D1.0 PURPOSE: Guidelines for Auditing Personnel to conduct audit Assignments efficiently and achieve TNV Certification objectives.

1.2 SCOPE: All certification activities undertaken by TNV

1.3 RESPONSIBILITY: CEO/Quality Manager/Assessment Manager

Contents

Division 1. Introduction:

Cl.	Topic	Guide
1.1	Introduction of Auditor Guide	This Handbook describes the duties and responsibilities of TNV's auditing personnel (Auditor, Technical Expert, Observer, Guide, Translator etc.) while carrying out Assessment of Organization's (client) Management System for certification to ISO 9001/ 14001/22000 and ISO 45001 standards, as applicable.
1.2		This Handbook addresses the following specific areas: a) Code of Conduct b) Assessment Team Responsibilities c) Audit Guidelines d) Conduct of Pre-Audit e) Conduct of Assessment and Re- Assessment Conduct of Surveillance f) Procedures for Reporting g) Procedures referred in TNV Procedure Manual
1.3	Introduction of TNV	TNV Certification Private Limited is conformity assessment body provide Management System Certification Services and product certification services as per accreditation requirement. TNV is accredited by UAF which is member of IAF. TNV was registered in 2011 and have certified more that 10,000 client across the world. TNV have operation in approx. 50 countries.
1.4	Quality Policy	TNV Certification Pvt. Ltd.'s Quality Policy laid down by its top Management is as under:- Top Management of the TNV Certification P Ltd shall demonstrate that 1. TNV is committed to provide Transparent, Neutral, Independent, and Competent Management System Certification Services which reveal Veritas among the Business, Government & Society and Add value to its Client's Product & Services to the ultimate customer satisfaction. 2. The Management System of TNV is Established, Maintain and continually improve in accordance with the requirements of the Accreditation Board and to meet all Statutory & Regulatory Requirements in its entire process of Services to meet Accreditation Requirement. 3. TNV Certification Pvt. Ltd. will ensure that all possible "conflict of interest" situations arising out of its activities are identified and resolved timely and effectively. 4. TNV shall create & maintain an environment where each employee contributes to all aspects of our business process and shall strive for continual improvement to meet with Customer Satisfaction. The above policy may be reviewed for any changes, as and when required, by the Top Management. The above policy will be prominently displayed in TNV Certification Pvt. Ltd. office, website and brochures. Note: Latest copy of the quality policy is available on the website of the company.

Division 2. Terms & Definitions

This new Division 2 is added to the auditor guide to create awareness amongst the auditor of the TNV, this auditor guide is available on the portal of the TNV's website and auditor are always expected to refer the latest auditor guide while planning an audit. Latest changes are marked in blue for ease of identification of the latest changes.

Cl.	Topic	Guide
	Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled
	Audit Criteria	Set of policies, procedure or requirements used as a reference

Cl.	Topic	Guide
	Audit Evidence	Records, statements of fact or other information, which are relevant to the audit criteria and verifiable
	Audit Findings	Result of the evaluation of the collected audit evidence against audit criteria.
	Audit Conclusion	Outcome of an audit, providing by audit team after consideration of the audit objectives and all audit findings
	Audit Client	Organization or person requesting an audit
	Auditee	Organization being audited
	Auditor	Person with the competence to conduct an audit
	Audit Team	One or more auditors conducted an audit, supported by technical experts, if required.
	Audit Time	The audit time for all types of audits includes the **total** time **on-site** at a client's location (physical or virtual) and time spent **off-site** carrying out planning, document review, interacting with client personnel and report writing.
	Audit Programme	Set of one or more audits planned for a specific time frame and directed toward a specific purpose.
	Audit Plan	Description of the on-site activities and arrangements for an audit
	Audit Scope	Extent and boundaries of an audit
	animal food	single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to non-food-producing animals Note 1 to entry: Distinctions are made in this document between the terms food (3.18), feed (3.16) and animal food (3.19): — food is intended for consumption by humans and animals, and includes feed and animal food; — feed is intended to be fed to food-producing animals; — animal food is intended to be fed to non-food-producing animals, such as pets. [SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products”, “non” has been added and “directly” has been deleted.]
	Certification	The assessment that the client has a documented management system in place, the system in use, and the system conforms to the specific standard / specification under which it is audited
	Certification Cancellation	The permanent withdrawal of certification status. Certification documents are withdraw and the client is consisted to have non-certified status.
	Certification process	the entirety of functions relating to certification from receipt of application to the granting and maintenance of certification (as per IAF-MD 10)
	Certification function	a stage of the certification process, for example, application review, audit, certification decision (ref; ISO/IEC 17021:2011 Annex A) (as per IAF-MD 10)
	Client	The company or organization with whom TNV has a contractual agreement to conduct the audit of management system for certification purpose.
	Competence	**ability to apply knowledge and skills to achieve intended results**
	Complaint	A situation where a customer expresses dissatisfaction with a product or service
	Complainant/ Complainer	The individual or organization making the complaint
	Conflict of interest	A situation where a body or person could compromise their objectivity or put into question their independence
	critical control point	step in the *process* (3.36) at which *control measure(s)* (3.8) is (are) applied to prevent or reduce a *significant food safety hazard* (3.40) to an acceptable level, and defined *critical limit(s)* (3.12) and *measurement* (3.26) enable the application of *corrections* (3.9)
	critical limit	Measurable value which separates acceptability from unacceptability Note 1 to entry: Critical limits are established to determine whether a CCP (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products. [SOURCE: CAC/RCP 1-1969, modified — The definition has been modified and Note 1 to entry has been added.]
	Document Review	The process by which auditor systematically reviews the client’s documentation, including the Management System Manual and Procedures, to determine if the client’s documented management system satisfies the requirement of the relevant standard/ specification. The Document Review occurs prior to the certification audit

Cl.	Topic	Guide
	Corrective Action	Action taken to correct deficiencies or non-conformities within the management system. Note 1 to entry: There can be more than one cause for a nonconformity. Note 2 to entry: Corrective action includes cause analysis.
	documented information	information required to be controlled and maintained by an organization (3.31) and the medium on which it is contained Note 1 to entry: Documented information can be in any format and media, and from any source. Note 2 to entry: Documented information can refer to: — the management system (3.25), including related processes (3.36); — information created in order for the organization to operate (documentation); — evidence of results achieved (records).
	effectiveness	extent to which planned activities are realized and planned results achieved
	end product	product (3.37) that will undergo no further processing or transformation by the organization (3.31) Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.
	Feed	single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals Note 1 to entry: Distinctions are made in this document between the terms food (3.18), feed (3.16) and animal food (3.19): — food is intended for consumption by humans and animals, and includes feed and animal food; — feed is intended to be fed to food-producing animals; — — animal food is intended to be fed to non-food-producing animals, such as pets. [SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products” and “directly” has been deleted.]
	flow diagram	schematic and systematic presentation of the sequence and interactions of steps in the process
	food	substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs Note 1 to entry: Distinctions are made in this document between the terms food (3.18), feed (3.16) and animal food (3.19): — food is intended for consumption by humans and animals, and includes feed and animal food; — feed is intended to be fed to food-producing animals; — animal food is intended to be fed to non-food-producing animals, such as pets. [SOURCE: CAC/GL 81-2013, modified — The word “human” has been deleted.]
	food chain	sequence of the stages in the production, processing, distribution, storage and handling of a food (3.18) and its ingredients, from primary production to consumption Note 1 to entry: This includes the production of feed (3.16) and animal food (3.19). Note 2 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials. Note 3 to entry: The food chain also includes service providers.
	food safety	assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use Note 1 to entry: Food safety is related to the occurrence of food safety hazards (3.22) in end products (3.15) and does not include other health aspects related to, for example, malnutrition. Note 2 to entry: It is not to be confused with the availability of, and access to, food (“food security”). Note 3 to entry: This includes feed and animal food. [SOURCE: CAC/RCP 1-1969, modified — The word “harm” has been changed to “adverse health effect” and notes to entry have been added.]

Cl.	Topic	Guide
	food safety hazard	biological, chemical or physical agent in food (3.18) with the potential to cause an adverse health effect Note 1 to entry: The term "hazard" is not to be confused with the term "risk" (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard. Note 2 to entry: Food safety hazards include allergens and radiological substances. Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.4). Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended. [SOURCE: CAC/RCP 1-1969, modified — The phrase "or condition of" has been deleted from the definition and notes to entry have been added.]
	Follow-up Audit	If a major nonconformity is found within the management system, TNV will conduct a follow-up audit to ensure that effective corrective action have been taken within the required time frame
	Impartiality:	Presence of objectivity ~~(Actual and perceived word deleted)~~ Note-1: Objectivity means that conflict of interest do not exist or are resolved so as not to adversely influence subsequent activities of the TNV. Note-2: Other terms that are useful in conveying the elements of impartiality are: objectivity, Independence, freedom from conflict of interest, freedom from bias, Lack of Prejudice, neutrality, fairness, open-mildness, even-handedness, detachment & Balance.
	interested party	interested party (preferred term) stakeholder (admitted term) person or organization (3.31) that can affect, be affected by, or perceive itself to be affected by a decision or activity
	lot	defined quantity of a product (3.37) produced and/or processed and/or packaged essentially under the same conditions Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch. Note 2 to entry: The lot may be reduced to a single unit of product. [SOURCE: CODEX STAN 1, modified — Reference to "and/or processed and/or packaged" has been included in the definition and notes to entry have been added.]
	Invoice	The summary of fee and expenses incurred by TNV given to the client for payment
	Intended results	The outputs of a certification function that comply with the requirements of ISO/IEC 17021:2011 and the objectives of the CB's certification process (as per IAF-MD 10)
	Logo TNV	The mark used by TNV to signify certification of a management system to a given standard/ specification. The certified client may reproduce this logo provided the proper procedures and guidelines are followed.
	management system	set of interrelated or interacting elements of an organization (3.31) to establish policies (3.34) and objectives (3.29) and processes (3.36) to achieve those objectives Note 1 to entry: A management system can address a single discipline or several disciplines. Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation. Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations. Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.
	measurement	process (3.36) to determine a value

Cl.	Topic	Guide
	monitoring	determining the status of a system, a process (3.36) or an activity Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe. Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended. Note 3 to entry: Distinctions are made in this document between the terms validation (3.44), monitoring (3.27) and verification (3.45): — validation is applied prior to an activity and provides information about the capability to deliver intended results; — monitoring is applied during an activity and provides information for action within a specified time frame; — verification is applied after an activity and provides information for confirmation of conformity.
	Nonconformity	Non fulfillment of a requirement (not limited to Management System Standards but also include Legal & Statutory, Third Party or organization's own requirements)
	Major Non-conformity	The non-addressing of requirement of an appropriate clause of the management system (or) Existence of a non-conformity or a number of minor non-conformity or minor nonconformities when combined together are of such severity that a non-conforming product or service could be released to the customer (or) Persistent breach exiting which could be catastrophic to environment, health safety and food safety. Dealing with classification of nonconformity into minor or major is situation led decision and there is no racket science in classification of NCs. Non-fulfilment of one or more requirements of the management system that impacts the capability of the management system to achieve the intended outcomes. NOTE classifying nonconformities as major could be as follows: a significant doubt that effective process control is in place or products or services will meet specified requirements. a number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus, constitute a major non conformity a minor non-conformity that is persistent (or not corrected as agreed by the organisation) may be up-graded to major non-conformity
	Minor Non-conformity (3.13)	Non fulfillment of one or more requirement which does not impact the capability of the management system to achieve the intended outcomes.
	objective	result to be achieved Note 1 to entry: An objective can be strategic, tactical, or operational. Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process (3.36)). Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a FSMS objective, or by the use of other words with similar meaning (e.g. aim, goal, or target). Note 4 to entry: In the context of FSMS, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.
	operational prerequisite programme OPRP	control measure (3.8) or combination of control measures applied to prevent or reduce a significant food safety hazard (3.40) to an acceptable level (3.1), and where action criterion (3.2) and measurement (3.26) or observation enable effective control of the process (3.36) and/or product (3.37)
	organization	person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (3.29) Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

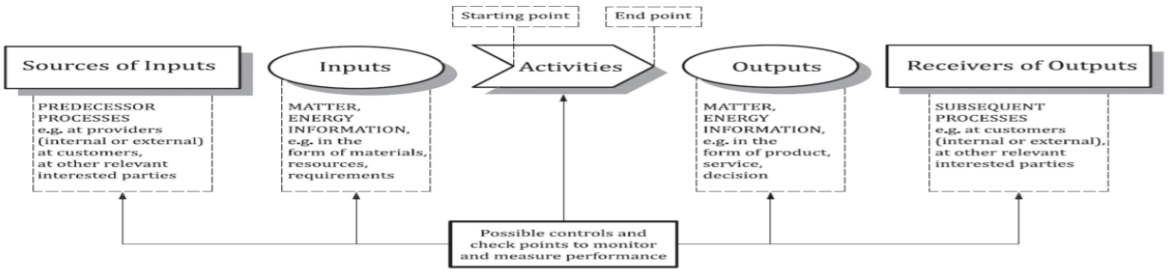
Cl.	Topic	Guide
	outsource, verb	make an arrangement where an external organization (3.31) performs part of an organization's function or process (3.36) Note 1 to entry: An external organization is outside the scope of the management system (3.25), although the outsourced function or process is within the scope.
	Performance	measurable result Note 1 to entry: Performance can relate either to quantitative or qualitative findings. Note 2 to entry: Performance can relate to the management of activities, processes (3.36), products (3.37) (including services), systems or organizations (3.31).
	policy	intentions and direction of an organization (3.31) as formally expressed by its top management (3.41)
	prerequisite programme PRP	basic conditions and activities that are necessary within the organization (3.31) and throughout the food chain (3.20) to maintain food safety Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).
	Process	set of interrelated or interacting activities which transforms inputs to outputs
	product	output that is a result of a process (3.36) Note 1 to entry: A product can be a service.
	requirement	need or expectation that is stated, generally implied or obligatory Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied. Note 2 to entry: A specified requirement is one that is stated, for example in documented information.
	Risk	effect of uncertainty Note 1 to entry: An effect is a deviation from the expected – positive or negative. Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood. Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these. Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence. Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in food (3.18), as specified in the Codex Procedural Manual.
	significant food safety hazard	food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by control measures (3.8)
	top management	person or group of people who directs and controls an organization (3.31) at the highest level Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization. Note 2 to entry: If the scope of the management system (3.25) covers only part of an organization, then top management refers to those who direct and control that part of the organization.
	Traceability	ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution. Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the food (3.18). Note 2 to entry: An object can be a product (3.37), a material, a unit, equipment, a service, etc. [SOURCE: CAC/GL 60-2006, modified — Notes to entry have been added.]

Cl.	Topic	Guide
	update	immediate and/or planned activity to ensure application of the most recent information Note 1 to entry: Update is different from the terms "maintain" and "retain": — "maintain" is to keep something on-going/to keep in good condition; — "retain" is to keep something that is retrievable.
	validation	obtaining evidence that a control measure (3.8) (or combination of control measures) will be capable of effectively controlling the significant food safety hazard (3.40) Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures. Note 2 to entry: Distinctions are made in this document between the terms validation (3.44), monitoring (3.27) and verification (3.45): — validation is applied prior to an activity and provides information about the capability to deliver intended results; — monitoring is applied during an activity and provides information for action within a specified time frame; — verification is applied after an activity and provides information for confirmation of conformity.
	Verification	confirmation, through the provision of objective evidence, that specified requirements (3.38) have been fulfilled Note 1 to entry: Distinctions are made in this document between the terms validation (3.44), monitoring (3.27) and verification (3.45): — validation is applied prior to an activity and provides information about the capability to deliver intended results; — monitoring is applied during an activity and provides information for action within a specified time frame; — verification is applied after an activity and provides information for confirmation of conformity.
	Technical expert (3.14)	Person who provide specific knowledge or expertise *(which relates to the organisation, the process or activity to be audited or language or culture)* to the audit team but does not act as an auditor in the audit team.
	Certification scheme (3.15)	Conformity Assessment System related to management system to which the same specified requirement, specific rules and procedures apply.
	Audit time (3.16)	*Audit time is a time needed to plan and accomplish a complete and effective audit of the client organisation's management system.*
	Duration of management system certification audits (3.17)	*Part of audit time spent conducting audit activities which start from the opening meeting and end at closing meeting. Audit activities includes Opening Meeting, Document review, Communication during the audit, assigning roles and responsibility or guide and observer, collecting and verifying information, Generating audit finding, preparing audit conclusion, Conducting closing meetings, but does not include Travel from one location to another location, Lunch time and report wirting.*
	Management system consultancy:	Participation in establishing, implementing or maintaining a management system (for example; preparing or producing manual or procedure and giving specific advice, instructions, or solution towards the development and implementation of a management system) Note: Arranging training and participating as a trainer is not considered as consultancy, provided that where the course related to the management system or auditing, it is confined to the provision of the generic information that is freely available in the public domain ; i.e. the trainer must not provide company specific solutions.
	Observation	The situation which does not indicate a non-conformity but if the same condition is allowed to continue may lead to a non-conformity.
	Technical Expert	Person who provides specific knowledge or expertise to the audit team.

Cl.	Topic	Guide
	Virtual Site	Virtual location where a client organization performs work or provides a service using an on-line environment allowing persons irrespective of physical locations to execute processes. Note 1: A virtual site cannot be considered where the processes must be executed in a physical environment, e.g., warehousing, manufacturing, physical testing laboratories, installation or repairs to physical products. Note 2: A virtual site (e.g. company intranet) is considered a single site for the calculation of audit time.
	Regulatory Authority (RA) for QMS-MD	A government agency or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with legal requirements. Note: Within the European Medical Devices Regulation the Regulatory Authority as defined above is titled – Competent Authority.
	Product Packaging	Product packaging is considered as that which can be removed without the product disintegrating or being damaged.
	acceptable level	**level of a *food safety hazard* (3.22) not to be exceeded in the *end product* (3.15) provided by the *organization* (3.31)**
	action criterion	**measurable or observable specification for the *monitoring* (3.27) of an *OPRP* (3.30)**
	conformity	fulfilment of a *requirement* (3.38)
	contamination	introduction or occurrence of a contaminant including a *food safety hazard* (3.22) in a *product* (3.37) or processing environment
	continual improvement	recurring activity to enhance *performance* (3.33)
	control measure	acceptable level (3.1) Note 1 to entry: See also significant food safety hazard (3.40). Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.
	Correction	action to eliminate a detected *nonconformity* (3.28) Note 1 to entry: A correction includes the handling of potentially unsafe products and can therefore be made in conjunction with a *corrective action* (3.10). Note 2 to entry: A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

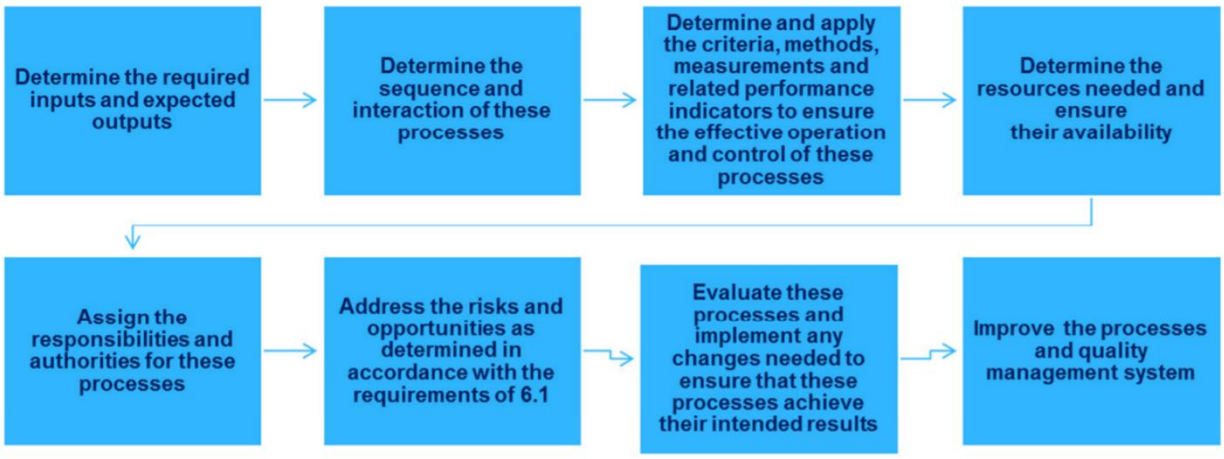
Division 3. Guidance on Auditing Processes

- **Part 1:** The description of the process approach in the 'Introduction' to ISO 9001 is purely informative and does not introduce any additional requirement by itself but is useful to understand the way that the process approach is deployed in the standard. The following picture (figure 1 from the "Introduction") provides a good understanding of a single process.



- **Part 2:** Clause 4.4 sets up comprehensive requirements for an organization to determine and apply the processes needed for its quality management system while also considering the PDCA cycle for

continual improvement and integrating risk-based thinking. Accordingly, audits should be oriented towards analyzing the processes of the organization. The following diagram will assist auditors in establishing the sequence to audit the processes of the organization:



- **Part 3:** The level of documented information needed for the processes (i.e. documents or records) needs to be determined by the organization, to the extent necessary to provide confidence that the QMS is effective, although the standard does not define any specific format or content.
  - Examples of possible documents are: process sheets, process maps, IT workflows, turtle diagrams, etc.
  - If the description of a process is not interpreted in the same way by the auditor and the auditee, the auditor should seek to understand the auditee's point of view and not impose his own view, unless it is clear (and supported with enough objective evidence) that the requirements of the standard are not met. The same is true if the auditor believes that certain processes have not been correctly identified or are missing.
  - The auditee has the right to use its own terminology, provided the requirements of the standard are met. The auditor should mentally develop a cross-reference list to ensure consistency and better understanding.
  - During the audit, the auditor should determine whether there is a problem of different use of terminology only, or whether there is a lack of real implementation of the process approach by the auditee.
- **Part 3:** Objectives, inputs, outputs, activities and resources
  - If the auditee does not understand that a process must have defined objectives (but they need not necessarily be quantitatively measurable), inputs, outputs, activities, and resources, the auditor should try reformulating the questions to the auditee avoiding the use of QM jargon.
  - Below you will find some example questions for auditing the process approach. For more guidance see the annex to this paper, which outlines typical checklist items which may be used to audit any process within any organization.
    - Can you explain to me your operations here?
    - What are the basic jobs carried out in your department?
    - What information do you need to start your work?
    - Where does it come from?
    - Who receives the result of your work?
    - How do you know if you've done your job correctly?
  - This should help the auditor to establish whether the processes are already defined, have clear inputs, outputs, objectives and so on. The auditor also need to verify that the organization has defined quality objectives for relevant processes that are aligned with its business objectives, and that these two sets of objectives do not conflict with each other.
  - The process performance indicators established for relevant processes may be used to monitor these objectives. In that case auditors should evaluate their suitability for the intended purpose.
  - The auditor should evaluate if the organization's performance indicators allow for the effective operation and control of its processes, and if they relate to the risks and opportunities for those processes.
  - Auditors should verify that established performance indicators are balanced, do not conflict between each other, are realistic and understood throughout the organization.
- **Part 4:** Processes should be analysed, monitored, measured, and improved

- If there is an absence of any documented information, or other proof, to demonstrate that the organization's processes are analyzed, monitored, measured, and improved, this could result in the auditor issuing a nonconformity.
- The level of monitoring, measurement and improvement of each process will depend on the organization's context, its strategic intent and its determined risks and opportunities.
- The auditor should not lose sight of the overall direction of the audit, and get sidetracked by superfluous details. It is important that the auditor keeps a close eye on the information provided by the auditee and especially on any documented information where the auditee defines the interaction of its processes. Interviews should also be performed in such a way that the auditors can determine the inputs and outputs of the process being audited.
- The auditor should be able to determine the importance of the process he is auditing at any time, and will therefore be able to keep sight of the overall direction of the audit. This will also help the auditor to understand the linkage between the processes.
- During an audit, the auditor has an opportunity to check the auditee's description of the interrelation of its processes. The auditor should take some samples to see if the descriptions presented in the auditee's documented information are a proper reflection of the actual interrelation of the processes, as this will help determine if the process description is adequate.
- Auditors must be aware that the application of the process approach will be different from organization to organization, depending on the size and complexity of the organization and its activities.
- Special consideration should be given to the situation in small and medium enterprises (SME's), where auditors should not expect so many processes in their QMSs.

- **Part 5:** Helping an auditee to interpret the process approach: If an auditor is faced with a complete misunderstanding by an auditee, this situation should normally be identified at the 1st stage of initial certification audit.
  - If an auditor is faced with a complete misunderstanding by an auditee, this situation should normally be identified at the 1st stage of initial certification audit. The auditor should refer the auditee to recognized information sources, such as the paper on "The Process Approach in ISO 9001:2015" (available from www.iso.org/tc176/sc02/public), which sets out different steps in the process approach and provides useful guidance with examples. The auditee should also pay sufficient consideration to - the establishment of process objectives, - process planning, - the availability of suitable documented information.
  - Auditees frequently identify too many processes; some or all of them are activities, or defined as one per clause of the standard, which do not fulfil the requirements of a process, in the sense that ISO 9001uses the concept. In this situation, an auditor should (in the 1st stage initial audit) raise an issue regarding the need for a redefinition of the processes, based on e.g. the criticality of the activities and the process approach. This might be particularly relevant for SME's.
  - Also in this situation the auditor should refer the auditee to relevant ISO documents, such as The Process Approach in ISO 9001:2015 (see above) which gives clear guidance on this matter.
  - Note: giving reference of the guidance note or management system standard shall not be considered consultancy, But auditor must refrain from giving any solution to the auditee.

Division 4. The Certification Process

Cl.	Topic	Guide
1.1		The Certification process consists of the following key stages, ENQUIRIES and QUOTATIONS, APPLICATION, Stage-I, Stage-II and SURVEILANCE VISITS. Re-Audits are also features of the certification process.
1.2		ENQUIRIES are received in several forms, by telephone, letter or facsimile. If they fall within TNV Certification scope of accreditation these result in the sending out of an Information Brochure pack, including an application form to be completed for the purpose of providing a quotation of fees for certification based upon the information made available, to be submitted to the client for acceptance.
1.3		Upon acceptance of the fee quotation, the client completes and submit the "Application Questionnaire "together with the Application fee upon receipt of which Technical Coordinator verifies the relevant details of the client's application with the fee quotation and completes a supplementary Contract Review including allocation of the scope sector of the clients activities coming under the applied scope of registration with the original Questionnaire to check that there is no discrepancy.

