Contents

I. NORMATIVE DOCUMENTS 3
II. POLICY STATEMENT 3
III. OUR VISION AND OBJECTIVES 3
IV. SCOPE AND PURPOSE 4
V. SALE PROCESS 4
5.1. Application requirements 4
5.2. Application review 4
5.3 Signed Contract 5
5.3.1. General 5
5.3.2. Changes to contract 5
VI. AUDIT PREPARATION 5
6.1. Audit Team Selection and Assignment 5
6.1.1. General 5
6.1.2. Use of Technical Expert 6
6.1.3. Auditor-in-Training 6
6.1.4. Initial Audit (stage 1 & stage 2) and Recertification Audit 7
6.1.5. Surveillance Audits 7
6.1.6. Team Leader's Responsibilities 7
6.1.7. Communicating to the audit team and Client 7
6.2. Audit Program and Audit Plan 8
6.2.1. Audit Program 8
6.2.2. Audit Plan 9
6.3. Scheduling 9
6.3.1. Planning stage 1 and stage 2 audits 9
6.3.2 Stage 1 – Initial Audit 10
6.3.3 Stage 2 – Main Audit 11
6.3.4 Surveillance Audit 11
6.3.5 Recertification Audit 12
VII. AUDIT REALISATION 13
7.1. Opening Meeting 13

Eurofins Property – Do not copy without explicit consent of Eurofins.

7.2. Conduct the Audit 14
7.3. Non-Conformities 14
7.3.1. NC Major 15
7.3.2 NC Minor 15
7.3.3. Opportunity for Improvement 15
7.3.4. NC in case of multi site organization 15
7.4. Closing Meeting 16
7.5. Audit Reporting 16
7.6 Follow up Visits 17
7.7. Closing Non-Conformities 17
7.7.1 Correction 17
7.7.2 Root Cause Analysis 17
7.7.3 Corrective Action 18
7.7.4 Audit time 18
VIII. CERTIFICATION DECISION 18
9.1. Certificate 18
9.2. Certificate Validity 19
9.3. Criteria for Certification Decision Making 20

Eurofins Property – Do not copy without explicit consent of Eurofins.

I. NORMATIVE DOCUMENTS

- ISO 17021-1:2015; ISO 17021-3:2017
- ISO 22003:2013
- ISO 17065
- IAF MD 1, MD2, MD4, MD5, MD11, MD23

II. POLICY STATEMENT

Our Policy, as defined by the Food Assurance Senior Management Team, is to provide our clients with consistent, quality service. To achieve this, Eurofins Food Assurance has established as part of its policy the following:

- To understand the importance of impartiality and confidentiality in carrying out its management system and process/product certification activities;
- To manage conflict of interest and ensure objectivity of its management system and process/product certification activities;
- To identify clients' requirements, measure its performance against those requirements, and continuously implement initiatives to improve its services;
- To continuously innovate ways to serve our clients'/stakeholders' needs;
- To develop and offer high-quality services that meet the needs of the community and our clients with regard to the quality/environmental/safety impacts of our operations and services;
- To maintain international recognition of our services in support of our clients' current and future requirements and expectations, including continuing professional development of our staff;
- To continually satisfy the requirements of ISO/IEC 17021 and ISO/IEC 17065, including the national/regional versions of the same, and the related IAF Mandatory Documents and the other documents related to the various services offered by Eurofins and issued by the relevant Accreditation Bodies and Sector Authority Organizations.
- This policy will be communicated to all levels of Eurofins staff as part of their orientation process.

III. OUR VISION AND OBJECTIVES

Our vision is: To be a premier global solution provider for all our customers' auditing and management systems needs and to support their growth in the international marketplace.

- In support of this vision and the above policy statement we have established the following objectives:
- To deliver outstanding results through sound and thorough financial practices, superior profitability and sustainable revenue growth;
- To provide value-added services and deliver innovative solutions to facilitate our customers' success in the global marketplace. To deploy a "best practice, act as lead for quality" philosophy throughout the organization
- To establish and continuously improve efficient and effective processes to support delivery of excellent services which add value to our customers' business
- To promote a culture where motivated and satisfied customer-oriented employees can flourish, experience professional fulfilment and reach their highest potential

Eurofins Property – Do not copy without explicit consent of Eurofins.

IV. SCOPE AND PURPOSE

This manual describes the scope, eligibility and procedures for certification process under Eurofins Assurance Vietnam (EAV) to comply with all requirements toward protection of the integrity of the scheme.

It is of the almost importance that those involved personnel in the certification process fully aware and understand the requirements in this document.

V. SALE PROCESS

5.1. Application requirements

To develop a proposal for potential or existing client, information is obtained from the client through the document “Application Form”. The information required includes:

- Standard of certification
- Details of activities for the definition of scope
- Client information:
  - Name, address, contact information
  - Information on sites to be covered by certification (complexity of sites, campus, multi-site)
  - Number and importance of temporary sites
  - Number of employees and details on shift activity
  - Significant aspects of organization process and operations, and relevant legal obligations
  - Information about outsourced process used by the client that will affect conformity to requirement
  - Information concerning the use of consultancy related to the management system Standard of certification

This necessary information and or data can be transmitted to EAV in any format (e.g. phone conversations, e-mail, product-related brochures provided by the client) and consolidated in Application Form. Records are retained either with the client file or by the commercial department.

