



Briefing Note Visual Inspection of Insecticide-treated Nets (ITNs) Allocation Period 2023-2025

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Note: Any comments, proposed changes or amendments to this Briefing Note should be directed to the Quality Assurance team at <u>HealthProductQualityAssurance@theglobalfund.org</u>

1. Overview

Background

As per the <u>Guide to Global Fund Policies on Procurement and Supply Management of</u> <u>Health Products</u> (the "PSM Guide" published in June 2021), Principal Recipients (PRs) of Global Fund grants are authorized to procure vector control products including Insecticide Treated Nets (ITNs) only when those products are:

Pre-qualified under the WHO Prequalification Programme. Recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES); and are compliant with specifications indicated in WHOPES. Acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

Within the WHOPES, quality control was considered essential to ensure that products meet their WHO product specifications and provide the best efficacy.

Review functions for these products, previously carried out by WHOPES within the Control of Neglected Tropical Diseases department, have been transferred to the WHO Prequalification team (PQ) to ensure that the approach to evaluation of these products is aligned with other health products and follows a product lifecycle approach. WHO is evolving its approach to supporting the development, evaluation and adoption of new vector control products and tools.

While maintaining quality control is important, implementing upstream quality assurance in design and manufacturing is equally critical. WHO specifications for pesticides¹ continue to provide an international point of reference against which products can be judged and thus prevent the procurement of poor-quality products under the grants.

In addition to quality control activities performed at pre-shipment stage, testing products upon arrival of the goods in country (i.e., post-shipment inspection and testing) may be required in specific circumstances, in particular when the products are suspected to have been exposed to unacceptable shipping and/or storage conditions. To avoid such cases, products should be transported and stored as per the manufacturers or suppliers' specifications and the conditions documented. In circumstances where recipients are made aware of an incident of not complying to the storage and transport conditions, they should liaise with the Global Fund Quality Assurance (QA) team as soon as practicable to discuss additional risk mitigation activities.

The quality control activities which should be performed at pre-shipment stage as suggested in the PSM Guide include:

¹ <u>https://extranet.who.int/pqweb/vector-control-products/who-specifications-pesticides</u>

- Sampling and testing products as per their WHO product specification (a small number of nets, as indicated by the Quality Control lab).
- Performing a visual inspection to check on physical condition of the ITNs (a larger number of nets, as indicated under sample size on the document).

The first set of activities is described in the Global Fund <u>Briefing Note on pre-shipment</u> <u>sampling and testing</u>, while this Briefing Note focuses on visual inspection.

The WHO specifications do not provide any norms for the required physical condition of the net, beyond mesh size. Therefore, the purpose of this document is to provide clarity on the requirements for the visual pre-shipment inspection of ITNs.

The Briefing Note is building on similar documents established by partners (e.g., UNICEF, USAID/PMI) with inputs from the Global Fund Procurement Service Agent (PSA) and based on discussion with industry partners/suppliers.

Purpose

As required by the PSM Guide, this Briefing Note supports the implementation of the Global Fund quality assurance requirements for sampling and inspection to ensure a consistent approach to the visual inspection, labelling verification and physical measurement of ITNs procured with Global Fund grants.

As per Section 6.4 of the PSM Guide, vector control products procured with Global Fund funding must comply with Global Fund quality assurance requirements, and PRs or the PSA acting on their behalf shall perform randomized pre-shipment inspection and sampling. In the case of sampling for visual inspection and physical measurements, the following principles must be implemented:

- Sampling and randomization performed according to WHO guidelines or based on the sampling procedures for "inspection by attributes" of the standards of the ISO 2859 series².
- Sampling, visual inspection and physical measurement conducted by an independent sampling agent.

The PSM Guide requests recipients to perform inspection at the pre-shipment stage. Some PSAs working on behalf of PRs may negotiate with suppliers and opt for postshipment inspection. This poses a greater risk to the manufacturer in case the products fail the inspection, but more provides assurance on quality to the grant recipient as nets are inspected at their destination.