Cl.	Topic	Guide
1.4		The Stage-I visit has two key functions. The first and most important is to review the Documented Management System (DMS) against the requirements of the relevant ISO 9001/14001/22000/ OHS 18001 / ISO 45001, ISO 13485, ISO 27001 Standard. A detailed report is raised, and copy left with the client. The second function is to have a preliminary evaluation of the implementation based upon which a plan for the Stage-II audit of the organization is discussed with the management.
		It is expected that the Management System has been in place for at least about three months before the Stage-I audit is considered. A period of two-Three weeks is normally recommended between Stage-I and Stage-II visits but the certification audit is scheduled on a mutually convenient date upon client's intimation of readiness.
		A pre-Audit is a trial audit which is conducted before the Certification audit at client's option to provide a macro level Audit of the status of implementation and identification of any major deficiencies in the compliance of the documented quality system with the requirements of the certification standards, for corrective actions to be taken in advance of the certification audit. It provides valuable inputs to give confidence to the clients and saves time for taking necessary corrective action, later.
		All audits begin with an "Opening Meeting", at which the Team leader introduces other members of the team and runs through the Audit programme. The Team leader will also explain the methodology of the Audit such as the duties of the guides, and the confirmation of confidentiality, scope as per the requirements stated in ISO 17021-1-2015.
		The purpose of the STAGE-II is to ensure that the requirements of relevant ISO standard as addressed by the documented management system are being complied with. The Auditors will be looking for objective evidence of compliance with the standards and Non compliances are brought to the attention of the guide and noted on a report form. At the end of Audit, these NC are discussed and the company's management representative is asked to sign the report acknowledging that he understands and accepts the findings.
		The Audit is concluded with a "Closing Meeting" at which the Team Leader presents the findings and makes a recommendations, either for certification to the applicable standards of ISO otherwise with a requirement for a verification audit in case of major non-conformances having been identified.
		In case where non-compliances are of a minor nature, certification is recommended subject to a corrective action plan that addresses the non compliances and observations raised in the report being submitted together with objective evidences for all non compliances within 2 weeks. When this corrective action plan and the objective evidences are received at the TNV Certification office, the audit reports are verified for conformance against the requirements of the certification standard. The client's file is reviewed to ensure an independent verification of compliance against certification checklist as per the applicable management system and grant of certification.
		Each certified organization is required to undergo a surveillance audit at minimum intervals of one year, during the term of validity of its certification. The continual conformance of the organization applicable management system with the certification standard is verified by auditing selected elements of the quality management system at each visit besides verification of the effectiveness of the corrective actions against the non-conformities raised during the previous audit.

Cl.	Topic	Guide
		The Auditors are required to complete the Reports in a precise and accurate manner. The justification for non inclusion of any element as per the ISO 9001 standards e.g. Design Control etc from the company's quality management system should be carefully verified and recorded in the Report.
	Audit Time:	Audit activities normally include: 1. Conducting the opening meeting 2. Performing document review while conducting the audit 3. Communicating during the audit 4. Assigning roles and responsibilities of guides and observers 5. Collecting and verifying information 6. Generating audit findings 7. Preparing audit conclusions 8. Conducting the closing meeting
	Audit Man-Day	The duration of an audit day is normally 8 hours and may or may not include a lunch break depending upon local legislation
	TEMPORARY SITES	Typically on-site audits of temporary sites would be performed. However, the following methods could be considered as alternatives to replace some on-site audits: 1. Interviews or progress meetings with the client and/or its customer in person or by teleconference. 2. Document review of temporary site activities. 3. Remote access to electronic site(s) that contains records or other information that is relevant to the assessment of the management system and the temporary site(s). 4. Use of video and teleconference and other technology that enable effective auditing to be conducted remotely. In each case, the method of audit should be fully documented and justified in terms of its effectiveness and with prior approval of the assessment manager.
	control of outsourced process	If any client organization outsources part of its functions or processes, it is the responsibility of the Audit Team to obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently deliver conforming products and services to its customers or to control its environmental aspects and commitments to compliance with legal requirements.
		The Auditor shall audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.
		The CB will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However, auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

Division 5. Code of Conduct

Cl.	Topic	Guide
1.1	Reference	The Auditors should understand that they are visiting the Client's premises as representatives of TNV and their conduct must reflect professional and ethical standards of the highest order.
1.2	Expectation	**Auditors are expected to**
		a) Be smartly dressed and well groomed. b) Be calm and polite during communication. c) Be well prepared and objective in conducting the audits ensuring effective Time management. d) Be direct and decisive e) Seek objective evidence of compliance and non-compliance f) Use only TNV documentation and follow the procedural requirements. g) All auditors are required to declare a denial of their involvement in providing Consultancy or professional interest of any company before undertaking an Auditing assignment in the Company. **h) Be ethical , open minded, diplomatic, good observant and determined.** i) Be discerning, versatile, tenacious and self-reliant
	Don'ts	**Auditors are not expected to**
		a) Correspond directly with the client unless authorized by TNV
		b) Offer advice that may be interpreted as consultancy to the company being assessed.
		c)

Division 6. Generic list of questions for auditing

By using this checklist an auditor can cover the majority of the requirements of ISO 9001

1. Who or what are the:
    a. Processes
    b. Process Owner
    c. Personnel Interviewed
    d. Documentation Reviewed
    e. Records Sighted
2. What are the resources needed for the process?
3. Are these resources appropriate?
4. Are authorities and responsibilities for required resources defined, documented and known throughout the organization?
5. Are these persons competent?
6. Are competency criteria defined? What are these criteria?
7. How is competency evaluated, approved and monitored, and by which method(s)?
8. Are these methods effective? – refer to outputs
9. Are the resources adequate? Which are they?

10. Are records available and appropriately maintained?
11. What are the inputs to this process?
12. Are these inputs documented and reviewed by competent persons?
13. Is a description of the processes available and documented?
14. Are these descriptions controlled? – Verify the effectiveness of the organization's documented information control procedure.
15. Who are the "customers" (internal and external) of the processes?
16. What are the requirements of these customers?
17. What are the characteristics of the intended results of the process?
18. What are the characteristics of the unintended results of the process?
19. Are correction and corrective action applied as appropriate?
20. What are the criteria for monitoring, measurement and analysis?
21. How are these criteria incorporated into the planning of the processes?
22. Are the business performance issues taken into proper account?
23. What methods are used for data gathering?
24. What records are kept and how these are maintained?
25. What are the communication channels?
26. How is external and internal information about the process provided?
27. What are the outputs of the process? – Identify outputs.
28. Do these outputs provide evidence of effective implementation of the process?
29. How is process performance monitored?
30. Are appropriate controls defined?
31. What measurements are applied?
32. How is the gathered information analyzed?
33. How are the results of the analysis taken into account?
34. How is feedback obtained?
35. What data is collected?
36. Is the issue of improvement of the processes properly addressed? How? What are the results?

Division 7. Auditor's Responsibilities

Cl.	Topic	Guide
1.1	**Auditor's Responsibilities**	The LA is responsible for planning and conduct of the Audit. LA is also responsible for ensuring that all relevant information concerning the Audit is reported. **(LA: - Lead Auditor)**
1.2		LA shall allocate tasks to each member of the audit team and LA shall ensure that the members of the team are fully prepared and capable of undertaking the auditing functions professionally and effectively. Audit recommendations are arrived at by the Audit team at the Pre-closing meeting where the LA will debrief the entire Auditor's. The final report & recommendation, however, shall be decided by the LA himself.
		During the planning phase of the auditing process, the LA and other members should prepare individual Audit Check lists for evaluating quality system elements assigned to them. These lists should be filled up in a manner as to provide evidence of an in-depth probe into quality systems. These should also bring out evidence of both positive and negative findings about the company's quality management systems.

Cl.	Topic	Guide
		The Lead Auditor should ensure that the completed check lists through notes of each auditor are attached to the audit reports before forwarding the same to **TNV Certification.**
		The lead auditor shall ensure that Guide, Observer, interpreter, translator does not influence or interfere the audit process or neither shall interfere in the outcome of the audit.
		Note The responsibilities of guide can include establishing contacts and timing for interviews, arranging visits to specific parts of the site or organization, ensuring that rules concerning site safety and security procedures are known and respected by the audit team members, witnessing the audit on behalf of the client, providing clarification or information as requested by an auditor.

Division 8. Conduct of Audits

Cl.	Topic	Guide
1.1	Introduction	The Lead Auditor /Audit Members will ensure that due caution is exercised in complying with the following requirements when conducting quality systems audits
1.2	Audit Planning/ Preparation	
	Audit Plan Matrix	The team has to prepare in advance a matrix of the elements of the standard against departments/functions to be audited. Tick marks the form after judicious cross reference to the auditees' activities. While making the audit plan the LA shall give consideration to below mentioned points but not restricted to this only
		• the scope and complexity of the client's management system; • products and processes (including services); • size of the client organization; • sites to be audited; • language of the client organization and languages spoken and written; • the requirements of sector or regulatory schemes; • client and their customers' requirements and expectations; • the number and timing of shifts; • audit time required for each audit activity; • competence of each member of the audit team; • the need to audit temporary sites; • results of the stage 1 audit or of any other previous audits; • results of other surveillance activities; • demonstrated level of management system effectiveness; • eligibility for sampling; • customer complaints; • complaints received by the certification body about the client; r) combined, integrated or joint audits; • changes to the client's organization, products, processes or its management system; • changes to the certification requirements; • changes to legal requirements; • changes to accreditation requirements; • risk and complexity; • organizational performance data [e.g. defect levels, key performance indicators (KPI) data, Rejection, Customer Satisfaction, Vendor Approval etc.]; • interested parties' concerns; • information gained during previous audits.

Cl.	Topic	Guide
	Audit Programme	After ascertaining the geographical location of various departments/functions and the quantum of work in each, the Team Leader should allocate time and auditing function to each auditor, including allocation of technical experts, if any, for critical areas of the auditees activities, in the Audit Plan. The Team Leader is required to discuss the Audit Plan/Schedule with the Audit Team Members and the Technical Experts, during Audit Team Briefing before the commencement of the Audit.
		Audit Plan and composition of Audit Team details are advised to the Auditee in advance for their acceptance and the same is explained in details at the time of opening meeting. The auditors need to communicate effectively either through their own skills or use interpreter if required. While developing the audit plan the Audit team need to the ensure that the objectives covers Management priorities, Commercial intentions, Management system requirements, Statutory, regulatory and contractual requirements, Need for supplier evaluation, Customer requirements, Needs of other interested parties and Risks to the organization.
		The extent of an audit plan may vary and will be influenced by the size, nature and complexity of the organization to be audited also consideration must be given to scope, objective and duration of each audit to be conducted, frequency of audit, number, importance, complexity, similarly and locations of the activities to be audited, Standards, statutory, regulatory and contractual requirements and other audit criteria, Conclusions of previous audit or results of a previous audit programme review, language, cultural and social issues, concerns of interested parties (EMS & OHS), Significant changes to an organization or its operations.
	Check Sheets/Recording of Observations/Use of TNV Reporting Documents	The Team Leader should ensure that each member prepares his individual check lists relating to his assigned function. The information gathered must be based on the type of industry and the scope of registration. Further, it is dependent upon the criticality of the function/product/process and its bearing on quality and safety. The auditor must verify the accuracy of the collected information in regard to conformity and non-conformity of any process. The evidences must be collected in a manner that it supports the audit findings and the compliance/non-compliance to lead a conclusion for the certification activity.
		The auditors need to assess those processes/factors which have an effect on the dependability of the audit finding and conclusions.
		While identifying and recording the audit findings the Lead Auditor/Auditor shall ensure the following points
		Audit findings summarizing conformity and detailing nonconformity and its supporting audit evidence are recorded and reported in the audit report to enable an informed certification decision to be made or the certification to be maintained.
		The Opportunities for improvement identified in the audit are recorded in the audit report, unless prohibited by the requirements of a management system certification scheme. Audit findings, however, which are nonconformities in accordance with 9.1.15 b) and c) of the manual will never be recorded as opportunities for improvement.
		Finding of nonconformity are be recorded against a specific requirement of the audit criteria contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based in the audit report. Discuss Nonconformities with the client to ensure that the evidence is accurate and that the nonconformities are understood. The lead auditor however shall avoid from suggesting the cause of nonconformities or their solution.
		Shall try to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded in the audit report.
		Shall not recommend specific solution related to any opportunity or NC identified

Cl.	Topic	Guide
	Guidance Documents	Auditor must read the study sector specific guidance material well before the audit. Based on this, emphasize some of the clauses which become critical because of the peculiar requirements of the sector specific industry.
	Audit Scope & Criteria	The audit scope describes the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited, as well as the time period covered by the audit.
		The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry / business sector codes of conduct.
		If the scope covers installation activities, the planning matrix should include onsite verification. If the auditee's scope includes design requirements, special care is to be taken in earmarking the team member with experience in design. Further the team leader should ensure that adequate amount of time is allotted for this function.
		The auditors need to ensure the confidentiality and security if the information gathered in the audit. The Team Leader confirms the scope of certification applied for, with the client, during the opening meeting. In the event an amended scope involving a major addition or change to the original scope is proposed by the company, the Team Leader should seek instructions from TNV office before proceeding with the Audit, as an amended scope may require additional audit man-days or sector scope competence. Minor changes in the scope of certification may, however, be accepted for Audit and reported, accordingly. Where a combined audit is to be conducted, it is important that the audit team leader ensures that the audit objectives, scope and criteria are appropriate to the nature of the combined audit.

Division 9. AUDIT EXECUTION

Cl.	Topic	Guide
1.1	Introduction	This section help the auditor to conduct the audit.
1.2	Time Management	TNV auditors follow good planning for management system certification audit by preparation of Audit Plan Matrix, TNV Programme sheet and check sheets prior to the commencement of the audit will ensure that team does not waste any time during the execution of the audit. An itinerary will be prepared by TNV for each audit giving tentative time schedule, covering clauses of the concerned standard and name of the auditor for guidance of audit team and auditee. This will be issued 7 to 10 days in advance. In case of integrated management system audit common clauses may be suitably clubbed under a single auditor to avoid duplication of effort.
	Check of Interface Activities	Good planning and thorough preparation by detailed study of the various functions/departments of the company will ensure that its interface activities are covered. While conducting audit in one department/function, do not see it in isolation. See with which other functions, it is inter-related/ inter-dependent/interacting. It is essential that we look into these areas/interfaces during our audits.

Cl.	Topic	Guide
	In-depth Probing/Questioning	Auditors should seek objective evidence of compliance of each audit function with the standards and scope of registration by in-depth verification of the related documents, operations and processes (e.g. note an instrument in production area with calibration sticker duly affixed and check its calibration status in Calibration Laboratory. Again note down particulars of an operator who is not performing as per work instructions and look for his training records in HRD) and seek objective evidence. This should be compared with the relevant clause of the standard in order to arrive at Non Conformities. This should be agreed to by the auditee during the execution of Audit. In case of any element of applicable ISO standard being considered not applicable to the auditees operations, a suitable explanation is required to justify the exclusion of the element from the audit on page 1 of Report.
	Audit Trail	Audit plan for each auditee function relevant to the clauses of the standard should provide for audit to be conducted in a logical sequence, consistent with the flow of work rather than leap forging. Auditors nominated for production areas may cover in one sequence planning, issue of material, preparation of material, machine shop, fabrication, assembly and final inspection. Auditors while auditing inspection/testing, verify the calibration status while going forward or backwards in your visit to Calibration Department. In the Food sector verify the calibration certificate of the master equipment by which calibration is carried out i.e., traceability certificate
	Organizational Situations	The auditors skills need to include the following
		• organizational size, structure, functions and relationships • general business processes and related terminology • cultural and social customs of the auditee
	Method to collect evidence	The Methods to collect information shall include, but are not limited to: a) Interviews; b) Observation of processes and activities; c) Review of documentation and records. d) Customer Satisfaction e) Data Analysis
	Communication during audit	The Lead Auditor need to adopt following steps of communication during any audit;
		During the audit the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.
		Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety, strike, non-cooperation, threatening), the audit team leader shall report this to the client and, if possible, to the TNV CEO/MD to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to TNV CEO/MD.
		Review with the client any need for changes to the audit scope which becomes apparent as on-site auditing activities progress and report this to TNV CEO/MD

Cl.	Topic	Guide
		If during the auditor identifies any breach of an Act of Parliament, or a contravention of a regulatory requirement Non Conformity is issued immediately and communicated to the Top Management

Division 10. Concluding the audit

Cl.	Topic	Guide
1.1	Introduction	This section help the auditor to conduct the audit.
1.2		Before commencing the closing meeting, the audit team shall do the audit conclusion which must cover the following:
		• **Debriefing of the audit finding and development** • review the audit findings, and any other appropriate information collected during the audit, against the audit objectives; • agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process; • identify any necessary follow-up actions; • confirm the appropriateness of the audit programme or identify any modification required (e.g. scope, audit time or dates, surveillance frequency, competence). • An explanation needs to be given in case of any differences from the information presented to the organisation at the closing meeting during OHSAS audit.
	Audit Evidence	The Lead Auditor must ensure that he collects sufficient objective evidences for conformity towards the audit objectives, scope of the certification, the processes including verification for conformity towards the standards requirement and organizations laid down requirement which is collected by appropriate sampling and verified.

Division 11. Performance Evaluation

Cl.	Topic	Guide
1.1	Introduction	This section help the auditor to conduct the audit Performance Evaluation of Audit Team Members.
1.2		The Audit Team Leader will evaluate each member/observer as per the need /guidance from TNV office of his team against the various parameters listed in No. (TNV- F-020).The performance reports should be forwarded separately to the CEO OF TNV and these will be treated confidentially. The Reporting Auditor may suggest any training need where necessary.
1.3	Performance Evaluation of Auditor / Team Leaders	The performance of the Team Leaders will be verified through witness Audits independently by TNV qualified Lead Auditors who will report on the Auditor's performance as per (TNV- F-019). Each Auditor's/ performance will be verified once a year/and lead Auditor and once in 3 years.

Cl.	Topic	Guide
1.4	Performance Evaluation of Observer Auditors – Training & Assignment Of "Observer Auditors"	a) All auditors who have qualified at an approved QMS/EMS/OHSAS/FSMS Lead Auditors Course and fulfilled the other qualification criteria for empanelment of external auditors are required to obtain auditing experience for 20 audit man-days as per the requirements of ISO 19011:2011 before qualifying for assignment as an audit team member for Management System audits on behalf of TNV. b) The requisite audit experience is obtained through attachment with audit teams for conduct of third party audits of quality management systems including Documentation Review, Pre-Audits, Certification and Surveillance Audits. c) Observer Auditors are assigned for working strictly under the direction and supervision of the assigned Team Leader and do not undertake any audit function, independently, during training. d) The Team Leader is responsible for ensuring that the Observer Auditor is guided and trained in the methodology and practical conduct of all aspects of auditing of a management system as per the ISO standards (9001/14001/18001/22000) e) The Team Leader is required to assess the understanding and performance of the 'Observer Auditor' under his supervision and report on his compliance with the various attributes and skills as per TNV Performance Report (TNV) including recommendation for desirable corrective actions and improvement. f) The Performance Report is required to be forwarded for each audit by the Team Leader in respect of each Observer Auditor for review by the AM and record. The Observer Auditor will be advised of any deficiencies and improvement required in his performance. g) Upon completion of the requisite man-days of auditing as an 'Observer Auditor ', the AM will assess his overall performance on the basis of the performance reports and confirm his up gradation to the Audit Team Member's grade or recommend further training, where necessary. h) The up gradation of an 'Observer Auditor' will be duly recorded and his name entered in the TNV List of Approved Auditors.
1.5	Technical Experts	Technical expertise are selected for a specific scope sector and assigned as and when required. Before their appointment the Qualification, Industry experience and current technical knowledge are verified for any particular audit. Also their performance is reported by the team leader and evaluated by Quality Manager.
1.6	Translator & Interpreters	Translators & Interpreters appointed to the audit team shall work under the direction of Audit team or individual auditor. The translator and interpreters are selected in a manner that they do not unduly influence the audit and the same must ensure by the Audit team.
1.7	Auditor in Training	In case of any auditor in training included in the team as participant, the Lead Auditor/Evaluator has the final responsibility for the activities and findings of the trainee auditor.

Division 12. Audit Trail (Questioning Mechanism)

1. **How do you contribute to achieving your organization's objectives?**

   Closely related questions include:

   a. How are objectives determined?
   b. How are employees trained on objectives?
   c. How is progress against objectives communicated to the organization?
   d. What processes and/or tools are in place to help achieve objectives?
   e. Is there evidence of progress?

2. **What happens if your product, materials, or supplies are nonconforming?**

During an audit, find some examples of nonconforming products—if any exist—and follow-up with these questions:

a. How are nonconforming products identified?
b. Where are they located?
c. What are the responsibilities and authorities related to dealing with nonconforming products?
d. How do dispositions get determined and implemented?
e. What are the records of nonconforming products and actions taken on them?
f. What are the trends in nonconforming products?
g. How is the procedure linked to the corrective action process?

3. **How do you access product requirements?**

Specific points of inquiry related to product requirements include:

a. Are product requirements complete?
b. How does the organization ensure that correct versions are available?
c. How are requirements reviewed prior to acceptance?
d. How do you ensure that product meets the stated requirements?
e. What happens when changes are made to product requirements?

4. **How are problems prevented?**

Additional points of inquiry related to preventive action include:

a. How do data trends get analyzed?
b. How do employees communicate their improvement ideas?
c. How do preventive actions get recorded?
d. Are statistical techniques used?
e. How are customer perceptions captured on a proactive basis?

5. **How do you use data on customer perceptions?**

Here are some related audit questions:

a. How are data on customer satisfaction analyzed?
b. How are opportunities identified and prioritized?
c. What's the connection to the corrective and preventive action systems?
d. What are the organization's long-term trends in customer satisfaction?
e. How are resources for customer satisfaction identified and provided?
f. What connections exist between customer satisfaction and the organization's objectives?

6. **How are customer complaints handled?**

Here are some related questions:

a. What's the largest complaint category?
b. What's being done about it?
c. Has the amount of complaints changed over time?
d. How are personnel trained in their roles in preventing complaints?
e. How are customers made aware of actions on their complaints?
f. What tools are used to identify the causes of complaints?

7. **How does top management review the organization's performance?**

Here are some related questions:

a. Who's involved in reviewing the organization's performance?
b. What actions have resulted from these reviews?
c. How are records of the reviews generated?
d. Are all required inputs and outputs addressed by records?

e. How does the rest of the organization learn of actions and decisions that are determined during reviews?

8. **What evidence can you provide of continual improvement?**

These are some related lines of inquiry:

a. Who's involved in improvement efforts?
b. What tools are used to pursue continual improvement?
c. How are personnel trained to use improvement tools?
d. How are improvement ideas prioritized?
e. How are employees made aware of improvement efforts and successes?

9. **How are training needs determined?**

Here are some related questions:

a. What kind of orientation training is provided when employees are hired?
b. How are personnel made aware of the organization's mission, values, and measurable objectives?
c. How is the effectiveness of training evaluated?
d. What happens when training is determined to have been ineffective?
e. What records of training are maintained?

10. **What's the most important thing about your job?**

Consider these related questions:

a. What's the hardest thing about your job?
b. What are some things you'd like to change about your job?
c. What resource would help you be more effective?
d. What should your manager know that he or she currently doesn't know?
e. If you were the manager here, what would you do differently?

Division 13. Pre Audits (Document Review):

TNV consider onsite Document Review pre-audits on systems as an optional part of the certification process. TNV performs pre-audits on site on request.

A complete pre-audit program consists of the following elements:
Review of the system documentation,
Pre audit at the premises of the organisation during a number of days,
Preparation of a detailed pre-audit report,
Presentation of the results of the pre-audit.
The organisation is free to decide about the pre-audit program.

For the performance of a pre-audit, the TC assigns an auditor (LA or AD). The auditor contacts the organisation and makes further arrangements.

The auditor performs the pre-audit in a similar way as a certification audit, with exception of:
Only the activities agreed with the organisation shall be audited.

No corrective action shall be requested for the non-conformities presented at the exit meeting. Pre-audit man-days shall not exceed the stage 2 man-days and auditors involved in a pre-audit should preferably not be involved in the certification audit of the same organization.

There are no specific rules concerning the format of a pre-audit report. Format and content should be agreed with the customer.

Division 14. Certification Audit Visits (Stage 1 & Stage 2):

1. DEFINITION OF SCOPE

The Scope of certification of a client company is defined to cover the type and range of the company's products or/and services to which the management system is applicable
(ISO 9001/14000/22000/18001) and is to be assessed.

2. Stage -1

Stage 1 Audits are a review of a client company's readiness for Audit against the following objectives:

a) To audit the clients management system documentation.
a) To review the clients location and site-specific conditions and to undertake discussions with the clients personnel to determine the preparedness for the stage-2 audit.
b) To review the client's status and understanding regarding requirement of the standard, in particular with respect to the identification of key performance or significant aspects, processes objectives and operation of the management system.
c) To collect necessary information regarding the scope of the management system, processes and locations of the client's, and related statutory and regulatory aspects and complex (e.g. quality environmental, legal aspects of the client's operation, associated risks, etc.)
d) To review the allocation of resources for stage-2 audit and agree with client on the details of the stage-2 audit.
e) To provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects.
f) To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.
g) The OHSAS management system includes adequate processes to identify the organizations OHS hazards and determine their significances as well.
h) The OHS management system provides an adequate description of the organization and its on-site processes.
i) An overview of the applicable regulations, agreement with approving authorities has been included in the OHSAS management system, also if there is any OHS license requirement in application the relevant activities of the organization are in place.
j) The OHSAS management system is designed to achieve the organization's OHS policy.
k) To verify that at least one cycle of Internal Audit & Management Review has been conducted and the OHSAS management system programme is implemented properly and the preparedness for the conduction of Stage 2 audit. To collect necessary information for on-site audit of temporary sites considering the sites as per the complexity category.
l) To verify that the information derived from the Contract Review is complete and appropriate in all the terms for the OHS management system.
m) To collect necessary information and identify the issues which will need special attention during the stage 2 audit.
n) The organization has identified PRPs appropriate to the business (e.g. regulatory and statutory requirements), Auditor need to verify that When client organisation selecting and/or establishing PRP(s), have they considered and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices, national, international or sector standards]. Reference while checking international standards, reference of the following should be taken:
    i ISO/TS 22002-1 Prerequisite programmes for food safety – Part 1: Food manufacturing
    ii ISO/TS 22002-2 Prerequisite programmes for food safety – Part 2: Catering
    iii ISO/TS 22002-3 Prerequisite programmes for food safety – Part 3: Farming
    iv ISO/TS 22002-4 Prerequisite programmes for food safety – Part 4: Food packaging manufacturing.
    v ISO/TS 22002-5 Prerequisite programmes for food safety – Part 5: Transport and storage
    vi ISO/TS 22002-6 Prerequisite programmes on food safety - Part 6: Feed and animal food production
o) The FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations)
p) Food safety legislation is in place for the relevant sector(s) of the organization
q) Food safety legislation is in place for the relevant sector(s) of the organization
r) FSMS implementation programme justifies proceeding to the Stage 2 audit
s) The validation, verification and improvement programmes conform to the requirements of the FSMS standard
t) The FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties

u) Additional documentation needs to be reviewed and/or what knowledge needs to be obtained in advance.
v) Where an organization has implemented an externally developed combination of control measures, the stage 1 audit shall review the documentation included in the FSMS to determine if the combination of control measures is suitable for the organization, was developed in compliance with the requirements of ISO 22000, and is kept up to date. The availability of relevant authorizations should be checked when collecting the information regarding the compliance to regulatory aspects.