5.2. Application review

The application received from the client is reviewed by competent personnel to:

- Determine the type of accreditation that can be offered;
- Ensure that EAV has the ability and competence to perform the audit;
- Determine the audit scope;
- Ensure competent resources are available to perform the audit;
- Ensure impartiality threats have been reviewed (with the support of the Impartiality Committee where necessary) and results of the review confirm the risks are at an acceptable level as described in Impartiality Procedure.
- Determine audit time
- Confirm that a single management system is deployed across the organization; in case of multisite organization AND understand the legal and contractual arrangements for each site;

If EAV declines the application following the application review, the reasons for declining an application shall be documented and made clear to the client.

Eurofins Property – Do not copy without explicit consent of Eurofins.

Audit time is determined according to

- specific rules per product
- the complexity of client sites and processes

5.3 Signed Contract

5.3.1. General

When a client signs the proposal, this then becomes the contract, therefore once this is received from a client the sales back office shall review the document to ensure that no changes have been made or requested by the client. If all details are consistent with the original proposal, the signed contract is passed to the production back office for action, the sales back office shall also indicate the clients preferred initial audit period.

If the clients asks for a second and different accreditation after contract review stage, and initial certification decision has been made and the certificate issued, this requires a new and separate certification decision.

5.3.2. Changes to contract

Amendments to contract shall be considered when significant changes are occurring to management system of the client, such as but not limited to, increase and decrease of audit days, additional sites, extension and reduction of scope, additional products, number of employees.

In addition a review shall be made to determine audit activities necessary to decide whether the certification can be maintained or not. These additional audit activities can be performed either during surveillance audit or additional audit.

Where amendments to the contracts are made, the reasons for the changes shall be documented. The information, collected for the original contract review, is modified and the differences highlighted. Adjustments to the relevant sections of the contract shall be made i.e. Audit days, product codes, sites and the contract shall be agreed by the client.

EAV shall notify its clients of any changes to certification requirements. This rule is in EAV General Conditions of Services.

VI. AUDIT PREPARATION

6.1. Audit Team Selection and Assignment

6.1.1. General

The audit team shall be appointed and composed of auditors who between them have the totality of the competences identified for the certification of the client.

When selecting the audit team the following issues shall be considered:

- Audit objectives, scope, criteria and estimated time of the audit
- The type of audit (combined, integrated joint)
- Standard (Product) to be audited and any other certification requirements (including any applicable statutory, regulatory or contractual requirements)
- Product codes i.e. CQS and overall competence of the audit team needed to achieve the audit objectives
- Auditor status i.e. Lead Auditor / Auditor
- Geographical location of the audit site
- Language and cultural considerations

Eurofins Property – Do not copy without explicit consent of Eurofins.

- Impartiality issues and rotation of auditors.

For multi-site audits it is important that the entire audit team is competent to audit the scope of certification.

The actual activities at each location must be clear before the audit commences and documented on the audit plan.

Activities for which the technical code is required MUST be audited by a team (or individual) with the competencies for that code area (supplemented by the use of technical experts where necessary).

Locations with support process activities not having any direct impact on product or process realization can be audited by a team (or individual) with the competencies for the process being audited, unless otherwise specified by the scheme standard. A team member with client specific technical coded profile shall be however available for consultation if required for any clarification in the process based audit which may have the cross references requiring a full understanding of the technical area.

In ALL cases it is the responsibility of the lead auditor to ensure that all technical activities are audited by a team or individual who has the necessary competence for that activity this must be fully documented and justified in the audit plan and the lead auditor must ensure that the audit team or individual is fully supported at all times.

The Team Leader conducting planning session for extended audit approach shall be competent as a Lead Auditor for all the standards within the IMS scope and additionally qualified as an application reviewer.

6.1.2. Use of Technical Expert

Where technical expert(s) are used to support the audit teams' technical knowledge; the technical expert(s) must be used for the duration of the audit, up to and including the closing meeting. This is to ensure that any questions from the client for the technical expert may be answered clearly.

A technical expert shall not act as an auditor in the audit team, and he/she shall always be accompanied by an auditor

The team leader shall ensure that if non-conformities are raised following input from the technical expert these shall be confirmed with the client at the time the technical expert is on site. There shall be no surprises for the client at the closing meeting. The technical expert may attend the closing meeting by conference call – this may be especially applicable for large audits but shall be fully justified on the audit plan and agreed with the client at the opening meeting.

For multi-site audits involving a technical expert, the audit plan shall clearly detail which sites the technical expert visits and the processes covered.