However, the Global Fund QA team does not recommend performing post-dispatch (shipment) inspections, except in special circumstances where information collected at the receipt of the products on the storage or transport conditions may lead to a risk for the quality or performances of the nets. In case a PR opts for a post shipment inspection, the PR should engage an independent third-party inspection agency. The independent third-party inspection agent is expected to provide a greater level of reassurance and impartiality and apply the correct methodologies to perform the

² <u>https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en</u>

inspection properly. It is also beneficial and highly recommended that the manufacturer or their representative be present during the inspection.

Abnormal findings during post shipment inspection may not be categorized as an outof-specification and may need more complex investigations.

In addition, this Briefing Note provides further information on the reporting requirements as stated in the PSM Guide Section 6.10.

Scope

This Briefing Note is applicable to all brands of ITNs currently recommended by WHOPES or WHO Prequalification or ERP products and procured with Global Fund grant funds.

Requirements for sampling for quality testing are not covered in this document, but they are detailed in a specific <u>Briefing Note for sampling and testing of ITNs</u>.

Responsibilities

For ITNs procured through the Global Fund's Pooled Procurement Mechanism (PPM), the PSA is in charge of implementing the procedures outlined in this Briefing Note.

For ITNs procured with grant funds but not through the PPM, PRs are responsible for implementing the procedures outlined or are requested to instruct their PSA (if applicable) to implement similar procedures providing the same level of assurance.

This Briefing Note should be sent by PSAs and PRs to all agents performing inspection services. Inspection agency representative should use it as supporting information and guidance for any inspection.

Important Limitations

This Briefing Note is based on statistical techniques and in particular the concept of Acceptance Quality Limit (AQL): it is a common technique used to take a delivery sample to determine if the entire delivery meets customer specifications. As an example, an AQL of 2.5% means that the buyer accepts defects to be present in the manufactured goods at a level of 2.5%.

The AQLs taken by the Global Fund in this Briefing Note are similar to the ones taken by other partners procuring nets at global level.

2. Description of Activities / Procedure

2.1 Basic principles

ITNs procured with Global Fund grant funds can be classified in two categories based on the different regulatory pathways: Prequalified ITNs: Products which have been prequalified by the WHO Prequalification Program having satisfactorily completed the whole spectrum of assessment and review planned for WHO prequalification.

ITNs acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

The list of ITNs eligible for Global Fund procurement can be found in the dedicated Global Fund webpages³.

At present, there is no randomization process implemented and all batches are to be visually inspected.

Exceptional circumstances

In exceptional situations, the visual inspection can be waived subject to prior agreement between the inspection agent and the PR or PSA making a request. In such cases, the Global Fund QA team must approve the change before implementation.

2.2 Sampling for visual inspection purpose

a) Sampling by an independent sampling agent

Before sampling, the PR or PSA should select an independent sampling agent who is responsible for the operational and logistics arrangement for sampling – see detailed guidance in WHO Guidelines for procuring public health pesticides⁴.

b) Request for sampling and inspection

The PR or the PSA acting on its behalf should make the request for sampling and visual inspection to an independent sampling agent. The instructions and documents should include:

- Instruct to draw a specific number of samples per batch;
- Methods and tools for sampling;
- Compliance to importation requirements for samples into the country where the testing laboratory is located;
- Certificate of Analysis (CoA);
- Purchase Order (PO);
- Packaging list;
- Approved final artwork.

c) Sampling Method

Samples are to be drawn and handled as indicated under Section 9 of the WHO Guidelines for procuring public health pesticides. Samples should not be taken from

³ https://www.theglobalfund.org/en/sourcing-management/quality-assurance/other-products/

⁴ https://www.who.int/publications/i/item/9789241503426

products previously opened for inspections. Only products in original packaging should be sampled, either as individually packaged nets or packaged as bales.

d) Sampling procedure

The sampling agent should have a specific procedure for sampling, visual inspection and documenting inspection conclusions – see detailed guidance in WHO Guidelines for procuring public health pesticides under Section 9.

The sampling should consider separately each manufacturing batch identified within a consignment. In the case of continuous manufacturing (e.g., production of largescale batches), the sampling agent should select samples taken for different bales distributed equally within the same batch on as many bales as possible.

e) Sample size

The sample size for inspection purpose is defined primarily based on the type of inspection to be performed such as normal or tightened inspection.

