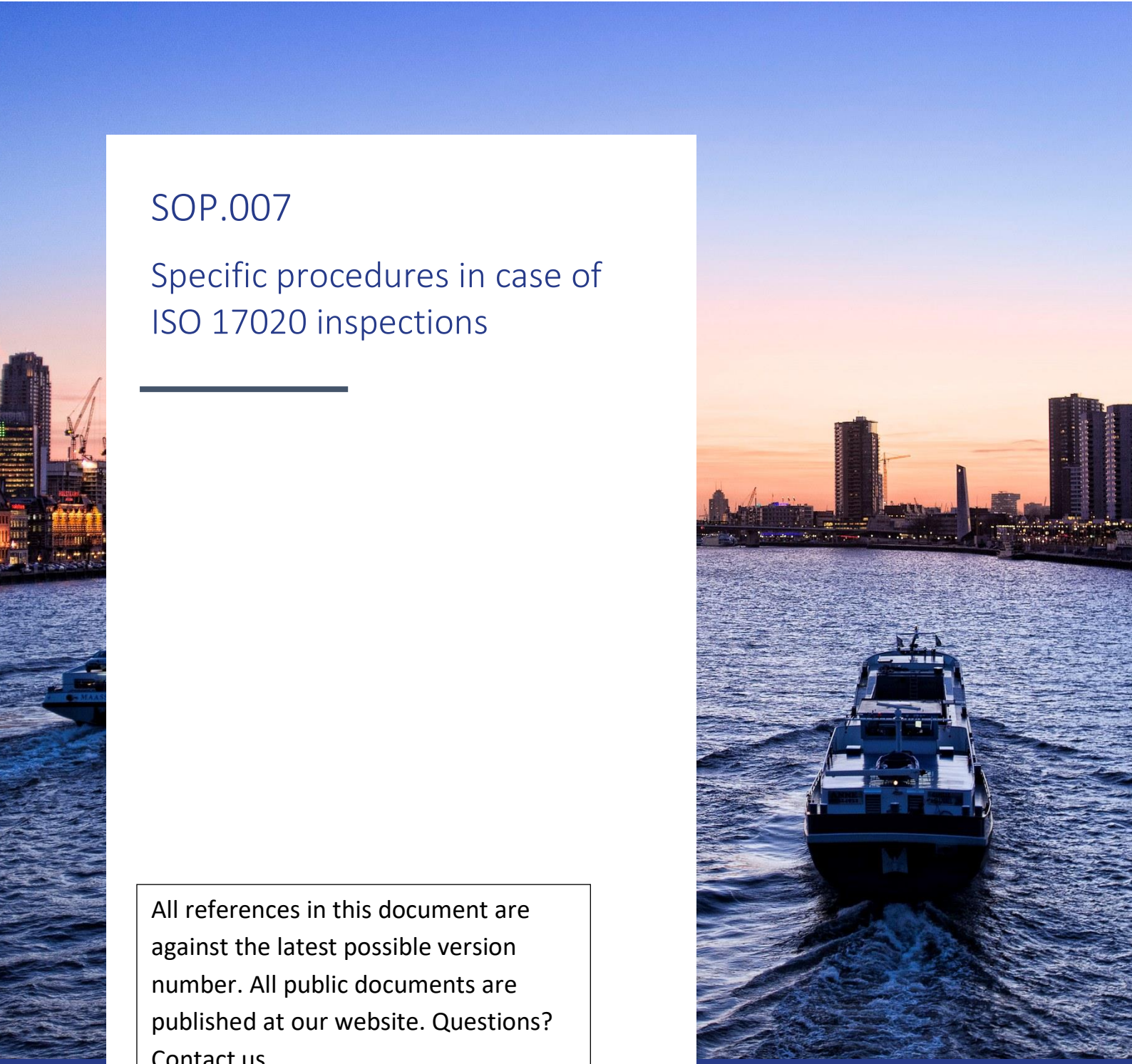

SOP.007

Specific procedures in case of ISO 17020 inspections

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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Contents

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 ensures compliance against ISO/IEC 17020:2012 and established a specific procedure for the application and interpretation of PD.001 when used for inspection-based Conformity assessment. It lays down requirements for the selection, usage, maintenance, verification, control and calibration of equipment and facilities and the article 7 requirements of ISO/IEC 17020:2012.

2.2

The provisions of this document are binding for any inspection carried out by EMCI Register under the RvA accreditation scope.

2.3

The articles of this document are considered binding and inserted in the QMS.

3. Procedures

3.1

EMCI Register shall use the methods and procedures for inspection which are defined in the requirements against which inspection is to be performed. Where these are not defined, EMCI Register
shall develop specific methods and procedures to be used (see 7.1.3). EMCI Register shall inform the client if the inspection method proposed by the client is considered to be inappropriate.

3.2

EMCI Register shall have and shall use adequate documented instructions on inspection planning and on sampling and inspection techniques, where the absence of such instructions could jeopardize
the effectiveness of the inspection process. Where applicable, EMCI Register shall have sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results.

3.3

If EMCI Register decides to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented.

3.4

All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of EMCI Register shall be maintained up-to-date and be readily available to the personnel through CETOOL.

4. Data and inspections

4.1.