6.1.3. Auditor-in-Training

Auditors-in-training may be used in the audit team as participants, if an auditor is appointed as an evaluator. A record of the evaluation is made in Witness Audit report and takes into account the required attributes of an auditor. The evaluator shall be competent to take over the duties of the auditor in training if required, and has final responsibility for the activities and findings of the auditor in training.

During the transition period, auditors, who join Eurofins Assurance after completing Lead Auditor courses for revised ISO 9000, 22000 may be assigned to audits on both previous revision and mix of previous and new revisions of the standards, in order to meet the qualification criteria.

Eurofins Property – Do not copy without explicit consent of Eurofins.

6.1.4. Initial Audit (stage 1 & stage 2) and Recertification Audit

One of the audit team members shall be a qualified Lead Auditor. One of the auditor team shall be designated for the role of Team Leader; this does not have to be the qualified Lead Auditor but can be a Lead Auditor in training

6.1.5. Surveillance Audits

All of the audit team members for surveillance audits shall be qualified Auditors.

For all audits (initial, recertification and surveillance), if there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit. Auditors displaying the competencies to lead audit teams shall demonstrate a deeper understanding of presentation skills and audit management skills (for example, the leadership of a large audit team over a multi-site audit.)

6.1.6. Team Leader's Responsibilities

Team Leader Responsibilities are:

- Plan the audit, ensuring effective use of team resources (in-scope auditor allocated to critical processes)
- Represent the audit team in communication with auditee, this includes conducting opening and closing meetings
- Organize and direct audit team members
- Provide direction to auditors-in-training. (Where the Team Leader is a Lead Auditor in training, this responsibility is that of a qualified Lead Auditor who is a member of the team)
- Lead the audit team to reach the audit conclusions
- Prevent and resolve conflict
- Prepare and compete the audit report.

6.1.7. Communicating to the audit team and Client

EAV shall provide the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client to object to the appointment of any particular auditor or technical expert and to allow EAV time to reconstitute the team in response to any valid objection. This information is also sent to the audit team leader.

The tasks given to the audit team shall be defined and require the audit team to:

- Examine and verify the structure, policies, processes, procedures, records and related documents of the client relevant to the Management System (MS) standard;
- Determine that these meet all the requirements relevant to the intended scope of certification;
- Determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's MS;
- Communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets.

Eurofins Property – Do not copy without explicit consent of Eurofins.

6.2. Audit Program and Audit Plan

6.2.1. Audit Program

An Audit Programme for the full certification cycle shall be developed to clearly identify the audit activities required to demonstrate that the client's MS fulfils the requirements for certification to the selected standard(s) or other normative document(s). This audit programme shall be created during the early stages of the relationship with the client and shall be revised as needed (changes to certification, legal or accreditation requirements, organizational performance data, complaints, relevant interested parties' concerns). In the case where the client operates shifts, the activities that take place during these shifts shall also be considered in the audit programme and the audit plan.

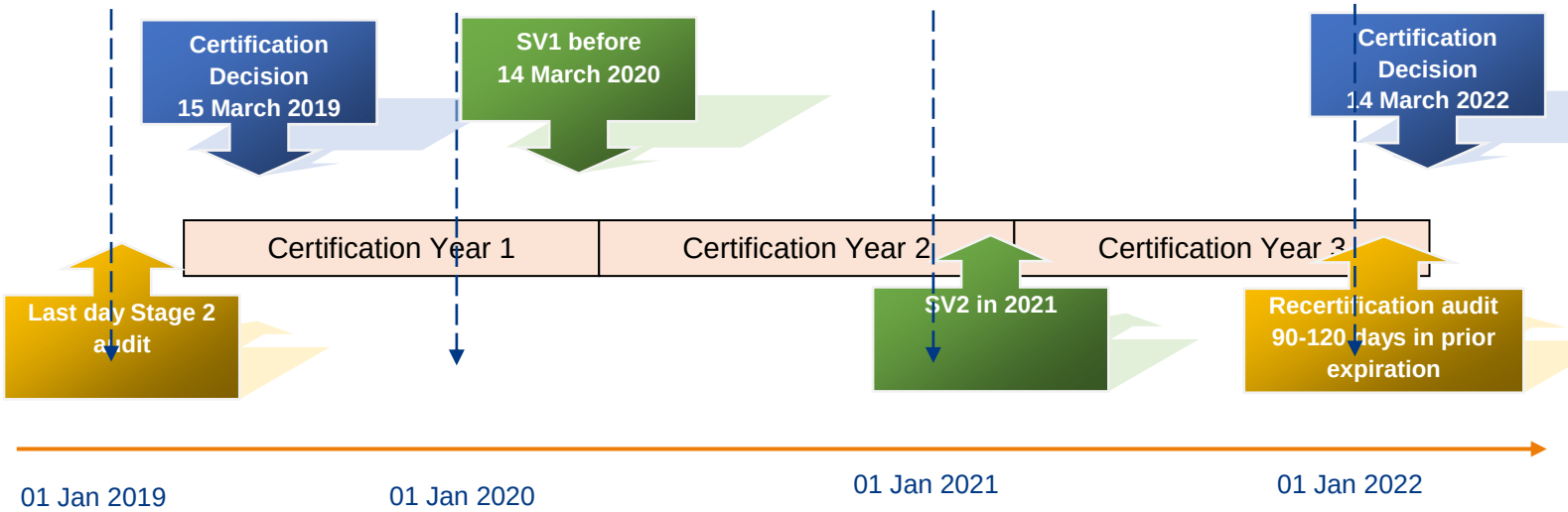
It is intended to audit either part of second or third shift during the certification or re-certification audit, as the number of man-days is comparatively higher then as compared to surveillance audits. The balance shift can then either be covered during any surveillance OR otherwise appropriately justified in the surveillance audit reports, in case it is decided not to audit shifts subsequently during the cycle.

