Guidance for Factory Inspectors
Annex Special Requirements
For Europe
Foreword

The aim of this Operational Document is to provide guidance for Factory Inspectors (in the following referenced as “Inspectors”) undertaking Factory Surveillance Services and completing form OD-4001 Factory Surveillance Report including Annexes SR.

This part gives instruction to Inspectors. It gives detailed information on what the Inspector is looking for and how he makes the assessment. The aim is to ensure that, irrespective of which Surveillance Body conducts the Surveillance, the same criteria are used to assess whether the Manufacturer’s premises meet the Minimum Requirements of the IECEE CB-FSS.

Pre- or Post-certification initial assessment of the production

Completion of the report serves as a verification that the quality system and the testing procedures as applied by the Manufacturer will ensure the compliance with the requirements of the IECEE CB-FSS.

The visit has to be pre-announced to ensure that the contact person, knowledgeable of the quality system is available.

The Manufacturer shall be made aware that at the time of the visit all relevant documentation and test equipment shall be available and ready for inspection.

Factory Surveillance

Completion of the report serves as a periodic verification that the quality system and test procedures are still maintained and are in compliance with the current requirements of the IECEE CB-FSS.

Additional information

Due to confidentiality reasons, it might be necessary to issue two or more reports if the same factory is used for more than one customer, product, brand name and / or certificate holder.

Due to application of basic and additional requirements the time frame for FSS will be more than 4h as today for Factory Inspections.

Factory Surveillance Report Annexes SR

*Note: the Factory Inspectors are requested to write the report in a legible manner.*

Surveillance carried out by

- CB-FSB: enter name of your Surveillance organisation (CB-FSB – CB Scheme Factory Surveillance Body).
- Reference number: enter your reference number. The reference number has to be indicated at each single page.

Note

a) Please tick as appropriate.
b) Explain clearly, and in each case, why you consider a question as not applicable.
c) Unless self-evident all “yes” and ‘no’ answers require explanation on the “Inspector’s Evaluation Informative page” or in the provided field of the report.

Records

The records need to be carefully reviewed.

The minimum period for record retention shall not be less than the period between two Surveillance Activities. The Manufacturer shall state the retention time.
1 Surveillance Details see SR-EU-Annex 1

2 Periodic Product Verification Tests (PVT)

Data are added in the applicable Annex, otherwise N/A is checked (added)
Annex 2 will be filled in when PVT are required
Note: Details of any non-required PVT should be entered by the Inspector on the Inspector’s Evaluation instead of on the Test Data Sheet.

Describe on the Annex 2-1, Test Data Sheet (PVT) what tests the Manufacturer is performing in order to verify continuous compliance of the certified products with the relevant standard(s). Copy of the manufactures PVT record is also sufficient

Example of how to complete the table on Test Data Sheet (if applicable)

Annex 2-1 Test Data sheet – Product Verification Tests / Periodic Tests (PVT)

<table>
<thead>
<tr>
<th>Special requirements for NCB</th>
<th>Product, Sampling rate, Standards Clause or Test-parameters, Results, Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEKRA</td>
<td>Hair dryer, type ER4, one unit per type per year from running production</td>
</tr>
<tr>
<td></td>
<td>Tests acc. To EN/IEC 60335: Marking, protection against electric shock,</td>
</tr>
<tr>
<td></td>
<td>mechanical strength, creepage distances, clearances.</td>
</tr>
<tr>
<td></td>
<td>Verification of components with originally approved versions</td>
</tr>
<tr>
<td></td>
<td>Dielectric strength test for class II – accessible metal parts against live</td>
</tr>
<tr>
<td></td>
<td>parts 2500V a.c. 60 sec.</td>
</tr>
<tr>
<td></td>
<td>Abnormal operation: blocking air outlet – functioning of thermostat</td>
</tr>
<tr>
<td></td>
<td>Tests performed in Manufacturers own laboratory</td>
</tr>
<tr>
<td></td>
<td>No ongoing testing during visit, however records show that tests were</td>
</tr>
<tr>
<td></td>
<td>satisfactory.</td>
</tr>
</tbody>
</table>

SR-EU-Annex 2 for PVT

2.1 Verify if specific equipment required by the CB-FSS is available and tick the relevant box. If the equipment could not be seen, for example because it was located elsewhere than at the factory, then this should be noted on the Inspector’s Evaluation Informative page.

2.2 Self-explanatory

2.3 Self-explanatory

2.4 Self-explanatory
2.5 Verify that a procedure exist to take corrective actions if deviations are found. Check if these corrective actions are sufficient. In case no actions are taken or if you are in doubt about the actions taken, specify on Inspector’s Evaluation Informative page.

2.6 Self-explanatory

2.7 Self-explanatory

3 Manufacturer’s self-assessment of the manufacturing- and control process of certified products

Check if applicable, if so fill in the SR-EU-Annex 3

The use of the OD-4001 document, completed by manufacturer’s personnel, to document the results of the self-assessment is acceptable.

3.1 The Inspector shall verify that the Manufacturer has a system which will ensure that all tests/Surveillance/procedures are followed and are effective.

3.2 If records could not be examined, for example because they were located elsewhere than at the factory, this should be noted on the Inspector’s Evaluation Informative page.

3.3 Proof of independence and competence in assessment shall be demonstrated

4 Selection and shipping of samples for re-examination

Check if applicable, if so fill in the SR-EU-Annex 4.

Number of sample to be selected is normally specified on the Certification bodies production control specifications.

Give information about where samples were selected and how they are transferred to the NCB or Testing Laboratory by using code letter.

Note: Some NCBs do not require their Certification Marks to appear on the product – Samples still need to be selected if shown on their certification lists.

All comments related to the selected sample(s) shall be stated in the table “Identification of selected samples” This may include information about changes made to the product, suspected misuse of the Certification Mark, etc.

4.1 If no sample selection is made explain the reason why by using the tick box.

4.2 When a sample not bearing the Certification Mark is selected, explain why the sample was selected by using the tick boxes. At least get Manufacturers confirmation that the selected sample is identical to the certified product.

Care is to be taken when products are not marked but references are given in sales pamphlets, installation instructions, manuals, etc. Follow the individual Certification Bodies guideline if in such cases samples without any Certification Mark applied need to be selected.
5 See OD-4001 clause 17.3 Attachments added for SR-EU

Please count the number of pages of the individual SR-EU-Annexes and calculate the sum. This sum shall be added to the table 17.3 in OD-4001.