Quality Management

Appendix A to Audit Report

No. 1603015674

Audit No.: 1603015674

Initial Factory Inspection and Factory Production Control (FPC) Inspection [year]: 2012

Organizational unit/location: Hiep Phu Corporation -G.02B lot, Long Hau industrial zone, Can Giuoc, Long An Province, Vietnam.

Date: 2012-02-15

Created by: NTAT, DAW

Distribution list: Mr. Nguyen Truong Hai (General Manager)

Audit details:

The following audit was conducted according to annual audit plan [year]: 2012

Organizational unit:	**HIEP PHU CORPORATION**
Type of audit:	Initial Factory Inspection and Factory Production Control (FPC) Inspection
Audited standards:	ASTM C1186-08, ASTM C1185-08, Reference to EN 12467-2004 & ISO 17025
Audit date:	2011/11/03&04 and 2012/01/10
Participants:	Mr. Nguyen Truong Hai (General Manager), Mr. Le The Anh (Laboratory Manager), Mr.Hoang Dinh Viet (QA/QC Manager)
Auditor(s):	Mr. Daniel Armin Waterkamp (DAW), Mr. Nguyen Tran Anh Tu (NTAT)

This summary report lists the findings that were evaluated during the initial and certification audit at the above listed manufacturer.

Scope of audit processes	P/A/NCF/N*)	Results - Initial audit, dated 2011/11/03&04	Results - Certification audit, dated 2012/01/10
Testing Lab – Hiep Phu Corporation			
Lab Organisation/ Management	P1	Organization Charts and Job descriptions are in place	Compliant
Lab Organisation/ Management	F1	Detailed matrix of tasks of lab personnel (main responsibilities, deputy) is missing.	Compliant
Lab Organisation/ Management	F2	Quality Manager of the lab was not appointed.	Compliant
Lab Organisation/ Management – Document Control	P2	Approved procedures & a list of procedures are existing and maintained	Compliant
Lab Organisation/ Management – Document Control	N1	Applicable standards are not on the list of controlled documents. For selected documents like standards it is recommended to define review cycle if an update is necessary (e.g. every 6 months)	Compliant
Procedure for Sampling	F3	Actual sampling procedure was not matching the described sampling procedure. Also the sample size shall comply with the rules described in the selected standard ISO 2589-1. E.g. for a daily output of 1201 – 3200 pieces 13 samples/day have to be taken (assuming S3 and AQL = 4 %) Recommendation: Ideally the tests on all parameters required for ASTM C1186-08, Type B compliant products, shall be performed for the entire sample amount.	Compliant
Training records	F4	Training records are available, but trainings records are always scheduled just for one day.	Compliant

		More intensive trainings for Lab newcomers shall be provided	
Sample storage & traceability	NC1	Samples are stored but sample labeling system shall be improved. Sample I.D. could e.g. indicate date, Batch number, type of sample (which cutting direction, test parameter), who took the sample, number of the sample…The Sample I.D. was not transferred properly to the test result record. Therefore the result could not be traced back to the right sample!	Compliant
Sample storage time	F5	According to Mr The Anh samples are retained for 1 year. This shall be described somewhere (e.g. add this to an existing procedure)	Compliant
Lab environmental conditions	NC2	Conditions of the lab environment (Temperature, Humidity) are not measured. Lab conditions shall be recorded every day.	Compliant, if following action is established: Meters for humidity and temperature were purchased and installed. Calibration is valid. But lab conditions have not yet been recorded. Daily records have to be implemented.
Work instructions	F6	Most of the work instructions (WIs) which describe the performance and evaluation of the required tests are already existing in draft stage. WIs shall be revised and completed. WIs shall also contain calculation procedures, Limit/target values with tolerances and ideally flow charts and figures for clear illustration.	Compliant, if following action is established: In some WI the conditioning step (acc. to ASTM 1185 C – 08) is missing. Update is required.
Equipment info and calibration records	N2	List of main equipment and calibration records is available, maintenance and calibration intervals shall be described.	Compliant

Test result records	F7	Test result records are sometimes inconsistent (sometimes 1, 2, 3 or 4 values), Pass and fail criteria are not given. Revision of all test records shall be made.	Compliant
Test specimen cutting and measuring	F8	For cutting the test specimen out of the whole sheet, the method using one single ruler doesn't seem to be very accurate. Use more suitable ruler type, e.g. right angle ruler. Accuracy should be ideally 0.5 mm not 1.0 mm.	Compliant
Control charts	N3	Control charts representing the target value of each parameter and the upper & lower limit strongly recommended for better overview of the quality control.	Compliant. Remark: Some control charts are already existing. The audit team recommends HPC to train lab staff to maintain control charts continuously.
Continuous control of testing equipment	NC3	Oven temperature shall be frequently crosschecked with calibrated thermometer and recorded (e.g. every 2 days). Scales shall be regularly checked with a suitable standard weight (e.g. every week).	Compliant
Test parameter - Dimensions	F9/NC4	Measures were taken without preconditioning (23 ± 2℃, 50 ± 5 % humidity) of the items. As it is not practicable to precondition the full test item (e.g. around 13 per day) because a large and costly conditioning chamber would be necessary, sampling might be done at site conditions. For this please record temperature & humidity at the time of sampling. (Problem: Most probable the specimen will not have reached equilibrium state at the time of	Compliant, if following action is established: Meters for humidity and temperature were purchased and installed. Calibration is valid. But lab conditions have not yet been recorded. Daily records have to be implemented.