The audit programme shall be prepared by either the lead auditor allocated to the client, or other individual who undertakes client management responsibility (for example, in the case of a client identified as a large contract.)

The audit programme shall include a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year prior to expiry of certification or within 6 months following expiry. Surveillance audits shall be conducted once a calendar year and the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date as per figure below.

The three-year certification cycle begins with the certification or recertification decision. The determination of the audit programme and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its MS, products and processes, shift operations, as well as demonstrated level of MS effectiveness and the results of any previous audits.

The audit programme clearly describes what audit activity EAV intends to carry out over the full certification cycle. This is different from an audit plan which describes activities at a single audit event.



Eurofins Property – Do not copy without explicit consent of Eurofins.

Any deviation to the audit programme shall be justified in audit report, and any amendment shall be transferred to the audit plans for next surveillances.

6.2.2. Audit Plan

An Audit Plan describes activities at a single audit event and is appropriate to the objectives and the scope of the audit. The audit plan shall be documented, sent to and agreed with the client prior to the actual audit, and is retained as objective evidence of the audit process, in the client file.

Audit plans shall be distributed to team members prior to the audit. The Team Leader shall decide on the best methodology for planning the audit. The preferred approach for the audit planning is either by department or process.

Audit plans shall ensure adequate on site audit coverage in case of multiple sites of certification to multiple system standards.

As a minimum the audit plan and accompanying documentation include the following information:

- The audit objectives
- The audit criteria and reference documents
- The audit scope, including identification of the organizational and functional units and processes to be audited
- The dates and places where the on-site audit activities are to be conducted
- The expected time and duration of on-site audit activities, including meetings with the auditees management and audit team meetings
- The roles and responsibilities of the audit team members and accompanying persons
- The allocation of appropriate resources to critical areas of the audit

Audit plans can be modified during the audit performance to face unexpected event (for example, client staff not available).The revised plan shall cover the same items as the initial one.

Where the certification scope includes activities such as installation, repair, servicing etc. that is conducted off-site, the audit planning activity shall consider these activities and allow time for specifically auditing them.

***Temporary Site:** A temporary site is a location, physical or virtual, where a client organization performs specific work or provides a service for a finite period of time and which is not intended to become a permanent site. Such sites shall be incorporated into the audit programs, which might increase the overall audit duration.

6.3. Scheduling

6.3.1. Planning stage 1 and stage 2 audits

Initial audits are planned in two stages that are not usually performed back to back. Initial audits are performed on-site. Remote audit is not allowed, except for Stage 1 audit, and shall be justified and documented. In this case all information received from the client to achieve the objectives of the Stage 1 audit, as if it was performed on-site shall be retained.

When different standards are combined, the prevailing rules are the ones of the standard requiring a Stage 1 audit to be performed on-site. The interval between Stage 1 and Stage 2 (Main Audit) shall not exceed 6 months: the first day of the Stage 2 audit shall not be performed more than 180 days after last day of Stage 1.

If Stage 1 and 2 audits are exceptionally planned back to back:

Eurofins Property – Do not copy without explicit consent of Eurofins.

- The customer shall be informed about the risk of having the stage 2 postponed if the stage 1 audit does not result in a satisfactory level of readiness of the client. This notification shall be documented.
- The audit plan shall show where the results of the Stage 1 audit are reviewed and communicated to the client, including the decision to proceed to the Stage 2 audit.
- Product Manager shall review any areas of concern identified at Stage 1, and any non-conformities identified at Stage 2, to ensure there has not been "soft grading", and that any recommendation for certification is justified.

The audit time includes the time spent by the auditor on site and time for planning and report writing (off site), and is chargeable. The time spent on-site cannot be less than 80% of the total audit time calculated as above.

Where additional time is required for planning and or report writing this shall require additional time to be added and charged and is not justification for reducing on-site auditor time. This applies to all types of audits.