3. REVIEW OF MANAGEMENT SYSTEMS DOCUMENTATION

Before an Audit of a company can be undertaken, TNV must ensure that the company can be undertaken; TNV must ensure that the company has a documented Management system complying with the relevant part of **ISO 9001/14001/22000 & OHS18001** as the case may be. Management system documentation will normally take the form of a Policy Manual a Procedures Manual, work instructions and formats. In some cases, particularly with small companies, it may be practicable for all of the documented system companies; it may be practicable for all of documented system to be included in a single manual. However, in many instances, detailed documented procedures will be contained in supplementary manuals which are referenced by the Documented Management System Manual (Guidance of Documented Management System structure and content can be found in Section A13, Section A14 & Section 15). It is obviously not possible to carry out an exhaustive examination of the clients' system documentation. However the Auditor must ensure that each relevant clause of the Standard is addressed and that written procedures or records are included as per mandatory requirement.

If the Auditor feels that the requirements of the Standard are not addressed in the documentation, he will note them for discussion with the client. Instances where it is agreed that a requirement of the Standard is not addressed by the documentation will be recorded in the report as a non-conformance.

4. (STAGE- I)

After a review of the complete Management System documentation, the Auditor will record his findings in the Stage 1 Report identifying the non conformities agreed with the client after discussing observations of deficiencies in the addressal of the requirements of the applicable standard.

If the Auditor is satisfied that the company's Management System documentation will comply with the requirement after necessary corrective actions in respect of the reported concerns have been completed by the client, he recommends that the company may proceed with the stage-II of the Audit, as agreed.

In the event that Management System documentation is found to be seriously deficient in addressal of the stipulated requirements, the Auditor may recommend a fresh Stage 1 audit which will be detailed in the Report. **TNV** will advise the client of the additional fees chargeable as applicable and the proposed dates for supplementary review of Management System documentation.

A copy of the Stage 1 Report is handed over to the client and it is incumbent upon the company to take necessary actions against the reported concerns and submit a corrective .action plan within the stipulated period of approx 2 weeks days to TNV Head office. The company is entitled to clarify the nature of concerns with the Auditor's who should be helpful in explaining as appropriate but he/she should not put himself/herself in the position of acting as consultant.

5. Time Plan for Stage-II audit.

While planning in the interval between **stage-I and stage-II** audit consideration is toward the need of the client to resolve the areas of concerns identified in stage-I audit. If during the stage 1 audit there is some mismatch from the initial details which affect the audit man-days and auditor competency, the contract review needs to be reviewed again for the conduction of the Stage 2 audit.

6. GUIDANCE DOCUMENTS

QM will arrange where necessary for generation of sector specific Guidance Documents including Checklist and Briefing

Notes relevant to the auditing of industry scope sectors as per Technical Area / NACE Code Classification with the assistance of the Experts in each field. The documents will be approved by the Impartiality Committee.

The purpose of these documents is to advise the auditors with the type of applicable Management System Standard against which the audit is to be conducted. Further, the aim of these guidelines is to provide sector specific expertise in Technological Processes and associated Regulatory requirements in respect of the Management Systems applicable to the products or services.

The Auditors should make use of these documents to audit critical areas, relevant to the specific Auditee activity in depth so that the critical production processes affecting the quality of the final product are properly identified and audited.

The draft guidance notes are prepared with the assistance of Expert Panel Members representing specific industry sectors and other specialists competent in that industry and are required to be approved by the Expert Committee before being released for circulation to the audit personnel, as necessary.

7. Audit Planning (Stage-II) Activities:-

The audit plan should ensure the following

a) the audit objectives;
b) the audit criteria and any reference documents
c) the audit scope, including identification of the organizational and functional units and processes to be audited
d) the dates and places where the on-site audit activities are to be conducted.
e) the expected time and duration of on-site audit activities, including meeting with the auditee's management and audit team meetings
f) the role and responsibilities of the audit team members and accompanying persons
g) the allocation of appropriate resources to critical areas of the audit.

The audit schedule is communicated to the client via TNV- F-005.

The Certification audits ***Stage-II*** are scheduled on dates agreed with the client who is advised of the above details in advance for his confirmation and acceptance including the audit team members.

A detailed audit plan giving the allocation of the audit team members and the time schedules for various auditing functions / depts. etc is forwarded to the Auditee Company in advance together with the agreed traveling arrangements.

The Lead Auditor is responsible for the detailed planning and organization of the audit plan. This plan is based upon the competence and audit Manday requirements of the contract review and is designed to verify the relevant clauses of the standard and give the appreciate areas of the company's establishment.

The purpose of the stage-II audit is to evaluate the implementation including, effectiveness, of the clients management system and documentation at site.

a) Stage –II shall include conformity to applicable management system and evidence of implementation
b) Review of objective and targets and check the performance on monitoring, measurement and reporting.
c) Management System performance for legal compliance.
d) Monitoring of process control
e) Verification of internal auditing and management Review process
f) Verification of management responsibility of its commitment towards policies.
g) Verify the Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions
h) Various mandatory records to ensure that the management system is operational
i) Evidence of the monitoring of customer satisfaction
j) The organisation adheres to its own OHSAS policies, objectives and procedures
k) The OHS management system conforms to all the requirements of the OHS standard and is achieving the organization's policy objectives for providing a safe and healthy working environment.

l) Verify effective implementation of OHS including temporary sites.

CONTROL OF EXTERNALLY PROVIDED FUNCTIONS OR PROCESSES (OUTSOURCING):

- If client organisation outsources part of its functions or processes, Auditor need to obtain evidence that the organization has effectively determined the type and extent of controls to be applied in order to ensure that the externally provided functions or processes do not adversely affect the effectiveness of the MS, including the organization's ability to consistently deliver conforming products and services to its customers or to control its environmental aspects and commitments to compliance with legal requirements.
- The TNV's Auditor will audit and evaluate the effectiveness of the client's management system in managing any supplied activity and the risk this poses to the delivery of objectives, customer and conformity requirements. This may include gathering feedback on the level of effectiveness from suppliers. However auditing the supplier's management system is not required, considering that it is included in the scope of the organization's management system only the control of the supplied activity, and not the performance of the activity itself. From this understanding of risk any additional audit time shall be determined.

Division 15. Surveillance & Renewal Audit:

1. Surveillance Audits:

The conduct of a Surveillance visit is similar to that of an initial audit in that it consists of an opening meeting, Audit and closing meeting. However, it is undertaken on a selected sample of the company's activities. The Team Leader shall check if the company's quality system has been amended since the last visit and to record the latest issue of the Management System documentation on the front page of the report. The effectiveness of the changes indicated will be verified by the Team Leader.
The corrective action against the non-conformities identifies during the previous visits shall be verified to ensure that corrective actions have been effectively implemented, as per the agreed corrective action plan and the NC is closed out.
If the surveillance audit plan requires a visit to an operational site, this will be planned by the Team Leader, when arranging the date of the visit with the company.
It is a fundamental requirement that the following elements are checked at each visit and details entered into the Surveillance Audit report of the respective management system standard:
1. The verification and closing out of the corrective action of previously raised non-compliances.
2. The company's own system review procedure, including internal audits.
3. Management Responsibility including review of the analysis of data and improvement Plans.
4. Preventive and Corrective Actions.
5. Management Review.
6. Changes required to Scope of Registration if any.
7. Use/miss-use of logo with certificate number, the relevant part of ISO **(9001/14001/22000/OHS 18001** as applicable) and supplementary Audit criteria where applicable.
8. Achievement of the measurable targets and objectives.
9. Number of employees in the company
10. Treatment of Complaints
11. New Customers Orders, new developments in the organisation, organisational structural changes etc.
12. The continuing conformity with regulatory requirements applicable to the OHS hazards, and is fully implemented
13. Regulatory Compliance has been evaluated and the action has been taken in cases of nonconformity with relevant regulations
14. Check records of employee safety committees and other relevant bodies
15. Check Appeals
16. Complaints and disputes brought before TNV, where any nonconformity or failure to meet the requirements of certification is revealed, that the organization has investigated its own systems and procedures and taken appropriate corrective action.
Other requirements of applicable ISO Standard shall be sampled over the programme period. The areas covered at previous visits will be taken into consideration when deciding which areas to audit. It is intended that the implementation of the whole of the company's documents Management system is verified by use of surveillance visits over a period of 3 years, after initial Audit. At each visit an entry onto the surveillance audit record will be made and clauses needed for next audit

verification are indicated. Corrective Action Plans arising from a surveillance visit must be returned, to the TNV. office, by the company within 2 weeks from the date of Audit.
17. Verify the OHS for the respective objectives and targets
18. Hazard Identification & Assessment Controls
19. Compliance towards Legal & Other requirement including customer requirements
20. Verify the OHS management systems at the temporary site
21. Verify the OHS management at the Multisite based on the Audit Program

2. Renewal Audit:

2.1 The process of recertification would include a re Audit of the organization's documented quality management system including a review of the Management System documentation, where necessary, to be conducted before the expiry of three years term of validity.

2.2 Renewal Audit is a requirement of ISO 17021:2011 and is intended to verify overall continuing effectiveness of the organization's applicable management systems in its totality.
2.2.1 Renewal Audit provides a review of the past performance of the management system over the period of previous certification, including examination of the documents/records relating to the internal audits, management review and effectiveness of corrective and preventive actions, etc.
2.2.2 The above Renewal Audit may replace or extend regular surveillance audits, as considered appropriate.
2.2.3 In the case of multiple site or certification to multiple management system standards being provided by TNV, the planning for the audit ensures adequate on site audit coverage to provide confidence in the certification.
2.2.4 The re-certification audit shall include on site audit covering the followings:

a) Verification of management systems effectiveness w.r.t. change (internal and external) and applicability to the scope of certification
b) Verification of the management commitment for overall performance improvement.
c) Verification of the achievement of policies and objectives.

2.2.5 In case of non-conformities observed during re-certification audit time limits are fixed for corrective action before the expiry date of certification.
2.2.6 TNV takes the decision based on

a) Complaints received from users of certification
b) Performance of system over period of certification.
c) Results of the re-certification audit.

2.5.7 The recertification audit will include an on-site audit that addresses at least the following:

a) The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
b) Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
c) Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.
d) Effective handling of customer complaints, corrective and preventive system implementation throughout the organization.
e) Overall effectiveness of the system in its entirety in the light of changes in operations
f) Demonstrated commitment to maintain the effectiveness of the system
g) Summary of Previous Audit Reports
h) Whether all areas/ processes/ clauses have been audited at least once in the last three year cycle
i) Any concentration of non-conformities against particular clauses/areas and effectiveness of corrective actions taken on nonconformities identified by TNV shall be closed within 15 days of recertification audit
j) Objectives and Continual Improvement
k) Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives
l) In the case of multiple sites or certification for multiple management system standards being provided by the TNV, the planning for the audit ensure adequate on-site audit coverage to provide confidence in the certification
m) Verify the OHS for the respective objectives and targets
n) Hazard Identification & Assessment Controls
o) Compliance towards Legal & Other requirement including customer requirements
p) Verify the OHS management systems at the temporary site
q) Verify the OHS management at the Multisite based on the Audit Program

Division 16. Reporting:

1. Audit Report Responsibility:

The responsibility of report preparation and submission to the organization as well as TNV lies with the lead Auditor and the LA is responsible for the contents of the report.

The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following:
a) Identification of the TNV logo
b) The name and address of the client and the client's management representative;
c) The type of audit (e.g. initial, surveillance or recertification audit);
d) The audit criteria;
e) The audit objectives;
f) The audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
g) Identification of the audit team leader, audit team members and any accompanying persons;
h) The dates and places where the audit activities (on site or offsite) were conducted;
i) Audit findings, evidence and conclusions, consistent with the requirements of the type of audit;
j) Any unresolved issues, if identified.

2. REPORTING:

The Stage1 Audit, Stage 2 Audit and Surveillance Audit visits will be reported on TNV Audit Report Forms. The Audit Report is based upon the Reporting Formats as per Guidelines of Accreditation Board on compiling of Reports on Management System Audits. The Auditor's attention is drawn to following specific requirements.
(a) Page 1 of the Audit Report is the cover sheet. It contains details regarding names of the Auditors and Auditee and provides space for signature of the company representative. Format No. as follows
QMS: St 1: TNV-F-014Q, St2: TNV-F-015Q, Surveillance: TNV-F-065Q
EMS: St 1: TNV-F-014E, St2: TNV-F-015E, Surveillance: TNV-F-065E
OHSAS: St 1: TNV-F-014O, St2: TNV-F-015O, Surveillance: TNV-F-065O
FSMS: St 1: TNV-F-014F, St2: TNV-F-015F, Surveillance: TNV-F-065F
(b) Audit Activity Summary, Non Compliance/Observations, Audit Summary and Corrective Action Plans are described in the underlying paragraphs.
c) Places for entering name of the Auditing Organization, the auditee and the places where the representatives of TNV and the Company sign are indicated in these formats.
d) Besides, the Team Leader should initial at the left bottom of each page where there is no place for signature of the Auditor.
(e) Where a technical expert is required to be included in the team, his clarifications and guidance, where obtained may also be suitably recorded.
f) Audit matrix must contain details of documentation and/or items examined during the audit. Also the auditors are required to verify and record the following:
1. Customer Complaint Procedures
2. Use of TNV Logo
3. Applicable exclusion.

3.0 Non-Compliance/Observation

Observation shall be recorded in the audit report. Non-compliances shall be reported on the TNV-F-011. A non-compliance or observation as issued by the auditor shall be explained to the auditee as soon as possible and discussed with the company's representative(s). This will allow the company's representative(s) to accept agreement of the facts by signing the Non-compliance/Observation report, thus evoking later defensive arguments when detailed evidence may not be readily available.

Each Non-compliance/Observation, in addition to the information required at the head of the form shall refer, as appropriate, to the following:
a) The requirement of ISO 9001/14001/22000, OHS18001 standard against which the non-compliance is listed.

b) The documents verified including a precise observation/evidence.
c) The observed non-compliance against the company's documented procedure.

Non-compliances and Observations may be recorded on the same report page. In fact, if non-compliance and observation are recorded against the same clause, these shall be grouped together.
The Non-compliance/Observation shall be factual in stating what does not comply with the requirements, using as far as possible the same language as the requirement itself.

Objective Evidence: It is essential that each Auditor prepares individual audit notes of his findings, observations and comments on the areas of activity audited by him. These notes which should be attached to the Audit Report by the Team Leader before submission to TNV, should report on the positive and negative aspects of the company's documented Quality/Environment/OHSAS/Food Safety system and the records/documents verified to indicate the depth of audit carried out Team Leader is also required to comment on the effectiveness of the MRM and the IQA in the audit summary.

4.0 Categories of Non-Conformities

All non-conformities, identified, during an audit should be distinctly classified under the following categories:-
Major Non-Conformity (Category 'A'): A major non-compliance relates to the absence of a required procedure or the total breakdown in the implementation of a procedure. A number of minor non-compliances listed against the same clause of ISO 9001/14001/22000/OHS18001 represents a total breakdown of a system and thus collectively constitute a major non-compliance.
Where any nonconformity poses an immediate threat to OHS, LA shall demand Corrective Action Plan immediately and communicate to the client that the audit is suspended till the concern is either removed or mitigated. In any case the time for closure of Non Conformity shall not be more than 3 months. In any such cases the time allowed for the closure will be reviewed by CEO.
Minor Non-Conformity (Category 'B'): A minor non-compliance relates to a single observed lapse in the effective implementation of a documented procedure/work instruction which indicates a deficiency requiring a corrective action.
Observation (Category 'C'): An observation is a matter about which the Auditor is concerned but which can not be clearly stated as non-compliance. Observations also indicate trends which may cause problems in the future and need to be considered for corrective action by the company but does not justify verification by the auditor.

Major non-compliances will be clearly identified in 'Comments' section of the Report in addition to the Non-Compliance. Non-conformities/Observations shall never be worded in such a way as to advise the company of action which should be taken in order to comply with the requirements. However, it must be emphasized that any concerns the Auditor may have, and particularly the specific reasons for non-certification must be detailed in the comments sectioned as major non compliances. The Auditor is also encouraged to make positive comments regarding the Audit here.

The auditors are required to specifically report on the status as well as the degree of reliability that can be placed on the implementation of client's internal audit and the management review procedures Recommendations for certification are not to be made where the effectiveness of the Internal Audits and management Review has not been established.

5.0 Recommendation

A clear and unambiguous recommendation must be made with defined time scales for corrective action.

Follow up Action

Again a clear and unambiguous statement of the next step must be made. This is particularly important in the case of non-certification, where the period before Re-Audit can be conducted must be stipulated.

Distribution of the Report

Copy shall be retained by the Auditor for forwarding to TNV office for inclusion in the client file. The copy of the report shall be handed to the company's representative at the closing meeting. Ownership of the audit report shall be maintained by the certification body.

6.0 Effectiveness of Corrections and Corrective Actions

The auditor must verify the corrective action taken by the organization based on the Corrective action submitted and the effectiveness of the corrective action must be verified in the next audit. The corrective action submitted must include sufficient evidence for closing the Non Conformity.

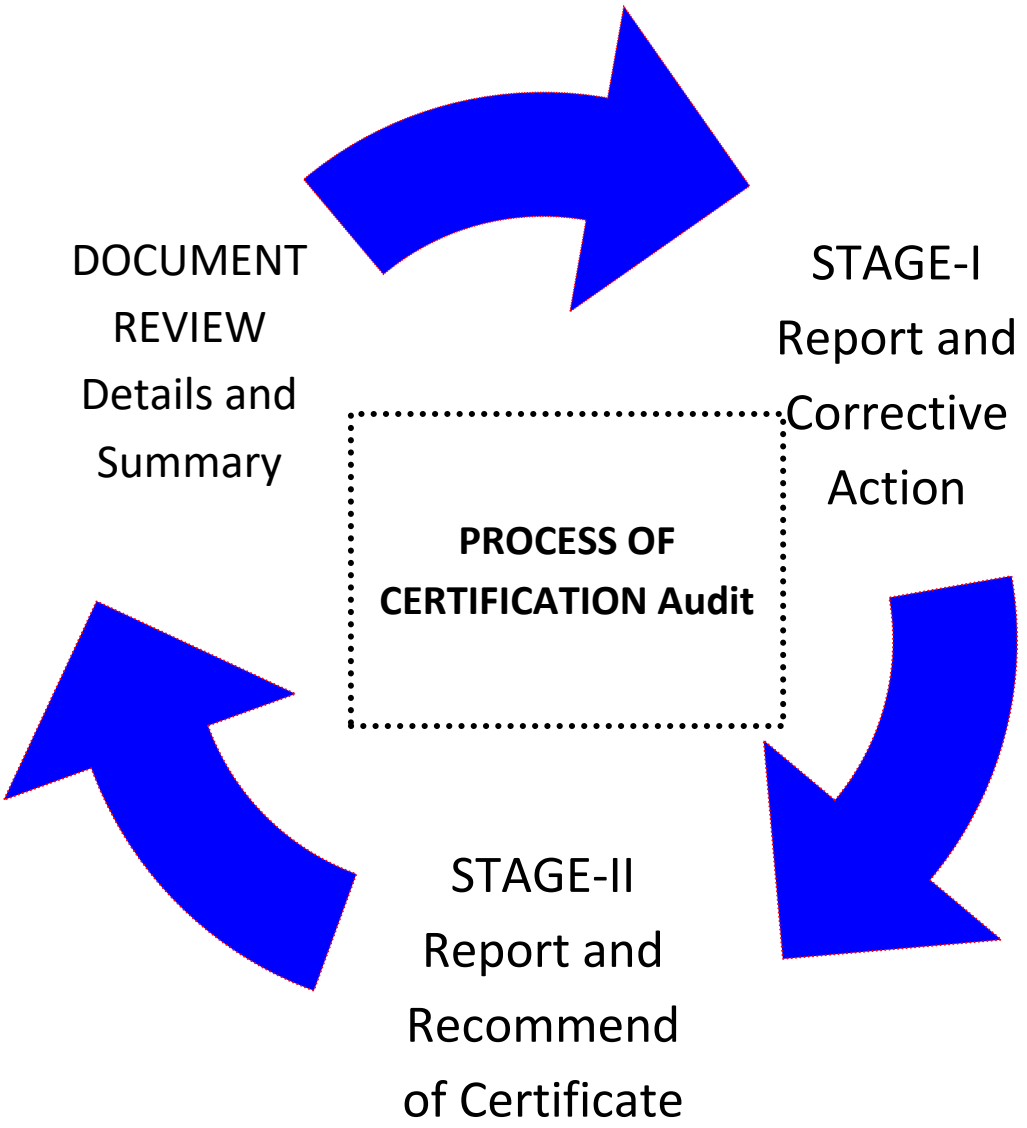
The auditor needs to communicate the client about the acceptance or denial of the Corrective Action submitted by the client.

Corrective Action Plan

The Company shall be advised to address both Non-conformities and observations raised by completing a Corrective Action Plan on the sheets provided by the Auditor and return the same to TNV office within 2 weeks of the audit. The AFAR pages are appended to the relevant report and MUST therefore carry the Company Name. The Auditor must write the report number on each CAP sheet before handing it to the company. The CAP is closed out by the Auditor after verification of the effective implementation of the corrective actions against each non-conformity before issue of certification or at a subsequent surveillance visit. Corrective Actions against **A** categories of nonconformities require to be closed out through verification at site and against Category 'B' nonconformities through verification at site or provision of objective evidence of the implication of corrective actions. Observations (Category C) need to be verified for closing out at the at the first or subsequent surveillance visits.

The closed out status is endorsed after recording the reference of the objective evidence provided by the Auditee in each case. All the stage –I and Stage-II findings are considered before making the decision.

The Audit Report shall be forwarded to the TNV office by the Lead Auditor within one week of the completion of audit together with AFAR if any, Auditors Rough Notes by each audit team member and other documents relating to the Audit.


DOCUMENT REVIEW Details and Summary
STAGE-I Report and Corrective Action
PROCESS OF CERTIFICATION Audit
STAGE-II Report and Recommend of Certificate

Division 17. ISO 9001:2015

Under Revision: New version of ISO 9001 will be released in Sept. 2015 and client need to make transition plan for the new version:

a) ISO9001:2008 Concepts and Changes: ISO9001:2008
Approach: The salient points are:
ISO 9001:2008 has been developed in order to introduce clarifications to the existing requirements of ISO 9001:2000 and to improve compatibility with ISO 14001:2004. ISO 9001:2008 does not introduce additional requirements nor does it change the intent of the ISO 9001:2000 standard
Certification to ISO 9001:2008 is not an "upgrade", and organizations that are certified to ISO 9001:2000 should be afforded the same status as those who have already received a new certificate to ISO 9001:2008.
No new requirements were introduced in this edition but, in order to benefit from the clarifications of ISO 9001:2008, users of the former version will need to take into consideration whether the clarifications introduced have an impact on their current interpretation of ISO 9001:2000, as changes may be necessary to their QMS
B) Validity One year after the publication of ISO 9001:2008(i.e. from 15-11-2009) all accredited certifications issued (new certifications or re-certifications) shall be to ISO 9001:2008. Twenty four months after publication by ISO of ISO 9001:2008(after 14-11-2010), any existing certification issued to ISO 9001:2000 shall not be valid. That means the certificates issued against the ISO9001:2000 will be valid up to 14-11-2010 only.

C) Main Changes to look at during the audit:

Clause 4: Address the outsourced Processes and ensuring the controls

Cl 5: Management Representative to be a part of the Clients management

Cl 6.2 Achievement of necessary competence

Cl 6.3 Supporting services including Information Systems

Cl 6.4 Work environment (Temperature, lighting etc) as per the need of the Process/Product

Cl 7.21.1 Post delivery activities like warranty, service needs

Cl 7.3.1 Design and development review, verification, validation can be conducted and recorded separately and /or in combination

Cl 7.5.4 can include personal data

Cl 7.6 Clear calibration status and Confirmation of the ability of computer software to satisfy the intended application

Cl 8.2.1 Monitoring customer perception can be done by various inputs as described like surveys, opinions, warranty claims data etc

Cl 8.2.3 while determining the suitable monitoring method, the consideration needs to be given to the control on process and effectiveness of QMS

Cl 8.2.4 Records shall indicate the person(s) authorizing release of product for delivery to customer

Cl 8.5.2 Review the effectiveness of the corrective actions taken

Cl 8.5.3 Review the effectiveness of the preventive actions taken

Division 18. Opening & Closing Meeting

Management System Assessment Visits (Stage- 1/ Stage 2/ Surveillance/Re-certification)

Basic Elements of an Audit

The Audit shall comprise of the following elements:
a) An "Opening Meeting" between the Audit Team and the Company's Representatives.
b) Auditing
c) A "Closing Meeting" at which the findings of the Audit Team are given to the company.
d) A checklist for opening and closing meetings is attached for guidance Aide Memory for all company visits

1. OPENING MEETING

The purpose of the opening meeting is communicating the methodology of the audit activities. The Opening Meeting is held on arrival and immediately before the commencement of the Certification Audit/surveillance. The meeting record shall be recorded on TNV- F-009.

