO3-Malaria team on a periodic basis. The frequency will depend on the amount of information collected in a specific time period, generally 6 or 12 months.

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/28/07	00	N/A	New Issue.
10/18/07	01	9/28/07	Change SOP name from ACT to Pharm



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

Task Order 3- MALARIA

Quality Assurance Procedures

<b>TITLE:</b> Interim (Emergency) Quality Assurance strategy for the procurement of Coartem®		<b>DOCUMENT No.:</b>  TO3-QA-Pharm-38
<b>DATE ISSUED:</b> 9/28/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / Family Health International	<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File – September 28, 2007 <b>OBSOLETE – 10/18/07</b>	

## 1.0 PURPOSE:

<b>1.1</b>	To establish an interim (Emergency) quality assurance strategy for procuring Coartem® for the treatment of Malaria for the USAID   DELIVER Project -Task Order 3 Malaria.
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## 2.0 BACKGROUND:

<b>2.1</b>	<p>The granting of Task-Order 3 –Malaria in April 2007, created a challenging obstacle with regard to procuring products. Timing is critical in obtaining and sending products to countries where outbreaks are likely to occur (seasonal). It’s imperative that the necessary drugs can be procured in the case of emergencies.</p> <p>Coartem®, manufactured by Novartis, is well known and has been supplied to government programs for many years. There are no known quality related problems with this drug. This <b>emergency</b> quality assurance strategy allows for the pre-qualification and pre-shipment testing of Coartem® to be waived.</p> <p>Note: This strategy does not apply to other pharmaceutical drug products.</p>
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## 3.0 REFERENCE DOCUMENTS:

<b>3.1</b>	1) Lumefantrine and Artemether tablets-United States Pharmacopeia 2) 21 CFR 210 and 211 Good Manufacturing Practices
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## 4.0 RESPONSIBILITIES:

<b>4.1</b>	<b>Responsibilities</b>		
4.1.1	The procurement and quality assurance of ACTs involves a team of partners. These include;		
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>	<b>Other Responsibilities</b>
	1. John Snow Inc.	Procurement Pre-Qualification	Audits
	2. PATH	Procurement Pre-Qualification	Audits/ Field evaluations

	3.	Crown Agents	Procurement Pre-Qualification	Sampling agency Audits Field Technical Assistance
	4.	Family Health International	Oversight of QA- Activities	Standard Operating Procedures Audits Monitoring suppliers Complaints
	5.	United States Pharmacopeia	Field Technical assistance/ Drug Testing	Audits

**5.0 QUALITY ASSURANCE INTERIM STRATEGY FOR PROCUREMENT OF Coartem®:**

<b>5.1</b>	<b>Pre-qualification of manufacturer(s) General Requirements:</b>			
5.1.1	The pre-qualification process provides confirmation of management systems necessary for manufacturers to produce a quality product on a consistent basis. When the required systems work successfully, they provide protection for both the buyer and supplier. There are generally three steps in the pre-qualification process: (1) Selection Criteria; (2) Site Evaluation; (3) Product Evaluation. Manufacturers conforming to the requirements of all three steps shall be placed on USAID's Approved Supplier List.			
<b>5.2</b>	<b>Selection Criteria-General requirements</b>			
5.2.1	To be considered a potential supplier of pharmaceutical drug products to USAID, manufacturers must meet the listed requirements. This information will be compiled through information provided by donor organizations, field consultants, and other CAs. Suppliers meeting all requirements will qualify for possible site evaluations. The requirements are listed in APPENDIX A: Additional information may also be requested i.e.;			
	1.	Stated interest in supplying drug products to USAID programs.		
	2.	Minimum annual production capacity		
	3.	Credible references of production capability/quality (i.e.: other donors)		
	4.	Properly capitalized and financially stable		
	<b>This section of the pre-qualification is waived for procuring Coartem®</b>			
<b>5.3</b>	<b>Manufacturing Site Evaluation-General requirements</b>			
5.3.1	Manufacturers will be evaluated for the following: See APPENDIX A			
	1.	Management & Technical Expertise – Credentials		
	2.	Production Capability		
	3.	Adequacy of Quality Control Systems		
	4.	Suitability of the Product Stability Program		
	5.	Compliance with Regulatory Bodies		
	6.	Materials Control and Storage		
	7.	cGMP compliance		
	<b>This section of the pre-qualification is waived for procuring Coartem®. Novartis (New York-site) is an FDA approved facility.</b>			

<b>5.4</b>	<b>Product Evaluation-General requirements</b>
5.4.1	<p>Three –five representative production lots, manufactured within a 6 month period shall be evaluated for compliance with internationally accepted standard test methods and specifications. If the method is not listed in international publications (USP or BP) then the manufacturer must provide a copy of the test method to the independent laboratory conducting the pre-qualification testing.</p> <p><b>Note: The United States Pharmacopeia is currently reviewing a draft test method for publication. The test method under review is for the purpose of USAID and the QA partners and is confidential and not for distribution. See APPENDIX B.</b></p> <p><b>Pre-qualification testing of Coartem is waived.</b></p>
5.4.2	<p>The production lots shall be randomly selected by an independent body and submitted to FHI or other designated laboratory for evaluation. – <b>waived.</b></p> <p>An audit testing program consisting of at least 10% of the manufactured lots will be established in the near future to provide independent data analysis.</p>
5.4.3	<p>The manufacturer must provide its internal test results for the prescribed tests for comparison purposes. – <b>waived.</b></p> <p><i>The manufacturer must provide a certificate of analysis for each batch of Coartem® to JSI and FHI.</i></p>
5.4.4	<p>The manufacturer must provide copies of its stability test records substantiating its claimed expiration date. – <b>waived.</b></p> <p>In the near future, an audit activity will be to review the stability profile of the drug. Understanding the vulnerabilities of the drug and container/packaging is critical to responding to any field questions and post market surveillance testing.</p>
5.4.5	<p>Samples may also be subjected to extended periods of oven conditioning to verify manufacturer’s stability records. – <b>waived.</b></p> <p>In the future, an independent stability study may be conducted.</p>
<b>5.5</b>	<b>Manufacturing site visits and audits</b>
5.5.1	<p>For the Emergency strategy, the site visit is <b>waived</b> based on the history of Novartis. However, in the event that quality problems are encountered early in the procurement process, a site visit including audit may be conducted.</p>
5.5.2	<p>Following this interim (Emergency) procurement period, a site visit and audit of the manufacturer will be conducted by the QA-team on an as needed basis and after sufficient data has been collected and reviewed.</p>

<b>5.6</b>	<b>Production Surveillance Testing-General requirements</b>
5.6.1	The routine testing of lots (pre-shipment testing) by an independent laboratory is not recommended based on the history of this manufacturer – <b>waived</b> . In the future, as part of a production surveillance independent audit review, a minimum of 10% of the lots may be analyzed.
<b>5.7</b>	<b>Post Market Surveillance- General requirements</b>
5.7.1	For this interim period, no post market surveillance testing will be performed. However, in the case of any field complaints or negative feedback from country programs, the post market surveillance for Coartem® will follow <i>TO3-QA-ACTs-Conducting Post Market Surveillance</i>
<b>5.8</b>	<b>Monitoring supplier performance-General requirements</b>
5.8.1	A supplier performance report card will be generated based on independent test data, audit findings, stability and post market surveillance information and delivery schedules. Because of the special circumstances involved in the Emergency procurement period, a limited report card may be developed.
<b>5.9</b>	<b>Feedback</b>
5.9.1	Any country feedback, positive or negative, regarding any aspect of the procurement and product quality will be monitored and communicated to USAID. A continuous process improvement model will be used.