The ISO 2859-1 standards provide the number of nets to be sampled in relation to the number of nets of the batch inspected by allocating a sample code alphabetical letter. The nets should be taken out from their packaging and be taken randomly from the same batch.

Normal Inspection

The Global Fund uses ISO 2859-1 $(1999)^5$ as a guidance for inspection and acceptance with a general inspection level at I and applies a normal inspection level 2-A – see table below.

General Inspec	ction level	I	Normal inspection table 2-A		
Total number bed nets			Sample code	Size	
1,201	to	3,200	Н	50	
3,201	to	10,000	J	80	
10,001	to	35,000	К	125	
35,001	to	150,000	L	200	
150,001	to	500,000	Μ	315	
500,000	and	over	Ν	500	

• Switching rules for tightened inspections

As per ISO 2859-1, switching rules to tightened inspection is needed if two or more batches fail to meet the requirements. In such an occurrence, the PR or the PSA acting

⁵ <u>https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en</u>

on its behalf should instruct the inspection company to implement the change as per the switching rules to the tightened inspection for future procurement. In such a case, the Global Fund QA team needs to be informed and confirmation to proceed is needed.

General inspection level remains as G-I and the sample size code as per table 1 remains the same.

General Inspection level I			Tightened inspection table 2-B		
Total number bed nets			Sample code	Size	
1,201	to	3,200	Н	50	
3,201	to	10,000	J	80	
10,001	to	35,000	К	125	
35,001	to	150,000	L	200	
150,001	to	500,000	Μ	315	
500,000	and	over	Ν	500	

f) Sampling strategy

If the consignment that needs to be inspected consists of more than one batch then it should be assured that batches are separated, and inspection is applied to each batch separately.

The nets should be taken out from their packaging which should be taken randomly from the same batch. Once inspection is complete, the nets should be packaged and shipped with the consignment.

g) Sampling record

The information to be collected at each sampling step is recorded in a sampling report, which can be combined with the pre-shipment inspection report.

The bale number for each sample taken should be recorded, if available. In case an individual identification number is attached to each individual ITN, this number should be recorded.

A typical sampling report is provided in Annex 4 of the WHO Guidelines for procurement of public health pesticides.

2.3 Performing the visual inspection and measurement

The packaging integrity of the bales and of the nets should be verified and recorded by the inspectors during the pre-delivery inspection (PDI).

a) Measurement of ITNs⁶

The flat method of dimension measurements needs to be followed. Before measuring dimensions, it is necessary to flatten the net fabric on a horizontal clean surface. Measurements can then be taken based on the procedure described below based on the type of nets.

• Measurement of rectangular ITNs

Measure the length and width of the nets using adjacent corners seams on the top edges/seams of the ITN. Measure the height of the nets on the vertical seam from top corner to bottom edge. During measurement, the nets should be flattened, free of creases or wrinkles. If the ITNs have been packed tightly in bales, they may have to be stretched to get the original shape with gentle force. If the seam is stretched with force, then it should be allowed to return to its original shape and measurements should be taken after one minute only.

Individual measurements should be reported up to a precision of 0.5 cm. Any net that initially does not seem to be within requirements should be measured at any vertical seam and two adjacent vertical seams. The average of each dimension (two seams) should then be reported as final and expressed with a precision of one decimal.

• Measurement of conical ITNs

Circumference: Fold net twice along seams and measure along bottom edge and then multiply measurement by 4 to get an approximation of the circumference.

More accurate measurement can be determined by measuring the diameter and multiplying this measurement by 3.14.

Height: Measure along a vertical seam from top to bottom edge as described above for rectangular nets. During measurement, the nets should be free of creases or wrinkles.

b) Workmanship and appearance

The visual inspection is performed for each net sampled, trying to identify the various potential defects as recalled in Annex 1 and some visual examples provided in Annex 2.

2.4 Classification of the defect, calculation and decision

a) **Defect classification**

All the defects or non-compliance for each batch are recorded by type of defects such as major and minor.