The meeting is chaired by the Lead Auditor and addresses the following elements:

Sl. No.	Topic	Particular	Covered
1	Thanks	Give an expression of thanks to the auditee for Choosing TNV.	
2	Attendance	Request attendees to record their attendance	
3	Introduction	• Remind timeline to close opening meeting in 15-30 minutes.	
		• Request to give brief introduction with brief roles (participants, observers, guides & Translators)	
4	Scope / Summery	Confirmation of the audit objectives (Assessment for ISO 9001:2008), scope and criteria;	
5	Changes	Changes in documents/Fact to the Application/Stage-1 Audit.	
6	Plan	Confirmation of the audit plan and other relevant arrangements with the auditee, such as the date and time for the closing meeting, any interim meetings between the audit team and the auditee's management, and any late changes;	
7	Method	Methods of Audit: Review of Documents & Records, Interview, Physical evidence... ***Debriefing meeting need to be conducted by team leader with client at the regular intervals to communicate auditee about progress of audit and any concerns/audit findings.***	
8	Sampling	Advise auditee that the audit is sample basis and findings will be based on a sample of the information selected;	
9	Communication Channel	Confirmation of formal communication channels between the audit team and the auditee; identify the facilitators.	
10	Language	Confirmation of the language to be used during the audit;	
11	Development	Confirmation that, during the audit, the auditee will be kept informed of audit progress;	
12	Resource	Confirmation that the resources and facilities (needed by the audit team are available;) like Guide, Interpreters, Observer, Facility etc.. (roles and identities)	
13	Confidentiality	Confirmation of matters relating to confidentiality and information security;	
14	Safeguard	Confirmation of relevant health and safety, emergency and security procedures for the audit team;	
15	Reporting of Findings	• NC may be against a clause of the standard i.e. ISO 9001, it's not against any person or department.	
		• Method of reporting audit findings & grading (Major, Minor & Observation)	
		• Time-span for corrective action (Minor-, Major-)	
		• Report time: Finding will be discussed at closing meeting and report will be given within 2 working days.	
16	Termination	Information about conditions under which the audit may be terminated;	
17	Audit Declaration	verify that all members of the organization know what is happening;	

Sl. No.	Topic	Particular	Covered
18	Union/Problem	Ascertain union relations or any potential problems;	
19	Confidentiality	Remind the auditees that the audit is confidential.	
20	Closing Meeting	Timing of closing meeting; Participation of the Top Management & where appropriate, those responsible for the functions or processes which have been audited in the closing meeting.	
21	Appeals / Complaint	information about any system for feedback from the auditee on the findings or conclusions of the audit, including complaints or appeals	

2.0 AUDIT

The Audit of the management system against the Standards requirements is undertaken on a sampling basis of that system but not a sampling of the clauses of I.M.S. The Audit is concerned with establishing that the company's documented quality system is well established and operable in accordance with the requirements of the applicable standard ISO 9001/14001/22000/OHS18001. The Audit should also include a verification of the legal/statutory requirements applicable to the company's products/services and compliance with the same requirements applicable to the company's products/services and compliance with the same.

The Audit team member(s) accompanied by the company's representative(s) shall start their audit in a chosen area by selecting at random a feature relevant to the appropriate part of the ISO 9001/14001 /22000/ OHS 18001 as applicable against which the company is to be audited and proceed according to the audit programme ensuring that the audit takes account of all requirements of applicable ISO Standards and any applicable documents. The team member(s) shall keep in mind the possibility that some elements may overlap over more than one department's functions.

For example, procedures for documentation and change control may be required in design office, production department, inspection department, dispatch department etc. Remembering our third party responsibility, it is emphasized that during the audit the auditor shall satisfy himself/herself that the company has adequately demonstrated that its Management system provides evidence that its finished product or service complies with the specification either stipulated by the customer or offered by the company. Specific attention requires to be focused to ensure that the company's Policy statement addresses its commitment to provide customer satisfaction and to continual improvement in the effectiveness of its quality/Environment/Food safety/ OHS management system. While there should be sufficient evidence to demonstrate the reliability of the company's internal auditing procedures and the effectiveness of the management review, the implementation of a process based approach using "PDCA" cycle should be verified.

The audit team shall compile and analyze the results of both stage-I and stage-II audit and discuss with the client and finalize the conclusions.

3. CLOSING MEETING

The objective of the closing meeting is to enable the Team Leader to present the summary of the result of the audit to the client company and the team's recommendations. The closing meeting could also be used to arrive at mutual agreement on the corrective actions and their completion dates. Lead Auditor shall held a formal closing meeting with the clients management systems including the personals who will be audited for process verification and the attendance of the participants in the closing meeting is recorded on TNV- F-009. The purpose of the closing meeting, which shall normally to be conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any nonconformity shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed. During the closing meeting the lead auditor shall ensure the written acceptance for the nonconformities identified in the audit and the Corrective Action plan.

The closing meeting shall be chaired by the TL and address the following:

Sl.	Topics	Particular	Verified
1	Introduction	Particularly if anybody not present at the opening meeting	

2	Thank to company	Thanks to your Team for cooperation during the audit and arrangements for the Audit.	
3	Reaffirmation of Scope	Reconfirm scope of activities assessed **and explanation of any differences from the information presented to the organisation at the closing meeting.**	
4	Confirm confidentially	Reassure the confidentiality for any information assessed during the audit.	
5	Appreciation	Comment on good points within the organisation	
6	Disclaimer	This was audit on sample basis, and it should not mean, that other deficiencies do not exist.	
7	*Audit Team Comment*	*Summary of individual findings from each auditor (if audit team consist more then 1)*	
8	*Decision*	• *Significance of categories of non-compliance and summary of findings ,* • *Summary of overall findings and recommendation/Decision*	
9	*Acknowledgment*	*Assure that client acknowledge the NCs.*	
10	*Future Plan*	*If any NC is identified, Submitting plan for corrective action together with the objective evidences*	
11	*Follow-up action*	*Where do we go from here? emphasizing that the final decision regarding certification will be taken by TNV Certification*	
	Surveillance Audit	*An explanation of the continual Audit (surveillance) procedure and other future actions*	
12	Appeal	Explain the Appeal & Complaint option available to the client against any decision of the Audit team.	
13	Invite questions	Invite questions, clarification from company (But no Consultancy)	
14	Signature	Obtain company representative's signature on report to acknowledge receipt.	

At the conclusion of the closing meeting the Team Leader shall leave with the company the copy of the Audit Report and take the acceptance of the Nonconformities identified in the audit.

Non-grant of Certification

In the event of there being major non-conformities which are considered to render the management system deficient and inoperable, a recommendation for certification cannot be made must be given. Depending upon the extent and nature of deficiencies, a recommendation for a supplementary audit for verification of corrective actions or Re-Audit may be made. In any case, a company will not be considered for grant of certification unless it has demonstrated effective implementation of the procedures for internal audits and the conduct of Management Review.

Non-certification implies that, although the company claims that its documented management system meets the requirements of the applicable ISO 9001/14001/22000/OHS18001, the audit has revealed major non-compliance/s or minor non-compliances which cumulatively amount to a major non-compliance necessitating major alterations to the company's documented procedures and implementation. The Team Leader shall ensure that all major non-compliances and matters of concern are recorded on the final page of the Audit report in the "Comments" section. The major non conformities should be reported on the Audit Report & Summary Section. These should be recorded objectively and precisely. Comments or concerns should be compatible and cross referenced with the Non-conformities / observations entered in the Audit report.

5.0 Action follows Non-Certification

Where an audit results in certification not being granted, the Team Leader will discuss further action with the company. Such action is left to the Team Leader discretion and may be anything from a 'follow up' action in areas of non-compliance

to a total Re-Audit depending on the severity of the deficiencies.

In the case of a 'follow-up' action (limited re-Audit), the Team Leader will agree on a re-visit date with the company and be responsible for drafting the Re-Audit plan, based on the non-compliances raised. The Team Leader MUST state the duration of the limited Re-Audit i.e. 1 man-day, 2 man days in his recommendation and the maximum time limit will be approx 60 days for the conduct of audit.

6.0 Right to Appeal against Non-certification

When the recommendation made at the closing meeting is for non-certification, the company must be advised of their **RIGHT TO APPEAL.** The company should submit its appeal within 14 days in writing to the Technical Coordinator. The Quality Manager will refer the appeal to the CEO/MD for further investigation. CEO will then make an appeals panel for the review of the appeal, the Appeals Panel decision will be final. The Appeals Procedure is fully defined in the Procedures Manual and can be lodged as available on www.isoindia.org.

7.0 Recommendations for Certification

a) In the event of major non conformities being identified (Category 'A') in respect of the implementation of any element of the quality system or several minor non-conformities being recorded against any one element which renders the system deficient but operable, a recommendation for certification is made subject to a CAP being submitted within 2 weeks and corrective actions being verified onsite and closed out through a special visit within 60 days of the Audit date, before certification is granted or as decided by CEO.

b) Where the audit has revealed only minor non conformities (Category 'B') which need to be addressed through corrective actions, the certification may be recommended subject to the **CAP (Corrective Action Plan)** being submitted by the company within 2 weeks together with objective evidences of the corrective actions taken. The corrective actions plan is required to be closed out upon physical verification of the satisfactory implementation at the first subsequent audit.

c) In the case of where "opportunities for improvement: (Category 'C') having been recorded during the certification audit, the actions, as applicable, are observed for effectiveness at the subsequent audit visit.

Division 19. Confidentiality Agreement

Confidentiality (including conflict of interest) Statement for all Personnel Internal or External of (TNV Certification Pvt. Ltd)

I, _____, S/D/W of _____

resident of _____

I am working as a _____ (Employee/Technical Expert/Empanelled Auditor) engaged under a contract of service with TNV Certification Pvt. Ltd. I undertake not to disclose/divulge any confidential information relating to business of TNV Certification Private Limited or any of its clients, which I may obtain because of or during the course of such association/ employment.

2. I shall take all reasonable steps to prevent any other person from gaining access to and use of the confidential information, during and after my association/employment with TNV Certification Private Ltd.

3. I agree to take good care of (any equipment or) documents which may from time to time to within my custody or control during the course of my engagement and shall not, except in the proper course of my duties, show or disclose or communicate the construction or contents thereof to anyone.

4. In the event of my being assigned any audit which includes an organization, where I have any commercial and other interest or to which I have provided consultancy services, including but not limited to conduct of on-site training and internal audits, within the last two years (prior to the planned audit date) I shall immediately inform TNV management of this who can take appropriate action on the same.

5. upon termination my engagement (for whatever reason) and at any other time at your request I shall, without retaining any copies or records thereof, immediately return all such (equipment and) documents or extracts of such documents and all other notes, memoranda, photographs, drawings, records or other material made or procured to be made by me or issued to me during my engagement relating to the business of TNV or any of its clients. For the purpose of this undertaking I acknowledge that Confidential Information means all technical and business information of TNV Certification Pvt. Ltd. and its clients which are of a confidential, trade secret and/ or proprietary nature.

6. I shall reveal any situation known to me that may pose threat to impartiality or any conflict of interest arising on the assignment to TNV from time to time

7. Further, I undertake that I shall not indulge into any activity which might influence the impartiality of certification process.

As part of such Agreement, I am obligated to execute this Confidential Information and No Conflict of Interest Agreement for each client for which I perform Certification Activities.

8) This section shall be confirmed by each audit team member

8.1) I confirm that I have not provided any consulting or other services to or on behalf of Client during the 24 months period prior to the date hereof directly or indirectly.

YES/ NO

8.2) I confirm that I will not during the 12 months period succeeding the last day on which I provide Registration Activities with respect to Client pursuant to the Agreement or any future agreement between TNV and me, directly or indirectly provide any consulting or other services (including, but not limited to Registration Activities) to or on behalf of Client.

YES/ NO

8.3) I shall keep Confidential Information secret and confidential, and not disclose such Confidential Information to any person or entity except for TNV and, if applicable, a Contracted Registrar providing services to Client.

YES/ NO

8.4) I shall deliver to TNV, or at TNV' direction to Client all materials and reports (including all copies) in my possession (including quality manuals, reports, computerized data contained in any form) upon receipt of a written letter from Client or TNV instructing me to return such materials.

YES/ NO

I understand that my obligations under this Confidential Information and No Conflict of Interest Agreement shall survive till the termination of "Contractual Agreement ".

I hereby execute this Confidential Information and No Conflict of Interest Agreement with respect to above Client and declare that I have no conflict of interest with the client.

Signature:_____

Date: _____

Name: _____

Designation_____

Division 20. Stage-1 & Stage 2 Auditing Methodology QMS

GUIDELINES FOR AUDITING OF QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

GENEAL REQUIREMENTS

1. QMS of the organization should be able to provide products or service that meets customer requirements and applicable regulatory requirements.

2. It should aim for enhancing customer satisfaction and provide for continual improvement.

3. Where any exclusions of applicability of any clause is claimed it should be limited to only within clause 7 and justification for any such exclusion has to be addressed in QMS documentation.

4. The organization should identify and document the various processes for the QMS and their sequence and interaction of these processes.

5. If any processes are out sourced such out sourced processes shall be identified with in QMS.

4.2 Documentation Requirements

Check for:

a) Documented quality policy and quality objectives. These may be included in the Quality manual or may be documented separately.

b) Quality Manual

c) Mandatory procedures required by the standard

d) Document needed by the organization to ensure the effective planning, operation and control of its processes.

e) Applicable records required by the standards

f) Check for the documentation of following mandatory procedures:

1) Document and data control
2) Quality records
3) Control of non-conforming products
4) Internal quality audits
5) Corrective Action
6) Preventive action.

4.2.2 Quality Manual

Check for:

a) Scope of QMS including details and justification for any exclusion

b) Procedures established for QMS or reference to them

c) Description of the interaction between the processes of QMS

4.2.3 Control of Documents

The procedure for control of all documents required by QMS should be described. This shall include documents of external origin (e.g. National Standards, Customer Supplied Drawings etc.) Where appropriate, the policy on the method of control on documents issued to site also is described. Documented Procedure for control of documents shall be maintained.

Check for:

a) Documents and forms having formal control e.g. issue status and revision status.

b) ISO 9001:2008 included in document control

c) Procedure for change control for all documentation including quality manual, procedures and work instructions.

d) Process specifications, test specifications, drawings and software to be included as part of document control.

e) Check for hand written amendments to issue status and form status

Distribution of quality manual and procedures to controlled copy holders and the named person having the appropriate and current manual/procedures.

4.2.4 **Control of Documents**

Check for

a) Complete list of all quality records with retention period

b) Quality records to be cross referenced to product, contract and work orders.

c) Adequate storage, maintenance and disposition

d) Maintenance of following records (as applicable) shall be evidenced

- Management review (5.6.1)
- Personal records of education, training skill and experience (6.2.2e)
- Realization process and product Vs requirements (7.1d)
- Review of customer requirements (7.2.2)
- Design input (7.3.2)
- Design reviews (7.3.4)
- Design verification (7.3.5)
- Record of validation results (7.3.6)
- Design change reviews (7.3.7)
- Supplier evaluation (7.4.1)
- Validation of special processes (7.5.2d)
- Product identification (7.5.3)
- Lost/damaged customer supplied product (7.5.4)
- Basis of non-standard calibration (7.6a)
- Results of calibration (7.6)
- Validity of previous measurements when equipment out of calibration (7.6)
- Results of internal audits (8.2.2)
- Verification that product passed tests (8.2.4)
- Non-conformances (8.3)
- Results and corrective action (8.5.2e)
- Results and preventive action (8.5.3d)

e) Management Responsibility

Top management's commitment shall be evidenced for:

1) Communicating the importance of meeting customer and regulatory requirement.

2) Conducting management review

3) Provision of adequate resources

4) Continual improvement of the effectiveness of QMS

5) Ensuring customer requirements are fulfilled

Quality Policy

Quality policy shall be appropriate for the organization and required to include for continual improvement. It shall be reviewed for continuing suitability.

5.4.1 Quality Objectives

Quality objectives shall be in established for each function and level. They shall be measurable and provide for continual improvement.

Quality objectives shall include those needed to meet the requirements for products/services

5.4.2 Quality Planning

Quality planning shall include the processes identified in QMS the resources and also provide for continual improvement.

5.5 Responsibility, Authority and Communication

The responsibility and authority shall be defined and communicated. Organization chart showing the reporting structure and M.R. shall be available,.

There should be brief description of key persons' quality related responsibility M.R. should be within the organization.

QMS shall be communicated to various levels through appropriate means.

The minimum periodicity of management review meeting should be stated. The policy statement should describe a standard agenda and require that minutes with designated actions be maintained.

Check for:

a. Minutes of Management review are signed and dated and key persons are present

b. Agenda is stated in quality manual/procedures and followed in the minutes

c. Person responsible for taking necessary actions for various agenda points and target date documented.

d. Review shall include the need for changes to QMS, Policy, and Objectives for continuing its suitability and effectiveness.

6. Resource Management

1. Adequate resources shall be provided to maintain continually improve the effectiveness of QMS and for enhancing customer satisfaction.
2. Competent personnel shall be provided for performing work affecting product quality

Check for:

a) Records of education, training, and skill experience

b) Training records shall provide evidence for evaluation of their effectiveness

c) The infrastructure facilities (building work space, associated utilities) shall be appropriate and adequate

d) Process equipment shall be appropriate to achieve customer requirements

e) Work environment shall be appropriate and relevant for product requirements

f) Hygienic and safety regulatory compliance records

g) Working conditions, ergonomics are suitable to provide consistency in product quality

7.1 Planning of realization process

Processes needed for the realization processes shall be available. A document specifying the processes and resources to be applied to a specific product, project or contract can be referred to a quality plan.

In planning product realization the following shall be available:

1) Requirements of the product
2) Resources specific for the product
3) Verification, monitoring requirements
4) Acceptance criteria

Check for:

a. Process control records

b. Inspection records.

7.2 Customer related processes

1. Product related requirements shall be defined (e.g. specifications, delivery requirements, requirements for indented use but not stated, statutory and regulatory requirements).
2. Product requirements shall be reviewed prior to commitment.
3. The manner of and responsibility for contract review shall be described.
4. The policy of review of amendments to contracts shall also be stated.
5. Responsibility and systems of communication with customer shall be defined for providing product information, inquiries, amendments, customer feedback and complaints.

Check for:

a. System of contract review as to how it is carried out

b. Signing authority for contract review

c. System for amendment to contract

d. Sample contracts, check dates and types

7.3 Design and Development

The basis of sound design practice shall be described. If a separate design control manual exists, across-reference should be made.

Check for:

a. System of implementation, control and verification of the design of the product to ensure that the specified requirements are met.

b. Plans which identify the responsibility for each design and development activity

c. Design and verification activities assigned to qualified personnel

d. Identification and documentation of design Input requirements relating to the product.

e. Is design output documented and expressed in terms of requirements, calculations and analysis.

f. Design output meeting design input requirement?

g. Are functions for verifying the design planned, established, documented and assigned to competent personnel.

h. Are changes to the design identified.

7.4 Purchasing

The existence of preferred vendors list shall be described along with the method for approving vendors included in the list and their performance.

The need to define the International Quality System Standard as appropriate to purchase orders shall be defined.

The policy for the content and initial review of purchase orders and their amendments shall be described

Check for:

a. System adequately defines activity

b. System exists for approving suppliers.

c. Approved supplier list, its contents and grading.

d. Samples of purchase orders.

e. Check dates, authorized signatures that vendor is from approved supplier list and for acceptance criteria and delivery requirements.

f. Approved supplier record to indicate product/service supplied and issue status.

7.5.1 Production and service provision

The policy for identifying specific product characteristics, specific work instructions, equipments, monitoring and measurement shall be described.

The processes that result in a product that cannot be verified subsequently shall be validated. The equipment and personnel carrying out such processes shall be qualified. The records of such special processes shall be maintained.

7.5.3 **Identification and Traceability**

The policy for identification and traceability, (where required) throughout production, service operation shall be provided. This shall include status of product with regard to the status of measurement and monitoring requirement

Check for:

a. Identification system and practice

b. Inspection and test status system and practices

c. Traceability records (where applicable)

7.5.4 Customer Property

The policy for exercising care and control on customers supplied products, if used shall be maintained. They shall be identified, verified, protected and safe guarded. Loss of any such material or their damage shall be reported to the customer and their records to be maintained.

7.5.5 Preservation of Product

Where appropriate the policy of working a FIFO (first-out) system for storage may be stated, along with any specified handling or storage requirements (e.g. hazardous materials, etc.)

Check for:

a. System and availability of instructions

b. Special handling requirements, e.g. chemicals and gases.

c. Storage conditions with reference to temperature, humidity and environmental condition.

d. Secure lockable quarantine area

e. Identification of materials in store/in process/delivery

f. Stock card quantity reflects actual/physical quantity

g. Shelf life items/materials are identified by materials control

h. Delivery requirements regarding customer's requirements/contract.

7.6 Control of Monitoring and Measuring Devices

The policy relating to calibration, traceability to National Standards and the control of measuring of test equipment shall be stated. If this clause is not applicable (e.g. in the service sector, a statement to indicate this should be made).

Check for:

a. System adequately covers calibration of each item

b. Calibration frequently/method quoted in Documented Quality System

c. Calibration records completed and up to date.

d. Criteria used for in-house calibration

e. External sources – Calibration certificate is valid and issued by national authority

f. Test software is included, identified and controlled

g. Jigs/fixture etc are included, identified and controlled

h. Calibration tables are used and are adequate and current

8. **Measurement, Analysis and Improvement**

The organization has to plan and implement the monitoring, measurement, analysis and improvement processes needed for:

1) Conformity of products - Check inspection records
2) Conformity of QMS - Check internal audit report and customer compliance
3) Improvement in the Effectiveness of QMS - Check Management Review Reports

8. Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer perception shall be monitored and methods for obtaining and using this information determined.

Check for:

a. Management Review Records
b. Customer/Market feedback reports
c. Customer complaint analysis

8.2.2 Internal Auditing

A **Documented Procedure** shall be maintained for planning and conducting audits and for maintenance of records. The need for auditors to be trained and independent of the function they audit shall be stated.

Check for:

a. Formal audit schedule/programme.
b. All ISO 9001, 14001, 18001 clauses are audited or programmed
c. All ISO 9001, 14001, 18001 clauses must be audited before final audit
d. Auditors to be trained by special audit course and certificate of training available.
e. Availability of all audit records.
f. Check for audit corrective actions identified to persons responsible
g. The "Closing out" of audits.
h. Independence of auditor in the area to be audited.
I. Review of internal audit results during Management Review

8.2.3 Monitoring and Measurement of process

Organization shall have to monitor and measure for achievement of planned results.

Check for:

a. Adequacy of process control system
b. Adequacy of process control and inspection tools and their inspection periodicity
c. Non conforming analysis reports
d. Corrective Action implementation records

8.2.4 Monitoring and measurement of product

The policy for all types of inspection shall be stated. This shall be extended e.g. to the need of inspection at installation site for goods delivered straight to that site.

Check for:

a. Availability of specification and acceptance criteria incoming material, finished products and for each in process stage
b. Sampling plan and application of statistical techniques for inspection
c. Inspection records.
d. Identification of inspection personnel
e. Authority for release of accepted materials
f. Non conforming products not identified/segregated.

Testing and Inspection Records.

1. Documented evidence of Inspection and test activities not complete/not held/not available/ not easily retrievable.
2. Records do not identify clearly passed/failed results.
3. Test result sheets not signed/stamped and dated
4. Test result sheet not crossed referenced to the product and specification.

8.3 Control of Nonconforming Product

A Documented Procedure shall be maintained for control of non-conforming products with responsibility and authority for their disposal. The system for the segregation, identification and review of nonconforming products shall be stated.

Check for:

a. Identification on label
b. Recording/logging
c. Segregation/quarantining
d. Disposition should be recorded or authorized.

8.4 Analysis of data

Effective use of statistical tools should be used for analyzing effectiveness of QMS and for continual improvement.

Check for:

a. Trend analysis chart
b. Cause wise analysis of product defects, process deviation and customer complaints
c. Achievement of targets of specified quality objective
d. Performance data of suppliers

8.5 Improvement

Organization shall continually improve the effectiveness of **QMS**. This can be verified through:

1) Quality Policy Statement
2) Achievement of specified Quality Objectives and targets
3) Internal Audit results and their analysis
4) Analysis of data
5) Corrective and Preventive Action
6) Management review records.

8.5.2 Corrective Action

Organization shall have Documented Procedure for review of non-conformities and for taking corrective action.

Check for:

a. Review of system non-conformities-
b. Analysis of process non-conformities
c. Analysis of product non-conformities
d. Customer complaint recording and taking Corrective Actions
e. Review of corrective actions taken
f. Records of corrective actions taken.

8.5.3 Preventive Action

The organization shall have a Documented Procedure for preventive action for determining Action to eliminate the causes of potential non-conformities.

Check for:

a. Identification of potential non-conformities and their causes

b. Action taken to prevent their occurrence

c. Review of effectiveness of preventive actions

d. Records of preventive action taken

e. Check management review records for discussion of preventive actions.

Division 21. Stage 1 & Stage 2 Auditing Methodology OHSAS

GUIDELINES FOR AUDITING OF OHSAS - OHS 18001:2007

Mandatory Guideline: During the audit if the Audit Team identifies violation of any Act of Parliament or breaking Regulatory it must be reported as a Major Non Conformity and must be communicated to the organization Top Management. The audit team should normally spend the majority of the Stage 2 audit time verifying the effective implementation of the management system in the locations where the organization's activities takes place including on-site audits of temporary sites.

4.1 General Requirements:

Has the Company developed a documented OHSAS that satisfies the theoretical requirement of Clause 4.2 to 4.6 of the standard.

Check For:

Are the Elements of the Documented OH& SMS available for use in all appropriate places and departments of the company?

4.2 OHSAS Policy:

Has the company developed a documented Policy that satisfies the requirements and is appropriate.

Check For whether the OH&S Policy complies to the following requirements

- Authorised by organisation's top management?
- Appropriate to nature and scale of O&H risks?
- Commitment to Continual Improvement?
- Commitment to comply with current OH&S legislation and
- other requirement to which management subscribes ?
- Is documented , implemented and maintained? .
- Is communicated to all employees ?
- Is available to interested parties ?
- Is reviewed periodically to remain relevant and appropriate?

4.3.1 Hazard Identification, Risk Audit & Determining Control

1. Has the company developed a documented procedure or procedures for the future identification of Hazards and evaluation of risks and implementation of necessary control measures and includes:-

- Routine and Non – Routine Activities.
- Activities of all persons having access to the workplace (including contractor workers and visitors)

-facilities at workplace whether provided by organization or others?

2. Is the information kept up-to-date?

3. Does the methodology provide for identification of Hazards and Audit and classification of risks?

4. Does it provide for classification of risks that are to be controlled /eliminated by setting objectives and OH&S management program(s)?

5. Is it consistent with operating experience and capabilities of control measures?

6. Does it provide inputs for determination of facility requirements, identification of training needs, and development of operational controls?

7. Does it provide for monitoring of required actions taken to ensure both the effectiveness and timeliness of implementation?

4.3.2 Legal & Other Requirements: please note that any violation of the statutory and legal requirement shall be taken as Non Conformity. If any member of the audit team, in their professional judgement, discovers a breach of an Act of Parliament, or a contravention of a regulatory requirement. Auditor must consider such incident (any recognized breach or contravention) seriously and auditors are required to mark such violation as

nonconformity as soon as practicable and urgently communicated to the organisation (preferably at the time of the closing meeting).

1. Has the company developed a procedure to ensure that it identifies and has access to all appropriate legal and other requirements?