## 6.0 DOCUMENT HISTORY:

Date Issued	History	Previous issue date	Reason for change
9/28/07	00	N/A	New Issue.
10/18/07	Obsolete	9/28/07	This was an interim document and is now obsolete

## **APPENDIX A**

### **Pre-Qualification- Desk Audit**

Suppliers are required to provide documentation of their manufacturing capabilities, technical and specifications standards of the processes used to manufacture the medical device or pharmaceutical being audited. If any process or service directly related to the manufacturing of the product(s) is subcontracted, a separate documentation packet must be submitted for the subcontractor. Documents in languages other than English must include a translation and should be submitted in addition with the original non-translated document. Below is a list of documents requested for Pre-Qualification;

- Certified copy of current license in country where primary manufacturing is conducted.
- A copy of Drug Master File(DMF) **or** a brief description of the chemical / physical preparation of the product along with test methods and limits for precursors, side and degradation products for the product(s) being subject to this questionnaire
- Certified Letter of Authority indicating company contacts for Management, Quality Control, Quality Assurance and Production.
- Manufacturer's Quality Manual and Standard Operational Procedures in Microsoft-Word compatible CD form
- Certification that the commodities are manufactured according to EN, ISO, WHO, GMP, FDA standards, whichever applies.
- Any laboratory certification that contains the scope of tests directly related to the manufacturing of medical devices or pharmaceutical products of interest on this audit.
- Copies of company's environmental policy and any citations, infractions, fines, or legal actions the company has been involved in as a result of violations.

**Pharmaceutical and Medical Supplier Questionnaire**

Date \_\_\_\_\_ Product(s) \_\_\_\_\_

---

**1. General Information:**

Pharmaceutical or Medical Product Supplier Name: \_\_\_\_\_

Parent Company (Full Legal Name) : \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Telephone #: \_\_\_\_\_ Fax #: \_\_\_\_\_ e-mail: \_\_\_\_\_

Management Contact Name, Tel # and e-mail: \_\_\_\_\_

---

Quality Control Contact Name, Tel. and e-mail: \_\_\_\_\_

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Quality Assurance Contact Name, Tel. and e-mail: \_\_\_\_\_

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Production Contact Name, Tel. and e-mail: \_\_\_\_\_

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**2. Organization and Personnel**

2.1 Attach Organizational Chart

2.2 Number of employees:

Total:	_____
Production Dept. only	_____
QC Dept. only	_____
QA Dept. only	_____
Sales/Marketing Dept. only	_____

2.3 Employee training file:

Is there documentation of personnel training and education Yes  No

Frequency of training;	SOPs	_____
	GMP	_____
	Safety	_____
	GLP	_____

List any special training for QC and QA personnel; \_\_\_\_\_

**3. Quality Control/Quality Assurance**

3.1 Is your company certified to any of the following? check box for all applicable and write certificate number;

- DIN EN ISO Certificate No.: \_\_\_\_\_
- DIN ISO 14000 or latest version Certificate No.: \_\_\_\_\_
- GMP Certificate No.: \_\_\_\_\_
- Other Certificate No.: \_\_\_\_\_

3.2 Does your company hold a Manufacturing Authorization according to the drug law of your country?

Yes  Issuing Authority: \_\_\_\_\_ No   
 Date of issue: \_\_\_\_\_

If Yes: List product groups for which Manufacturing Authorization has been issued:

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

3.3 Has your company been inspected by the FDA?

Yes  date of last inspection: \_\_\_\_\_ No

Were any warnings issued? If so, what were the corrective actions and has the issue been cleared?

Please provide inspection report.

3.4 Are your manufacturing facilities subject to any other type(s) of inspection?

Yes  No

If yes, please state type of inspection and inspection level.

Area Inspected	Product	Authority	Date

3.5 Does your facility have a formal system by which engineering changes are evaluated for process, product, regulatory, and environmental impact prior to implementation? Yes  No   
 Briefly describe system, include approval responsibilities.

3.6 Does your company have a Quality Control laboratory on site Yes  No   
 Is it accredited? Yes  No ,  
 If yes, by whom \_\_\_\_\_  
 Is any quality control testing subcontracted? Yes  No   
 If yes, write their names, accreditation credentials and accredited scope \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

3.7 Is microbiological monitoring performed on a regular basis for:

- |                                       |  |
|---------------------------------------|--|
| Raw materials                         | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Product                               | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Air, floor, walls, machines/equipment | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Water                                 | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Personnel                             | Yes <input type="checkbox"/> No <input type="checkbox"/> |

Please provide records for review

3.8 Does your company perform internal audits on a regular basis? Yes  No   
 Are these audits recorded? Yes  No   
 Are corrective and preventive actions addressed and recorded? Yes  No   
 Are there any reoccurring problems Yes  No , if yes describe

3.9 a) Do you have a DMF for the API of interest? Yes  No   
 b) What is that DMF #? or #'s? \_\_\_\_\_

c) Has the FDA or appropriate agency reviewed this DMF? Yes  No   
 d) What is the notification process for DMF changes?

e) Are customers notified of changes to the DMF?

3.10 Is there a formal procedure for qualifying and monitoring subcontractors? Yes  No ,  
 If so what services are subcontracted

3.11 Does your facility have procedures to protect the integrity, confidentiality and safety of records? Yes  No ,  
 If yes, briefly describe

3.12 Do you prepare Annual Quality Review Reports for each API? Yes  No

3.13 Briefly describe document control system (SOP, batch records, specifications, methods) in terms of hierarchy, revisions, approval authority and control.

- 3.14 Describe formal investigation procedures for non-conforming lots or discrepancies occurring during all stages of manufacturing. Please provide examples of investigations.
- 

#### 4. Receiving Control

- 4.1 Are quarantined raw materials and rejected raw materials clearly identified, segregated and documented?  
Yes  No ,  
if yes describe how this  
is accomplished
- 4.2 a) Are conditions for raw materials storage areas controlled and monitored? Yes  No   
b) Are these systems alarmed? Yes  No   
c) Do you use the same warehouse for the storage of incoming components and final APIs?  
Yes  No
- 4.3 Do you have written internal specifications or acceptance criteria for each lot of raw material and/or packaging component received? Yes  No
- 4.4 a) Is a supplier Certificate of Analysis(COA) required for each lot of raw material and/or packaging component received? Yes  No   
b) Is an identity test performed on each lot? Yes  No
- 4.5 Is each lot of raw materials assigned a unique lot number on receipt even if the vendor batch number is the same? Yes  No   
Explain lot numbering system.

