

0 INTRODUCTION

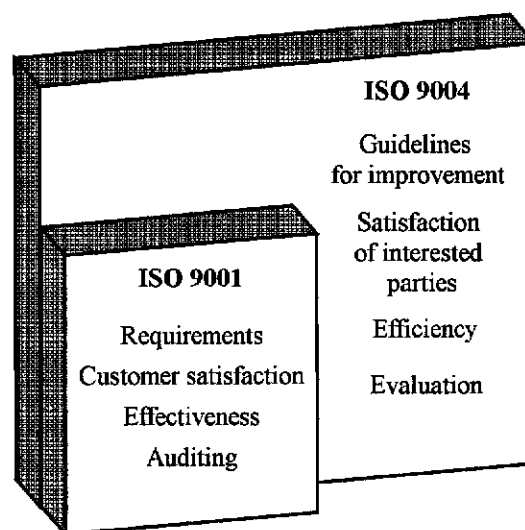
0.1 The UNE-EN ISO 9004:2000 Standard for Facilitating Improvement

Numerous organizations wish to improve their competitiveness by achieving higher levels of effectiveness and efficiency based on the application of quality management systems.

Many of them have opted to use standards of renowned international prestige and proven effectiveness, such as the series of UNE-EN ISO 9000 standards.

In this context, the **UNE-EN ISO 9004 standard** establishes a path to improvement towards excellence on the basis of the following aspects:

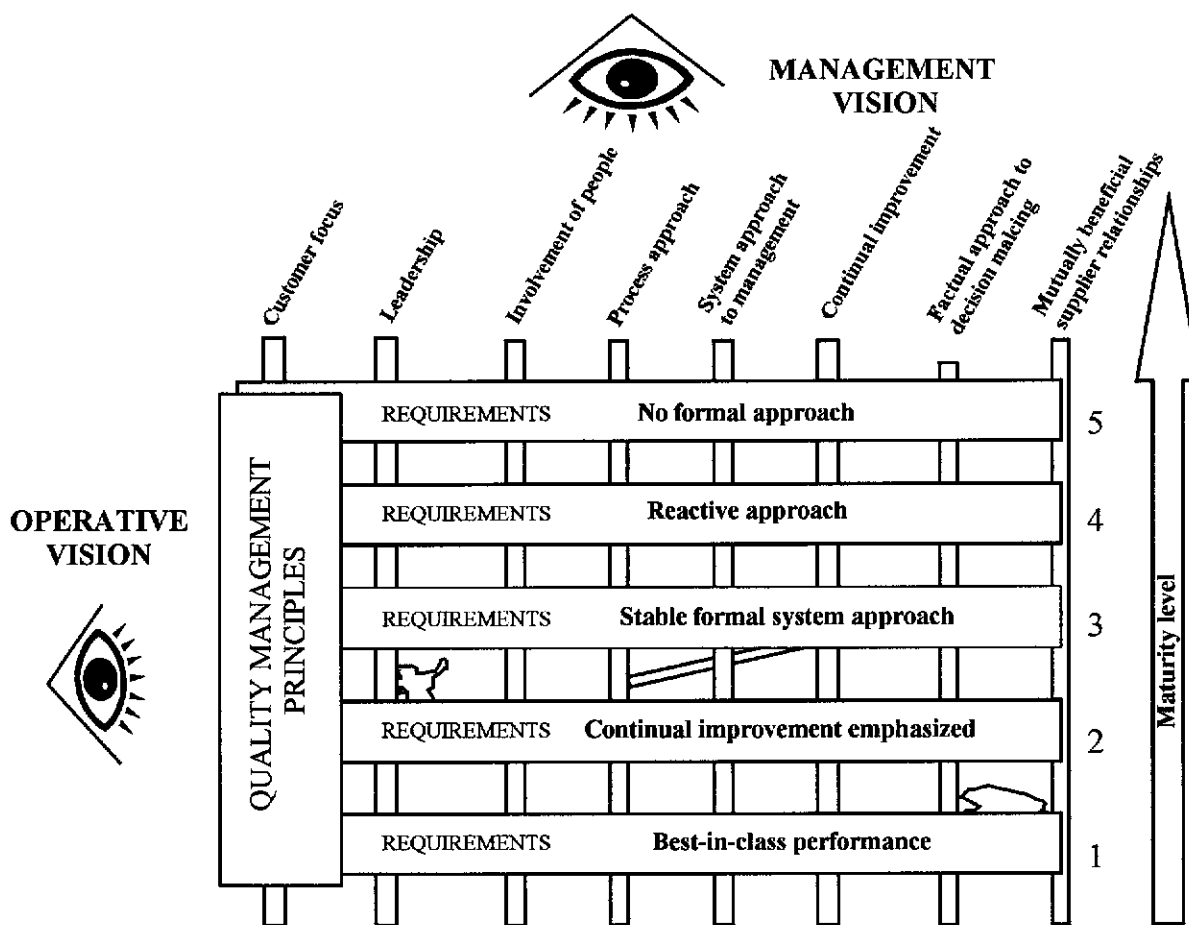
- **UNE-EN ISO 9004:2000 guidelines complement the requirements of UNE-EN ISO 9001:2000**, since their objective is an effective and efficient business management through the satisfaction of the needs and expectations of customers and interested parties;
- **UNE-EN ISO 9004:2000 facilitates the transition for organizations using UNE-EN ISO 9001**, since they practically have the same sections as UNE-EN ISO 9001:2000 and use the same language;
- **UNE-EN ISO 9004:2000 facilitates the integration of standardized management systems**, such as environmental management in accordance with ISO 14000, since it contemplates the satisfaction of the interested parties which, like society, are affected by the environmental impact of their organization's activities;
- **UNE-EN ISO 9004:2000 is a complementing standard to the models of performance evaluation**, since these models identify the aspect to be improved while UNE-EN ISO 9004:2000 sets guidelines on "how" to improve;
- **UNE-EN ISO 9004:2000 is a quality management model based on the 8 principles of quality management**, values on which the quality culture of an organization rests;
- **UNE-EN ISO 9004:2000 establishes a step-by-step path to improvement passing through 5 maturity levels or stages**, as well as the criteria for self-assessment based on these maturity levels (see annex A "Guidelines for Self-Assessment" of UNE-EN ISO 9004:2000).