		measurement)	
Test parameter - Workmanship	N4	Proper workmanship is assessed directly in the production process, damaged pieces are sorted out. Record of number of specimens sorted out should be established.	Compliant
Test parameter - Density	NC5	Procedure for weight stability (< 0.1 % deviation, see ASTM C1185-08 standard) was not established	Compliant
Test parameter – Moisture Movement	NC6	Test parameter not yet established.	Compliant. Test parameter and WI are implemented
Test parameter – Moisture Movement	N5	It is planned to measure the moisture movement by increasing the humidity from 0 - 90 % instead of 30 – 90 %. As previous would be a worst case scenario, this could be accepted if deviation of the procedure will be mentioned in the manufacturers test report. Humidity shall measured in the desiccator.	Compliant, if following action is established: Humidity in the desiccator shall be cross-checked via hygrometer.
Test parameter – Water absorption	N6	Water absorption measurement can be combined with the density measurement	Compliant.
Test Parameter – Moisture content	NC7	Condition at 23 ± 2℃, 50 ± 5 % humidity was not performed. The test parameter shall not be combined with the parameter density.	Compliant, if following action is established: Conditioning step shall be performed and recorded.
Test parameter – Surface Burning Characteristics	NC8	Not established in the Lab. Either own test facility has to be set-up or the test has to be subcontracted to a capable lab. Frequency of the test: Ideally all samples shall be tested. If impracticable alternative concepts can be proposed and have to be justified and noted in the manufacturer test report.	Compliant. The type test report “B4284.01-106.31” of the accredited lab “Architectural Testing, Inc.”, USA revealed product compliance with the requirements of ASTM C1186-08.

Lab Chemicals	NC9	Chemicals shall be labeled with name, if possible CAS-Nr., Concentration, Date, Date of expiry, Name of the person…Also mark risky properties (e.g. flammable, toxic…), Every lab worker shall have an own lab book to note non standard activities which are not recorded in the standard forms (e.g. preparation of solutions).	Compliant.
Lab Safety	N7	Wearing safety glasses during work with chemicals strongly recommended! Also wear suitable protective gloves if necessary	Compliant.
Lab Safety	N8	Installation of a fume hood for handling of volatile chemicals recommended (Ammonia, strong acids…)	Compliant.
FPC Audit – Hiep Phu Corporation			
Equipment (exists for the control and measurement of the products/ production)	NC1	According to procedure HP-QTNC-03, "Notes" column mentions "usage of the gauge block to weigh and compare" . ⇨ No records were available ⇨ The method of calibration shall be described	Compliant, ⇨ "Bien ban Hieu chuan noi bo- F-QTNC-22-03" for thermometer and hygrometer – 'HPC-031' is record by 22 December 2011. ⇨ The method of calibration has been described in "HP-HDNC-24 HUONG DAN HIEU CHUAN NOI BO _REV 1_1"
Review of Quality Management System / Quality Plan	NC2	Documentations and instructions of suitable operation parameters were not available (Worker act by experience) Recommendation: The quality	Compliant, the documentation HP-QTNC-26 is available

		plan should be established. The operation parameter requirements shall be adequately defined for each type of product (e.g.: 3.5mm sheet) in each stage of production. E.g.: content of mixture, speed control, time, temperature, pressure…	
Action taken to resolve previous non-conformities	P1	After the incoming materials are mixed, samples are taken to analyze the composition. If the analysis result (30 min after sampling) shows non conforming composition, potentially non-conforming products can be predicted and sorted out.	Compliant
Purchasing	F1	A procedure to control the supplier is available, but the manufacturer doesn't apply for this task .	Compliant
Production	NC3	Temperature at dry stage doesn't meet with requirement described in "HP-QDNC-23" at No. 13.4, 5. and 6. - The Production manual requires a temperature range of 50 - 70℃ and a residence time of 4 – 6 hrs. The parameters were not controlled. No record was available, neither for temperature nor for time. - There was no effective product traceability REMARK: Product traceability shall ensure that the outgoing product can get traced back to the incoming material. A proper	Compliant. -The records are available. -The production code for traceability are stamped on product.

		procedure is required especially when the original batch number is not used throughout the whole process.	
Records	NC4	The inline record from QC department shows 'Fault' in some case, But no corrective action and root cause analysis for this Non conformity are provided. Documentation about root cause analysis and corrective actions shall be established There was no template for Non-Conformity-Reports available. Records for production should be kept at least 2 years, for the testing they should be kept at least 5 years.	Compliant. -The records are available in NC-book F-QTHT-30-01, with the NC date on 26/12.

P = Positive; A = Additional Information; NC = Nonconformities; F = Findings; N = Notes for Improvements

The content of this audit report was discussed with the audit participants and is accepted as objectively correct.