---

#### 5. Manufacturing Facility

- 5.1 Are there adequate and up-to-date facility drawings for critical systems such as

- HVAC , water purification systems, etc. available for the facility? Yes  No
- 5.2 a) Is there a system to identify each major piece of equipment? Yes  No   
Describe the system
- b) Are qualification, maintenance and calibration records maintained for each piece of equipment? Yes  No
- c) Describe preventative maintenance at the facility.
- 5.3 Does the facility have adequate lighting, ventilation, dust control, vector control, and proper physical barriers to prevent cross contamination? Yes  No
- 5.4 Is a Certificate of Suitability available for inspection? Yes  No   
Please provide for review
- 5.5 Are API synthesis operations performed in a segregated closed area with its own air handling system? Yes  No
- 5.6 Do you have a documented validation program for manufacturing processes? Yes  No   
If so, describe the key components of this program.  
Please provide documentation examples of validation program.
- 5.7 a) What grade of water is used during synthesis or formulation of APIs?
- b) Are there maintenance records for water purification equipment? Yes  No   
Provide example of records.
- c) What is the overall testing protocol, including parameters and frequency of testing? Please provide sample of reports.
- d) Are all points of use and sampling clearly identified? Yes  No
- 5.8 Is any raw material reused? Yes  No ,  
If so, what quality controls are in place to assure quality?
- 5.9 Is manufacturing facility dedicated exclusively to the product(s) being subject to this questionnaire? Yes  No ,  
If no, list other products and describe what measures are in place for preventing cross-contamination in terms of mixing ingredients, records and labels.

- 5.10 Have support systems (e.g. vacuum, air, water, steam) been validated? Yes  No
- 5.11 a) Are time, temperature and pressure-monitored processes documented and retained with batch records?  
Yes  No
- 5.12 Are there positive pressure differentials with all doors leading into less clean areas? Yes  No
- 5.13 Do pipes indicate contents and direction of flow? Yes  No
- 5.14 Are records maintained for tracing use of raw materials, intermediates and finished APIs?  
Yes  No
- 5.15 Is product(s) being subject to this questionnaire re-packed or re-labeled after it leaves manufacturer?  
Yes  No
- 5.16 Is there a formal stability program for key intermediates and API? Yes  No
- 5.17 Is there a procedure for customer notification of manufacturing processes? Yes  No
- 5.18 a) Is there a written procedure for cleaning methods? Yes  No
- b) Was cleaning procedure validated? Yes  No
- c) Are cleaning procedures documented? Yes  No
- d) Are there written cleaning schedules and procedures for the holding tanks, transfer lines and other equipment, which may be in contact with the intermediates and APIs? Yes  No
- Provide documentation for review.
- 5.19 a) Are manufacturing areas for controlled substances clearly defined and limited in access?  
Yes  No
- b) Are limited access areas under surveillance? Yes  No
- 5.20 a) Is there a written procedure to monitor the handling of controlled substances?  
Yes  No
- b) Are non-controlled and controlled drugs stored together? Yes  No
- c) Does your facility have license for handling controlled substances? Yes  No

---

**6. Computer systems**

- 6.1 Have computer systems and programs been validated? Yes  No   
If yes, to what specifications? Please provide documentation
- 6.2 Are computer systems backed up? Yes  No
- 6.3 Are computer systems secured against unauthorized access and changes? Yes  No
- 6.4 Do you use electronic batch records or electronic signatures? Yes  No   
6.5 Please explain how computers are used within QA/QC?
- 

**7. Components, containers and closures**

- 7.1 Are there written specifications for all components and closures for products being subjected to this questionnaire? Yes  No   
Please provide documentation
- 7.2 Is there a written procedure to QC components and closures? Yes  No   
Please provide documentation
- 7.3 Are there written specifications for product packaging procedures? Yes  No
- 7.4 Is container closure information part of DMF, ANDA or NDA? Yes  No   
Please provide documentation
- 

**8. Labeling and Packaging**

- 8.1 Are there written procedures for printing labels, label issuance, label storage, label disposal and product labeling? Yes  No   
Please provide documentation
- 8.2 a) Is there a Master label file for all labels? Yes  No ,  
Please provide documentation  
b) Is there a procedure and follow-up documentation to confirm label compliance? Yes  No
- 8.3 a) Are cut or roll labels used? Yes  No   
b) Is 'gang-printing' permitted? Yes  No
- 8.4 Is an area clearance performed between production lots? Yes  No
- 8.5 Is accountability and variance verified? Yes  No   
Describe this procedure.

- 8.6 If additional processing is performed, how is it identified on the label?
- 8.7 Are there written procedures that detail packaging specifications?  
Please provide documentation Yes  No
- 8.8 Is there a Master packaging list?  
Please provide documentation Yes  No ,
- 8.9 Are package lines validated? Yes  No
- 

**9.0 Complaints**

- 9.1 Write name of person(s) or department responsible for investigating and documenting complaints.  
\_\_\_\_\_
- 9.2 Is there a written procedure for investigating complaints? Yes  No
- 9.3 Are complaints analyzed for trends and CAPA implemented?  
Please provide documentation. Yes  No
- 9.4 What type of re-occurring complaints have you experienced?
- 

**10. Returned product**

- 10.1 Is there a procedure for customer returned products?  
Briefly explain or provide documentation Yes  No
- 

**11. Final Acceptance**

- 11.1 a) Are all final APIs tested and released prior to shipment? Yes  No   
b) Who releases the final API?
- 11.2 a) Are retain samples maintained for each lot of product shipped? Yes  No   
b) How long are they retained for?  
c) How frequent are these retains tested?  
Please provide documentation of retain testing
- 11.3 Provide 1 year stability data for product subjected to this questionnaire
- 11.3 Are accurate distribution of records maintained? Yes  No



## APPENDIX B

### POST MARKET SAMPLE ANALYSIS

#### Lumefantrine and Artemether Tablets United States Pharmacopoeia – CONFIDENTIAL

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##### Introduction

This document provides specifications for the following tests for assessing the quality of lumefantrine and artemether tablets for the USAID/Deliver Project.

- Visual examination
- Identification
- Dissolution
- Related compounds (impurities)
- Assay

##### Reference standards

Some of the tests call for the use of reference standards. The specified reference standards would be available from The United States Pharmacopoeia at a future date.

##### Reagents

Unless otherwise specified, use the reagent grade specified under *Reagents* section of the current volume of the *United States Pharmacopoeia*.

##### Chromatographic techniques and Dissolution testing

If needed, additional helpful information regarding the chromatographic techniques used in this document and dissolution testing can be found in the United States Pharmacopoeia General Chapters *Chromatography* <621> and *Dissolution* <711>, respectively.

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#### 1. Visual Examination

The following list of questions is provided as an aid for visual examination of Lumefantrine and Artemether tablets for signs of mislabeling, improper storage, moisture exposure, deterioration, counterfeit, or adulteration. The list is not exhaustive and other visual inspections may be added as needed.