When EMCI Register uses information supplied by any other party as part of the inspection process, it shall verify the integrity of such information and justify this in the CETOOL. The lead auditor is responsible.

4.2

Observations or data obtained in the course of inspections shall be recorded, in CETOOL, in a timely manner so as to prevent loss of relevant information.

4.3

Calculations and data transfers shall be subject to appropriate checks.

4.4.

EMCI Register shall have documented instructions for carrying out inspection in a safe manner. For inspections carried out onsite for RCD only the general work safety instructions from Dutch legislation shall apply, and these shall be made available to inspectors on request.

4.5.

EMCI Register shall ensure items and samples to be inspected are uniquely identified in order to avoid confusion regarding the identity of such items and samples. In case of, the work EMCI Register carries out means this identification is implicit, if not the lead auditor is responsible.

4.6.

EMCI Register shall establish, in CETOOL, whether the item to be inspected has been prepared.

4.7.

Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded in CETOOL. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, EMCI Register shall contact the client before proceeding.

4.8.

EMCI Register does not have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility as the nature of the inspection activities ensures that there is no responsibility for the inspection items.

4.9

The inspection report or certificate shall be internally traceable to the inspector(s) who performed the inspection through CETOOL.

4.10

The work carried out by the inspection body shall be covered by a retrievable inspection report or inspection certificate in CETOOL.

5. Inspection report and certificate

5.1

These rules relate to inspection reports and certificates issued by EMCI Register as part of inspections. The rules for certificates are in addition to article 10 of PD.001.

5.2

Any inspection report/certificate shall include all of the following:

a) identification of the issuing body;

b) unique identification and date of issue;

c) date(s) of inspection;

d) identification of the item(s) inspected;

e) signature or other indication of approval, by authorized personnel;

f) a statement of conformity where applicable;

g) the inspection results, except where detailed in accordance with ISO 17020 7.4.3.

5.3.

EMCI Register shall issue an inspection certificate that does not include the inspection results [see ISO 17020 5.2 g)] only when EMCI Register can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other.

5.4
All information listed in article 5.2 and 5.3 of ISO 17020 shall be reported correctly, accurately, and clearly. EMCI Register does not subcontract activities.
5.5.
Corrections or additions to an inspection report or inspection certificate after issuance shall be recorded in accordance with the relevant requirements of this article. An amended report or certificate shall identify the report or certificate replaced.

6. Equipment

6.1

EMCI Register shall have available suitable and adequate facilities and equipment to permit all activities associated with the inspection activities to be carried out in a competent and safe manner. The equipment and facilities that EMCI Register requires for inspection to not require use for access or use.

6.2

EMCI Register shall ensure the continued suitability of the facilities and the equipment mentioned in ISO 17020 article 6.2.1 for their intended use.

6.3

All equipment having a significant influence on the results of the inspection shall be defined in ID.005 and, where appropriate, uniquely identified. ID.005 shall have an appropriate identification for this kind of equipment.

6.4

The maintenance of all equipment (see ISO 17020 6.2.4) does not require specific documented procedures and instructions.

6.5

Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme. This equipment shall be identified in ID.005 and the calibration status shall be visible.

6.6

The calibration of all equipment (see ISO 17020 6.2.7) does not require specific documented procedures and instructions, or a specific programme.

6.7

EMCI Register works with rented equipment, meaning that no in-service checks are required before an inspection.

6.8

EMCI Register shall, on the day of the inspection, check and ensure equipment is fit for use, calibrated by an ISO 17025 accredited lab if required, and the results of this check must be documented in CETOOL.

6.9

EMCI Register does not store inspection items, nor does it perform any conformity assessment on incoming goods and/or services. We thus also do not need procedures on verification of incoming goods or for storage facilities.

6.10
EMCI Register does not use computers or automated equipment in connection with inspections. CETOOL is defined as excluded from this definition.

6.11
Defective equipment shall be removed from service by segregation, prominent labeling/marking on ID.005 and clear communication. EMCI Register shall examine the effect of defects on previous inspections and, when necessary, take appropriate corrective action.

6.12
Relevant information on the equipment, including software, shall be recorded. This shall include identification and, where appropriate, information on calibration and maintenance.

6.13
EMCI Register notes that there is no specific procedure for the selection of suppliers due to the nature of the activities performed. Equipment is approved and used in accordance with this SOP which is sufficient for RCD 2013/53/EU inspections.

7 Facilities and reference material

7.1

Inspections carried out under the EMCI Register accreditation scope have no specific facility requirements.

7.2

No specific equipment is required for the performance of EMCI Register inspections that have specific facility requirements (i.e. temperature storage).

7.3

EMCI Register inspections do not involve reference material and criteria relating hereto are excluded.

8. PD.001 exemptions

8.1.

In case PD.001 is applied in conjunction with SOP.007 the following articles of PD.001 are not applicable to the process of inspection, the client, or EMCI Register.

8.2

If the inspection is not related to NANDO based certification or inspection article 16 does not apply.

8.3

Article 12, dossiers inspected under ISO 17020 do require a separate technical review before the certificate is issued. Once a lead auditor has approved the inspection report the Supervising lead auditor (= technical manager as defined in ISO 17020) will act as HCD. Any provision requiring a separate HCD is excluded, if the Technical manager is also the supervising lead auditor no review is required.