⁶ There has been some debate on the most suitable methods of taking measurement especially for some types of nets that are more flexible. Hanging method is not considered suitable so flat method should be used.

Adding up or combining minor observations should not result in a higher class (major) defect. If more than one batch of a supplier failed to comply with the requirements, switching rules apply.

b) Use of Acceptance Quality Limit (AQL)

The Acceptance Quality Limit needs to be applied to each batch separately and by type of defects taking into consideration if normal or tightened inspection levels are applicable.

• Normal Inspection: Major defects using an AQL level of 2.5

The different type of major defects observed are added and need to be reviewed as per the table 2 below.

General Inspection level I			Normal inspection table 2-A		AQL 2.5	
Total number of bed nets			Sample code	Size	Ac	Re
1,201	to	3,200	Н	50	3	4
3,201	to	10,000	J	80	5	6
10,001	to	35,000	К	125	7	8
35,001	to	150,000	L	200	10	11
150,001	to	500,000	Μ	315	14	15
500,000	and	over	N	500	21	22

Table 2

• Normal Inspection: Minor defects using an AQL level of 4.0

The different type of minor defects observed are added and need to be reviewed as per the table 3 below.

Table 3

General Inspection level I			Normal inspection table 2-A		AQL 4.0	
Total number of bed nets			Sample code	Size	Ac	Re
1,201	to	3,200	Н	50	5	6
3,201	to	10,000	J	80	7	8
10,001	to	35,000	К	125	10	11
35,001	to	150,000	L	200	14	15
150,001	to	500,000	М	315	21	22
500,000	and	over	N	500	*	*

*Assess result based on 315 samples as given for sample size M.

Other observations are included for information and review of the Global Fund and to give feedback to manufacturers for continuous improvement.

• Tightened inspection: Major defects using an AQL level of 2.5

Acceptance norms as per table 2-B below (single sample plan for tightened inspection).

AQL levels of 2.5 for major defects at tightened inspection.

The different type of major defects observed are added and need to be reviewed as per the table 4 below.

Table 4

General Inspection level I			Tightened inspection table 2- B		AQL 2.5	
Total number bed nets			Sample code	Size	Ac	Re
1,201	to	3,200	Н	50	2	3
3,201	to	10,000	J	80	3	4
10,001	to	35,000	К	125	5	6
35,001	to	150,000	L	200	8	9
150,001	to	500,000	М	315	12	13
500,000	and	over	Ν	500	18	19

• Tightened inspection: Minor defects using an AQL level of 4.0

The different types of minor defects observed are added and need to be reviewed as per the table 5 below.

Table 5

General Inspection level I			Tightened Inspection table 2-B		AQL 4.0	
Total number bed nets			Sample code	Size	Ac	Re
1,201	to	3,200	Н	50	3	4
3,201	to	10,000	J	80	5	6
10,001	to	35,000	К	125	8	9
35,001	to	150,000	L	200	12	13
150,001	to	500,000	М	315	18	19
500,000	and	over	Ν	500	*	*

*Assess result based on 315 samples as given for sample size M.

c) Decision

For a said sample code, the acceptance should be based on the number of defects allocated by the standard for acceptance (Ac) or rejection (Re).

As a matter of example, 315 samples of nets will have to be taken from a batch of 300,000 nets (M sample code). After visual inspection of the 315 nets performed as per a tightened inspection, 13 nets have been identified having major defects. Based on these findings the batch must be rejected.

3. Once the Inspection is Completed

3.1 Review of storage conditions

During the visual inspection, the independent inspection agent should describe and record the environmental storage conditions under which ITNs are kept at the time of inspection and sampling (e.g., temperature monitoring, stacking of the bales, cleanness of the storage area). In cases where ITNs are stored outside the supplier WHO approved manufacturing site, the inspection agent should request evidence that the facility meets good storage practices (e.g., certificate of audit by an independent agent). Storage conditions should be described in the reports for each location.

3.2 Reporting

The inspection company is expected to document and archive all raw data for seven years and make them available on request. The visual defects need to be supported by pictures in the final report.