Examine the product and write down a response (*Yes* or *No*) to each question. Add a comment to the response, if necessary. A “*No*” response to any of the questions may require further investigation and confirmation.

##### A. Packaging

- a. Does the packaging and closure protect the drug from outside environment including light? Is it well closed/sealed?

##### B. Label

- a. If packaged in a carton, does the labeling information on the carton match the labeling information on the container?
- b. Is the trade name spelled correctly and does the symbol ® follow the trade name?
- c. Are the active ingredient name(s) provided and spelled correctly? Does it correspond to the registered drug?
- d. Is the manufacturer’s name and logo legible and correct?
- e. Is the manufacturer’s full address legible and correct?
- f. Is the strength (active ingredient(s) per unit clearly stated on the label?

- g. Is the dosage form clearly indicated?
- h. Is the number of units per container clearly indicated? Does it match what is stated on the container?
- i. Is the batch (or lot) number clearly provided?
- j. Are the manufacture and expiry dates indicated on the label? Is the drug within the shelf life (not expired)?
- k. Are the storage conditions indicated on the label? Has the drug been properly stored?
- l. Is a package insert provided?

C. Tablet appearance.

Visually examine a minimum of 20 tablets and answer the following questions.

- a. Are the tablets uniform in:
  - i. shape
  - ii. Size and
  - iii. Color?
- b. Are the tablets free of powder and non-sticking?
- c. Are the markings (scoring, imprints, etc) uniform and identical?
- d. Are the tablets free of breaks, cracks, splits, or pinholes?
- e. Are the tablets free of embedded surface spots and foreign particles?

[NOTE: Coartem® Tablets are yellow, round, flat with beveled edges, scored on one side, and have the following imprint: first side: N/C, second side: CG].

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## 2. Identification

### A. Thin-Layer Chromatographic (TLC) Identification

*TLC plate:* Silica gel 60, F254, precoated 20 x 20 cm plate, or equivalent.

*Diluent:* Prepare a mixture of chloroform, methanol, ethyl acetate, and water (11:10:2:2, v/v).

*Artemether standard solution*—Dissolve an accurately weighed quantity of Artemether Reference Standard in *Diluent* to obtain a solution having a known concentration of about 0.8 mg per mL.

*Lumefantrine standard solution*— Dissolve an accurately weighed quantity of Lumefantrine Reference Standard in *Diluent* to obtain a solution having a known concentration of about 4.8 mg per mL.

*Test solution*—Transfer a portion of powdered Tablets equivalent to 20 mg of artemether and 120 mg of lumefantrine to a suitable vessel. Add 2 mL of water, 2 mL of ethyl acetate, 10 mL of methanol, and 11 mL of chloroform. Sonicate for 15 minutes, centrifuge at 4000 rpm, and use the clear supernatant.

*Developing solvent system*—Prepare a mixture of petroleum benzin (petroleum ether, boiling range 40 – 60°C); ethyl acetate; and glacial acetic acid (20:5:2.5, v/v).

*Procedure*—Allow the developing chamber lined with paper to equilibrate for 15 minutes. Separately apply 20 µL each of *Artemether standard solution*, *Lumefantrine standard solution*, and *Test solution* on the *TLC plate*, and allow to dry in a stream of cold air for 10 minutes. Allow the plate to develop in the chamber until the solvent front has moved about 12 cm. Remove the plate and dry it in a stream of warm air for about 10 minutes. Spray the plate with a solution containing 20% sulfuric acid in methanol and place the plate in oven at 140°C for about 10 minutes. Evaluate the spots under daylight and under UV light at 366 nm. The artemether appears as a grayish-purple spot on a white background under daylight and as a light yellow fluorescent spot on a blue background under UV light at 366 nm. The lumefantrine appears as a grayish-yellow spot on a white background under daylight and as dark spot on a blue fluorescent background under UV light at 366 nm. The *R<sub>f</sub>* values and appearances of artemether and lumefantrine spots obtained from the *Test solution* correspond to those exhibited by the corresponding standard solutions. [NOTE: *R<sub>f</sub>* is the ratio of the distance from the origin to the center of a spot divided by the distance from the origin to the solvent front].

## B. HPLC Identification

The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

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### 3. Dissolution<sup>1</sup>

#### DISSOLUTION OF ARTEMETHER

Medium: Deionized water, partially degassed (approximate oxygen level: 6.5 – 7mg per L)

Medium volume: 1000 mL

USP Apparatus 2 (Paddle): 100 rpm

Temperature: 37 ± 0.5°C

Sampling times: 1 hour and 3 hours

1 Refer to United States Pharmacopeia General Chapter Dissolution <711> for number of units tested at the S1, S2, or S3 stages.

Determine the amount of artemether dissolved by employing the following HPLC procedure.

[NOTE: Use HPLC grade reagents only.]

*Mobile phase*—Prepare degassed mixture of acetonitrile, water, 1-propanol, trifluoroacetic acid (500:400:100:1). Make adjustments if necessary.

*Diluent*—Prepare a mixture of acetonitrile and water (1:1).

*Standard solution*—Dissolve an accurately weighed quantity of Artemether Reference Standard in *Diluent* to obtain a solution having a known concentration of about 0.2 mg per mL. Dilute 10 mL of this solution with *Medium* to 100 mL.

*Test solution*—At the specified sampling times, withdraw about 10 mL of the dissolution sample and allow the suspended particles to settle for about 3 minutes. Pass the sample through a suitable filter<sup>2</sup>.

*Chromatographic system*—The liquid chromatograph is equipped with a 210-nm detector and a suitable 4-mm x 12.5-cm column<sup>3</sup> that contains 5-µm packing L1 (octadecyl silane chemically bonded to porous silica). The flow rate is about 1.0 mL per minute. Chromatograph the *Standard solution* and record the peak responses as directed under *Procedure*. The relative standard deviation for replicate injections is not more than 2.5%. [NOTE—Adjustment of chromatographic conditions to meet the system suitability requirement may be necessary.]

*Procedures*—Separately inject equal volumes (about 100 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses for artemether. Calculate the amount of artemether (C<sub>16</sub>H<sub>28</sub>O<sub>5</sub>) released, as percentage of the labeled content using the formula:  $100 \times 1000 \times (CS/L)(rU/rS)$  in which 100 is the conversion factor to percentage; 1000 is the volume of the of the *Medium*, in mL; *CS* is the concentration, in mg per mL, of artemether in the *Standard solution*; *L* is the tablet label claim for artemether, in mg; and *rU* and *rS* are the peak responses for artemether obtained from the *Test solution* and *Standard solution*, respectively.

*Tolerances*—Not less than 40% (Q) of the labeled content of artemether is dissolved in 1 hour.

Not less than 60% (Q) of the labeled content of artemether is dissolved in 3 hours.

<sup>2</sup> A suitable filter is GF Acrodisk- glass fiber filter.