2. Does the procedure allow for the analysis of these requirements and is this analysis used and cross –referred in other elements including the setting of Objectives and Targets?

Check For

1. Are Objectives and Targets and actual quantified improvements achievements and time scales appropriate and acceptable in the context of the company's circumstances?

2. Is the organization understands of documentation of legal and other requirements complete and appropriate?

4.3.3 Objectives & Programmes

1. Has the company developed documented Objectives and Targets to quantify to quantify its commitment to Continuous improvement?

2. From information gathered during initial Audit and Document Review, are the Objectives and Targets appropriate to the risk Audit and legal compliance situation of the company, and consistent with OH&S policy?

3. Does the documentation submitted indicate or mandate the methods and occasions when Objectives & Targets will be either revaluated or newly created?

4. Has the company established OH&S programmes either overall or individual department programmes in support of the Objectives & Targets.

Check For

1. Are all necessary legal considerations –existing non-compliances etc considered in the Objectives and Targets established by the organization? (match with actual recorded compliance reporting).

2. Have any of the circumstances when the review of existing Objectives and Targets should be required actually occurred –if so provide details –and if so have the management carried through necessary and appropriate review and revision?

3. Does the OH&S programmes provide adequate detail and direction on Structure and responsibility Stages and Monitoring of achievement milestones?

4.4 Implementation And Operation

4.4.1 Resources, Roles, Responsibility, Accountability and Authority

1. Does the documentation provide adequate and description of Management programmes –either overall or individual departmental programmes –in support of the Objectives and Targets.

Does the Documentation clearly identify the appointment of a mgmt. appointee/ employee OH&S representative appropriate for the position?

Check For

1. Do the management programmes provide adequate detail and direction on RESPONSIBILITY, Stages and Monitoring of achievement milestones?

4.4.2 Competence, Training and Awareness

1. Has the company developed a documented procedure ,or procedures ,that ensures adequate training of all personnel including appropriate sub-contractors and contractors –who are employed in activities that may create risks.

2. Does the procedure (S) identify the training needs and ensure that the importance of conformance with the requirements of the relevant elements OH& S MS are understood?

3. Does the training procedure ensure that the potential consequences of non-conformances with requirement are well understood?

Check For

1. Review appropriate personnel's including contractor's onsite –levels of knowledge on the basis of selected activities are viewed ,by the company to have the ability to significantly affect the OH&S performance of the company and impact on the OH&S .(Provide examples and detail).

4.4.3 Communication, Participation and Consultation

4.4.3.1 Communication

Has the Organization developed a procedure (s) for passing pertinent information to and from employees and other interested parties?

Does the procedure provide for employee involvement and communication in the

The development and review of policies and procedures to manage risks?

Check For

Does the implementation take note of all appropriate interested parties including complaints?

4.4.3.2 Participation and Consultation

Procedure for the participation of the workers/operating team for involvement in the OHSAS activities. Consultation where there are changes that affect workplace health and safety?

Representation in Safety and Health Matters.

4.4.4 Documentation

Does the documentation submitted provide clear direction to related documentation?

Documentation must be in proportional to the levels of complexity, hazards and risks and is kept minimum

Check For

Verify that all documentation in use is as directed within the appropriate levels of documentation?

4.4.5 Control of Documents

Does the documentation submitted provide for positive document and data control and are the company's statement on the methods of document control evidenced on the documentation reviewed during the study?

Check For

Review selective samples of documentation during site audit to establish and verify the correct and effective implementation of the document control requirements-provide details and examples.

4.4.6 Operational Control

1. Has the company developed documented procedures and instructions for operational controls?

2. Are the documented Operational controls –from the circumstances known at the time of the document review appropriate to the risks at the site?

3. Is there clear association between control and magnitude of risk?

4. Do the documented operational controls indicate criteria for effective performance

5. Has the Organization developed and documented appropriate procedure for:

i) Supplier Approval.

ii) Supplier Control

iii) Maintenance

Check For

1. Review Operational Controls for identified Hazards for effectiveness and appropriateness-provide details.

2. Do the Operational controls demonstrate compliance with either external or internal standards?

3. Review implementation of supplier and contractor controls- Provide Details.

4.4.7 Emergency, Preparedness and Responses

Has the company developed and documented Emergency Preparedness contingencies and is there clear indication that such plans will be subject to test and review?

Check For

Review emergency plans for appropriate consideration of suitable emergency circumstances and control of OH&S risks arising.

4.5 Checking

4.5.1 Performance Measurement and Monitoring

1. Has the company established documented procedure (S) for monitoring and measurement of appropriate controls?

2. Do monitoring and measuring procedures provide for :-

i) Both qualitative and quantitative measures approprite to the need of the organization?

ii) Extent to which OH&S objectives are met?

iii) Proactive Measures of performance that monitors compliance with OH& S management programmes, operational criteria, and applicable legislative and regulatory requirements?

iv) Reactive measures of performance to monitor accidents, ill health, incident including near misses and other historical evidence of deficient OH&S performance?

v) Recording of Data and results of monitoring and measurement sufficient to facilitate subsequent corrective and preventive action analysis?

3. Has the company developed and documented a procedure dealing with calibration of monitoring and measurement equipment ,either in –house or externally supplied? Is the calibration procedure appropriate in its coverage?

Check For

1. Review Records of implementation of monitoring and measurement and evaluate and establish compliance levels – provide details.

2. Ensure by sampling that all relevant risks are being monitored.

3. Review equipment calibration records and verify calibration status.

4.5.2 Evaluation of Compliance

4.5.2.1 Procedure and Frequency of the evaluation with applicable legal Requirements.

4.5.2.2 Compliance with and other requirements as applicable.

4.5.3 Incident, Investigation, Nonconformity, Corrective and Preventive Action

4.5.3.1 Incident Investigation

Has the Organization established and maintained procedure for defining responsibility and authority for the handling and investigation of :-

a) Accidents, Incidents, Nonconformance's and its Investigations and analysis.

b) Taking action to mitigate any consequences from accidents, incidents or non conformances.

c) the initiation and completion of corrective and preventive actions.

d) confirmation of the effectiveness of corrective and preventive action .and identification of continual improvements.

e) communicate the results of such investigation.

4.5.3.2 Nonconformity, Corrective and Preventive Action

1. Whether corrective actions and preventive actions have been reviewed through risk Audit procedure prior to implementation.

2. Whether procedure provides for implementing and recording any changes in the documented procedures resulting from corrective and preventive action and

3. Effectiveness is reviewed with respect to OH and S consequences.

Check For

Review records of Non conformance and verify suitability of corrective and Preventive actions taken, including ongoing monitoring (for suitable periods) of effectiveness of implementation.

4.5.4 Control of Records

Has the organization documented a procedure for the identification, protection, maintenance and disposition of records?

Are retention period defined?

4.5.5 Internal Audit

Has the company documented a procedure for the periodic OH&S management system audits to be carried out in order to:

A) Determine whether or not OH& S management system conforms to:

i) conforms to planned arrangements for OH&S management including the requirements of OH&S certifications

ii) Has been properly implemented and maintained.

iii) Is effective in meeting organization's policy and objectives.

B) Review the results of previous audits.

C) Provide the results of audit to management.

Check For

1. Whether the audit schedule is based on the results of risk Audit of organization's activities.

2. Whether Audit procedure covers Scope, Frequency, Methodologies, and complexities, as well as responsibilities for conducting audits and reporting results.

3. Whether audits have been conducted by personnel independent of those having direct responsibility for the activity being examined.

4. Does procedure allow scheduling of audits on the basis of relative importance of activities to OH&S performance and the results of previous audits?

5. Does the procedure provide clear explanation of the requirements for conducting audits?

4.6 Management Review

1. Does the documented submitted indicate that Management Review Shall be conducted considering suitability of effectiveness of the system ,Policy, and Objectives and Targets?

2. Does the documentation indicate that frequency of such reviews will be appropriate?

3. Does the documentation indicate that all appropriate indicators of effective OH&S MS implementation shall be considered?

Check For

Review Records of Management Review and establish that reviews do consider appropriate detail and sources of information. Evaluate management decisions and recommendations arising from such management reviews.

Division 22. Stage 1 & Stage 2 Auditing Methodology EMS

GUIDELINES FOR AUDITING OF EMS –

GENERAL

Is an Environmental Management System documented, implemented and maintained for all above defined areas?

Does the system ensure that:

- an appropriate environmental policy is established and implemented within the organisation,
- all significant environmental aspects associated with past and present activities are identified and controlled, including potential emergency circumstances.
- relevant environmental legislation is identified and complied with.
- environmental objectives and targets derived from the organisations significant aspects are established and achieved in accordance with the environmental policy.
- an environmental management program is established including identification of priorities and resources.
- the effectiveness of the system is regularly monitored through an audit programme.
- top management is continuously informed of the results.

Is the system auditable? Specifically; is the system documented and referenced to the applicable sections of the Standard?

Is the environmental management system understood by all employees, applicable to their area of responsibility and work area?

Is the system based on best available technology where economically viable and cost effective?

Has an initial environmental review been carried out? (not mandatory, however, recommended)?

Are the results of the initial environmental review documented, and is there evidence that they have been included in the system?

4.1 ENVIRONMENTAL POLICY

Has top management defined its environmental policy and is the policy integrated into the overall company policy?

Is the environmental policy appropriate to the nature, scale and environmental impacts of the activities of the organisation?

Is top management committed to achieving the continual improvement of its environmental performance and to pollution prevention?

Does the policy include a commitment to comply with all applicable legislative and regulatory requirements and have these been identified?

Are quality, safety and health policies consistent with the environmental policy and the overall company policy?

Does the organisations environmental policy fit within the context of a broader corporate policy?

Does the environmental policy include a commitment to other industry and/or NGO codes of practice, declarations etc., (i.e. ICC Charters, Responsible Care)?

Does the policy reflect a framework for setting objectives and targets and is this framework used to set appropriate objectives and targets?

Is the documented environmental management system implemented and maintained, and reliably communicated to all employees?

Is the environmental policy communicated to, and understood by, all employees, including those to whom English is not their first language ?

Is the environmental policy published and made available to the public?

Does the EMS aim to prevent pollution?

4.3.1 PLANNING ENVIRONMENTAL SPECIFIC ASPECTS

Does the organisation have documented procedures to identify its environmental aspects and keep this information up to date?

Has the organisation identified those environmental aspects over which it has control and those which it can influence?

Is the process for identifying those aspects which the organisation can influence reasonable and adequate?

Are the following environmental aspects considered in sufficient detail:

- air emissions
- discharges to water and/or land
- waste management
- soil contamination
- raw material and natural resource usage
- human health (where relevant), aesthetics, noise, smell, heat
- other site specific issues

Are the following operational aspects considered, where appropriate:

- normal, abnormal and potential emergency circumstances
- start-up and shutdown conditions
- development of new processes, products and services

- construction phase
- dismantling,
- decommissioning and follow-up monitoring

Is a process available to select and rank the significance of the organisations environmental aspects?

Is the selection and ranking process reasonable and adequate?

Is it based on a defined methodology such as AS/NZS 4360, AS 3931 etc.

Does it take into account synergistic, antagonistic and cumulative impacts, where necessary?

Is life cycle Audit used to determine the environmental impact of selected processes, products, and services?

Where LCA is used is the rationale /model used documented, reasonable and adequate?

- ***Is the EMS based on evaluation of environmental aspects?***
- ***Does the EMS aim to control and improve environmental performance?***

4.3.2 PLANNING - LEGAL AND OTHER REQUIREMENTS

Does a process exist to identify and document relevant environmental legislation with which the organisation is required to comply or to which it subscribes?

Does the process identify and link the activities, process, products/services subject to legislative requirements with relevant legislation?

Does the process include consents, license conditions, agreements etc.?

Is this information kept up to date and the source of the information credible?

Is this information disseminated to those within the organisation who are required to act upon it?

Where action is taken with respect to complying with new or changed legislative requirements is this completed within a timely manner?

- ***Does the EMS aim to ensure the organization complies with legislation?***

4.3.3 PLANNING - OBJECTIVES AND TARGETS

Have performance related environmental objectives and targets been defined and documented at all levels of the organisation and are they kept up to date?

Are objectives and targets quantified, where practicable?

In setting objectives and targets does the Organisation consider:

- compliance with relevant environmental legislation and other requirements
- the significant environmental aspects
- the criteria for selection of adequate technology
- financial, best available technology, cost effectiveness and business considerations
- the views of the interested parties

Are the objectives and targets consistent with:

- environmental policy and statement
- where applicable, the commitment for continual improvement of the organisations environmental performance
- the commitment for reduction of pollution?

Are the time periods set for meeting the objectives and targets documented and based on an adequate rationale?

Is the EMS based on documented objectives and targets?

4.3.4 PLANNING – ENVIRONMENTAL MANAGEMENT PROGRAM(S)

Does the organisation maintain a environmental management program to achieve the objectives and targets?

Does top management provide the resources necessary to achieve the objectives and targets?

Does the management program include the designation of responsibility for achieving the objectives and targets at each relevant functions and levels of the organisation?

Have the means and time frame by which the program is to be achieved, been provided?

Is the programme, where appropriate, revised and amended to provide for new developments, new or changed activities, products/services and /or environmental aspects?

And do these adjustments define:

- objectives to be achieved
- means to achieve objectives
- processes to control changes and adjustments during project execution
    - corrective actions where required?

4.4.1 IMPLEMENTATION AND OPERATION : STRUCTURE AND RESPONSIBILITY

Are those personnel (positions) within the organisation whose work may create a significant environmental impact identified?

Are their roles and responsibilities clearly defined and documented especially with respect to potential emergency circumstances?

Are these personnel aware of their responsibilities?

Are the required human and other resources (technology, finance) for implementation and control of the environmental management system provided?

Is an organisation chart (or similar) available and are the appointed decision makers explicitly named? and

Are there appointed 'Management Representative(s)?

Do the personnel appointed in environmental management have the required competence?

Do these appointed persons have the appropriate knowledge, positions, responsibility and authority to:

- ensure development, implementation and maintenance of the environmental management system in accordance with this system's structure?

Do these appointed persons also have the authority and responsibility for:

- reporting to top management on the performance of the environmental management system as a basis for management review?
- reporting to management on the performance of the environmental management system as a basis for improvement
- initiating actions to ensure compliance to the environmental policy identify and document environmental compliance
- propose and initiate corrective action
- assess and control the implementation of corrective action
- act in emergency situations?

  Are there appointed personnel authorised to establish internal control mechanisms, to make the required resources available and to request for appropriate personnel?

4.4.2 IMPLEMENTATION AND OPERATION : TRAINING, AWARENESS AND COMPETENCE

Has a training needs analysis been performed to identify those personnel requiring training?

Are training requirements resulting from the use of new or changed activities, processes or equipment identified and reflected in a training data base?

Does the training programme ensure that personnel performing tasks which can cause significant environmental impacts are competent? and

Does this also apply for:

- the persons responsible for demonstrating compliance with environmental legislation
- the persons responsible for internal environmental audits
- personnel joining the organisation?

Does the training programme include and emphasise the:

- a) importance of conforming with to organisations environmental policy and procedures and with the requirements of the environmental management system
- b) significant-actual and potential-environmental impact of the work activities and the environmental benefits of improved personal performance
- c) roles and responsibilities in achieving conformance to the environmental policy and with the requirements of the management system including emergency preparedness and response
- d) potential consequences of deviating from specified operating procedures?

Does the communication process ensure that business partners and contractors are aware of the relevant requirements of the organisation's environmental management system?

4.4.3 IMPLEMENTATION AND OPERATION : COMMUNICATION

Does the organization have a procedure in place to receive and respond to communications from interested parties concerning its environmental aspects and environmental management system?

Does the above procedure take into consideration?

- internal communication between different levels and functions
- external communications in terms of receipt, documentation and prompt reply
- adequate reactions and where needed appropriate corrective actions
- communications in emergency circumstances

Does the procedure consider the organizations processes for external communications on its significant environmental aspects and record its decision?

4.4.4 IMPLEMENTATION AND OPERATION : EMS DOCUMENTATION

Is information available describing the core elements of the environmental management system and their interaction and provide direction to existing detailed documentation of the organisation?

Does the system description include additional documents such as organisational charts, process diagrams, internal work instructions, contingency plans and are they integrated into the system?

Is reference made between system documentation and the process descriptions?

Is the system documentation presented in a suitable media such as a manual, electronic data base etc.?

4.4.5 IMPLEMENTATION AND OPERATION : DOCUMENT CONTROL

Do the procedures ensure that documents and data:

- are periodically reviewed, revised and approved by authorised personnel
- current version is accessible at all localities where operations essential to the effective functioning of the system are performed
- obsolete documents are promptly removed from all points of issue and use?

Is there effective control in that data is legible, dated, revision numbers are up to date, readily identifiable maintained in an orderly manner and retained for a specified period?

Are responsibilities defined for development, control, authorisation, distribution, revision and maintenance of documents and date?

4.4.6 IMPLEMENTATION AND OPERATION OPERATIONAL CONTROL

Are all operations, activities and processes which have a significant environmental effect clearly defined?

Are processes available to identify, plan and control all those operations, activities and processes associated with the organisations significant environmental aspects?

Are the planned controls adequate in regard to the complexity and environmental relevance of the applicable activities and process?

Is the environmental policy and relevant objectives and targets reflected in specific work processes/procedures and work instructions for use by the responsible persons?

During development of the processes and instructions have the following elements been considered:

- activities where the lack of instructions may cause deviations from environmental policy requirements, objectives and targets
- stipulating criteria and limits for control of the most important process characteristics
- the control of processes where the goods and services used have significant environmental aspects
- release of new processes and equipment?

Are relevant procedures and requirements communicated to suppliers and contractors?

4.4.6 IMPLEMENTATION AND OPERATION: EMERGENCY PREPAREDNESS AND RESPONSE

Are procedures in place to identify potential emergency situations and to respond to accidents and for preventing and mitigating the associated environmental impacts?

Are the potential emergency situations identified reflected in the organisations list of significant aspects?

Are emergency preparedness procedures tested and/or periodically reviewed?

Are the emergency preparedness procedures, in particular after the occurrence of accidents and emergency situations, reviewed and modified where required?

4.4.7 IMPLEMENTATION AND OPERATION: EMERGENCY PREPAREDNESS AND RESPONSE

Are procedures in place to identify potential emergency situations and to respond to accidents and for preventing and mitigating the associated environmental impacts?

Are the potential emergency situations identified reflected in the organisations list of significant aspects?

Are emergency preparedness procedures tested and/or periodically reviewed?

Are the emergency preparedness procedures, in particular after the occurrence of accidents and emergency situations, reviewed and modified where required?

4.5.1 CHECKING AND CORRECTIVE ACTION: MONITORING AND MEASUREMENT

Are procedures established for monitoring and measurement of all key characteristics of those processes that have a significant environmental impact?

Is for all relevant activities:

- the required measurements and accuracy of results established to track performance
- the test procedures as well as time and location of measurements clarified
- control of measurements considered, including calibration of measuring equipment
- acceptance criteria for measurement accuracy established and processes clarified for unsatisfactory results
- protection of measured and test equipment ensured
- are relevant records maintained?

Are measurements carried out to monitor and control compliance to objectives and targets?

Are procedures established and maintained to ensure compliance to legal and other requirements?

4.5.2 CHECKING AND CORRECTIVE ACTION : NONCONFORMANCE, CORRECTIVE AND PREVENTIVE ACTIONS

Are procedures established and maintained for the investigation and handling of non-conformities (including complaints), and initiation of corrective and preventive actions?

Are procedures established and maintained describing action to be taken for non-conformance to objectives and targets?

Is it ensured that complaints by interested parties are integrated into the process?

Are authorities and responsibilities for initiation of these processes established?

Are the following elements integrated in the processes:

- determining the cause of non-conformance
- establishment and execution of correction action
- Documentation of modification and changes?

Is the corrective or preventive action taken within a timescale appropriate to the magnitude of the problem and the environmental impacts encountered?

4.5.3 CHECKING AND CORRECTIVE ACTION: RECORDS

Are procedures established and maintained for identification, maintenance, distribution and disposition of environmental records?

Do the records include the following elements:

- information on legislative and other requirements
- environmental aspects and impacts
- training records
- audit results
- records of management reviews
- records of contractors and suppliers?

Are the records stored to ensure that they are readily retrievable, protected against damage, deterioration or loss?

Are record retention times established?

Are records available to demonstrate appropriate maintenance and monitoring of the environmental management system and the achievement of objectives and targets?

Are records accessible internally and to external interested parties, as appropriate?

- ***Is the organization aware of the confidentiality agreements and the document retention times requirements?***

4.5.4 CHECKING AND CORRECTIVE ACTION: EMS AUDITS

Are procedures and programmes in place for the performance of periodic environmental management system audits?

Do environmental management system audits monitor whether the:

- system is properly implemented and maintained
- conforms to planned arrangements for environmental management including compliance to the standard
- effectiveness of the EMS in meeting the organisations environmental policy

Does the environmental management system audit provide the required information and results for management review?

Is the audit programme based on:

- Environmental importance of the organisation's activities
- Results of previous audits?

Does the audit program detail the frequency of audits, areas to audit, audit methods, and responsibility for audit execution as well as audit reporting?

Are individual audits planed and managed effectively?

Is audit team competence documented?

4.5.4 CHECKING AND CORRECTIVE ACTION: EMS AUDITS

INTERNAL AUDIT

- Is the internal audit system reliable?
- Is the auditing frequency adequate?
- Are members of the audit team competent (including experience and training)
- Are individual auditors independent of the area they audit?
- Does the auditing procedure and methodology consider:
  a) scoping of the audit?
  b) references and standards?
  c) checks and verifications performed?
  d) resources available for the audit?
  e) audit organisation?
  f) audit findings?
  g) management of the audit follow up?
  h) timeliness and effectiveness of corrective action?

MAIN AUDIT PLANNING INFORMATION REQUIREMENTS

- Has the scope for certification been determined?
- Has the number of sites to be audited been determined?
- Have the organisational and functional units to be audited been identified?
- Have key contact people for the various units been obtained?
- Has the estimated time and duration of the audit been determined?
- Has an approximate timeframe for the main Audit been agreed?
- Has the client approved the audit team members?
- Has the date and location of the document review process been agreed?
- Have the key reference documents been identified?
- Have the relevant environmental laws, regulations and other agreements been identified?
- Is there any evidence that the organisation has attempted to place activities or processes that create significant impacts off site in order to gain certification at a particular?

4.6 MANAGEMENT REVIEW

Is the environmental system periodically reviewed by top management for adequacy and effectiveness and continued suitability, and are these reviews documented?

Is the frequency of management reviews suitable for the organisation?

Are the reviews carried based on the following documents:

- audit results reports
- achievement of environmental management system targets
- adequacy of the system regarding continuous improvement of the system and the need of adjustment to changing environmental conditions
- concerns and complaints from relevant interested parties?

Division 23. Stage 1 & Stage 2 Auditing QMS/EMS/FSMS/OHS

1. An audit of a Management System consists of following activities/planning:

- Audit Plan Stage 1 & Stage 2,
- Opening meeting
- Performing the audit,
- Auditors meeting
- Closing meeting
- Acceptance for the NC identified
- Verification of the Corrective Action and subsequent evidences

2. Stage 1 Audit:

The purpose of stage 1 is to obtain the optimal preparation of the certification audit (stage 2). In principle the Lead Auditor takes care of the preliminary contact, but he may delegate this task to an other auditor of the team. Stage 1 shall normally have the form of a visit. It may exceptionally be executed by phone calls, faxes or mail.

a) A member of the audit team shall review the system documentation (usually the quality manual, supported by organisational procedures) before or during the site visit.
b) The stage 1 site visit mainly involves the Applicant's Management representative.
c) During stage 1, arrangements shall be made about:
d) Identifying date, site location and site specific conditions,
e) Collecting necessary information regarding the scope of the management system, areas, processes, compliance to related statutory and regulatory aspects and the responsible persons to be audited. Aspect & Impact Analysis/Hazard Analysis/PRP/HACCP Plan/CCP whether suitable or not as per the nature of work.
f) Confirming that internal audits and management review have been planned and performed.
g) Gathering reasonable knowledge about the client's management system and site operations in order to plan the stage 2 audit.
h) Review of client's status and understanding regarding the requirements of the standard and readiness for Stage 2 audit.
i) Review the allocation of resources for Stage 2 audit and to aware the client about the requirements of Stage 2 audit.
j) In case, during Stage 1 Audit, auditor finds the information provided by the client before submission of quote is incorrect, he shall immediately inform the Technical Coordinator / Assessment Manger / Quality Manager. Quality Manager / CEO shall ensure that the quote is reviewed and contract review is done to address the changes.
k) After the completion of Stage 1 audit, the lead auditor shall write and send the stage 1 audit report together with the stage 2 audit schedule to the organization.

The audit plan should cover following points

- Audit of the management system processes.
- Time required to audit those processes and its activities
- Audit team allocation
- Safety arrangement required

The minimum time gap between Stage 1 and Stage 2 should be reasonably one week, but could be reduced based on the customer requirements.

In case of any major area of concern during the Stage 1 audit, the lead auditor can postpone the date of Stage 2 audit (not over 90 days) so that the organization get the time for doing the improvements and inform the same to Administration.

3. Stage 2 Audit

The essential objective of an audit team is to verify:

- the existence of a Management System in the organization that meets all applicable requirements of the reference standard,
- the effective implementation of the Management System,
- the suitability of the elements of the Management System (such as, organizational structure, responsibilities, procedures, processes, technical documentation and resources), to meet the expectations of the customer and to respect statutory requirements. Necessary arrangements to meet the Impacts/Hazards/CCP, communication channel for any emergency situation/suppliers/staff/ regulatory bodies, emergency arrangements and records of mock situation, pest control and other safety conditions as identified by the organization and required for the nature of job.

4. Audit Process:

During the performance of the audit, the audit team verifies the following essential elements of a Quality/Environment/OHSAS/FS Management System:

- the availability of a system to identify without ambiguity the contractual requirements and the applicable codes, standards and statutory requirements,
- the suitability of the system to consider all identified requirements at the various stages of the process (engineering, procurement, production, inspection, installation, service, etc.),
- the availability of adequate resources, to achieve the desired results. This includes also the training aspects of the concerned personnel.

Therefore, the audit team examines during the audit, practical examples of running or terminated orders, with the purpose to verify that both upstream as well as downstream of the process indicators of the Quality/Environment/OHSAS/FS Management System and that the product or service meets the expectations of the customer.

This verification covers subjects that are directly related to the quality of the product or service (such as; key performance objectives, legal compliance, specifications, quality plan, work instructions, documents indicating the inspection and test status, inspection procedures and quality records) and during this verification the processes, aspects of completeness and coherence are reviewed.