3.3 Decision for release

The decision to release the products rests with the PR. However, delegation can be organized under specific contractual arrangements with the respective PSA. Any decision not to release products must be based on findings of non-compliance.

The release decision will be based on the satisfactory demonstration of the inspection requirements via the outcome of the inspection report and the findings of the preshipment visual inspection. This Briefing Note does not cover other non-compliance regarding procurement specifications, as they are not directly related to QA matters.

The final decision to release should be made by an authorized person, preferably the Head of Quality Assurance for the PR or PSA or somebody under their direct supervision. In some circumstances, products which do not comply with inspection specifications can be released using risk-based approaches. A good example is the use of Health Product Risk Committee (HPRC) within the Global Fund which can make quality assurance requirements derogations upon request by the PR.

In case of compliance, the authorized person records the decision and allows the release of the batches as per the planned arrangements with the PR or the PSA.

3.4 Management of non-conformities and poor storage practices

Any non-conformities highlighted in the inspection reports issued by the independent inspection agent should be recorded and the PR or PSA notified within five working days.

In case of product non-compliance, the PR or the PSA acting on its behalf is required to notify the Global Fund QA team within five working days using the Global Fund QA team email: <u>HealthProductQualityAssurance@theglobalfund.org</u>

Investigations must be performed in line with the contractual arrangement and impacted products should be maintained under quarantine conditions by the supplier until the end of the investigations performed by the supplier in collaboration with the PR or the PSA.

Regular updates by the PR or PSA should be provided to the Global Fund QA team for further guidance or advice.

PRs and PSAs are requested to notify the Global Fund QA team within five working days of any suspicion of poor storage practices related to storage conditions in the warehouse by the supplier.

3.5 Record keeping

Generally, all records related to the inspection activities described hereabove should be archived by the PR or the PSA acting on its behalf for at least seven years. Records should be made available to the Global Fund upon request.

3.6 Cost related to these activities

As per section 6.9 of the PSM Guide, the cost of conducting pre-shipment inspection activities of vector control products may be included in the grant budget to be paid with grant funds, as part of the procurement and supply management cost.

4. Acronyms & Abbreviations

AQL	Acceptance Quality Limit
CIPAC	Collaborative International Pesticides Analytical Council
СОА	Certificate of Analysis
ERP	Expert Review Panel
FAO	Food and Agriculture Organization
ISO	International Organization for Standardization
ITN	Insecticide-treated net
OOS	Out-of-specification
PDI	Pre-delivery inspection
РРМ	Pooled Procurement Mechanism
PQT	Prequalification Team
PR	Principal Recipient
PSA	Procurement Service Agent
PSM	Procurement and Supply Management
QA	Quality Assurance
QC	Quality Control
SOP	Standard operating procedure
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

5. Glossary of Terms

Batch

A defined quantity of material produced in a single series of operations (see WHO/FAO Guidelines Rev3)⁷.

Minor defect

A defect that is not likely to reduce materially the usability of the product for its intended purpose or a departure from established standards of quality, having little bearing on the effective use or operation of the product. Minor defects in workmanship and material are shown in this document under Section 6, Annex 1.

Major defect

A defect that is likely to result in a material failure or to render the product not fit for its intended purpose. Major defects in workmanship and material are shown in this document under Section 6, Annex 1.

Observation

Unwanted features not categorized as minor or major defects. These are to be reported in order to drive the continual improvement process required by ISO 9001⁸ (if appropriate).

⁷ https://www.fao.org/3/i5713e/i5713e.pdf

⁸ https://www.iso.org/standard/62085.html

6. Annexes

Annex 1. Visual Inspection: workmanship and appearance. Classification of defects

