World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	A to Z Textile Mills Limited
Corporate address of manufacturer	Plot No. 698, Net World Area, Dodoma Road, Kisongo Arusha, Tanzania
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	A to Z Textile Mills Limited **Address I:** Plot No. 698, Net World Area, Dodoma Road, Kisongo Arusha, Tanzania *Note: Only one of the two manufacturing sites at this address was covered during this inspection. The second manufacturing area belonging to another company, i.e.* Net Health Ltd*, was inspected separately and is not covered in this report.* **Address II:** Plot No. 156-160, Unga Ltd– Industrial area Arusha, Tanzania
Inspection details	
Dates of inspection	13-14 June 2018
Type of inspection	Initial inspection The criteria for the inspection was the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	A to Z Textile Mills Limited is involved in the manufacture of long lasting insecticide treated nets and other products such as garments and Polypropylene raffia bags. <u>A to Z Textile Mills Limited, Plot No. 698 Net World Area, Dodoma Road, Kisongo, Arusha, Tanzania:</u> The activities related to manufacture of the LLIN at this site included warehousing (storage) of raw materials and finished products, production of the master batch and fabric, quality control testing, packaging and labelling. <u>A to Z Textile Mills Limited, Plot No. 156-160, Unga Ltd– Industrial area, Arusha, Tanzania:</u> Activities carried out at this site related to further processing of fabric which included cutting, sewing and stitching, labelling and baling. The packaged finished bed nets were transported back to the warehouse located at the Kisongo site for storage and distribution.

General information about the company and site	A to Z Textile Mills Limited was inaugurated in 1966 and is a private manufacturing company involved in the manufacture of a wide range of products including LLIN. The manufacture of LLINs commenced in 2003. A to Z is a licensed manufacturing facility by the Ministry of Industry, Trade and Investment, Government of Tanzania with license number IND 17.4667 U/Q. The facility is also certified to ISO 9001:2015 The quality management system i.e. policies, procedures, processes and leadership were similar as observed at Net Health Limited.
History	This was the first WHO audit of the site
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited** • Quality Manual • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints • Non-conforming products • Data integrity • Product release • Batch processing records • Sampling and laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Site visited** • The production areas at the two addresses indicated above • Quality control laboratory • Raw material and finished goods ware houses
Exclusions and Non-applications of requirements in the QMS	ISO 9001:2015 Clause 8.3 Design and development for products and services
Out of scope	Products not submitted WHO for prequalification
Restrictions	None.
WHO products covered by the inspection	• MiraNet® (Alpha-cypermethrin 0.45%) 009-001 • Olyset® ® Net (Permethrin 2%) 009-002
Abbreviations	**Meaning**
CoA	Certificate of analysis
LLIN	Long-lasting insecticide nets

MSDS	Material safety data sheet
PPE	Personal Protective Equipment
QA	Quality assurance
QC	Quality control
QMS	Quality management system
WHOPES	World Health Organization Pesticide Evaluation Scheme

Part 2	**Summary of the findings and comments**

1. Organizational roles, responsibilities and authorities
The manufacturer had documented the organizational structure and defined designated responsibilities and authorities for key personnel. Reporting lines for quality and production were independent of each other.

2. Quality policy and quality objectives
Top management had established an adequate quality policy with commitments to satisfy applicable requirements and continual improvement. The quality policy was appropriate to the purpose of the organization and had been communicated within the facility. Quality objectives were documented, measurable and consistent with the quality policy.

3. Management review
The relevant procedure was reviewed. Management reviews were held at least twice a year. Management reviews were considered acceptable.

4. Leadership
Top management was committed to the effective implementation of the QMS. Resources necessary for implementation of the QMS were determined and provided. The manufacturer monitored and measured the ability of the quality management system to meet planned results. Top management engaged, directed and supported personnel in fulfilling their responsibilities and roles.

5. Control of documented information
Documented information was available both electronically and in hard copy. The procedure for document control was reviewed. Documented were distributed, accessed, retrieved and stored in accordance with the established procedure. Non-conformance raised in relation to this section have been addressed and the same shall be verified during future audits.

6. Personnel competence and training The manufacturer had an established procure for training. Training needs were identified by the training committee. The training schedule for the year 2017 and 2018 was reviewed. Training programs related to quality awareness were also included. Most of the trainings were in-house. Training records were reviewed. The effectiveness of the training was assessed.

7. Risks and opportunities
The relevant procedure and risk register were reviewed. A SWOT Analysis had been conducted to determine the risks that needed to be addressed to provide assurance that quality management system can achieve its intended results and attain improvement.