In combination with the verification of the effectiveness of complementary aspects (such as; management review, document control, control of non-conforming products, internal audits, etc.), the audit team is able to make a judgement about the Quality/Environment/OHSAS/FS Management System of the organisation and particular about the essential elements of the system.

The audit team shall inform the organization regularly regarding the audit progress and results. In case of unreasonable accumulation of non-conformities indicating total breakdown of the system, the lead auditor shall have the authority to stop the audit.

5. Auditors Meeting:

After performance of the audit and prior to the exit meeting, the audit team joints together with the purpose to:

- discuss the results of the audit,
- define formally the detected non-conformities, if applicable,
- write the Non Conformity report, if applicable,
- Prepare the final meeting.

Non-conformities disclosed during an audit are divided into major and minor.

Major non-conformities

i) Lack of essential documentation or lack of implementation of an applicable criteria of the Quality Management System.

ii) Lack or inadequacy of a quality plan or lack of resources to assure the quality of the related products and/or services.

iii) High number of minor non-conformities

Minor non-conformities

i) Incomplete documentation on the condition that the missing documentation is not essential for the operation, or incomplete implementation of applicable criteria of the reference standard.

ii) Individual non conformities which does not impair the operability of the management system.

iii) Lack of evidence demonstration the conformity with a criterion of the reference standard.

A complete re-audit shall be requested under following circumstances:

i) high number of major non-conformities or total breakdown of system, or

ii) high number of customer complaints and no clear evidence of action taken towards customer satisfaction.

6. Closing Meeting:

Communicating the outcome of audit Recommended/not recommended for Certification/Next phase of audit, surveillance communication , scope confirmation, NC Acceptance & Communication about corrective action, opportunities for improvement, copy of report to organization

7. FOOD SAFETY RELATED REQUIREMENTS NEED TO BE CONSIDERED DURING THE AUDITING:

❖ CONDUCT OPENING MEETING

- Confirm certification scope
- Review audit criteria/methodology and explain outcome (e.g. audit as sampling, process approach)
- Establish communication channels
- Identify guides/escorts
- Confirm reporting method
- Identify food safety and security requirements
- Confirm audit plan
- Reaffirm time of closing meeting
- Complete meeting records

❖ CONDUCT DOCUMENT REVIEW (Stage-1)

- Obtain program documentation
- Review documentation against requirements
- Verify the organization's management system
- Determine if organization's documents meet requirements or identify non-conformities.
- Establish investigative lines for Stage 2 audit.
- Confirm readiness for Stage 2 audit

❖ PLANNING AUDIT ACTIVITIES

- Verify the scope of the audit
- Review history of facility to be audited
- Confirm resource needs
- Confirm travel plans
- Develop or confirm audit strategy and methodology
- Assign audit team roles, responsibilities and activities
- Develop audit plan, including sampling plan
- Review audit logistics
- Consider results of any previous audits and corrective actions
- Consider any regulatory requirements
- Plan audit team meetings

❖ COLLECTING AND VERIFYING INFORMATION:

- Verify process flow chart
- Assess effectiveness of implementation of control measures and processes
- Verify effectiveness of corrective actions of previous non-conformities/deficiencies
- Perform process approach audit

❖ **Preparation for closing meeting:**
- Hold audit team preparatory meeting (if required)
- Analyze audit findings and compare to requirements
- Confirm completion of audit plan
- Categorize, review and finalize any non-conformities and opportunities for improvement and relate them to the process and the system

❖ **Conduct closing meeting.**
- Present and review audit findings (non-conformities and/or opportunities for improvement)
- Confirm objectives of audit have been met
- Provide positive feedback
- Explain next steps (e.g. appeals, post-audit processes, certification decision-making timeline)
- Obtain written acknowledgement of non-conformities
- Complete meeting records

❖ **FINALIZE AUDIT REPORT**
- Describe findings against certification standard 's requirements (e.g. non-conformities, opportunities for improvement)
- Incorporate comments of competence and conformity**.**
- Describe final audit conclusions
- Judge effectiveness of corrective actions (when required)
- Finalize audit report

❖ **CONDUCTING POST-AUDIT ACTIVITIES**
- Conducting post-audit activities
- Deliver audit report
- Communicate information regarding nonconformity resolution timing
- Report any unusual circumstances that occurred during the audit
- Review corrective actions for appropriateness
- Determine requirements for verification of corrective actions
- Verify effectiveness of implementation of corrective actions
- Report any necessary adjustment of audit programme, as appropriate

Division 24. Guidance note for MD-QMS

1. Following are the Examples of nonconformities for MD-QMS:
   a. failure to address applicable requirements for quality management systems (e.g. failure to have a complaint handling or training system);
   b. failure to implement applicable requirements for quality management systems;
   c. failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects;
   d. products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling;
   e. the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements;

f. repeated nonconformities from previous audits;

g. an excessive number of any other nonconformities than ones shown in b) of 9.1.15 of ISO/IEC 17021 against a particular requirement for quality management systems.

Division 25. Mandatory documents for Management System Standards:

Part-A ISO 9001-2015

Cl.	Requirement for documented Information for ISO 9001-2015
Documented Information	
5.2	Quality Policy
6.2	Quality Objectives
4.3	QMS Scope
8.4.1	Criteria for evaluation and selection of suppliers
Mandatory Records	
7.1.5.1	Monitoring and measuring equipment calibration records
7.2	Records of training, skills, experience and qualifications
8.2.3.2	Product/service requirements review records
8.3.2	Record about design and development outputs review
8.3.3	Records about design and development inputs
8.3.4	Records of design and development controls
8.3.5	Records of design and development outputs
8.3.6	Design and development changes records
8.5.1	Characteristics of product to be produced and service to be provided
8.5.3	Records about customer property
8.5.6	Production/service provision change control records
8.6	Record of conformity of product/service with acceptance criteria
8.7.2	Record of nonconforming outputs
9.1.1	Monitoring and measurement results
9.2	Internal audit program
9.2	Results of internal audits
9.3	Results of the management review
10.1	Results of corrective actions

Part-B: ISO 14001-2015

Cl.	Requirement for documented Information for ISO 14001-2015
Documented Information (Mandatory)	
5.2	Environmental Policy
6.2	Quality Objectives
4.3	EMS Scope
6.1.1	Risk and opportunities to be addressed and processes needed
6.1.2	Criteria for evaluation of significant environmental aspects
6.1.2	Environmental aspects with associated environmental impacts
6.1.2	Significant environmental aspects

Cl.	Requirement for documented Information for ISO 14001-2015
6.2	Environmental objectives and plans for achieving them
8.1	Operational control
8.2	Emergency preparedness and response
Mandatory Records	
6.1.3	Compliance obligations record
7.2	Records of training, skills, experience and qualifications
7.4	Evidence of communication
9.1.1	Monitoring and measurement results
9.2	Internal audit program
9.2	Results of internal audits
9.3	Results of the management review
10.1	Results of corrective actions

Part-C: ISO 45001-2018

Cl.	Requirement for documented Information for ISO 45001-2018
Documented Information (Mandatory)	
5.2	OH&S Policy
4.3	Scope of the OH&S management system
5.3	Responsibilities and authorities within OH&SMS
6.1.1	OH&S process for addressing risks and opportunities
6.1.2.2	Methodology and criteria for assessment of OH&S risks
6.2.2	OH&S objectives and plans for achieving them
8.2	Emergency preparedness and response process
Mandatory Records	
6.1.1	OH&S risks and opportunities and actions for addressing them
6.1.3	Legal and other requirements
7.2	Evidence of competence
7.4.1	Evidence of communications
8.2	Plans for responding to potential emergency situations
9.1.1	Results on monitoring, measurements, analysis and performance evaluation
9.1.1	Maintenance, calibration or verification of monitoring equipment
9.1.2	Compliance evaluation results
9.2.2	Internal audit program
9.2.2	Internal audit report
9.3	Results of management review
10.2	Nature of incidents or nonconformities and any subsequent action taken
10.2	Results of any action and corrective action, including their effectiveness
10.3	Evidence of the results of continual improvement

Part-D ISO 22000-2018

Cl.	Requirement for documented Information for ISO 22000-2018
4.3	Determining the scope of the food safety management system
5.2.2	Food Safety Policy
6.2.2	FSMS Objectives
7.1.2	People

Cl.	Requirement for documented Information for ISO 22000-2018
7.1.5	Externally developed elements of the food safety management system
7.1.6	Control of externally provided processes, products or services
7.2	Competence
7.4.2	External communication
8.1	Operational planning and control
8.2	PRPs
8.3	Traceability
8.4	Emergency preparedness and response
8.5.1.1	Preliminary steps to enable hazard analysis
8.5.1.2	Characteristics of raw materials, ingredients and product contact materials
8.5.1.3	Characteristics of end products
8.5.1.4	Intended use
8.5.1.5.2	On-site confirmation of flow diagrams
8.5.1.5.3	Description of processes and process environment
8.5.2.2	Hazard identification and determination of acceptable levels
8.5.2.3	Hazard assessment
8.5.2.4.2	Selection and categorisation of control measures
8.5.3	Validation of control measure(s) and combinations of control measures
8.5.4.1	Hazard control plan
8.5.4.2	Determination of critical limits and action criteria
8.5.4.3	Monitoring systems at CCPs and for OPRPs
8.5.4.5	Implementation of the hazard control plan
8.7	Control of monitoring and measuring
8.8	Verification related to PRPs and the hazard control plan
8.9.2	Corrections
8.9.3	Corrective actions
8.9.4.1	Handling of potentially unsafe products
8.9.4.2	Evaluation for release
8.9.4.3	Disposition of nonconforming products
8.9.5	Withdrawal/ recall
9.1	Monitoring, measurement, analysis and evaluation
9.2	Internal Audit
9.3	Management review
10.1	Nonconformity and corrective actions
10.3	Update of the FSMS

Part-E: ISO 27001:2013

Cl.	Requirement for documented Information for ISO 27001:2013
Documented Information (Mandatory)	
4.3	Scope of the ISMS
5.2, 6.2	Information security policy and objectives

Cl.	Requirement for documented Information for ISO 27001:2013
6.1.2	Risk assessment and risk treatment methodology
6.1.3 d	Statement of Applicability
6.1.3e, 6.2	Risk treatment plan
8.2	Risk assessment report
A.7.1.2, A.13.2.4	Definition of security roles and responsibilities
A.8.1.1	Inventory of assets
A.8.1.3	Acceptable use of assets
A.9.1.1	Access control policy
A.12.1.1	Operating procedures for IT management
A.14.2.5	Secure system engineering principles
A.15.1.1	Supplier security policy
A.16.1.5	Incident management procedure
A.17.1.2	Business continuity procedures
A.18.1.1	Statutory, regulatory, and contractual requirements
Mandatory Records	
7.2	Records of training, skills, experience and qualifications
9.1	Monitoring and measurement results
9.2	Internal audit program
9.2	Results of internal audits
9.3	Results of the management review
10.1	Results of corrective actions
A.12.4.1, A.12.4.3	Logs of user activities, exceptions, and security events

Part-F: ISO 13485-2016

Cl.	Requirement for documented Information for ISO 13485-2016
4.1.1	Roles undertaken by the organization under applicable regulatory requirements
4.1.6	Procedure and records for the validation of the application of computer software
4.2.2	Quality Manual
4.2.3	Medical device file
4.2.4	Procedure for document control
4.2.5	Procedure for record control
5.3	Quality policy
5.4.1	Quality objectives
5.5.1	Responsibilities and authorities
5.6.1	Procedure and records for management review
6.2	Procedure for training
6.3	Requirements for infrastructure and maintenance activities
6.4.1	Requirements for work environment
6.4.2	Arrangements for control of contaminated or potentially contaminated product
7.1	Process for risk management in product realization
7.1	Outputs of product realization planning
7.2.2	Records of the results of the customer requirements review and actions arising from it
7.2.3	Arrangements for communication with customers
7.3.1	Procedure for design and development

Cl.	Requirement for documented Information for ISO 13485-2016
7.3.2	Design and development planning
7.3.4	Design and development outputs
7.3.5	Records of design and development review
7.3.6	Design verification plans, results and conclusions
7.3.6	Design validation plans, results and conclusions
7.3.8	Procedure for transfer of design and development outputs to manufacturing
7.3.9	Procedure and records for control of design and development changes
7.3.10	Design and development file
7.4.1	Procedure for purchasing
7.4.1	Criteria and records for evaluation and selection of suppliers
7.4.3	Record of verification of purchased product
7.5.1	Record for each medical device or batch that provides traceability
7.5.2	Requirements for cleanliness of product
7.5.3	Requirements for medical device installation and acceptance criteria for verification of installation
7.5.3	Records for medical device installation and verification of installation
7.5.4	Procedure and records for servicing of the medical device
7.5.5	Records of sterilization process
7.5.6	Procedure and records of production and service provision process validation
7.5.7	Procedure and records for validation of process for sterilization and sterile barriers systems
7.5.8	Procedure for product identification
7.5.9.1	Procedure for traceability
7.5.9.2	Records of traceability and name and address of the shipping package consignee
7.5.10	Report on changes on customer property
7.5.11	Procedure for preserving the conformity of product
7.6	Procedure for monitoring and measuring
7.6	Record of calibration
7.6	Procedure and records for validation of the application of computer software used for monitoring and measuring
8.2.1	Procedure for customer feedback
8.2.2	Procedure and records for complaint handling
8.2.3	Records of reporting to regulatory authorities
8.2.4	Procedure for internal audit
8.2.4	Records of audits and their results
8.2.6	Identity of the person authorizing release of product
8.3.1	Procedure and record of control of nonconforming product
8.3.4	Records of rework
8.4	Procedure and records for data analysis
8.5.2	Procedure and records for corrective action
8.5.3	Procedure and records for preventive action
Note:	Please note that some of the documents will not be mandatory if the company does not perform relevant processes

Division 26. Verification of Product Information

1. Proprietary/Brand Name
2. Brief description of the device;
3. Category of device;

4. Intended use and method of use;
5. Medical specialty in which the device is used;
6. Qualitative and quantitative particulars of the constituents;
7. Brief description of the method of the manufacture and specification of the material used;
8. Contraindications, warnings, precautions potential adverse events and alternate therapy,
9. wherever applicable;
10. List of accessories and other devices or equipment to be used in combination with the
11. device. Other descriptive information, including accessories packaged with the product;
12. Variations in shape, style or size of the device, if applicable;
13. Labeling details confirming to Drug and Cosmetic Rules, 1945;
14. Physician manual and promotional literature in English;
15. Packaging description including pack size;
16. Recommended storage conditions;
17. Summary indications of any reported problems;
18. Details of standards to which the device confirm along with the copy of the standard;

Division 27. Reference:

GHTF/SG4/N28: Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements GHTF SG 1 N 29 R 16:2005: Information Document Concerning the Definition of the Term "Medical Device"

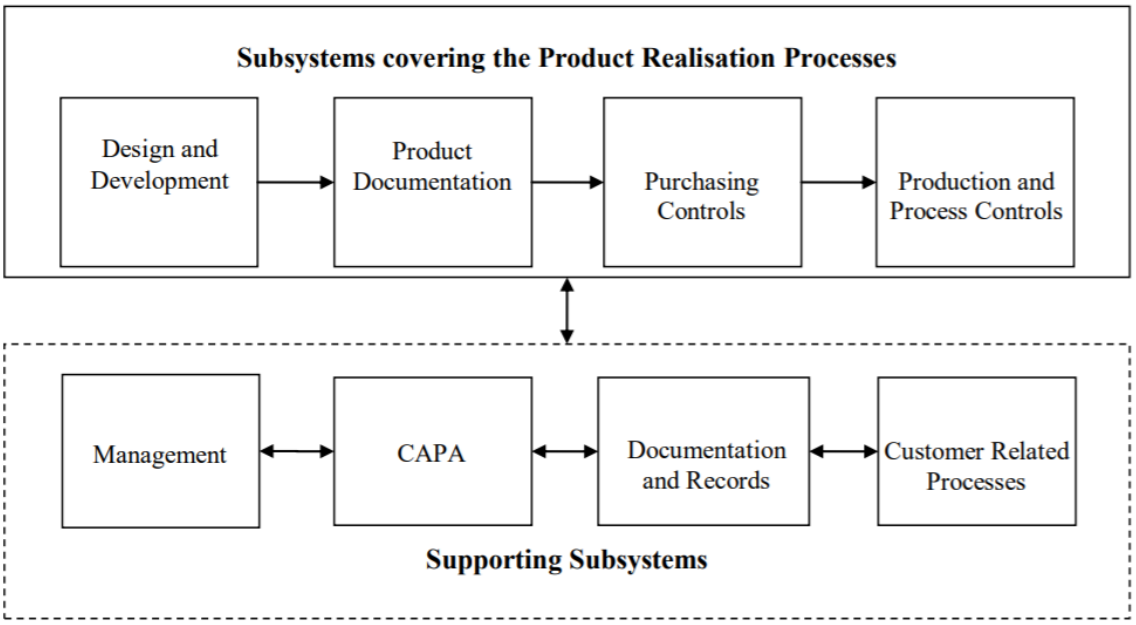
The subsystems and associated clauses of ISO 13485:2016 are:

How to plan Audit:

In the planning phase, the following information should be requested from the manufacturer to estimate the audit duration and to prepare the audit plan as described in GHTF Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements, Section 11.1.2 (SG4/N28)

A. manufacturer's name, address, including the corporate structure as well as all company names of the manufacturer used
B. contact name, telephone, fax numbers and e-mail addresses
C. total number of employees (all shifts) covered by the scope of the audit
D. product range and class of medical devices being manufactured (The class of a medical device may differ from one regulatory authority to another)
E. types of medical devices sold and/or planned to be sold in the countries and/or regions for which the regulatory requirements will be assessed, including a complete list of authorizations (e.g., licenses) issued for those medical devices (where applicable)
F. location and function of each site to be included in the audit
G. a list of activities performed at each site
H. any special manufacturing processes, e.g., software, sterilization, etc.
I. a list of the activities performed by significant suppliers and their locations, including the type of control that is exercised over those outsourced operations
J. if permitted, any existing audit results from other auditing organizations
K. is installation or servicing of the medical devices applicable
L. description of any changes since the last audit, if applicable

Figure 1: Examples of Subsystem Links



Production and Process Controls Subsystem

Production Process subsystem:

A. Verify that the product realization processes are planned – including any necessary controls and controlled conditions. (ISO 13485:2003: 7.1, 7.5.1).
B. Verify that the planning of product realization is consistent with the requirements of the other processes of the quality management system. (ISO 13485:2003: 7.1)
C. Review production processes considering the following criteria. Select one or more production processes to audit.

Verification of Production Process Sub System:

A. Verify that the processes have been validated if the result of the process cannot be verified. Verify that the validation demonstrates the ability of the processes to achieve planned result.
B. Verify that the equipment used in production and process control has been adjusted, calibrated and maintained.
C. Verify that the processes are controlled and monitored and operating within specified limits. In addition, verify that risk control measures identified by the manufacturer in production processes are controlled, monitored and evaluated.
D. Verify that risk control measures are applied to delivery, installation and servicing, where applicable
E. Determine the links to other processes.
F. Verify that personnel are appropriately qualified and/or trained to implement/maintain the processes.
G. Verify that the infrastructure and the work environment are adequate.
H. Verify that identification and traceability for processes and products are in place and are adequate
I. If the process is software controlled, verify that the software is validated for its intended use.
J. Verify that the control of the monitoring and measuring devices is adequate.
K. Verify that the system for monitoring and measuring of products is adequate. Ensure that any identified risk control measures are implemented.
L. Verify that acceptance activities assure conformance with specifications and are documented.

M. Verify that the control of nonconforming products is adequate.

CAPA Subsystem*

Verify that CAPA system procedure(s) which address the requirements of the quality management system have been established

Verify that accurate information is analysed for input into the CAPA system and that corrective and preventive actions were effective

When a CAPA results in a design change, verify that the hazard(s) and any new risks are evaluated under the risk management process

Determine if all appropriate sources of CAPA data have been identified and are being monitored to determine action when indicated. Confirm that data from these sources are analyzed, using valid statistical methods where appropriate, to identify existing product and quality problems that may require corrective action

Determine if failure investigations are conducted to identify the causes of nonconformities, where possible

Verify that controls are in place to prevent distribution of nonconforming products

Confirm that corrective and preventive actions were implemented, effective, documented and did not adversely affect finished devices

Determine if relevant information regarding nonconforming product and quality problem(s) and corrective and preventive actions has been supplied to management for management review

Verify that medical device reporting is done according to the applicable regulatory requirements

Confirm that the manufacturer has made effective arrangements for gaining experience from the post production phase, handling complaints (see also 7.8.3), and investigating the cause of non-conformance related to advisory notices/recalls with provision for feed back into the corrective and preventive action subsystem

Confirm that the manufacturer has made effective arrangements for the issue and implementation of advisory notices/recalls

Purchasing Controls Subsystem

Verify that procedures for conducting supplier evaluations have been established.

Verify that the manufacturer evaluates and maintains effective controls over suppliers, so that specified requirements are met

Verify that the manufacturer assures the adequacy of specifications for products and services that suppliers are to provide, and defines risk management responsibilities and any necessary risk control measures.

Verify that records of supplier evaluations are maintained.

Determine that the verification of purchased products and services is adequate.

Appendix 2: Factors used to determine the audit duration

A. Factors which may increase the audit duration
   a. Manufacturers using suppliers to supply processes or parts that are critical to the function of the medical device and/or the safety of the user or finished products, including own label products. When the manufacturer cannot provide sufficient evidence for conformity with audit criteria , then additional time may be allowed for each supplier to be audited. (Note: Component suppliers are exempt from the FDA Quality System Regulation and are not inspected routinely by FDA.)
   b. Manufacturers who install product on customer's premises. Note: Time may be required for customer site visits or installation records review
   c. Audits conducted in a foreign language (see GHTF Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – General Requirements, Part 1, Supplement 1: Audit Language Requirements)
   d. Multipurpose audits required by the manufacturer
   e. Poor regulatory compliance by the manufacturer b) Factors that may reduce the audit duration
      i. Low and medium risk medical devices
      ii. Any evidence of satisfactory audits from other third party or auditing organizations of suppliers
      iii. The result of previous audits conducted by the auditing organisation show compliance with regulatory requirements, i.e. regulatory compliance by the manufacturer
      iv. Reduction of the manufacturer product range since last audit
      v. Reduction of the design/or production process since last audit

Sterilization Process: Evaluate the sterilization process for adequacy as part of the evaluation of the Production Processes subsystem.

B. Determine that the sterilization processes are planned – including the controlled conditions
C. Determine that the planning of product sterilization is consistent with the requirements of the other processes of the quality management system
D. Determine that records of process parameters for the sterilization process for each sterilization batch are maintained and are traceable to each production batch
E. Select a sterilization process (es) for review. If there is more than one sterilization process use the following criteria:
   a. degree of difficulty to sterilize a medical device
   b. process used for the largest number of medical devices
   c. process that is most difficult to control
F. Determine that the sterilization process has been validated and review the validation for adequacy. Validation includes qualification of the sterilizer. Check that validation is up-to-date.
G. Determine that biological indicators are handled appropriately and validated.
H. Determine that the process is controlled and monitored including product bio burden. Verify that configuration of loads comply with validated configurations.
I. Determine that the process is operating within specified limits.
J. If data indicates that the process does not always meet process parameters, determine that non-conformances are handled appropriately and investigated and appropriate corrections and corrective actions are taken to address non-conformances.
K. If the sterilization process is software controlled, determine that the software is validated.
L. . Determine that the equipment used has been adjusted, calibrated and maintained.
M. . Determine that personnel are appropriately qualified and trained to validate, implement and maintain the process.

Approximate percentage of on-site auditing time

The approximate percentage of on-site time assigned to different subsystems can be estimated using Table 2:

Subsystems	Approximate percentage of on-site time	Clauses and sub clauses (links) of ISO 13485	Remarks
Management	5-10%	4, 5, 6, 7, 8	
Design and development	0 to 20%	7	Depends on regulatory requirements
Product documentation	5-20%	4, 7	
Production and process controls (including sterilization, where applicable)	20-30%	4, 6, 7, 8	
Corrective and preventive actions	10-30%	4, 5, 6, 7, 8	
Purchasing controls	5-20%	7	Depending on the proportion and importance of activities an outsourcing manufacturer is contracting
Documentation and records	5%	4	
Customer related processes	5%	7	

19. Question Checklist for MD-QMS Assessment:

Clause	Questioning Technique for ISO 13485	Response
0	General	
1.1	General questions for the certification	
0.1.1	Is the guideline "Regulation for the use of the TNV certificate symbols, the TNV documents and the TNV symbol "applied correctly?	
0.1.2	Are the improvement potentials to the QM-System, mentioned in the last audit report used?	
1.2	Additional requirements of the 93/42/EEC to establish the procedure	
0.2.1	Does the company keep the correspondence with TNV?	
0.2.2	Was the company completely informed about the previous and present (today's) activities of the auditortor (s)? Is the declaration " Auditors'/Experts' Independence and Objectivity " countersigned?	
0.2.3	Are the company and the products registered to the legal authorities?	