<sup>3</sup> A suitable column is Nucleosil 100-5 C<sub>18</sub> from Macherey-Nagel.

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#### DISSOLUTION OF LUMEFANTRINE

Medium: 0.1 M hydrochloric acid containing 1% benzalkonium chloride

Medium volume: 1000 mL  
USP Apparatus 2 (Paddle): 100 rpm  
Temperature:  $37 \pm 0.5$ °C  
Time: 45 minutes

Determine the amount of lumefantrine dissolved by employing the following procedure.

*Standard solution*—Dissolve an accurately weighed quantity of Lumefantrine Reference Standard in *Medium* and dilute quantitatively, if necessary, with *Medium* to obtain a solution having a known concentration of about 0.72 mg per mL.

*Test solution*—At the specified time, withdraw about 10 mL of the dissolution sample and allow the suspended particles to settle for about 3 minutes. Pass the sample through a suitable 0.5- $\mu$ m membrane filter.

*Procedure*—Determine the amount of C<sub>30</sub>H<sub>32</sub>Cl<sub>3</sub>NO dissolved from UV absorption at the wavelength of maximum absorbance at about 342 nm on portions of the *Test solution*, suitably diluted with *Medium*, in comparison with the *Standard solution*, using a 0.2-cm cell. Calculate the amount of lumefantrine (C<sub>30</sub>H<sub>32</sub>Cl<sub>3</sub>NO) released, as percentage of the labeled content using the formula:  $100 \times 1000 \times (AU / AS)(CS / L)$  in which 100 is the conversion factor to percentage; 1000 is the volume of the *Medium*, in mL; *AU* and *AS* are the absorbances of the *Test solution* and *Standard solution*, respectively; *CS* is the concentration, in mg per mL, of lumefantrine in the *Standard solution*; *L* is the tablet label claim for lumefantrine.

*Tolerances*—Not less than 60% (Q) of the labeled amount of lumefantrine is dissolved in 45 minutes.

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#### 4. Related compounds

##### TEST FOR ARTEMETHER RELATED COMPOUNDS

*TLC plate*: Silica gel 60 G, F254, precoated 20 x 20 cm plate, or equivalent.

*Diluent*: Prepare a mixture of acetonitrile and water (1:1).

*Standard stock solution*—Dissolve accurately weighed quantities of Artemether Reference Standard, Artemether Related Compound A Reference Standard (dihydroartemisinin), and Lumefantrine and Artemether Tablets

Artemether Related Compound B Reference Standard ( $\alpha$ -artemether) in *Diluent* to obtain a solution having a known concentration of about 0.1 mg per mL of each standard.

*Standard solutions*—Dilute an aliquot of *Standard stock solution* to obtain five Standard solutions having the following concentrations: 0.005 mg of each standard per mL, 0.015 mg of each standard per mL, 0.025 mg of each standard per mL, 0.050 mg of each standard per mL, and 0.075 mg of each standard per mL. These solutions correspond to 0.1%, 0.3%, 0.5%, 1%, and 1.5% respectively, of the content of artemether in the *Test solution*, based on the label claim.

*Test solution*—Allow a number of Tablets equivalent to 60 mg of artemether to disintegrate in 6 mL of water. Add 6 mL of acetonitrile, sonicate for 15 minutes, and centrifuge at 4000 rpm. Pass through a suitable 0.5- $\mu$ m membrane filter<sup>4</sup>.

*Developing solvent system*—Prepare a mixture of petroleum benzin (petroleum ether, boiling range 40 – 60°C); ethyl acetate; and glacial acetic acid (20:5:2.5).

*Procedure*—Allow the developing chamber lined with paper to equilibrate for 15 minutes. Separately apply 20  $\mu$ L of each *Standard solution* and also *Test solution* on the *Thin-layer chromatographic plate*, and allow the spots to dry in a stream of air at ambient temperature for about 15 minutes. Protect the chamber from light and allow the plate to develop in the chamber until the solvent front has moved about 12 cm. Remove the plate and dry it in a stream of air at ambient temperature for about 15 minutes. Expose the plate to UV light at 254 nm for 60

minutes. Spray the plate with a solution containing 20% sulfuric acid in methanol, place in oven at 140°C for about 10 minutes, and examine the plate under daylight. Estimate the percentages of related compound A (dihydroartemisinin) and related compound B ( $\alpha$ -artemether) the observed in the chromatogram obtained from the *Test solution* by comparing each spot with the corresponding spots obtained from the chromatograms of the *Standard solutions*. Estimate the percentages of all other impurities observed in the chromatogram obtained from the *Test solution* by comparing each spot with the spots corresponding to artemether in chromatograms of the *Standard solutions*. The approximate *R<sub>f</sub>* values and limits of impurities are given in *Table 1*.

4 Note—One suitable filter is Miller-LCR 0.5 $\mu$ m, available from Millipore

Table 1.

Compound	Approximate <i>R<sub>f</sub></i>	Limit (%)
Impurity 1a	0.25	1.5
Dihydroartemisinin b (related compound A)	0.3	1.0
Impurity 2c	0.35	0.5
$\alpha$ -Artemetherd (related compound B)	0.4	0.3
Artemether	0.55	—
Individual unspecified impurity	—	0.2
Total unspecified impurities	—	0.5

a 2-(4-Methyl-2-oxo-3-(3-oxobutyl)cyclohexyl) propanal

b (3 R,5a S,6 R,8a S,10 S,12 R,12a R)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12-epoxy-12 H-pyrano[4.3- j]-1,2-benzodioxepin.

c (3aS,4R,6aS,7R,8S,10S)-8-Methoxy-4,7-dimethyldecahydrofuro[3,2-*i*]isochromen-10-ylacetate

d (3 R,5a S,6 R,8a S,10 S,12 R,12a R)-Decahydro-10-methoxy-3,6,9-trimethyl-

3,12-epoxy-12 H-pyrano[4.3- j]-1,2-benzodioxepin.

#### TEST FOR LUMEFANTRINE RELATED COMPOUNDS

[NOTE: Use HPLC grade reagents only.]

*Ion-pairing solution* and *Diluent*—Proceed as directed in the *Assay*.

*Solution A*—Prepare a mixture of water, acetonitrile, *Ion-pairing solution*, and 1-propanol (50:25:20:5).

*Solution B*—Prepare a mixture of acetonitrile, *Ion-pairing solution*, water, and 1-propanol (65:20:10:5).

*Mobile phase*—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary.

*System suitability solution*—Dissolve an accurately weighed quantity of Lumefantrine Reference Standard and Lumefantrine Related compound A Reference Standard in *Diluent* to obtain a solution having a known concentration of about 1.2 mg per mL and 0.02 mg per mL, respectively.

*Test solution*— Allow a number of Tablets equivalent to 1200 mg of lumefantrine to disintegrate in 60 mL of water. Add 200 mL of 1-propanol, and sonicate for about 15 minutes. Add 200 mL of *Ion-pairing solution*, 400 mL of acetonitrile, sonicate again for 30 minutes, and dilute with acetonitrile to 1000 mL. Withdraw about 10 mL of the suspension, centrifuge for about 5 minutes at about 4000 rpm, and use the clear supernatant.