0.2 Quality Management Principles and their Relationship with the Requirements and Guidelines of the Quality Management System

The ISO 9000 Standards Series are based on the 8 principles of quality management. These principles and the UNE-EN ISO 9004:2000 guidelines are intimately related and interact with each other, configuring two aspects of the same reality (see annex B).

The Quality Management System has been represented in the following figure as a building in which the 8 principles of quality management are the vertical pillars, and the height of the floors represents an organization's level of experience in quality management, which in turn corresponds to different levels of maturity.



It may be appreciated in this figure how the organization's maturity level, and with it, its level of competitiveness, increases proportionally along with the organization's experience in the use of the 8 quality management principles and in the evolution of the requirements and guidelines of quality management.

The organization's "Management Vision" basically relates to the 8 principles of quality management ("the pillars"), since these serve as a reference to top management in directing and managing the organization visibly and systematically towards success through improvement in profitability, creation of value and in impelling the organization towards the improvement of operative management, and thus towards the improvement of results. This top level management is embodied in the form of strategies, policies and guidelines (see annex A).

A "Management Vision" is achieved through management evaluation (see Clause 4).

Likewise, an "Operative" or detailed vision of the organization relates to the application of the requirements and guidelines of quality management, since the strategies, policies and guidelines issued on the higher management levels are integrated into the requirements and guidelines of the quality management system, facilitating clear instructions on functioning and articulating an operational structure for the quality system aimed at the organization's personnel.

The "Operative" or detailed vision is achieved through detailed evaluation (see Clause 4).

1 SCOPE

This standard is based on UNE-EN ISO 9004:2000 and specifies the guidelines for the evaluation of the quality management system and the establishment of plans for those organizations wanting to improve their maturity level on the basis of UNE-EN ISO 9000 standards.

In particular, it specifies the activities to be carried out:

- the internal or external evaluation of the maturity level of the quality management system;
- the updating of policies and guidelines towards the improvement of the quality management system; and
- the plans for the improvement of the quality management system based on the results of evaluation.

The guidelines contained in this standard are generic and can apply to any type of organization, whether private, public, large or small and whether or not it has a quality management system compliant with UNE-EN ISO 9001:2000.

This standard is a management tool that serves the organization in order to:

- discover the maturity level of its quality management system;
- establish measurable objectives;
- set improvement plans;
- partially or totally measure improvement in the system's performance.

