SOP.001 Audit application

All references in this document are against the latest possible version number. All public documents are published at our website. Questions? Contact us.

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1. Definitions

1.1

The in this document mentioned terms are defined in the RD.004 (EMCI Register list of terms and conditions).

2. Purpose

2.1

This document regulates how EMCI Register uses the audit application for certification.

3. Marking

3.1

The audit application features a set defined of markings that indicate various non-conformities with regards to the audit.

3.2.

The markings are as follows:

- Conformity identified (CI) – The product meets the requirements of the criteria
- Advice (A) – NOT USED IN RCD 2013/53/EU.
- Not audited (N) – This criteria has not been audited.
- Not applicable (NA) – This criteria is not applicable to this product (i.e. wood requirements on a metal craft)
- Minor (MINOR) – A small issue has been detected that can be issued with a single document or file or performing a single test
- Major (MAJOR) – An issue has been detected that can be fixed with an adjustment to the craft.
- Major + (MAJOR +) – A fundamental change to the craft is required to conform to this criteria
- Major Exit (MAJOR EXIT) – The lead auditor has determined that the uploaded evidence, interaction with the auditee or other matters warrant the audit to be cancelled abruptly. The quality manager must be informed immediately.

3.3.

A lead auditor must mark each individual criteria item with CI, N or NA for an audit to be closed and a certification decision to be made.

4. Backups

4.1

EMCI Register makes a backup of the audit application twice a day in two different storage solutions.

5. Export documents

5.1

The audit application has the ability to generate documents in PDF format for use during the audit process.

5.2

The documents must fall into one of the following categories:

- Official EU mandated documents
- Direct read outs of the audit application
- An official EMCI Register document or templates (TE.XXX), versioned through Github and PD.007.

5.3

Documents may never be sent directly to clients. They must be reviewed by EMCI Register before sending to clients.

5.4

Documents, where applicable, must be subject to versioning and this must be individually detectable by the created document. This must be done in accordance with PD.007 and through Github.

5.5

Each document must have unique number in the footer in accordance with the following format:

- [project number]-[UNIX Stamp]

6. Uploaded documents

6.1

Proof of conformity must be uploaded to the audit application on a criteria-per-criteria basis.

6.2

Where one image/file proves conformity to multiple criteria the auditor justification must indicate where the corroborating evidence for their marking can be found.

7. Framework

7.1

The audit application is built on Craft CMS.

7.2

EMCI Register will ensure Craft CMS continues to be maintained or switch to a different platform.

8. Roles & access

8.1

The audit application defines a limited set of roles as follows:

- Supervisors
- Lead auditor
- Auditors
- Administrator
- Representatives

8.2

At the start of a dossier office operations will assign a limited amount of people to fill these roles. A lead auditor, administrator and supervising lead auditor must be present.

8.3

The Head of Certification must be added at the end of the process as a supervisor.

9. CAPA’s

9.1
Corrective and preventative action requests (CAPA’s) are used to signal a finding with the product and to provide the justification of the finding.
9.2
CAPA’s are bound to criteria.
9.3
CAPA’s can be open and closed. The default status is open meaning the problem needs to be resolved, closed means it has been resolved.
9.4
CAPA’s provide an explanation of specifically what/where the product does not conform to specific criteria.
9.5
CAPA’s may provide solution opportunities but may never explain what must be done or provide consultancy.
9.6
A CAPA can only be closed if the underlying problem has been resolved.

10. Reports

10.1
The audit application will generate an automatic audit report.
10.2
The audit report will contain the essential markings for all individual criterias.
10.3
The audit report will only be generated if the dossier is accepted by the EMCI Register board, HCD and lead auditors.

11 Checklists

11.1

During the lifecycle of a dossier various checklists must be filled in by office operations, the supervising lead auditor and the HCD.

11.2

The HCD must fill in the HCD Checklist, based on TD.003, once he has completed his process-oriented inspection.

11.3

Checklists may be based on an official EMCI Register Form (FO.XXX) document or be specifically designed for the audit application.

11.4

The checklist must list the version of the used form and the official name and/or version through Github.

11.5

Active dossiers must use the latest checklist at the time of intended usage.

12. Calculations

12.1

Verification calculations may be performed from within the audit application.

12.2

The calculations may strictly be used to verify information and conformity with the criteria/norm.

12.3

The calculations must be based on a used assessment norm. Calculations may also be done via Excel sheets, this is up to the determination of the lead auditor.

13. WIN Codes

13.1

The audit application automatically generates a WIN code.

13.2

In case on PCA this will be a fully qualifying WIN code to be used on WIN Plates.

13.3

In case of non-PCA the manufacturer serial number will be supplemented with XXX.

13.4

Before use, all WIN codes must be reviewed by the lead auditor.

14. Site visits & evaluations

14.1
On site evaluations may be required for certification.
14.2
Reports must be made of all evaluations once they have been completed.
14.3
Evaluations must be entered the audit application as site visits.
14.4
Site visits do not have to contain all points that are found during the audit. Each individual point must however be documented as a CAPA.

15. Testing

15.1
Testing must be performed by the person overall responsible for the CETOOL, this is currently the Chairman.
15.2
This testing must be performed by a human and must be performed in an environment that mirrors the production environment of the CETOOL.
15.3
Any change that is introduced to the production environment must undergo a testing procedure.
15.4
EMCI Register is free to deviate from this procedure provided it documents this accordingly.