*Chromatographic system*—The liquid chromatograph is equipped with a 300-nm UV detector and a suitable 4.0-mm  $\times$  12.5-cm column<sup>5</sup> that contains 5- $\mu$ m packing L1 (octadecyl silane chemically bonded to porous silica). The flow rate is about 2.0 mL per minute. The chromatograph is programmed as shown in *Table 2*.

Table 2.

Time (minutes)	<i>Solution A</i>	<i>Solution B</i>
0	25	75
14	25	75
19	0	100
25	0	100
26	25	75
35	25	75

Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution, *R*, between lumefantrine and lumefantrine related compound A is not less than 0.5; the tailing factor is between 0.8 and 5.0; and the relative standard deviation for replicate injections is not more than 2.0% for the lumefantrine peak. [NOTE—Adjustments of chromatographic conditions to meet the system suitability requirements may be necessary.]

*Procedure*—Inject about 5 µL of the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Tablets taken by the formula:  $100 \times (ri / rS)$  in which 100 is the percentage conversion factor; *ri* is the peak response for any individual impurity obtained from the *Test solution*; and *rS* is the sum of the responses from all of the peaks. Disregard any peak less than 0.05%. The limits are as shown in *Table 3*.

Table 3.

Compound	Relative Retention time	Limit (%)
Lumefantrine Related compound Aa	0.9	0.1
Lumefantrine	1.0	—
Any individual unspecified impurity	—	0.1
Total impurities	—	0.3

a (*RS, Z*)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)ethanol  
 5 A suitable column is Nucleosil C18, 5 µm.

## 5. Assay

[NOTE: Use HPLC grade solvents only.]

*Ion-pairing solution*—Prepare a mixture of 5.65 g of sodium 1-hexanesulfonate and 2.75 g of monobasic sodium phosphate in 800 mL of water. Adjust the pH to 2.3 using phosphoric acid, dilute with water to 1000.0 mL, and filter.

*Diluent*—Prepare a mixture of 100 mL of *Ion-pairing solution*, 100 mL of 1-propanol, and 30 mL of water, and dilute with acetonitrile to 500.0 mL.

*Solution A*—Prepare a mixture of *Ion-pairing solution* and acetonitrile (7: 3).

*Solution B*—Prepare a mixture of acetonitrile and *Ion-pairing solution* (7: 3).

*Mobile phase*—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary.

*Standard preparation*—Dissolve accurately weighed quantities of Artemether Reference Standard and Lumefantrine Reference Standard in *Diluent* to obtain a solution having known concentrations of about 0.2 mg per mL and 1.2 mg per mL, respectively.

*Assay preparation*—Allow a number of Artemether and Lumefantrine Tablets equivalent to 200 mg artemether and 1200 mg of lumefantrine to disintegrate in 60 mL of water. Add 200 mL of 1-propanol, and sonicate for about 15 minutes. Add 200 mL of *Ion-pairing solution* and 400 mL of acetonitrile, sonicate again for 30 minutes, and dilute with acetonitrile to 1000 mL. Withdraw about 10 mL of the suspension, centrifuge for about 5 minutes at about 4000 rpm, and use the clear supernatant.

*Chromatographic system*—The liquid chromatograph is equipped with either a programmable variable UV wavelength detector or two separate UV detectors capable of monitoring at 210 nm and 380 nm and with a suitable 3.9-mm × 15-cm column<sup>6</sup> that contains 5-μm packing L1 (octadecyl silane chemically bonded to porous silica). [NOTE—Set the detector for the first 30 minutes to 210 nm, then switch to 380 nm.] The flow rate is about 1.3 mL per minute. The chromatograph is programmed as shown in *Table 4*.

Table 4.

Time (minutes)	<i>Solution A</i>	<i>Solution B</i>
0	60	40
28	60	40
29	0	100
45	0	100
46	60	40
55	60	40

<sup>6</sup>One suitable column is Symmetry C<sub>18</sub>, 5 μm available from Waters.

Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the tailing factor is not less than 0.8 and not more than 4.5; and the relative standard deviation for replicate injections is not more than 2.0% for each peak. [NOTE—Adjustment of chromatographic conditions to meet the system suitability requirements may be necessary.]

*Procedure*—Separately inject equal volumes (about 20 μL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the artemether and lumefantrine peaks. Calculate the amounts of lumefantrine (C<sub>30</sub>H<sub>32</sub>Cl<sub>3</sub>NO) and artemether (C<sub>16</sub>H<sub>26</sub>O<sub>5</sub>), each as a percentage of the label claim, in the portion of Tablets taken by the formula:  $100 \times (CS/CU)(rU / rS)$  in which 100 is the percentage conversion factor; *CS* and *CU* are the concentrations, in mg per mL, of either artemether or lumefantrine, as appropriate, in the *Standard preparation* and the *Assay preparation*, respectively; and *rU* and *rS* are the peak responses of the corresponding analyte peaks obtained from the *Assay preparation* and the *Standard preparation*, respectively.

**The Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of lumefantrine (C<sub>30</sub>H<sub>32</sub>Cl<sub>3</sub>NO) and artemether (C<sub>16</sub>H<sub>26</sub>O<sub>5</sub>).**



**Task Order 3- MALARIA**

**Quality Assurance Procedures**

<b>TITLE:</b> QA Drug Testing for Pharmaceutical drug products obtained from other Agencies		<b>DOCUMENT No.:</b> TO3-QA- Pharm-40
<b>DATE ISSUED:</b> 10/18/07	<b>SUPERSEDES:</b> New	<b>Revision:</b> 00
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH / FHI / USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

**1.0 PURPOSE:**

<b>1.1</b>	The purpose of this procedure is to establish a process to test and accept drugs provided by Global Agencies.
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**2.0 BACKGROUND:**

<b>2.1</b>	In order to meet Emergency needs of vital anti-malaria drugs in developing countries, agencies such as MissionPharma, IDA, and UNICEF are able to assist the USAID   DELIVER Project- TO3 Malaria program with drugs from their existing inventories. A quality assurance plan to obtain these drugs through this process is required to ensure that the agencies supply of drugs meet established standard requirements.
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**3.0 REFERENCE DOCUMENTS:**

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>Sampling, Inspection, Testing of Pharmaceutical drugs Pre-shipment (TO3-QA-Pharm-32)</i>
	3.	<i>Sampling, Inspection and Testing of Pharmaceutical drugs – Post Shipment (TO3-QA-Pharm-33)</i>
	4.	<i>Post Market Surveillance (TO3-QA-Pharm-34)</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - Quality assurance partners under USAID   DELIVER – TO3 Malaria</b>	
4.1.1	These include;	
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>
	1. John Snow Inc.	Procurement
	2. PATH	Procurement
	3. Crown Agents	Procurement
	4. Family Health International	QA-Oversight, Audits, Supplier monitoring
	5. United States Pharmacopeia	Drug testing, Audits, Post market Surveillance