It also permits users of excellence models to set improvement plans based on UNE-EN ISO 9004:2000 guidelines so that these can improve their evaluation results.

2 NORMATIVE REFERENCE

UNE-EN ISO 9000:2000 – *Quality Management Systems. Fundamentals and Vocabulary.*

UNE-EN ISO 9001:2000 – *Quality Management Systems. Requirements.*

UNE-EN ISO 9004:2000 – *Quality Management Systems. Guidelines for Performance Improvements.*

3 TERMS AND DEFINITIONS

The following definitions are applicable to the purposes of this standard:

3.1 improvement action: An action oriented towards eliminating or diminishing a situation identified as a weakness following an evaluation process. Corrective and preventive actions would fall within this concept.

3.16 flow diagram: Representation with the images of the stages in a process, useful for investigating improvement opportunities by obtaining a detailed knowledge of the manner in which a process really functions at a moment in time.

3.17 Pareto's diagram: Bar chart organized from higher to lower levels of frequency, which compares the importance of the different factors intervening in a problem and helps to identify the priority aspects to be dealt with.

3.18 DOE (Design of Experiments): Statistical discipline developed for the study, analysis and comprehension of the variability of processes and data.

NOTE – This discipline involves carrying out one or several tests in which changes on system input variables are deliberately induced, thus making it possible to identify the causes which give rise to changes in response.

3.19 improvement team: Body participating in continuous quality improvement, the mission of which is to identify, analyze and propose solutions to working activities or solutions that may be potentially improved in one's own job or activity.

NOTE 1 – The action of improvement teams is based on the acknowledgment that quality is in everyone's area of responsibility and that those who are best acquainted with the work processes are those who do such work daily.

NOTE 2 – Improvement teams may be composed of persons from different professional units and backgrounds, since what counts is the analysis that is made of their own work processes and the proposals that are achieved in order to improve these.

3.20 strategy: Structured plans to achieve objectives.

3.21 corporate ethics: Universal moral laws that the organization adopts and by which it governs its activity.

3.22 competence assessment: Assessment of the competences and abilities of an individual through different methods (individual interviews, diagnostics, self-diagnosis, tests, etc.).

3.23 evaluation of suppliers: Systematic and objective examination that demonstrates whether a supplier or subcontractor has the capacity to supply a product or service in compliance with established requirements.

3.24 management excellence: Outstanding practices in the management of the organization and the achievement of results based on fundamental concepts that include: result orientation, customer orientation, leadership and perseverance, processes and facts, personal involvement, continual improvement and innovation, mutually beneficial partnerships and social responsibility.

3.25 360° feedback: Survey to ascertain degree of satisfaction, conducted on workers, their suppliers, their internal customers and their work colleagues.

3.26 FIFO (First In First Out): Rotation system for stocked products so as to prevent their expiry.

3.27 total quality management: Management system through which the company continually identifies, accepts, satisfies and transcends the expectations and needs of the entire human community related to it (customers, employees, managers, suppliers, etc.) with respect to the products and services that it provides.

3.28 knowledge management: Management of the intellectual capital of an organization aiming at adding value to the products and services that it offers to the market and differentiating them competitively.

3.29 degree of customer satisfaction: Level that reflects the customer's perception of the extent to which his requirements have been complied with.

3.30 indicator: Data or set of data that help in objectively measuring the evolution of a process or an activity.

3.31 process capacity index: Index that describes the capacity of a process in relation to the specified tolerance.

3.32 JIT (Just in Time): Logistic method to diminish the supplies stocked by a customer based on close customer-supplier collaboration, which makes the rapid delivery of small orders possible on the basis of production department needs.

3.33 leadership: Process of directing and orienting the activities of the members of a group and exerting influence on them to channel their efforts toward the achievement of a specific goal or goals.

3.34 process map: Graphic representation of the sequence and interaction of the different processes taking place in an organization.

NOTE – The process map is a highly useful tool for evaluating work processes. It contributes to visualizing the work carried out in a company in a different way to how it is normally perceived.

3.35 mission: Declaration that describes the purpose or raison d'être of an organization.

3.36 maturity level: Measurement of an organization's capacity to achieve results through its knowledge and experience in the application of the quality management system.

3.37 objective: Something that is sought to be achieved or which is aspired for.

NOTE – The objectives define "what" has to be done and their degree of achievement is measurable.