6.3.2 Stage 1 – Initial Audit

Stage 1 does not require a formal audit plan and shall be performed

- To review client MS documentation
- To evaluate the client location and site specific conditions and to undertake discussions with the client personnel to determine the preparedness for the stage 2 audit
- To review the client status and understanding regarding requirement of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operations of the MS
- To collect necessary information regarding the scope of the MS, processes and locations of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of the client operation, associated risks, etc,)
- To review the allocation of resources for stage 2 and agree with the client on details of the stage 2. Evidence of this review shall be available
- To confirm that audit time and planning are considering the complexity of the sites (campus, multiple building...) and processes.
- To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the MS substantiates that the client is ready for stage 2.

Documented conclusions are produced at the end of stage 1 and communicated to the client, including the identification of any areas of concern that could be classified as non-conformities during the stage 2 audit. An unsatisfactory Stage 1 can be repeated if needed. After a satisfactory Stage 1 the arrangements for Stage 2 can be finalised (audit duration, audit team, audit plan, interval between Stage 1 and Stage 2):

***FSMS:** Stage 1 audits focus on how the client has met the intent of the FSMS and to plan for Stage 2. The FSMS Document Review must be performed to ensure the establishment and documentation of Food Safety Management System in accordance with the requirements of the Standard, and must include a detailed review of:

Eurofins Property – Do not copy without explicit consent of Eurofins.

- The hazard analysis, including determining whether all potential hazards are evaluated
- Flow charts
- Food Safety manual and Food safety procedures
- 7 Principles of HACCP
- CCP plan
- Statutory and regulatory requirements
- Organizational structure, including working shift information

The Stage 1 audit shall be performed on-site and shall address the following:

- Verification of scope
- FSMS Document Review
- Site inspection
- Completion of relevant parts of validation, verification with corrective actions implemented

6.3.3 Stage 2 – Main Audit

The purpose of the stage 2 audit is to evaluate the implementation, including effectiveness of the client MS. Stage 2 is always performed on-site except for cases described in IAF MD 4 concerning remote audits.

It includes at least the following:

- Information and evidence about conformity to all requirements of the applicable MS standard or other normative document
- Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable MS standard or other normative document)
- The client MS and performance as regards legal compliance
- Operational control of the client process
- Internal auditing and management review
- Management responsibility for the client policies
- An audit report is produced at the end of stage 2, including the identification of findings of both Stage 1 and 2.

When producing the report for both audit stages, the auditor shall refrain from simply copying the report contents from stage 1 to stage 2, but rather reflect the different topics audited in each stage.

6.3.4 Surveillance Audit

Surveillance audits shall be conducted at least once a calendar year, with the first surveillance after initial certification not more than 12 months from the certification decision date.

The 12 month rule does not apply for the recertification cycle, but the gap between two surveillance audits shall not be more than 18 months.

The frequency of surveillance audits shall be either every 6 or 12 months. Other frequencies may be used, providing the number of audit days delivered over the period of the certification is consistent with the 6 and 12 month approach.

Where surveillance periods are switched from 6 month to 12 month intervals, no reduction in man-days shall occur over the surveillance period (current and future).

Eurofins Property – Do not copy without explicit consent of Eurofins.

Team allocation requirements for surveillance activities are consistent with the requirements for initial and recertification audits. However for surveillance audits where a single auditor is required, the auditor shall have competences to lead a team.

Surveillance audits are performed to verify that the MS is efficiently maintained and shall review:

- Internal audit and management review
- Review of actions taken on NCR raised during the previous audits
- Complaints
- Effectiveness of the MS with regards to achieving the client objectives
- Progress of planned activities aimed at continual improvement
- Continuing operations control
- Review of any changes and
- Use of marks and other references to certification. Remember to check client website to verify use of marks.
- Impact of changes in client's organization: organization changes, number of employees, locations, scope etc.

As a minimum all elements of the management standard shall be audited once during the three-year certification cycle.

- Surveillance may cover other topics such as:
- Enquiries to clients on aspects of certification
- Reviewing any clients statements with respects to its operations (promotional material, website)
- Request to the client to provide documents and records and
- Other means of monitoring the client performance

6.3.5 Recertification Audit

6.3.5.1 Planning

The recertification audit shall be planned 90-120 days before expiry date to allow:

- closure of any NCRs, and
- any approval of corrective actions before expiry of current certificate.

Once expired, certification can be restored on two conditions: it must be done within 6 months and all outstanding recertification activities are completed. If these recertification activities are not completed, at least a stage 2 audit shall be performed. The new cycle is based on the new certification decision date. Please refer to Certification Decision and Recertification procedure for audit efforts required under a given situation for recertification

Performance of the MS over the period of certification shall be considered. This includes a review of the previous surveillance audit reports. This review output is documented and is part of the recertification report.

6.3.5.2 Scope

The scope of recertification audit is to evaluate the following:

- Continued fulfillment of all requirements of MS standard.
- Effectiveness of the whole MS considering internal and external changes and MS continual relevance and applicability to the scope of certification

Eurofins Property – Do not copy without explicit consent of Eurofins.