**5.0 PROCEDURE:**

<b>5.2</b>	<b>Review of Agency Procedures</b>										
5.2.1	Acceptance testing procedures, material specifications, and other documents are obtained from the agency potentially supplying the drug.										
5.2.2	Documents are reviewed for; <table border="1" data-bbox="467 533 1312 699"> <tr> <td>1.</td> <td>Supplier Certification Information</td> </tr> <tr> <td>2.</td> <td>Certificate of Analysis</td> </tr> <tr> <td>3.</td> <td>Material Specifications match those in current USP-NF or other monograph</td> </tr> <tr> <td>4.</td> <td>Storage conditions</td> </tr> <tr> <td>5.</td> <td>Product has not passed expiration date</td> </tr> </table>	1.	Supplier Certification Information	2.	Certificate of Analysis	3.	Material Specifications match those in current USP-NF or other monograph	4.	Storage conditions	5.	Product has not passed expiration date
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4.	Storage conditions										
5.	Product has not passed expiration date										
<b>5.3</b>	<b>Pre-Shipment Sampling and Testing</b>										
5.3.1	A 100% Pre-shipment sampling and testing plan will be used when obtaining drugs from other agencies. Obtaining drug products from other organizations will follow the same process as outlined in <i>TO3-QA-Pharm-32-Sampling, and Testing of Pharmaceutical Drugs at Pre-Shipment.</i>										
<b>5.4</b>	<b>Post-Shipment Sampling/Testing</b>										
5.4.1	Any post-shipment sampling and testing will follow <i>TO3-QA-Pharm-33 Sampling and Testing of Pharmaceutical drugs at Post-Shipment.</i>  The acceptable pre-shipment test results may allow for the concurrent testing at post-shipment. Wherever possible, an identification test is required upon arrival in-country and prior to drug distribution. The identification test upon arrival, provides evidence that counterfeit product has not infiltrated the consignment.										
<b>5.5</b>	<b>Post Market Surveillance</b>										
5.5.1	Any post –market surveillance activities will follow TO3-QA-Pharm-34..										

**6.0 DOCUMENT HISTORY:**

Date Issued	History	Previous issue date	Reason for change
10/18/07	00	N/A	New Issue.



# USAID | DELIVER PROJECT

FROM THE AMERICAN PEOPLE

## Task Order 3- MALARIA

## Quality Assurance Procedures

<b>TITLE:</b> Quality Assurance for AS (Artesunate) + AQ (Amodiaquine HCl) from Missionpharma and Guilin Pharmaceuticals		<b>DOCUMENT No.:</b> TO3-QA- Pharm-41
<b>DATE ISSUED:</b> 10/26/07	<b>SUPERSEDES:</b> 10/18/08 rev01	<b>Revision:</b> 02
<b>WRITTEN BY &amp; DATE:</b> JSI / Crown Agents / PATH /FHI /USP		<b>APPROVED BY &amp; DATE:</b> Steve Hamel-Signature on File

### 1.0 PURPOSE:

<b>1.1</b>	<p>This document intends to communicate the specific quality assurance/quality control (QA/QC) measures employed by John Snow, Inc (JSI) to guarantee the integrity of a one-time, unique procurement of a non-US produced pharmaceutical, sourced from Guilin Pharmaceuticals.</p> <p>Guilin Pharmaceuticals N.24 Shanghai Road Guilin, Guangxi, China +86 773 355 8138</p> <p>While the dire nature of the situation necessitates this atypical expedited procurement, the practices described herein are accepted, validated processes routinely incorporated in QA/QC programs.</p>
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### 2.0 BACKGROUND:

<b>2.1</b>	<p>Liberia is facing pending stock out of its first-line antimalarial, artesunate-amodiaquine (AS+AQ), for which there are too few treatments remaining in their central stores. In order to meet the emergency need for this vital antimalarial in Liberia, JSI will acquire emergency AS+AQ treatments through the Missionpharma organization and Guilin Pharmaceuticals. A quality assurance plan to obtain the drug through this process is required to ensure that the agencies supply of drugs meet established standard requirements, which is described herein.</p>
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### 3.0 REFERENCE DOCUMENTS:

<b>3.1</b>	1.	<i>President's Malaria Initiative: Technical Guidance on the Prevention and Control of Malaria in Africa</i>
	2.	<i>Sampling, Inspection, Testing of Pharmaceutical drugs-Pre-shipment (TO3-QA-Pharm-32)</i>
	3.	<i>Sampling, Inspection and Testing of Pharmaceutical drugs – Post Shipment (TO3-QA-Pharm-33)</i>
	4.	<i>Post Market Surveillance (TO3-QA-Pharm-34)</i>
	5.	<i>ACT Procurement and Distribution Quality Assurance Guidelines for PSI Programs Version 1.06, February 2007</i>
	6.	<i>WHO malaria treatment guidelines</i>

**4.0 RESPONSIBILITIES:**

<b>4.1</b>	<b>Responsibilities - USAID   DELIVER – TO3 Malaria partners</b>	
4.1.1	These include:	
	<b>Quality Assurance Partners</b>	<b>Major Responsibility</b>
	1. John Snow Inc.	Procurement
	2. PATH	Procurement
	3. Crown Agents	Procurement
	4. Family Health International	QA-Oversight, Audits, Supplier monitoring
	5. United States Pharmacopeia	Drug testing, Audits, Post market Surveillance

**5.0 PROCEDURE:**

<b>5.2</b>	<b>Review of Guilin Pharmaceuticals document submission to Missionpharma</b>		
5.2.1	John Snow Inc. will obtain copies of documents submitted by Guilin Pharmaceuticals to Missionpharma. These include certificates of analysis for each of the specific drug lot(s).		
<b>5.3</b>	<b>Pre-Shipment Sampling and Testing</b>		
5.3.2	The Guilin Pharmaceutical product will be sampled by a Crown Agents representative. Crown Agents is a global independent sampling and inspection agency, whose services are routinely employed by JSI and have historically proven to be both technically competent and reliable.		
5.3.3	Crown Agents will sample each AS+AQ lot using the statistical model of “square root (N) + 1.” This sampling procedure is an industry standard model widely accepted by regulatory agencies. Samples are collected at different points: from the beginning, middle, and end portions of each lot. This allows for a representative selection of samples from the entire lot.		
	Example:		
	Number of cases of drug product in inventory per/lot	square root (N) + 1 Random selection of cases	Number of blisters/presentations required for each of the 11 cases to equal 100 tablets