3.38 organization chart: Synopsis or scheme of the organization of an entity, company or task.

3.39 strategic plan: Process of systematically evaluating the nature of a business, defining its long-term objectives, identifying quantitative goals and objectives, developing strategies to reach the said objectives, and localizing resources to carry out the said strategies.

NOTE – The strategic plan begins by answering these three questions: – Where are we today? – Where do we want to go? – How can we arrive at where we want to go?

3.40 management plan: Document that specifies the objectives to be achieved by an organization or a part of it for a given period, as well as the functions responsible for its management and the projected execution timelines.

NOTE 1 – In companies, management plans are usually written on an annual basis.

NOTE 2 – The management plan is complemented by the action plan.

3.41 PDCA (Plan, Do, Check, Act): Continual improvement cycle or Deming's cycle.

3.42 "poka-yoke": Set of rules and techniques designed to prevent errors in a process or product. When used jointly along with the appropriate inspection methods, "poka yoke" yields substantial improvements in the quality and duration of the cycle.

NOTE 1 – The expression "poka-yoke" comes from Japanese and is made up of the words "poka", avoid, and "yokeru", inadvertent error.

NOTE 2 – "Poka-yoke" is represented by simple or complex mechanical or electronic devices included in the production process or in the design of products and processes to avoid errors being committed.

3.43 key process: Sequence of activities oriented towards generating added value on an input, so as to achieve a result that fully satisfies the organization's objectives and strategies and the customer's requirements.

NOTE – One of the main characteristics of key processes is that they are interfunctional; i.e., they are capable of crossing the organization vertically and horizontally.

3.44 critical process: A key process that significantly influences the strategic objectives and is decisive to the success of the business.

3.45 lean manufacturing: Approach that pursues simultaneous improvement in all operational production metrics through the elimination of waste, making intelligent use of resources through projects that change the physical organization of work on the production line, in logistics and in the control of production all throughout the supply chain, and in the manner in which human efforts are applied to production as well as to support tasks.

3.46 QFD, Quality Function Deployment: System that seeks to centre the design of products and services on the response to customers' needs. This means aligning what the customer demands with what the organization produces.

3.47 social responsibility: A balanced corporate approach towards dealing with economic, social and environmental aspects such that their objectives are to benefit the personnel, the community and society.

3.48 design revision: Activity undertaken to assure the convenience, adoption and effectiveness of design in fulfilling its established objectives.

3.49 system revision: Activity undertaken to assure the convenience, adoption and effectiveness of the quality management system, thus fulfilling the established objectives.

3.50 labour risk: Combination of the frequency or probability that may derive from the materialization of a hazard to the health of workers.

NOTE – The concept of risk always has two elements: the frequency with which a risk materializes and the consequences that may derive from it.

3.51 environmental risk: Combination of the frequency or probability that may derive from the materialization of damage to the environment.

3.52 six Sigma: Working philosophy and business strategy based on a customer-oriented approach, efficient data management and robust methodologies and designs that make it possible to eliminate variability in processes and to reach an error level that is less or equal to 3 or 4 defects per million.

3.53 management system for the prevention of labour risks: Part of the general management system of the organization that defines prevention policies, and which includes organizational structure, responsibilities, practices, procedures, processes and the resources to carry out these policies.

3.54 design validation: Confirmation that the resulting product is capable of satisfying the requirements for its specific projected use or application when this is known, through objective evidence.

3.55 values: Concepts and expectations that describe the behaviour of persons in the organization and determine all their relationships (for example: trust, support, principles).

3.56 design verification: Confirmation that the results of the design and development process comply with the requirements of the specifications input for the design and development process, through objective evidence.

3.57 **vision:** Declaration describing what the organization wants to be in the future.

4 EVALUATION OF MATURITY LEVEL

4.1 General

This standard includes two evaluation tools: Management Evaluation and Detailed Evaluation, the summaries of which are shown in the following table:

	MANAGEMENT EVALUATION	DETAILED EVALUATION
Evaluation criteria:	Maturity levels corresponding to the application of the 8 management principles of UNE-EN ISO 9000.	Maturity levels corresponding to the application of the sections of UNE-EN ISO 9004.
Evaluation method:	Comparison of the reality of the organization with described situations relating to the principles of quality management for each maturity level.	Questionnaire of specific questions for each subclause of the standard containing examples of evidence to facilitate the evaluator's task.
To be done by	Managers	Technicians and Personnel in charge of Processes
Approximate duration	2 hours	1 to 2 days
Perspective given by the evaluation	Global and strategic MANAGEMENT VISION of the quality management system in relation to strategies, policies and guidelines.	Detailed OPERATIVE VISION of the quality management system in relation to operations, processes, requirements and methods.
Objectives	<ul style="list-style-type: none"> - To know and measure the maturity level of the quality management system in a rapid and comprehensive manner. - To establish measurable improvement objectives. - To prioritize the requirements and guidelines included in UNE-EN ISO 9004 that need to improve or be evaluated in detail. - To visualize the new scenario or the maturity level to be achieved and establish or update strategies, policies and guidelines. - To monitor the evolution of the maturity level. - To improve management style. 	<ul style="list-style-type: none"> - To measure overall maturity level or the level of each subclause in the quality management system, as well as to identify strong points and areas for improvement. - To establish measurable improvement objectives. - To prioritize and establish detailed plans of action to take on the requirements and guidelines of UNE-EN ISO 9004 and the areas identified as weak points. - To monitor the evolution of the maturity level and the impact of the actions for improvement adopted. - To make it possible to compare Management Vision with Operative Vision.

Both tools are complementary. For this reason, it is recommended to apply the management evaluation as well as the detailed evaluation to the entire organization, with the aim of tackling the improvement of the entire quality management system. Nonetheless, depending on the resources of the organization, the use of the detailed evaluation may be limited to those subclauses of the quality management system considered as more critical.

Likewise, the management evaluation and the detailed evaluation may be used independently or consecutively. In this latter case, it is recommended to undertake the management evaluation first and the detailed evaluation in the second place.

4.2 Management Evaluation

4.2.1 General. Management evaluation is a tool designed to enable the managers of an organization (without specific knowledge of quality or of the standards UNE-EN ISO 9000) to carry out a rapid and global evaluation of their organization's quality management system, know its maturity level, prioritize the UNE-EN ISO 9004 resources and guidelines that should be improved, and establish policies and guidelines geared towards improving maturity level.

This evaluation was designed on the basis of the eight principles of quality management (see Subclause 0.2) and is formulated in terms of five accumulative stages or phases that coincide with the five maturity levels set forth in UNE-EN ISO 9004. The evaluation criteria applied develop the "Level of performance and orientation" described in UNE-EN ISO 9004.

The evaluation is done by comparing the situation of the organization being evaluated with the situations or scenarios described for each quality management principle and maturity level, making it possible to visualize the new scenario or maturity level to be reached, and to establish and update the strategies, policies and guidelines necessary to achieve it, as well as to improve management style. It also serves the purpose of establishing measurable improvement objectives, since the results are numerically rated, and for monitoring the evolution of maturity level.

The estimated time for carrying out this evaluation may vary from 30 min to 120 min depending on the size and complexity of the organization and the knowledge that the manager or management team doing the evaluation has of it.

If the management evaluation is carried out by the management team as opposed to a single individual, it may yield more objective results, being reliant on different points of view, thus being more enriching for management.

The annexes mentioned below may be applied to the management evaluation:

Annex A – Comparative framework for management evaluation.

Annex B – Relationship matrix between the subclauses of the standard and the principles of quality management (only for consultation purposes).

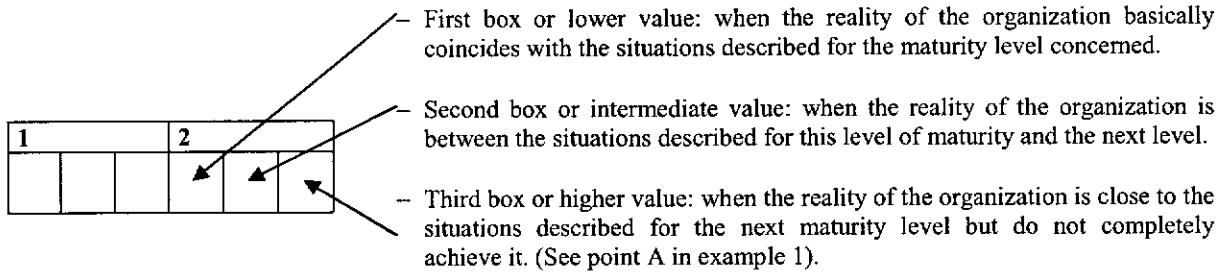
Annex C – Results sheet of the management evaluation.