- Demonstrate commitment to maintain the effectiveness and improvement of the MS to enhance overall performance
- Whether the operation of the certified MS contributes to the achievement of the organization's policy and objectives.
- Additional planning may be needed for clients with multiple sites or multiple MS certificates. The audit plan shall always justify the decisions made for audit duration and coverage of sites to ensure confidence in the certification is maintained.

6.3.5.3 Exceptional Stage 1

As an exception, EAV decides to perform a stage 1 audit at the time of recertification, in following cases:

1) The recertification is performed after 60 days from expiry
2) There were significant changes to
- the MS,
- the organization
- the context in which the MS operates
- in the scope.
3) As a review of previous cycle performance for large clients, upon client's request.
4) Previous suspension.
5) Statutory violations, adverse publicity in media, public outcry, etc. related to MS during previous cycle.
6) Other incidents that may affect confidence in implementation of the MS.

6.3.5.4 Follow up Audit

At any stage of the certification cycle (Stage 2, surveillance and recertification), if the results of corrective actions need to be verified on site e.g. as a result of a major non-conformity being raised or multiple minor non-conformities being raised, the Team Leader will initiate an additional follow-up visit. Follow up audits can also be arranged to address complaints when the complaint cannot be addressed remotely or the degree of importance of the complaint requires it is completed before the next planned audit. Follow up audits may also be conducted after a suspension of a client.
The process for these audits is the same as any normal audit and the scope will focus on complaint investigation or determine whether the suspension can be lifted.
If a follow-up audit is to be conducted the EAV office shall arrange the date with the client and in conjunction with the Team Leader will also determine which auditor is most qualified to conduct the on-site follow-up audit.

VII. AUDIT REALISATION

7.1. Opening Meeting

A formal opening meeting shall be held with the client's management and, where appropriate, those responsible for the functions or processes to be audited. Key people to attend the opening meetings are: Managing Director or equivalent, Head of Departments (Subject to audit), Management Representative.

Eurofins Property – Do not copy without explicit consent of Eurofins.

The opening meeting, is chaired by the audit team leader, and provides a short explanation of how the audit activities will be undertaken. The degree of detail shall be consistent with the familiarity of the client with the audit process. The opening meeting shall include the following elements:

a) Introduction of the participants, including an outline of their roles;
b) Confirmation of the scope* of certification;
c) Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management;
d) Confirmation of formal communication channels between the audit team and the client;
e) Confirmation that the resources and facilities needed by the audit team are available;
f) Confirmation of matters relating to confidentiality;
g) Confirmation of relevant work safety, emergency and security procedures for the audit team;
h) Confirmation of the availability, roles and identities of any guides and observers;
i) The method of reporting, including any grading of audit findings;
j) Information about the conditions under which the audit may be prematurely terminated;
k) Confirmation that the audit team leader and audit team representing the certification body is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails;
l) Confirmation of the status of findings of the previous review or audit, if applicable;
m) Methods and procedures to be used to conduct the audit based on sampling;
n) Confirmation of the language to be used during the audit;
o) Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns;
p) Opportunity for the client to ask questions.

*Confirmation of the scope includes confirmation on the effective number of employees, site(s) and scope of certification with respect to the type of activities, products and services as applicable at each site without being misleading or ambiguous. If that differs from what is reported in the application form and the approved Contract Review, the Lead Auditor shall report it. In some cases where the discrepancy is significant, the Lead Auditor shall call the back office and agree next actions.

7.2. Conduct the Audit

The audits are carried out through:

- Interviews
- Observation of process and actions
- Review of documentation and records

7.3. Non-Conformities

The auditor shall raise NCR on template “FA25 Non-conformity Report”, and document areas of NCR in the audit report. The client will investigate the root cause and submit objecive evidences for correction and corrective action implementation. The report shall also contain as appropriate Opportunities for Improvement of the client’s management system.

The Team Leader shall agree with the client how the NCR shall be processed to closure, normally the timeline for NC closure is the maximum 30 calendar days for NC Major, 90 calendar days for NC Minor

Eurofins Property – Do not copy without explicit consent of Eurofins.

Time limits for corrections and corrective action are defined in order to have them implemented prior to expiration of certification.

7.3.1. NC Major

A Major NC is a non-conformity (non-fulfilment of a requirement) that affects the capability of the management system to achieve the intended results. Some examples but not exhaustive are:

- A failure of the clients system to address a specified requirement of the standard.
- A frequent or purposeful failure to follow specified requirement written within the company system.
- A failure to achieve the fundamental aim of a system requirement.
- A failure of the client's management system to achieve legal or statutory requirements. Where the client has identified this system failure via their own Internal Audit and Corrective Action process, and a corrective plan is in place and being implemented, then EAV auditor does not need to raise NC.
- Multiple minor NC within the same requirement of the standard or company system.
- A purposeful failure of the company to correct NC.

7.3.2 NC Minor

- Failure to comply with requirement (as stated above), which based on judgment & experience is not likely to result in failure or reduce the ability to assure controlled processes & products or Services
- An isolated system failure in some part of organization's documented system relative to applicable management system standard.
- "Noise in the system" not indicative of system collapse.