8. Control of changes

The relevant procedures for control of changes were reviewed. No changes had been registered since the implementation of the requirements of the ISO 9001:2015 standard in April 2017.

9. Internal Audits

The procedure for internal audits was reviewed. Internal audits were planned, and an internal audit program implemented. Internal audits were conducted biannually for each department by qualified internal auditors. Internal audit schedule for the year 2018 and 2017 were reviewed. Internal audit reports were in place. Audit results were communicated to top management and were reviewed in management review meetings.

10. Control of non-conforming products

The procedure for control of non-conforming products was reviewed. Records were available, and these showed that the requirements of the procedure were being implemented.

11. Performance evaluation

The manufacturer monitored and analysed key processes and product quality parameters such as denier, temperature content of active ingredient, bursting strength. This data was compiled on a weekly basis and analysed. The reviewed results indicated that the processes were within control.

12. Complaint handling

Complaints were handled according to a documented procedure. At the time of the audit no customer complaint related to LLINs had been registered. Customer feedback was actively sought by use of questionnaires.

13. Design and development of products

No design and development conducted at the facility.

14. Support

Infrastructure and work environment

The facility was generally well maintained. The work environment was found adequate with personnel wearing PPE. MSDS were available in warehouse.

Monitoring and measuring resources

The documented procedure for preventive maintenance, preventive maintenance schedule and records were available. Calibration records for selected balances were reviewed. Equipment calibration status was displayed.

15. Production and service provisions

Control of Production

The manufacturing of the *Permethrin* master batch involved mixing, heating, cooling, cutting and packing. The manufacture of the master batch was carried out in a dedicated area.

The manufacturing of the fabric involved blending of permethrin master batch with HDPE followed by heating, extrusion, cooling, pre-setting, cooling, warping and knitting. The manufacture of the fabric was done in a dedicated area. The fabric was then transported to the A to Z Textile Mills site located at Plot No. 156-160, Unga Ltd– Industrial area Arusha. At A to Z Textile Mills, the fabric was cut, sewed, stitched, labelled and packaged depending on the customer specifications. At various stages

during the manufacturing process, nets were inspected for defects such as holes, tears, stains. The packaged finished bed nets were transported to the warehouse located at Kisongo for storage and distribution.

The manufacture of LLINs was performed according to documented production instructions. Production records were maintained, and processing temperatures were monitored. In process tests were performed throughout the manufacturing process and results documented.

The QC function was independent of the other departments and was shared with the company Net Health Ltd. The QC laboratory was responsible for performing physical and chemical tests on raw materials and finished products. The laboratory equipment was uniquely identified and calibrated.

Completed batch manufacturing records for the *Permethrin* master batch and Olyset® fabric were reviewed. Non-conformance raised in relation to this section have been addressed and the same shall be verified during future audits.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. Non-conformance raised in relation to this section have been addressed and the same shall be verified during future audits.

Release of products and services

Finished products were released following review of production and quality control data. The products were released by the QA manager.

16. Preservation

Raw materials and finished products were stored at ambient temperatures. Inventory was adequately controlled. Materials were adequately identified. Non-conformance raised in relation to this section have been addressed and the same shall be verified during future audits.

17. Post-delivery Activities

Storage Stability:

Stability Studies were conducted at the African Health Research Centre in Arusha. The stability study program and report for Olyset® was reviewed. The results complied with the required specifications. The shelf life of Olyset® was 3 years.

18.Control of externally provided processes, products and services

The manufacturer had an established procedure for selection of suppliers. There was an established criterion for evaluation of external providers. Evaluation of suppliers was conducted every two years. The evaluation reports for suppliers were available.

Part 3	Conclusion – Inspection outcome

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned ***A to Z Textile Mills Limited*** located at ***Plot No. 698, Net World Area, Dodoma Road, Kisongo Arusha, Tanzania*** and ***Plot No. 156-160, Unga Ltd– Industrial area Arusha, Tanzania*** was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard.

All the non-conformances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of Standards and Guidelines referenced in the inspection report

1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5th edition (2015), ISO/FDIS 9001: 2015 ***Short name: ISO 9001:2015***
   https://www.iso.org

2. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange, Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. Manual on the Development and Use of FAO and WHO Specifications for Pesticides, First edition - third revision. Pesticide specifications. FAO plant production and protection paper (228), FAO/WHO Joint Meeting on Pesticide Specifications (JMPS), Rome 2016
   http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/