Clause	Questioning Technique for ISO 13485	Response
0.2.4	Is there a procedure in place to inform TNV about essential changes of the Medical Devices covered by the Quality Management System? (Advice company about the application forms 360.1.11 (Certification application) & 360.1.12 (Product application) and hand it out).	
4	Quality management system	
4.1	General requirements	
4.1.1	Is the MDD 93/42/EEC Annex II/V/VI (and if necessary the MPG/the MPV for Germany) referenced correctly?	
4.1.2	Is, if necessary, an authorized representative designated within the EEC?	
4.1.3	Does the organization ensure the control of any outsourced processes, that affects product conformity with requirements and is the control of such outsourced processes identifiable within the QM system?	
4.2	Documentation requirements	
4.2.1	General	
4.2.1.1	-a quality manual? - documented procedures as required by the standard? - all other by national or regional regulations required documents and records?	
4.2.1.2	documented statements of a quality policy and quality objectives ?	
4.2.1.3	documents needed by the organization to ensure the effective planning, operation and control of its processes?	
4.2.1.4	records as required by the standard?	
	Product documentation	
4.2.1.5	Are files available, containing all products specifications and quality assurance specifications, or is the location of those documents described exactly? (>NB-MED 2.5.1-5) (see also Annex II / V/ VI 93/42/EWG and if necessary TNV Support checklists)	
4.2.1.6	Is this information available and comprehensible for each type or each model of the medical device? (if necessary also the information for installation / maintenance)	
4.2.1.7	Are correct declarations of conformity issued? (> EK-MED 3.9 A4)	
4.2.1.8	Are the classifications of the Medical Devices traceable to the MDD?	
4.2.1.9	Are designated harmonized standards, which are applicable to the product / procedures defined and available (Is the adherence systematically ensured)? If no harmonized standards are available, is there proof, which ensures the safety and suitability of the products?	
4.2.1.10	Is it defined and documented for each product how the applicable “Essential Requirements (Annex I)“ are fulfilled and are there proofs to validate the statements made?	
4.2.1.11	Are there, for all products/product groups, complete risk analyses defined and documented? (copy the risk analysis to the documents for the TNV as example; if necessary apply 370.2.13 Checklist Risk Management)	
4.2.1.12	Are all the possible safety risks comprehensibly determined? Are the initial risks evaluated? Is the evaluation of the risks comprehensible?	
4.2.1.13	Do designated suppliers with activities having a substantial influence on the quality identified exist? (EK-MED 3.9 B17) (see 360.1.5 BasicData-Organization)	
4.2.1.14	Are they listed including their activities and are appropriate certificates of the subcontractors/ suppliers available?	
4.2.1.15	If no appropriate certificates for subcontractors/suppliers are available, are they appropriately assessed to fulfill the requirements of the suppliers / subcontractors??	
4.2.1.16	Are contractual declarations/agreements signed with subcontractors/suppliers with defined activities and responsibilities, if they have a substantial influence on the quality?	
4.2.1.17	Does the contract with e.g. OEM suppliers contain sufficient descriptions and regulations on notification of the legal authorities and to ensure appropriate information in case of vigilance? (>EK-MED 3.9 B16)	

Clause	Questioning Technique for ISO 13485	Response
4.2.1.18	Is there a procedure to evaluate the actuality of the subcontractor's/supplier's proofs (certificates of analysis, etc.)?	
4.2.1.19	Has the company established that the purpose is fulfilled? (in accordance with MDD Annex X)	
4.2.1.20	Are there corresponding pre-clinical product reviews for the products?	
4.2.1.21	Is there a evaluation of the essential requirements of the Machinery Directive, if this is applicable to the product? (NB-MED 2.2 Rec. 5)	
4.2.1.22	If the destination of the products falls below the standards for personal protective equipment, is a notified body involved for this?	
4.2.2	**Quality manual**	
	Does the quality manual include ...	
4.2.2.1	the scope of the QM system, including details of and justifications for any exclusions and / or non-application?	
4.2.2.2	-the documented procedures established for the QM system, or reference to them? - a description of the interaction between the processes of the QM system?	
4.2.2.3	an overview of the structure of the used documentation?	
4.2.3	**Control of documents**	
4.2.3.1	Is there a procedure in place for control of documents (including external documents)	
	Has a documented procedure been established to define the controls needed to ...	
4.2.3.2	approve documents for adequacy prior to issue? Review and update documents as necessary and re-approve documents?	
4.2.3.3	ensure that changes and the current revision status of documents are identified?	
4.2.3.4	ensure that relevant versions of documents are available at point of use and that documents remain legible / readily identifiable?	
4.2.3.5	ensure that documents of external origin are identified and that their distribution is controlled	
4.2.3.7	prevent the unintended use of obsolete documents (to apply suitable identification to them, if they are retained for any purpose)?	
4.2.3.7	Does the organization ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions?	
4.2.3.8	Is a retention period set for the keeping of at least one copy of outdated documents, especially if these documents contain specifications of how the medical devices were manufactured? Are manufacturing and test documents for the life time of the medical device accessible?	
4.2.3.9	Does period ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements?	
4.2.4	**Control of records**	
4.2.4.1	Has a documented procedure been established to define the controls of records (Identification, storage, protection, retrieval, legibility, retention periods and disposal of records)?	
4.2.4.2	Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the QM system?	
4.2.4.3	Are the quality records maintained for the life time of the products (at least 2 years after product release / date of shipment) or according to the storage requirements of the relevant rules (MPG min. 5 years, for implants min. 15 years)	
5	**Management responsibility**	
5.1	Management commitment	

Clause	Questioning Technique for ISO 13485	Response
5.1.1	Communicating to the organization the importance of meeting customer, as well as statutory and regulatory requirements?	
5.1.2	Does top management provide evidence of its commitment to the continues improvement of the quality system? Is the availability of necessary resources ensured?	
5.2	Customer focus	
5.2.1	Does top management ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction gets attended?	
5.3	Quality policy	
5.3.1	Is the quality policy appropriate to the purpose of the organization and does it provide a framework for establishing and reviewing quality objectives?	
5.3.2	Does the quality policy include a commitment to comply with requirements and continually improve the effectiveness of the QM system?	
5.3.3	Is the quality policy communicated and understood within the organization?	
5.4	Planning	
5.4.1	Quality objective	
5.4.1.1	Are quality objectives (preferably measurable) established at relevant functions and levels within the organization? Are the quality objectives measurable and consistent with the quality policy?	
5.4.1.2	Are there objectives needed to meet the requirements for products?	
5.4.2	Quality management system planning	
5.4.2.1	Does top management ensure that the planning of the QM system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives?	
5.4.2.2	Is it ensured that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?	
5.5	Responsibility, authority and communication	
5.5.1	Responsibility and authority	
5.5.1.1	Does the top management ensure that the responsibilities and authorities are defined, communicated and documented within the organization?	
5.5.1.2	Does the top management establish the interrelation of all personnel who manage, perform and verify work affecting quality?	
5.5.1.3	Is the necessary independence and authority to perform these tasks ensured and is particular attention paid to the nomination of specific persons responsible for activities related to product monitoring from the post-production stage and reporting adverse events?	
5.5.2	Management representative	
	Has the top management appointed a member of the organization's management who has responsibility and authority that includes ..	
5.5.2.1	ensuring that processes needed for the QM system are established, implemented and maintained?	
5.5.2.2	reporting to top management on the performance of the QM system and any need for improvement?	
5.5.2.3	ensuring the promotion of awareness of customer requirements throughout the organization?	
5.5.2.4	Who is appointed (and trained) as Medical Device Safety Representative? Is the expertise provided sufficiently?	
	(§ 30 MPG; > Statement in the report)	
5.5.2.5	Are the Medical Device Safety Representative's responsibilities and competencies defined and documented and was the Medical Device Safety Representative notified to the legal authorities?	
5.5.3	Internal communication	

Clause	Questioning Technique for ISO 13485	Response
5.5.3.1	Does top management ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QM system?	
5.6	Management review	
5.6.1	General	
5.6.1.1	Does top management review the organization's QM system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?	
5.6.1.2	Does this review include assessing opportunities for improvement and the need for changes of the QM system, including the quality policy and quality objectives?	
5.6.1.3	Are records from management reviews maintained?	
5.6.2	Review input	
	Does the input to management review include information on ...	
5.6.2.1	- results of audits? - customer feedback?	
5.6.2.2	- process performance and product conformity? - status of preventive and corrective actions?	
5.6.2.3	- follow-up actions from previous management reviews? - changes that could affect the QM system?	
5.6.2.4	- recommendations for improvement? - new or revised regulatory requirements?	
5.6.3	Review output	
	Does the output of the management review include any decisions and actions related to ...	
5.6.3.1	- improvement of the effectiveness of the QM system and its processes?	
5.6.3.2	- improvements needed to maintain the effectiveness of the quality management system and related to customer requirements?	
5.6.3.3	resource needs?	
6	**Resource management**	
6.1	Provision of resources	
	Does the organization determine and provide the resources needed to…	
6.1.1	- to implement and maintain the quality management system, to continually improve its effectiveness and enhance customer satisfaction by meeting customer requirements?	
6.1.2	to implement and maintain the quality management system, to continually improve its effectiveness and to meet regulatory and customer requirements?	
6.2	Human Resources	
6.2.1	General	
6.2.1.1	Is personnel competent on the basis of appropriate education, training, skills and experience if they perform work affecting conformity to product requirements?	
6.2.1.2	Is the training of new medical device representatives and sales personnel planned, executed and recorded?	
6.2.2	Competence, training and awareness	
	Does the organization….	
6.2.2.1	determinate the necessary competence of personnel performing work affecting conformity to product requirements?	
6.2.2.2	provide training or take other actions to achieve the necessary competence?	
6.2.2.3	evaluate the effectiveness of the actions taken?	
6.2.2.4	ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?	
6.2.2.5	maintain appropriate records of education, training, skills and experience?	
6.3	Infrastructure	
6.3.1	Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements?	

Clause	Questioning Technique for ISO 13485	Response
6.3.2	Does that include, as applicable, buildings, workspace and associated utilities, process equipment (both hardware and software) and supporting services (such as transport, communication or information system)?	
6.3.3	Are the documented requirements for maintenance activities, including their frequency established, when such activities or lack thereof can affect product quality?	
6.3.4	Are records of such maintenance getting maintained?	
6.4	Work environment	
6.4.1	Does the organization determine and manage the work environment needed to achieve conformity to product requirements?	
6.4.2	Has the organization established documented requirements for health, cleanliness and clothing of personnel, if contact between such personnel and the product or work environment could adversely affect the quality of the product?	
	If work environment conditions can have an adverse effect on product quality:	
6.4.3	Does the organization establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions?	
6.4.4	Does the organization ensure that all personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained person?	
6.4.5	If necessary: are special arrangements established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel?	
7	**Product realization**	
7.1	Planning of product realization	
7.1.1	Does the organization plan and develop the processes needed for product realization? Is the planning of product realization consistent with the requirements of the other processes of the QM system?	
	Does the organization determine the following, as appropriate, in planning product realization ...	
7.1.2	quality objectives and requirements for the product?	
7.1.3	the need to establish processes and documents, and to provide resources specific to the product?	
7.1.4	required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance?	
7.1.5	records needed to provide evidence that the realization processes and resulting product meet requirements?	
7.1.6	Is the output of this planning in a suitable form for the organization's method of operations?	
7.1.7	Has the organization established the documented requirements for risk management throughout product realization?	
7.1.8	Are records arising from risk management including the results getting maintained? (throughout the entire lifecycle of products, see for example EN ISO 14971)	
7.2	Customer-related processes	
7.2.1	Determination of requirements related to the product	
7.2.1.1	Are procedures and competencies for contract reviews defined?	
	Does the organization determine ...	
7.2.1.2	Does the organization review the requirements related to the product? Is this review conducted prior to the organization's commitment to supply a product to the customer (for exemple: Submission of tenders, acceptance of contracts or orders, acceptance of a contract or orders, acceptance of changes to contracts or orders)	
	Does this review ensure that ...	

Clause	Questioning Technique for ISO 13485	Response
7.2.1.2	requirements specified by the customer, including the requirements for delivery and post-delivery activities?	
7.2.1.3	requirements not stated by the customer but necessary for specified or intended use, where known?	
7.2.1.4	statutory and regulatory requirements applicable to the product and any additional requirements considered necessary by the organization?	
7.2.2	Review of requirements related to the product	
7.2.2.1	Does the organization review the requirements related to the product? Is this review conducted prior to the organization's commitment to supply a product to the customer (for exemple: Submission of tenders, acceptance of contracts or orders, acceptance of a contract or orders, acceptance of changes to contracts or orders	
	Does this review ensure that ...	
7.2.2.2	a) product requirements are defined and the organization has the ability to meet the defined requirements?	
7.2.2.3	b) contract or order requirements differing from those previously expressed are resolved?	
7.2.2.4	Are the records of the results of the review and actions arising from the review maintained and stored?	
7.2.2.5	Does the organization confirm the customer requirements before acceptance, where the customer provides no documented statement of requirement?	
7.2.2.6	Does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	
7.2.3	Customer communication	
7.2.3.1	Has the organization determined and implemented effective arrangements for communication with customers in relation to: product information, enquiries, contracts or order handling, including amendments and customer feedback, including customer complaints and advisory notices (see 8.5.1)?	
7.3	Design and development	
7.3.1	Design and development planning	
7.3.1.1	Are documented procedures and the responsibilities and authorities for the design and development determined?	
	Does the organization determine during the design and development planning	
7.3.1.2	- the design and development stages, the review, verification and validation that are appropriate to each design and development stage?	
7.3.1.3	- design and development transfer activities? If the design and development results to the manufacturing process proved to be suitable?	
7.3.1.4	Are the interfaces between different groups involved in design and development managed? Are effective communication and clear assignment of responsibilities ensured?	
7.3.1.5	If the output of planning is updated, as the design and development progresses	
7.3.1.6	If in the design planning, the legal requirements, especially in regard to the licensing and reporting requirements are intent?	
7.3.2	Design and development inputs	
7.3.2.1	Are inputs related to product requirements determined and records maintained?	
	Do these inputs include ..	
7.3.2.2	- functional, performance and safety requirements according to the intended use?	
7.3.2.3	- applicable statutory and regulatory requirements, as well as the results from the risk management	
7.3.2.4	- where applicable, information derived from previous similar designs and other requirements essential for design and development	
7.3.2.5	Are these inputs reviewed for adequacy and approved?	
7.3.2.6	Are these requirements complete, unambiguous and not in conflict with each other	

Clause	Questioning Technique for ISO 13485	Response
7.3.2.7	Has the applicable harmonized standards for safety requirements for medical devices systematically identified?	
7.3.2.8	If no harmonized standards were applied: Has the safety requirements completely identified (systematically)?	
7.3.3	Design and development outputs	
7.3.3.1	Are the outputs of the design and development in a form suitable for verification against the design and development input?	
7.3.3.2	Are the outputs of the design and development approved prior to release? Do the design and development outputs contain or reference product acceptance criteria?	
7.3.3.3	Do the design and development outputs provide appropriate information for purchasing, production and for service provision?	
7.3.3.4	Do the design and development outputs specify the characteristics of the product that are essential for its safe and proper use?	
7.3.4	Design and development review	
7.3.4.1	Are systematic reviews of design and development performed at suitable stages to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions?	
7.3.4.2	Do the participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed? Is specialist personnel included, where necessary?	
7.3.4.3	Are records of the results of the reviews and any necessary actions maintained?	
7.3.5	Design and development verification	
7.3.5.1	Is verification performed and recorded to ensure that design and development outputs have met the design and development input requirements?	
7.3.6	Design and development validation	
7.3.6.1	Is the design and development validation performed to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use?	
7.3.6.2	Is validation completed prior to the delivery or implementation of the product or completed until the product has been formally transferred to the customer?	
7.3.6.3	Are records of the results of validation and any necessary actions maintained?	
7.3.6.4	Are sufficient clinical data provided, to prove that the product fulfills the performance, design characteristics and intended purpose of the device as stated in MDD 93/42/EEC Annex I (clinical evaluation or if necessary clinical investigation)?	
7.3.7	Control of design and development changes	
7.3.7.1	Are design and development changes identified and records maintained and reviewed, verified and validated, as appropriate? Are design and development changes approved before implementation?	
7.3.7.2	Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered?	
7.3.7.3	Are records of the results of the review of changes and any necessary actions maintained?	
7.3.7.4	Which procedures guarantee that the TNV is informed when substantial modifications are done to the products?	
7.4	Purchasing	
7.4.1	Purchasing process	
7.4.1.1	Have documented procedures been established to ensure that the purchased products conforms to specified purchase requirements?	
7.4.1.2	Does the organization evaluate and select suppliers to ensure that products are delivered in accordance with the requirements of the organization?	
7.4.1.3	Are the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?	

Clause	Questioning Technique for ISO 13485	Response
7.4.1.4	Are criteria established for selection, evaluation and reevaluation? Are records maintained of the results of evaluations and any necessary actions?	
7.4.2	Purchasing information	
7.4.2.1	Does the purchasing information describe the product to be purchased?	
	Does the information include, where appropriate ...	
7.4.2.2	a) requirements for approval of product, procedures, processes and equipment?	
7.4.2.3	b) requirements for qualification of personnel?	
7.4.2.4	Is the adequacy of specified purchase requirements ensured, prior to their communication to the supplier?	
7.4.2.5	Maintains the organization copies of the relevant purchasing information, i.e. documents and records to the extent required for traceability?	
7.4.3	Verification of purchased product	
7.4.3.1	Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements?	
7.4.3.2	Where the organization or its customer intends to perform verification at the supplier's premises: are the intended verification arrangements and method of product release stated in the purchasing information?	
7.5	Production and service provision	
7.5.1	Control of production and service provision	
7.5.1.1	General Requirements	
7.5.1.1.1	Does the organization plan and carry out production and service provision under controlled conditions?	
	Do these controlled conditions include, as applicable ...	
7.5.1.1.2	- the availability of information that describes the characteristics of the product?	
	and the availability of work instructions?	
7.5.1.1.3	- the use of suitable equipment and the availability? - the use of monitoring and measuring devices?	
7.5.1.1.4	- the implementation of monitoring and measurement? - as well as the implementation of defined operations for labeling and packaging?	
7.5.1.1.5	- the implementation of release, delivery and post-delivery activities?	
7.5.1.1.6	Does the organization establish and maintain a record for each batch of medical devices that provides traceability to the extent specified in 7.5.3?	
7.5.1.2	Specific requirements	
7.5.1.2.1	Cleanliness of product and contamination control	
7.5.1.2.1.1	The organization shall establish documented requirements for cleanliness of product if, - the product is cleaned by the organization prior to sterilization and/or its use or, - the product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use or, - the product is supplied to be used non-sterile and its cleanliness is of significance in use or, - process agents are to be removed from product during manufacture.	
7.5.1.2.2	Installation activities (if applicable)	
7.5.1.2.2.1	Has the organization established documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device?	
7.5.1.2.2.2	If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, has the organization provided documented requirements for installation and verification?	
7.5.1.2.2.3	Are records of installation and verification performed by the organization or its authorized agent maintained (see 4.2.4)?	
7.5.1.2.3	Servicing activities (if applicable)	

Clause	Questioning Technique for ISO 13485	Response
7.5.1.2.3.1	Has the organization established documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements?	
7.5.1.2.3.2	Are those records of servicing activities carried out by the organization maintained?	
7.5.1.3	Particular requirements for sterile medical devices	
7.5.1.3.1	Does the organization maintain records of the process parameters for the sterilization process which was used for each sterilization batch, and are these sterilization records traceable to each production batch of medical devices (see 7.5.1.1)	
7.5.2	Validation of processes for production and service provision	
7.5.2.1	General requirement	
7.5.2.1.1	Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement? (> EK-MED 3.9 B18	
7.5.2.1.2	Does this include any processes where, as consequence, deficiencies become apparent only after the product is in use or the service has been delivered?	
7.5.2.1.3	Does the validation demonstrate the ability of these processes to achieve planned results?	
7.5.2.1.4	Has the organization established arrangements for these processes including, as applicable ...	
7.5.2.1.5	- defined criteria for review and approval of the processes? - approval of equipment and qualification of personnel?	
7.5.2.1.6	- use of specific methods and procedures? - requirements for records (see 4.2.4.)?	
7.5.2.1.7	- revalidation?	
	If software is used within the production process and in service delivery and this has a influence to the product quality/specification:	
7.5.2.1.8	Are documented procedures for the validation of the application of computer software (and changes and / or its application) for production and service provision that affect the ability of the product to conform to specified requirements established?	
7.5.2.1.9	Are such software applications validated prior to initial use? Are records of validation maintained?	
7.5.2.2	Particular requirements for sterile medical devices	
7.5.2.2.1	Has the organization established documented procedures for the validation of sterilization processes?	
7.5.2.2.2	Are sterilization processes validated prior to initial use?	
	Are records of validation of each sterilization process maintained?	
7.5.2.2.2	Where such records of the production process stored (including sterilization) to demonstrate that the products were manufactured according to the validated process? Are the results recorder of each batch release?	
7.5.3	Identification and traceability	
7.5.3.1	Identification	
7.5.3.1.1	Does the organization identify the products by suitable means throughout product realization according to a documented procedure?	
7.5.3.1.2	Are documented procedures established to ensure that medical devices returned to the organization are identified and distinguished from conforming product	
7.5.3.2	Traceability	
7.5.3.2.1	General	
7.5.3.2.1.1	Are documented procedures for traceability established?	
	Is the extent of product traceability defined and are the records required for traceability defined (see 4.2.4, 8.3 and 8.5)?	
7.5.3.2.1.2	Does the documented and established traceability facilitate the necessary corrective actions? (Note: e.g. simulate a product recall; time needed until the necessary data and records are collected should be less than 1 day	

Clause	Questioning Technique for ISO 13485	Response
7.5.3.2.2	Particular requirements for active implant able medical devices and implant able medical devices	
7.5.3.2.2.1	In defining the records required for traceability, are all components, materials and work environmental conditions included, if these could cause the medical device does not fulfill its specified requirements?	
7.5.3.2.2.2	Does the organization require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and are such records are available for inspection?	
7.5.3.2.2.3	Is ensured that the name and address of the shipping package consignee is recorded (see 4.2.4)?	
7.5.3.3	Status identification	
7.5.3.3.1	Is the identification of product status maintained and recorded to ensure the monitoring and measurement requirements throughout production, storage, installation and servicing of the product?	
7.5.4	Customer property	
7.5.4.1	Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?	
7.5.4.2	Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product?	
7.5.4.3	Does the organization report to the customer and maintain records if any customer property is lost, damaged or otherwise found to be unsuitable for use?	
7.5.5	Preservation of product	
7.5.5.1	Are documented procedures established for preserving the conformity of product during internal processing and delivery to the intended destination?	
7.5.5.2	Does this preservation include identification, handling, packaging, storage and protection?	
7.5.5.3	Does this preservation also apply to the constituent parts of a product?	
7.5.5.4	Are documented procedures or documented work instructions established for the control of product with a limited shelf-life or requiring special storage conditions?	
7.5.5.5	Are such special storage conditions controlled and recorded?	
7.6	Control and monitoring of measuring equipment	
7.6.1	Are documented procedures established for the control of monitoring and measuring equipment?	
7.6.2	Does the organization determine the monitoring and measurement to be taken and is the required monitoring and measuring equipment determined?	
	Is the measuring equipment, where necessary to ensure valid results, ...	
7.6.3	- be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards?	
7.6.4	- is the basis used for calibration or verification recorded, where no such standards exist?	
7.6.5	- have identification in order to determine its calibration status, be safeguarded from safeguarded from adjustments that would invalidate the measurement result and adjusted or re-adjusted, as necessary?	
7.6.6	- be protected from damage and deterioration during handling, maintenance and storage?	
7.6.7	Is the validity of previous measuring results assessed and recorded, when the measuring equipment is found not to conform to requirements? Does the organization take appropriate action on the measuring equipment and any product affected?	
7.6.8	Are records of the results of calibration and verification maintained?	
7.6.9	Is the ability of computer software to satisfy the intended application confirmed, when used in the monitoring and measurement of specified requirements?	
7.6.10	Is this undertaken prior to initial use and reconfirmed, as necessary	
8	**Measurement, analysis and improvement**	
8.1	General	

Clause	Questioning Technique for ISO 13485	Response
	Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed to	
8.1.1	- demonstrate conformity of the product?	
8.1.2	- ensure conformity of the QM-System and to maintain the effectiveness of the QM-System?	
8.1.3	- continually improve the effectiveness of the QM-System?	
8.1.4	Does this include determination of applicable methods, including statistical techniques, and the extend of their use?	
8.2	Monitoring and measurement	
8.2.1	Customer satisfaction	
8.2.1.1	Does the organization monitor information relating to customer perception as to whether the organization has met customer requirements?	
8.2.1.2	Is this information, as one of the measurements of the performance of the QM-System used and are the methods determined for obtaining and using this information determined?	
8.2.1.3	Is a documented procedure for a feedback system established? Is this feedback system used for early warning of quality problems and for input into the corrective and preventive action processes?	
8.2.2	Internal audit	
8.2.2.1	Is there a documented process for planning / conducting internal audits? (Responsibilities, planning, execution, reporting, record keeping, corrective actions)	
8.2.2.2	Are internal audits at planned intervals conducted to determine whether or not the QM-System conforms to the requirements of this International standard and to the QM-System requirements established by the organization and is effectively implemented and maintained?	
8.2.2.3	Is the audit programme planned taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? (Audit criteria, scope, frequency, methods)	
8.2.2.4	Does the selection of auditors ensure objectivity and impartiality of the audit process? (Auditors shall not audit their own work).	
8.2.2.5	Does the management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes?	
8.2.2.6	Do follow-up activities include the verification of the actions taken and the reporting of verification results?	
8.2.3	Monitoring and measurement of processes	
8.2.3.1	Does the organization apply suitable methods for monitoring and, where applicable, measurement of the QM-Systems processes?	
8.2.3.2	Do these methods demonstrate the ability of the processes to achieve planned results?	
8.2.3.3	Are correction and corrective action taken to ensure conformity of the product, as appropriate, when planned results are not achieved?	
8.2.4	Monitoring and measurement of product	
8.2.4.1	Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?	
8.2.4.2	Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements and documented procedures	
8.2.4.3	Is evidence of conformity with the acceptance criteria maintained and do the records indicate the person(s) authorizing release of product?	
8.2.4.5	Does product release and delivery of service not proceed until the planned arrangements have been satisfactorily completed?	
8.2.4.6	Is the identity of personal recorded, which performs any inspection or testing?	
8.3	Control of nonconforming product	

Clause	Questioning Technique for ISO 13485	Response
8.3.1	Does the organization ensure that product which does not conform to product requirements is identified and controlled to prevent is unintended use or delivery?	
8.3.2	Is there a documented procedure established to define the controls and related responsibilities and authorities for dealing with nonconforming product?	
	Does the organization deal with nonconforming product by one or more of the following ways ...	
8.3.3	- by taking action to eliminate the detected nonconformity or by taking action to preclude is original intended use or application?	
8.3.4	- by authorizing its use, release or acceptance under concession	
8.3.5	Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained maintained?	
8.3.6	Is it ensured that nonconforming product is accepted by concession only if regulatory requirements are met?	
8.3.7	Is the identity of the person(s) maintained who authorizes the concession?	
8.3.8	When nonconforming product is corrected; is it subject to reverification to demonstrate conformity to the requirements?	
8.3.9	Does the organization take action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started?	
8.3.10	If product needs to be reworked, does the organization document the rework process in a work instruction, which undergone the same authorization and approval procedure as original work instruction?	
8.3.11	Prior to authorization and approval of the work instruction, is it assured that a determination of any adverse effect of the rework upon product is made and documented?	
8.4	Analysis of data	
8.4.1	Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QM system and to assess and evaluate where improvement of the effectiveness of the quality management system can be made	
8.4.2	Does this include data generated as a result of monitoring and measurement and from other relevant sources?	
	Does the analysis provide information relating to ...	
8.4.3	- customer satisfaction?	
	- customer feedback? - conformity to product requirements?	
8.4.4	- monitoring the market about incidents with their own or similar products?	
8.4.5	- characteristics and trends of procedures, processes and products including opportunities for preventive action and suppliers?	
8.4.6	Are records of the results of the analysis of data be maintained?	
8.5	Improvement	
8.5.1	General	
8.5.1.1	Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	
8.5.1.2	Does the organization identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system?	
8.5.1.3	Are thereby used: the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?	
8.5.1.4	Are documented procedures established for the issue and implementation of advisory notices?	
8.5.1.5	Are these procedures capable of being implemented at any time?	
8.5.1.6	Are records of all customer complaint investigations maintained?	