7.3.3. Opportunity for Improvement

Process, activity or document, while currently conforming, can be improved to bring benefits to the client are considered as opportunity for improvement. When raising OFI's the team leader shall ensure that these are OFI's and not NC.

7.3.4. NC in case of multi site organization

When NC (s) are found at any individual site, either through the organization's internal auditing or from auditing by EAV, investigation shall take place to determine whether the other sites may be affected. Therefore, EAV shall require the organization to review the NC (s) to determine whether they indicate an overall system deficiency applicable to other sites or not. If they are found to do so, corrective action shall be performed and verified both at the central office and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to the certification body the justification for limiting its follow-up corrective action.

EAV shall require evidence of these actions and increase its sampling frequency and/or the size of sample until it is satisfied that control is re-established. At the time of the decision making process, if any site has a NC, certification shall be denied to the whole network of listed sites pending satisfactory corrective action.

It shall not be admissible that, in order to overcome the obstacle raised by the existence of NC at a single site, the organization seeks to exclude from the scope the "problematic" site during the certification process. Such exclusion can only be agreed in advance.

Eurofins Property – Do not copy without explicit consent of Eurofins.

7.4. Closing Meeting

A formal closing meeting, where attendance shall be recorded, shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited.

Attendees at the closing meeting shall be those as at the opening meeting

The purpose of the closing meeting, which shall be chaired by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any NC shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed.

"Understood" does not necessarily mean that the NC (s) have been accepted by the client.

The closing meeting shall also include the following elements. The degree of detail shall be consistent with the familiarity of the client with the audit process:

a) Advising the client that the audit evidence collected was based on a sample of the information; thereby introducing an element of uncertainty;
b) The method and timeframe of reporting, including any grading of audit findings;
c) The certification body's process for handling NCR including any consequences relating to the status of the client's certification;
d) The timeframe for the client to present a plan for correction and corrective action for any NCR identified during the audit;
e) The certification body's post audit activities;
f) Information about the complaint handling and appeal processes.

The client shall be given opportunity for questions. Any difference in opinion regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible.

Any diverging opinions that are not resolved shall be recorded and referred to the Product Manager as soon as possible.

7.5. Audit Reporting

Team Leader ensure that a meeting takes place between the audit team and the client organization's management prior to leaving the premises, at which the audit team provides a written or oral indication regarding the conformity of the client organization's management system with the particular certification requirements Audit Reporting.

At the end of every audit (Stage 2, Surveillance, Follow up and Recertification) the audit team shall produce an audit report. For Stage 1 audit, the deliverable is limited to documented conclusions.

Where the audit report is only submitted after closure of NCR, the final report shall be submitted within 7 days of the closure of the NCR.

The final report is consolidated and summarised by the audit team leader. For initial audits, the conclusions of the stage 2 audit report will include and summarize both Stage 1 and Stage 2 findings.

Stage 2 audit reports shall include a recommendation for granting or not certification.

Note: It is important that the Audit Conclusion contain positive remarks to show that the organisation has arrangements for management reviews and internal audits have been implemented are effectively, and will be maintained.

Surveillance audit reports shall include any issues that may lead to suspension or withdrawal or certification. In such cases the file is submitted to the technical manager for review or decision.

Eurofins Property – Do not copy without explicit consent of Eurofins.

Recertification audit report shall include recommendation for renewal of Certification

7.6 Follow up Visits

At any stage of the certification cycle (Stage 2, surveillance and recertification), if the results of corrective actions need to be verified on site e.g. as a result of a major NC being raised or multiple Minor NCR being raised, the Team Leader will initiate an additional follow-up visit

Short notice audits can also be arranged to address complaints when the complaint cannot be addressed remotely or the degree of importance of the complaint requires to do it before the next planned audit. Short notice audits may also be conducted after a suspension of a client.

The process for these audits is the same as any normal audit and the scope will focus on complaint investigation or determine whether the suspension can be lift up or not.

If a follow-up audit is to be conducted the Eurofins Assurance office shall arrange the date with the client and in conjunction with the Team Leader will also determine which auditor is most qualified to conduct the on-site follow-up audit. Follow up visits are charged at the same man-day rate as the corresponding visit that initiated the follow up visit.

7.7. Closing Non-Conformities

Client response to NCR shall be reviewed by the lead auditor in three parts; correction, RCA and corrective actions.

In reviewing the three parts, the auditor looks for a plan and then evidence that plan is being implemented.

It is expected that the auditor at the closing meeting will debrief the client on the timeframes to address the NCR as well as mandatory steps such as:

7.7.1 Correction

The extent of the NCR has been determined (NCR has been corrected & the client has examined the system to see if there are other examples that need to be corrected). Ensure that correction answers the question “Is this isolated case or not?” in other words “Is there a risk that this can reoccur at the other site / department?”

If correction cannot be immediate; a plan to correct the NCR may be appropriate (responsible & date).