	<table border="1" data-bbox="467 262 1377 342"> <tr> <td data-bbox="467 262 511 294">1.</td> <td data-bbox="511 262 714 294">100</td> <td data-bbox="714 262 966 294">11 cases</td> <td data-bbox="966 262 1377 294">100 tablets (total)</td> </tr> <tr> <td colspan="4" data-bbox="467 294 1377 342"><i>Estimated cost of sampling per lot: \$1,500</i></td> </tr> </table> <p data-bbox="467 380 1414 512">The 100 – 200 tablets/lot are selected and shipped in an appropriate container to the designated testing laboratory. Samples will be shipped to the USP laboratory in the United States, where sample packages must clearly state that "<i>Samples are for analytical testing purposes only. Not for distribution in the US.</i>"</p> <p data-bbox="467 583 976 821">Address:  <u>Primary Drug Testing Laboratory</u>  Attn: Mr.Sanford Bradby  United States Pharmacopeia  Research Analytical Research and Development  12601 Twinbrook Parkway  Rockville, MD 20852-1790  Phone: 301-881-0666 ext:8417</p>	1.	100	11 cases	100 tablets (total)	<i>Estimated cost of sampling per lot: \$1,500</i>			
1.	100	11 cases	100 tablets (total)						
<i>Estimated cost of sampling per lot: \$1,500</i>									
5.3.4	<p data-bbox="467 856 1344 919">The pre-shipment testing plan will use specifications from the International Pharmacopeia for AS samples and from the USP-NF for AQ samples.</p> <table border="1" data-bbox="467 953 1333 1083"> <tr> <td data-bbox="467 953 511 984">1.</td> <td colspan="3" data-bbox="511 953 1333 1083"> <i>Estimated cost of AS and AQ: \$10,966 per lot. Pre-and Post shipment test cost. AS + AQ Presentation requires testing of two drugs</i>   <i>Expected turn-around time for one lot of AS + AQ is 7-10 days</i> </td> </tr> </table>	1.	<i>Estimated cost of AS and AQ: \$10,966 per lot. Pre-and Post shipment test cost. AS + AQ Presentation requires testing of two drugs</i>  <i>Expected turn-around time for one lot of AS + AQ is 7-10 days</i>						
1.	<i>Estimated cost of AS and AQ: \$10,966 per lot. Pre-and Post shipment test cost. AS + AQ Presentation requires testing of two drugs</i>  <i>Expected turn-around time for one lot of AS + AQ is 7-10 days</i>								
5.3.5	<p data-bbox="467 1108 1425 1440">The AS + AQ lot(s) can not ship until pre-shipment testing has been completed by USP. The test report is reviewed by USP and sent to Mr. Steve Hamel at Family Health International (JSI's Quality Assurance Partner). Family Health International has QA oversight responsibilities for TO3-Malaria. Mr. Steve Hamel, Deputy Director of Product Quality and Compliance for Family Health International, is responsible for review and acceptance/rejection of the test results from independent laboratories [Mr. Hamel is the critical contact person for review and acceptance of test results. In his absence, Dr. David Jenkins is the designee]. The test results must meet the requirements stated in the International monograph for AS and the USP-NF for AQ.</p> <p data-bbox="467 1476 797 1602">Address:  Family Health International  2810 Meridian Pkwy. Suite 133  Durham, NC 27713  Ph. 919-544-7040 ext 680</p> <p data-bbox="467 1640 1425 1835">Mr. Hamel will provide an independent review of USP's test results. In addition, USAID's Technical Advisor for TO3-Malaria, Ms. Jennifer Murphy, will conduct a 2<sup>nd</sup> cursory review of the independent testing and the <i>Certificate of Conformance</i> prepared by Family Health International. <i>The Certificate of Conformance</i> establishes a document of approval on behalf of the USAID   DELIVER Project.</p>								

5.3.6	<p>The approved, signed <i>Certificate of Conformance</i> together with USP's test report is submitted to JSI for document submittal to Liberia.</p> <p>National Drug Service of Liberia  Name: Mr. Tom Gulley  Position: Managing Director  Address: National Drug Services, JFK Compound,  UN Drive, Sinkor, Monrovia</p> <p>Telephone: 06523530</p> <p>JSI, USAID, and Family Health International will retain a copy of the <i>Certificate of Conformance</i> and test reports.</p>		
<b>5.4 Post-Shipment Sampling/Testing</b>			
5.4.1	<p>It is critical to ensuring sample integrity and maintaining QA/QC that identification testing be carried out directly after arrival in-country, as resulting data provides evidence that counterfeit products have not infiltrated the consignment.</p> <table border="1" data-bbox="467 798 1347 903"> <tr> <td data-bbox="467 798 532 903">1.</td> <td data-bbox="532 798 1347 903"> Identification test from the compendia methods of AS and AQ.  <i>Expected turn-around time for one lot (Identification test) of AS + AQ is 4-5 days</i> </td> </tr> </table> <p>The consignee in Liberia will collect a minimum of 100-200 tablets per lot and submit to the USP laboratory. A random sampling selection plan will be used as described in section 5.3.3.</p>	1.	Identification test from the compendia methods of AS and AQ. <i>Expected turn-around time for one lot (Identification test) of AS + AQ is 4-5 days</i>
1.	Identification test from the compendia methods of AS and AQ. <i>Expected turn-around time for one lot (Identification test) of AS + AQ is 4-5 days</i>		
5.4.2	<p>The testing laboratory will be notified that the test samples are in transit. A DHL tracking number will be provided to the testing laboratory. If DHL is not the courier, than another global courier may be used, for example, Fed-X. The sample package must clearly state that "<i>Samples are for analytical testing purposes only. Not for distribution in the US.</i>"</p> <p><u>Primary Drug Testing Laboratory</u>  Attn: Mr.Sanford Bradby  United States Pharmacopeia  Research Analytical Research and Development  12601 Twinbrook Parkway  Rockville, MD 20852-1790 Phone: 301-881-0666 ext:8417</p>		
5.4.3	<p>An identification test is to be performed immediately upon receipt of the product by the testing laboratory and results sent to Family Health International- attn Mr. Steve Hamel. The same process as section 5.3.5 will be used to review and communicate the test results.</p>		
5.4.4	<p>The post-shipment identification test report and <i>Certificate of Conformance –Post Shipment</i> is submitted to;</p> <p>USAID-PMI- Ms. Jennifer Murphy, Ms. Sonali Korde  JSI-TO3 Malaria- Mr. Miguel Jaureguizar, Mr. Paul Stannard, Mr. Ralph Rack  National Drug Service of Liberia, Mr. Tom Gulley</p> <p><b><u><i>The acceptance of the identification test allows for drug distribution in Liberia.</i></u></b></p>		

**6.0 DOCUMENT HISTORY:**

<b>Date Issued</b>	<b>History</b>	<b>Previous issue date</b>	<b>Reason for change</b>
9/24/07	00	N/A	New Issue.
10/18/07	01	9/24/07	SOP name change from ACTs to Pharm; added USP-India Laboratory
10/26/07	02	10/18/07	Provided address for Guilin, clarified price of testing. All testing to be conducted by USP in USA.

**USAID | DELIVER PROJECT**

John Snow, Inc.

1616 Fort Myer Drive, 11th Floor

Arlington, VA 22209 USA

Phone: 703-528-7474

Fax: 703-528-7480

Email: [deliver\\_project@jsi.com](mailto:deliver_project@jsi.com)

Internet: [deliver.jsi.com](http://deliver.jsi.com)