	Defect description	Classificatio	on/AQL
1	Dimension Each net should be within plus or minus 7.5 % of its nominal dimensions ⁹ .	Major	2.5
2	Hole (tear, cuts or bursts in the netting fabric with size bigger than 2x2 mesh or 0.5x0.5 cm whichever is bigger).	Major	2.5
3	Open seam: Hole is observed in the seam with size bigger than 5 mesh or longer than 1 cm whichever is bigger.	Major	2.5
4	 Joint defect: More than 3 vertical seams in the side panel or more than 1 connecting seam in the roof of rectangular net, and: Roof: width of connecting panel is not to be less than 30 cm. Panel: width of connecting panel is not to be less than 50 cm. 	Major	2.5
5	Loop defect: Missing loop, ring (only with conical net) or loop can be easily removed by hand pulling (>=1/3 seam is detached).	Major	2.5
6	Label defect: Missing label(s) & difference from reference label or PO requirements.	Minor	4.0
7	Repaired hole: Hole or run, defined in item 1, with proper repair (repaired with patch). No more than 3 patches allowed.	Minor	4.0
8	Small knitting defect Hole with less than or equal to 2 x 2 mesh or 0.5 x0.5 cm. A net with 3 or more holes of this type is to be classified as a major defect.	Minor	4.0
9	 Imperfect seam Breaking 1 thread in double-thread seam without hole. Too loose or too tight, uneven seam or lower than 3 stitches/cm seam. Seam split bigger than 3 mesh or 0.5 cm and less than or equal to 5 mesh or 1 cm. 	Minor	4.0
10	Trimming defect:Raw or uncovered seams with height of 1 cm or above.Untrimmed thread ends of longer than 5 cm.	Minor	4.0

⁹ It is expected that manufacturers produce within 5% norms. However due to baling and stretching of nets before taking dimensions during pre-inspection, the norms for the inspection company are set less tight.

	Defect description	Classificati	on/AQL
11	Stain: Oil, dirt spot with reasonably significant size (>= 5x5 mesh or 1 cmx1 cm) or multiple (>=6) small spots.	Minor	4.0
12	Chalk mark, spotty oil spot with size less than 5x5 mesh.	Observa	tion
13	Blurred stamp ink.	Observa	tion
14	Fold at the corner.	Observa	tion
15	Seam split less than 3 mesh or 0.5 cm.	Observa	tion
16	Noticeable difference in color shade should be compared to the standard color of each supplier.	Observa	tion
17	Trimming defect: - Raw or uncovered seams with height less than or equal to 1 cm. - Untrimmed thread ends of less than 5 cm.	Observa	tion

Annex 2: Examples of workmanship and appearance defect

Major defect No. 2:

Hole (tear, cuts or bursts in the netting fabric with size bigger than 2x2 mesh or 0.5x0.5 cm whichever is bigger).



Major Defect No. 3:

Open seam: Hole is observed in the seam with size bigger than 5 mesh or longer than 1 cm whichever is bigger.



Major Defect No. 4:

Joint defect. More than 3 vertical seams in the side panel or more than 1 connecting seam in the roof of rectangular net, and:

- Roof: width of connecting panel is not to be less than 30 cm
- Panel: width of connecting panel is not to be less than 50 cm



Major defect No. 5:

Loop defect. Missing loop, ring (only with conical net) or loop can be easily removed by hand pulling (>=1/3 seam is detached).



Minor Defect No.7:

Repaired hole. Hole or run with proper repair (by patch or stitching).



Minor Defect No.8:

Small knitting defect:

- Hole with less than 2x2 mesh or 0.5x0.5 cm.
- A net with 3 or more holes of this type is to be classified as a major defect.



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Minor Defect No.9:

Imperfect seam:

- Breaking 1 thread in double-thread seam without hole.
- Too loose or too tight, uneven seam.

- Seam split bigger than 3 mesh or 0.5 cm and less than or equal to 5 mesh or less than or equal to 1 cm.



Minor Defect No.10:

Trimming defect:

- Untrimmed thread ends of longer than 5 cm.
- Raw or uncovered seams with height of 1 cm or above.



Minor Defect No.11:

Stain: oil, dirt spot with reasonably significant size (> = 5x5 mesh or 1x1 cm).





Observation No. 12:

Chalk mark, spotty oil spot with size less than 5x5 mesh or 1x1 cm.



Observation No. 14:

Fold or pleat at the corner.



Observation No. 13: Blurred stamp ink



Observation No. 15: Seam split less than 3 mesh or 0.5 cm.