Evidence that the correction was implemented or evidence that the plan is being implemented

7.7.2 Root Cause Analysis

The Root Cause Analysis (RCA) is not simply repeating the finding, neither is the direct cause of the issue.

Well thought out analysis to determine the true root cause: e.g. someone did not follow a process would be direct cause; determining why someone did not follow a process would lead to the true root cause.

- Ensure that the root cause answers the question, “What in the system failed such that the problem occurred?”
- Blaming the employee will not be accepted as the only root cause
- Address problems with the process as well as what detection system failed
- Following reasons: missed, forgot,…UNACCEPTABLE for determining the root cause

The root cause statement shall focus on a single issue without any obvious "why" questions remaining.

Eurofins Property – Do not copy without explicit consent of Eurofins.

If a "why" question can reasonably be asked about the RCA, this indicates that the analysis did not go far enough.

7.7.3 Corrective Action

The corrective action or corrective action plan addresses the root cause(s) determined in the RCA. If you have not defined true root cause you cannot prevent the problem from its reoccurrence

In order to accept the plan it shall include;

- Actions to address the root cause(s)
- Identification of responsible parties for the actions and
- A schedule (dates) for implementation.
- Always include a “change” to your system. Training and/or publishing a newsletter are generally not changes to your system

In order to accept the evidence of implementation:

- Enough evidence is provided to show the plan is being implemented as outlined in the response (and on schedule).
- Note : Evidence in full is not required to close the NCR; some evidence may be reviewed during future audit when verifying the corrective actions.

If the nonconformity cannot be closed within the timeline required, the certification scope shall be reduced or certification shall not be granted, shall be suspended or withdrawn.

7.7.4 Audit time

The duration of an audit day is normally 8 hours and may or may not include a lunch break depending upon local legislation.

VIII. CERTIFICATION DECISION

9.1. Certificate

All certificates use Eurofins Assurance templates and, as a minimum, they detail the following information;

a) The name and geographic location of each client whose management system is certified (or the geographic location of the headquarters and any sites within the scope of a multi-site certification); Multi-site certificates shall identify the headquarters site and all other sites. Sites can be listed in an annex to the certificate, the head office being on the main page of the certificate. The scopes related to each individual location must be recorded on this appendix. The address must be precise enough to identify the location of the company without any ambiguity (especially where countries are using P.O. box or Plot Nr.) In this case the identification of the company shall be as shown on detailed on the business license of the organization. The same applies for any organization "trading as" (T/A.) The evidence supplied from the client showing these relationships must be retained in the client file.

b) The dates of granting, extending or renewing certification;

c) The expiry date or recertification due date consistent with the recertification cycle.

d) A unique identification code and QR Code;

e) Management system standards and/or other normative documents to which management systems is certified, and their version date/edition (e.g: ISO 9001:2015, ISO 14001:2015, ISO 22000:2018)

Eurofins Property – Do not copy without explicit consent of Eurofins.

f) The Scope of the certification with respect the product (including service), process, etc.. Where the scope is different for specific sites this must appear on the appendix to the certificate.

g) The name, address and certification mark of Eurofins Assurance; other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous.

For ALL certificates the certificate history has been removed. It is acceptable to add the statement "certified since xxxx" (where xxxx is the original certification date) IF there has been an unbroken certification history since that date.

If the certification due dates are missed and continuity is lost there must be no reference to the previous certification date – the new certification cycle must be in line with the new certification decision date.

If a client requests a supporting letter may be sent to the client detailing the certificate history.

Changes to the wording of this letter must be approved by Product Manager

If the client logo is used it must NOT be located adjacent to the accreditation body logo.

The implementation of EU Directive 765 means that all accredited certificates must show the address where Eurofins Assurance – Vietnam Branch is established.

It is permitted to also show local office address and telephone number if applicable

- Any other information required by the standard and/or other normative document used for certification;
- In the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

9.2. Certificate Validity

Certification Cycle commences with the certification decision and ends 3 years later minus one day.

The recertification decision shall be taken within the 3 years cycle, before the expiration of the current certificate

In case the recertification requirements are completed before the certification expiry date, the new certification cycle is based on three years from the previous/ original expiry date (no change to previous certification cycle).

In case the certificate has a validity period shorter than 3 years, there is no need for a new certification decision to issue a new certificate within the existing 3 years validity period.

In case the recertification audit is not satisfactorily completed before the expiry date of the existing certification, recertification shall not be recommended and the validity of the certification shall not be extended.

Client shall be informed about this situation and associated consequences. After any expiration of certification, certification can be restored within six months provided that the outstanding recertification activities are completed otherwise at least a stage 2 shall be conducted. The effective date of the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certificate cycle.

Eurofins Property – Do not copy without explicit consent of Eurofins.

9.3. Criteria for Certification Decision Making

Certification files shall be reviewed in prior to initiate decision-making process by qualified person. But this isn't the template to document the decision. Any format can be used to document the decision; minimum criteria mentioned in this list shall be verified.

Eurofins Property – Do not copy without explicit consent of Eurofins.