Clause	Questioning Technique for ISO 13485	Response
8.5.1.7	If investigation determines that activities outside the organization contributed to customer complaints, is there relevant information between the organizations involved exchanged (see 4.1.)?	
8.5.1.8	If any customer complaint is not followed by corrective and/or preventive action, is the reason authorized and recorded?	
8.5.1.9	Is a procedure defined and documented for notify the regulatory authorities and the TNV of those adverse events which meet the reporting criteria? (Data base for incidents, or rather initial and final reporting of incidents forms) (MEDDEV 2.12/1)	
8.5.2	Corrective action	
8.5.2.1	Does the organization take action to eliminate the causes of nonconformities in order to prevent recurrence?	
8.5.2.2	Are corrective actions appropriate to the effects of the nonconformities encountered?	
	Is a documented procedure established to define requirements for ..	
8.5.2.3 -	reviewing nonconformities (including customer complaints)? - determining the causes of nonconformity?	
8.5.2.4	- evaluating the need for action to ensure that nonconformities do not recur?	
8.5.2.5	- determining and implementing action needed, including, if appropriate, updating documentation (see 4.2)?	
8.5.2.6	- recording of the results of any investigation and of action taken? - reviewing the corrective action taken and its effectiveness?	
8.5.2.7	- Are the results of recent risk evaluation included? - Do the reflected results flow back to the risk management and are they covered by the risk management documents?	
8.5.2.8	- Is it also checked in the analysis whether the error can occur for comparable products/processes?	
8.5.3	Preventive action	
8.5.3.1	Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence?	
	Are preventive actions appropriate to the effects of the potential problems?	
	Is a documented procedure established to define requirements for ...	
8.5.3.3	- determining potential nonconformities and their causes? - evaluating the need for action to prevent occurrence of nonconformities?	
8.5.3.5	- determining and implementing action needed? - recording of the results of any investigations and of action taken?	
8.5.3.1	- reviewing preventive action taken?	

Guidance Document Technical Files / Design Dossiers
Non Active Medical Devices

Whereas the expression "***Technical File***" is preoccupied for Medical Devices of class I, class IIa and class IIb, and "***Design Dossier***" for the class III products.

Technical Files are retained in the premises of the manufacturer or the Authorized Representative for potential review of Competent Authorities and Notified Body. Design Dossiers have to be submitted to the Notified Body for review prior CE-Marking of the product. After successful review, the Notified Body issues a design examination certificate according to the Annex II.4 of the Council Directive certifying compliance with the relevant provisions of the Annex I of the MDD.

Article 5 of the Council Directive describes consideration of the European harmonized standards

by the manufacturer in order to demonstrate compliance with the Essential Requirements. This aspect is even more important as International Standard Organizations have adopted European Norms (and vice versa) and demonstrating compliance with these standards could be very helpful in international mutual recognition of the CE-Marking process.

It is not necessary to include all documents in the design dossier which have already been subject to an ISO / EN / MDD Audit by the Notified Body. Examples of documents not necessary to be included are Quality Manuals and related lower level documents. A brief summery of manufacturing processes (flow chart including inspection and preventive monitoring steps) and validation of sterilization processes should be included in the design dossier.

This is even more important if a Competent Authority or another Notified Body wishes to review the documentation. If the manufacturer of a class III device provides detailed information according to the checklist described below, the requirements of the Directive are appropriately addressed.

Generally, the informations should be provided as conclusions, summaries, reports, tables or flow charts (with reference to the full documentation in the Essential Requirement checklist). A complete pagination of the design dossier or another type of control mechanism is necessary. Two copies of the documentation are required to achieve an appropriate review time.
In general, design changes described in the MDD (93/42/EEC), Annex II.4.4 shall be reported to the Notified Body in order to ensure conformity with the requirements defined in the Annex II.4.4 and that the design dossiers retained in the NB archives are complete **and up-to-date**.

The structure of a design dossier or technical file can be broken down in 12 sections as follows:

1. Introduction
2. Essential Requirements Checklist
3. Risk Analysis
4. Drawings, Design,- Product - Specifications
5. Chemical, physical and biological tests
5.1 In Vitro Testing - Preclinical Studies
5.2 Biocompatibility Tests
5.3 Biostability Tests
5.4 Microbiological Safety, Animal origin tissue
5.5 Coated Medical Devices
6. Clinical Data
7. Package Qualification and Shelf life
8. Labels - Instructions for use
- patient informations
- advertising materials
9. Manufacturing
10. Sterilization
11. Conclusion
12. Declaration of Conformity (Draft)

Compilation of Technical File and Design Dossier
Table of Content
Name and postal address of the manufacturer and if applicable the European Representative

have to be declared

1. Introduction

□□Brief product description
□□Product History (i.e. market release, items sold)
o Intended Use
o Indication
o Contraindications
o Warnings
□□Accessories for the product, Integral parts of package
□□Regulatory approvals
o i.e. FDA 510(k) or PMA clearance
□□Planned changes
□□Classification of the device and accessories according to annex IX of MDD
□□Conformity Assessment Route that has been chosen

Essential Requirements Checklist

European Norms and Standards and other Documents
supporting Technical Files and Design Dossiers

Risk Analysis

EN ISO 14971
Table format is acceptable for the Hazard Analysis and FMECA
Post market surveillance (complaint history)
Clinical experience and clinical risks
EN 12442 part 1 -3 and MEDDEV 2.5-8 (Risk Management Animal Tissue)
The document (Risk Management File) which describes the result of the risk analysis process should contain at least the following information:
General information
□□Summary
□□Purpose of the document
□□Scope (which part of the complete system is covered?); product identifica-tion and description; intended use
□□List of referenced documents (standards, specification documents, design documents, procedures)
□□Definition of terms, abbreviations and acronyms
Methodology
□□When (in which project phase) was the risk analysis performed and reviewed
□□Participants of the risk analysis team (persons and organisations), their qualification (especially medical knowledge) and responsibility
□□Requirements for review of Risk Management activities
□□**Hazards in normal condition**: Hazard Analysis; patient/user related (top-down approach)
o Method for identification of applicable hazards; used sources of in-formation
o System used for categorization of severity levels
o Method for determination of the potential causes of each hazard
o System used for categorization of probability estimates of each hazard cause (frequency in e.g. 'events per device')
o Scheme for combination of severity and probability to risk level
o Criteria for acceptability of a risk level
□□**Hazards in fault condition**: FMECA; device related (bottom-up approach)
o Method for identification of applicable failure modes; used sources of

information
o System used for categorization of severity levels
o Method for determination of the potential causes of each failure mode
o System used for categorization of probability estimates of each failure mode (frequency in e.g. ‘events per device’)
o System used for categorization of detectability of each failure mode

o Scheme for combination of severity, probability and detectability to risk level
o Criteria for acceptability of a risk level
□□Procedure to review information in the post-production phase
□□Complaint history and data from literature review

□□**Result** (signed and dated documents)
o **Hazards in normal condition:** list of applicable hazards; for each hazard:
□□List of potential causes (in hierarchical structure, if applicable)
□□Estimation of risk before mitigation (severity, probability, risk)
□□Definition of risk reduction measures including reference to methods (e.g. design, testing, manufacturing) and results of verification (effectiveness of implementation)
□□Estimation of risk after mitigation (severity, probability, risk)
o **Hazards in fault condition:** list of applicable failure modes; for each failure mode:
□□List of potential worst case effects and causes (in hierarchical structure, if applicable)
□□Estimation of risk before mitigation (severity, probability, detect-ability, risk)
□□Definition of risk reduction measures including reference to methods (e.g. design, testing, manufacturing) and results of verification (effectiveness of implementation)
□□Estimation of risk after mitigation (severity, probability, detectability, risk)
o Assessment of risks associated with new hazards generated by risk mitigation measures.
□□**Final judgment, statement of:**
o Completeness of risk evaluation
o Overall acceptability of residual risk
o Risk / benefit weighting
o Signed and dated by the team leader or person responsible.

4. Drawings, Design,- Product - Specifications
o Comprehensive description of the product
o Components and materials
o **Sample of Product**
o Photographs
o Blueprints
o Pre-Production Design Control (brief description)
o QS (ISO EN 9001, ISO 13485) Certificate of design facility
o Final product release criteria including reference to verification test / validation

5. Chemical, physical and biological tests
5.1 In Vitro Testing - Preclinical Studies

Bench Testing - chemical and physical testing
o (i.e. tensile strength tests, durability,- corrosion tests, fatigue tests, long term stability) **Note:** for Implants Standards like EN 14630 have to be considered!
o Bench Testing - chemical, biological, pharmacological / pharmacokinetical / toxicological Studies
o i.e. purity, toxicity, ADME (adsorption, distribution, metabolism, elimination) studies, LD50)
o Efficacy Tests
o Performance Testing
o Sterilization qualifications
Is the performance of the device adversely affected by the sterilization process?
o Drug Compatibility
Interaction between Drug and Device (i.e. adsorption)

o **Test protocols**
o Standard applicability matrix
o List of each item
o Justification if particular items are not applicable
o Reference to verification test / validation
o Justification if applicable standards are not considered
o Testing performed on finished product (devices from the normal manufacturing and sterilization)
o Accelerated and real time ageing prior to testing
o Conditions of accelerated ageing
o For each test:
o Parameters to be measured and test description including reference to test procedure if applicable
o Measuring and testing equipment
o Calibration arrangements
o Acceptance criteria
o Number of test samples including sample size rationale
o **Test reports**
o Deviations from the protocols and justification
o Raw data
o statistical analysis

o interpretation of data and conclusion(s)
o approval signature(s)

5.2 Biocompatibility Tests
□□Applied standard
- mention the relevant standards here
□□Categorization of the device
- Intended use
- Nature and duration of body contact
- The category defines the tests to be performed (ISO 10993-1, table 1)
Listing of components/materials having direct or indirect body contact
List the contact materials here or refer to the applicable section of the design dossier which contains the materials listing
- Where appropriate define total surface area contacting the body or body fluids

- Statement on the test samples used (final product, component, raw material, sterile state)
□□Overview of tests performed
- Description and justification for tests performed
□□Justification for tests not performed
- Literature data, references, existing clinical experience
□□Conclusion
- Final statement of the manufacturer; that in his opinion, based on the submitted documentation, the product safety is ensured

5.3 Biostability Tests

Influence of the biological matrix on the device
i.e. Surface Stress Cracking on Polymers
Corrosion of load-bearing metal screws
Coating Stability

5.4 Microbiological Safety, Animal Origin tissue

Viral, Bacterial, Prion Evaluations in case of tissue
o **EN 12442 part 1 - 3** (Animal tissue and their derivates used in the manufacture of medical devices)
o **MED DEV 2.5-8** (Guidelines on evaluation of medical devices incorporating materials of animal origin with respect to viruses and transmissible agents)
o **Directive 2003/32/EC** (applies to material from bovine, ovine, caprine species, deer, elk, cat, and mink only)

The manufacturer has to consider the following points and submit the relevant documentation for evaluation:

o Justification for the use of animal tissues or derivates
o Starting materials, species used
o Assessment of the clinical benefit / potential risk / possible alternatives
o Studies of the elimination / inactivation of BSE/TSE agents and/or alternatively literature research on the subject
o Well documented strategy in risk analysis and risk management and thereby demonstrating that a high level of benefits and safety for the patient has been attained

o Consideration of all relevant aspects of the TSE agents and measures to ensure that infection is minimised
o Manufacturers control of the sources of raw materials, finished products, and subcontractors
o The need to audit matters related to sourcing, including third party supplies
o EDQM Certificate, if applicable

5.5 Coated Medical Devices (Biomimicry) - i.e.:

o Heparin - Coating
o Silver / Gold - Coating
o Pyrolytic Carbon Coating
o MPC - ML - Coating (Methacryloyl Phosphoryl Choline Lauryl Methacrylate)
o Parylene Polymer Coating
o Collagen / Gelatine Coating
o PEG Coating (Polyethyleneglycol as Lubrication)
o E-Beam Treatment (Cross linkage)
o Titanium / HA Spray – Coating

Requirements on Performance and Product Safety

Stability of Coating in Biological Matrix
o Hydrophilic
o Microbiological Evaluation
o Fibrinogen Adsorption
o Platelet Adhesion / Activation
o Contact Activation Tests

6. Clinical Data

o MDD (93/42/EEC) - Annex 10
o ISO EN 14155-1 and -2
o MEDDEV 2.7.1
o GCP (good clinical practice) requirements

Clinical Studies are required for:

o Complete new device - components, features, methods of action unknown
o Existing device is modified - modification may significantly affect safety and per formance
o New indication for established device
o New materials with body contact
o Device used for a significant longer time

If clinical studies are described, the final study report shall contain:

o Intended use of the device
o Specific aspects of the design and use of the device
o Effects, side effects and undesirable effects of the device
o Assessment of benefit and possible hazard to the patient treated with the device
o Risks should be compared with all alternative methods currently available
o Possible technical solutions minimising the existing foreseeable risks
o Medical procedure or the process in which the device is implemented

Along with the final report of the study the trial protocol, Ethics Committee opinion(s) and comments as well as the authorities “letter of no objection” need to be submitted.

Critical evaluation of all data collected during the clinical investigation

For ongoing studies, a study design, scope of study and expected results (intermediate report) should be described within the clinical section part as well as when final data are available.

Documents to be provided for clinical assessment

o Clinical Report acc. to MEDDEV 2.7.1
o Copies of the literature quoted in the clinical report
o Instructions for use including indications, contraindications, risks / side effects / ad verse events
o Risk analysis including clinical risks
o Post market surveillance data, if applicable
o Study protocol, final study report of pre-clinical or clinical studies, if applicable
o Clinically relevant bench testing reports

Signature of clinical report by medical expert necessary (attach c.v.)

7. Package Qualification and Shelf life

Physical package qualification
Performance of the product after real time and/or accelerated aging
Shelf life: Maintenance of sterility and performance over the shelf-life of a product, i.e per:

o EN 868 -1 ff packaging materials for sterilization of wrapped goods,
o ISO 11607
o ASTM D999 -tests,
o NAmSA Dust Drum Tests
o Real time aging,
o Q10 - accelerated aging test

Following documents are required for the evaluation of sterile devices:
o Detailed description of the packaging and packaging materials
o Supplier certificates
o Compliance of the packaging material with the proposed sterilization method
o Biocompatibility of packaging, if necessary
o Packaging integrity test (including visual inspection and dye penetration test)
o Microbial barrier test
o Labelling compatibility
o Seal strength test
o Real time aging study
o Accelerated aging study, if applicable
o Shipment simulation test (vibration-, drop- and roll test)
o Packaging process validation report

8. Labels - Instructions for use - patient information - advertising materials

- Demonstrate compliance with Annex I.13, EN 980, EN 1041, ISO 15223 Example of Labels (shipping labels, sterile package labels) - Instructions for use - patient information
- Submission of labels / IFU in one language (german/english), only is acceptable, but verify compliance with European Language Requirements!
- Instructions for Use: Description / Indication for Use / Contraindications / Warnings / Precautions / Adverse Events / Operation

9. Manufacturing

Description of the manufacturing process

- Flow chart
- Manufacturing conditions in compliance with i.e. FS 209E, ISO 14644, ISO 14698
- QS (EN ISO 9001, ISO 13485) certificate from a Notified Body or other registrar for the manufacturing plant
- EC-certificate according to Annex II, 3 (Full Quality Assurance System)
- Labeling control
- Traceability
- Product and environmental bioburden, particles
- Pyrogene testing
- Preventive monitoring of processes (i.e. SPC)
- Viral- Prion Deactivation steps

10. Sterilization

EN 550 series, ISO 11130 series

- Brief description of the installation qualification and validation summary (method shall assure at least a SAL of 10-6).
- Process Validation Report with physical performance qualification and microbiological performance qualification
- Sterilization plant certified by a Notified Body (ISO 9001/2, ISO 13485 / 13488, EN550 series, 11130 series).

11. Conclusion

Summary of the design dossier data
Risk vs. benefit statement

European Norms and Standards and other Documents supporting Technical Files and Design Dossiers

- Document Number Title of Document
- EN ISO 9001 Quality Systems
- ISO 13485 Particular requirements for the application of ISO 9001
- EN 550 EtO Sterilization
- EN 552 Irradiation Sterilization
- EN 554 Sterilization by moist heat
- EN 556 General requirements for medical devices _abelled sterile
- ISO 14155 Clinical Investigations of medical devices
- ISO 11134 Sterilization of health care products – Steam Sterilization
- ISO 11135 Sterilization of health care products – EtO Sterilization
- ISO 11137 Sterilization of health care products – radiation sterilization
- ISO 10993 Part 1 Biological testing of medical devices – general requirements
- ISO 10993 part 5 In-vitro tests for cytotoxicity
- ISO 10993 part 11 Tests for systemic toxicity
- EN 980 Terminology, symbols for use in Medical Device labels
- ISO 15223 Symbols to be used in Medical Device labels, labelling and information to be supplied
- EN 1041 Terminology, symbols and information provided with medical devices information supplied by the manufacturer with Medical Devices
- ISO 14971 Application of risk management to medical devices
- EN 868 Part 1 Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods
- ISO 14644 Cleanrooms and associated controlled environments
- ISO 14698 Cleanrooms and associated controlled environments – Biocontamination
- USP United States Pharmacopeia
- Eph Pharmacopoea Europaea
- EN 45014 General criteria for suppliers declaration of conformity
- MEDDEV 2.12/1 Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12/1
- NB-MED/2.5.2/Rec2 Reporting of design changes and changes of the quality system
- MEDDEV 2.7.1 Evaluation of Clinical Data

See also ISO 16142 Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

Division 28. Cross references

Cross reference b/w HACCP &ISO 22000

Cross references between the HACCP Principals and application steps and clauses of ISO 22000:2005

Annex A (informative) Cross references between the CODEX HACCP and this document

Table A.1 — Cross references between the CODEX HACCP principles and application steps and clauses of this document

CODEX HACCP Principles	CODEX HACCP application steps[a]		This document	
	Assemble HACCP team	Step 1	5.3	Food safety team
	Describe product	Step 2	8.5.1.2	Characteristics of raw materials, ingredients and product-contact materials
			8.5.1.3	Characteristics of end products
	Identify intended use	Step 3	8.5.1.4	Intended use
	Construct flow diagram	Step 4	8.5.1.5	Flow diagrams and descriptions of processes
	On-site confirmation of flow diagram	Step 5		
Principle 1 Conduct a hazard analysis	List all potential hazards	Step 6	8.5.2	Hazard analysis
	Conduct a hazard analysis Consider control measures		8.5.3	Validation of control measure(s) and combinations of control measure(s)
Principle 2 Determine the critical control points (CCPs)	Determine CCPs	Step 7	8.5.4	Hazard control plan
Principle 3 Establish critical limit(s)	Establish critical limits for each CCP	Step 8	8.5.4	Hazard control plan
Principle 4 Establish a system to monitor control of the CCP	Establish a monitoring system for each CCP	Step 9	8.5.4.3	Monitoring systems at CCPs and for OPRPs
Principle 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control	Establish corrective actions	Step 10	8.5.4	Hazard control plan
			8.9.2	Corrections
			8.9.3	Corrective actions
Principle 6 Establish procedures for verification to confirm that the HACCP system is working effectively	Establish verification Procedures	Step 11	8.7	Control of monitoring and measuring

CODEX HACCP Principles	CODEX HACCP application steps[a]		This document	
			8.8	Verification related to PRPs and the hazard control plan
			9.2	Internal audit
Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application	Establish documentation and record keeping	Step 12	7.5	Documented information
a CODEX publications are available via Reference [12].				

Annex B
(informative)

Division 29. Cross Reference Between this document and ISO 22000-2005 and ISO 22000-2018

Table B.1 — Main structure

This document	ISO 22000:2005
4 Context of the organization	New heading
4.1 Understanding the organization and its context	New
4.2 Understanding the needs and expectations of interested parties	New
4.3 Determining the scope of the food safety management system	4.1 (and new)
4.4. Food safety management system	4.1
5 Leadership	New heading
5.1 Leadership and commitment	5.1, 7.4.3 (and new)
5.2 Policy	5.2 (and new)
5.3 Organizational roles, responsibilities and authorities	5.4, 5.5, 7.3.2 (and new)
6 Planning	New heading
6.1 Actions to address risks and opportunities	New
6.2 Objectives ofthefoodsafetymanagement systemandplanningto achieve them	5.3 (and new)
6.3 Planning of changes	5.3 (and new)
7 Support	New heading
7.1 Resources	1, 4.1, 6.2, 6.3, 6.4 (and new)
7.2 Competence	6.2, 7.3.2 (and new)
7.3 Awareness	6.2.2
7.4 Communication	5.6, 6.2.2
7.5 Documented information	4.2, 5.6.1
8 Operation	New heading
8.1 Operational planning and control	New
8.2 Prerequisite programmes (PRPs)	7.2

8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7 (and new)
8.5 Hazard control	7.3, 7.4, 7.5, 7.6, 8.2 (and new)
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	7.8, 8.4.2
8.9 Control of product and process nonconformities	7.10
9 Performance evaluation	New heading
9.1 Monitoring, measurement, analysis and evaluation	New heading
9.1.1 General	New
9.1.2 Analysis and evaluation	8.4.2, 8.4.3
9.2 Internal audit	8.4.1
9.3 Management review	5.8 (and new)
9.3.1 General	5.2, 5.8.1

Division 30. Table B.1 *(continued)*

This document	ISO 22000:2005
9.3.2 Management review input	5.8.2 (and new)
9.3.3 Management review output	5.8.1, 5.8.3
10 Improvement	New heading
10.1 Nonconformity and corrective action	New
10.2 Continual improvement	8.1, 8.5.1
10.3 Update of the food safety management system	8.5.2

Division 31. Table B.2 — Clause 7: Support

This document	ISO 22000:2005
7 Support	New heading
7.1. Resources	6
7.1.1 General	6.1
7.1.2 People	6.2, 6.2.2 (and new)
7.1.3 Infrastructure	6.3
7.1.4 Work environment	6.4
7.1.5 Externally developed elements of the food safety management system	1 (and new)
7.1.6 Control of externally provided processes, products or services	4.1 (and new)
7.2 Competence	6.2.1, 6.2.2, 7.3.2
7.3 Awareness	6.2.2
7.4 Communication	5.6
7.4.1 General	6.2.2 (and new)
7.4.2 External communication	5.6.1
7.4.3 Internal communication	5.6.2
7.5 Documented information	4.2
7.5.1 General	4.2.1, 5.6.1
7.5.2 Creating and updating	4.2.2
7.5.3 Control of documented information	4.2.2, 4.2.3 (and new)

Division 32. Table B.3 — Clause 8: Operation

This document	ISO 22000:2005
8 Operation	New heading
8.1 Operational planning and control	7.1 (and new)
8.2 Prerequisite programmes (PRPs)	7.2
8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7
8.4.1 General	5.7
8.4.2 Handling of emergencies and incidents	New
8.5 Hazard control	New heading
8.5.1 Preliminary steps to enable hazard analysis	7.3
8.5.1.1 General	7.3.1
8.5.1.2 Characteristics of raw materials, ingredients and product contact materials	7.3.3.1
8.5.1.3 Characteristics of end products	7.3.3.2
8.5.1.4 Intended use	7.3.4

Division 33. Table B.3 *(continued)*

This document	ISO 22000:2005
8.5.1.5 Flow diagrams and description of processes	7.3.5.1
8.5.1.5.1 Preparation of flow diagrams	7.3.5.1
8.5.1.5.2 On-site confirmation of flow diagrams	7.3.5.1
8.5.1.5.3 Description of processes and process environment	7.2.4, 7.3.5.2 (and new)
8.5.2 Hazard analysis	7.4
8.5.2.1 General	7.4.1
8.5.2.2 Hazard identification and determination of acceptable levels	7.4.2
8.5.2.3 Hazard assessment	7.4.3, 7.6.2 (and new)
8.5.2.4 Selection and categorization of control measure(s)	7.3.5.2, 7.4.4 (and new)
8.5.3 Validation of control measure(s) and combination(s) of control measure(s)	8.2
8.5.4 Hazard control plan (HACCP/OPRP plan)	New heading
8.5.4.1 General	7.5, 7.6.1
8.5.4.2 Determination of critical limits and action criteria	7.6.3 (and new)
8.5.4.3 Monitoring systems at CCPs and for OPRPs	7.6.3, 7.6.4 (and new)
8.5.4.4 Actions when critical limits or action criteria are not met	7.6.5
8.5.4.5 Implementation of the hazard control plan	New
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	New heading
8.8.1 Verification	7.8, 8.4.2
8.8.2 Analysis of results of verification activities	8.4.3
8.9 Control of product and process nonconformities	7.10
8.9.1 General	7.10.1, 7.10.2
8.9.2 Corrections	7.10.1
8.9.3 Corrective actions	7.10.2
8.9.4 Handling of potentially unsafe products	7.10.3

8.9.4.1 General	7.10.3.1
8.9.4.2 Evaluation for release	7.10.3.2
8.9.4.3 Disposition of nonconforming products	7.10.3.3
8.9.5 Withdrawal/recall	7.10.4

Division 34. Cross references

https://committee.iso.org/sites/tc176sc2/home/page/iso-9001-auditing-practices-grou.html

QMS auditing topics for ISO 9001:2015

1. General

- Adding value
- Code of Conduct and Ethics
- Cultural Aspects
- Expected Outcomes
- Impartiality
- Scope of ISO 9001, Scope of Quality Management System and Scope of Certification
- Technical Experts
- Two stage initial certification audit

Zip file of all the above documents

2. Auditing General

- Added Value Audits versus Consultancy
- Audit Planning
- Audit Reports
- Audit Trail
- Checklist
- Deal with consultants
- Demonstrate conformity to the standard
- Effective use of ISO 19011
- Effectiveness
- Electronic documented information systems
- Evidence collection
- Nonconformity – Documenting
- Nonconformity – Review and closing

Zip file of all the above documents

3. Auditing to ISO 9001:2015

- Competence
- Context
- Customer Communications
- Customer Complaints
- Customer Feedback
- Design and Development Process

- External providers
- Improvement
- Internal audit
- Internal communication
- Measurement traceability
- Monitoring and measuring resources
- Organizational Knowledge
- Policy, objectives and management review
- Processes
- Resources
- Risk Based Thinking
- Service organizations
- Statutory and Regulatory requirements
- Top management