NOTE – Mainly due to of the evaluation method, the results of the management evaluation normally exceed the results of the detailed evaluation.

4.2.2 Evaluation method. The real situation of the organization to be evaluated is compared with the corresponding description of maturity level and the situations of the quality management system described in annex A for each level of maturity and each one of the eight principles of quality management.

The maturity level that comes closest to the reality of the organization is selected, and the said value is noted down as the case warrants, by marking a cross on the results sheet of the management evaluation (see annex C).

A point system between one and five is established in order to evaluate each principle. Moreover, each of these values is subdivided into three boxes, for the evaluator to select one of them:



Example 1 – Filling in the management evaluation results sheet

DONE BY														
QUALITY MANAGEMENT PRINCIPLES	MATURITY LEVEL IN ACCORDANCE WITH THE IMPLEMENTATION OF QUALITY MANAGEMENT PRINCIPLES													
	1	2	3	4	5	6	7	8	9	10				
CUSTOMER FOCUS		X												
LEADERSHIP	X													
INVOLVEMENT OF PEOPLE		X												
PROCESS APPROACH			X											
SYSTEM APPROACH TO MANAGEMENT				X										
CONTINUAL IMPROVEMENT		X												
FACTUAL APPROACH TO DECISION MAKING			X											
MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS					X									
Number of boxes scored (columns)	0	1	1	2	1	2	1	0	0	0	0	0	0	0
Value assigned to each box	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5	6
Points obtained per column (n° boxes x value)	0	1.4	1.7	4	2.4	5.4	3	0	0	0	0	0	0	17.9
FINAL RESULT = sum of all columns / 8													2,2	

The arithmetical mean of the sum of the points obtained is calculated to get the final result (E), and for this purpose:

- 1) The number of scored boxes in each column (B) is recorded.

- 2) The points obtained for each column ($D = B \times C$) are calculated multiplying the number of boxes scored (B) by the value assigned to each box (C).
- 3) The total number of points obtained for each column are added up (D), and its arithmetical mean is calculated, dividing the total by 8 (number of principles rated), which yields the final result (E).

It is recommended to round up the final result and express it with a single decimal place.

4.2.3 Analysis of Results and Preparation of the Improvement Plan

a) Analysis of the results obtained and the possibilities for improvement

A graphic result of the situation status may be obtained by joining the boxes marked on the results sheet of the management evaluation with one line and tracing another vertical line above the value of the average achieved. This way, those principles with a lower rating would be to the left of the line and those with a higher rating would be to the right.

Visualize the scenarios corresponding to the maturity levels to be reached and identify the strategies, policies and guidelines that should be implemented to reach the new maturity level. To do this, select the scenarios described in the management evaluation comparative framework (see annex A) corresponding to the lower-rated principles.

Read those sections of UNE-EN ISO 9004 strongly related to the lower-rated principles identified in the management evaluation results sheet (see annex C) to know the requirements and guidelines of the standard which demand action in order to improve the score.

b) Preparation of the Improvement Plan

The content of the improvement plan may cover the following elements:

- The establishment of the new maturity level desired, to be reached within a specified timeline;
- The detailed evaluation of the entire quality management system or, at least, of those subclauses of the standard related to the principles that have achieved a lower rating. To do this, the subclauses of UNE-EN ISO 9004 related to the lower-rated principles may be identified using the relationship matrix between the subclauses of the standard and the principles of quality management (see annex B);
- The actions to be taken by management in order to set or update strategies, policies and guidelines.

The contents of Clause 5 of this standard may be used as a basis for establishing the improvement plan.

4.3 Detailed Evaluation

4.3.1 General. Detailed evaluation is a tool designed to ascertain and measure overall maturity level or the maturity level of the requirements and guidelines contained in each subclause of UNE-EN ISO 9004, to identify strong points and areas for improvement and to establish priorities and detailed plans of action to take on the subclauses of the standard and the areas identified as weak points.

This evaluation is based on a questionnaire detailing the 27 subclause of UNE-EN ISO 9004, making it possible not only to obtain a result from the section being rated, but also to identify the strong points and areas for improvement detected by the evaluator. Likewise, each question of the evaluation questionnaire also refers to the requirements of UNE-EN ISO 9001, since this is contained in UNE-EN ISO 9004:2000.

The questions on the evaluation questionnaire (see annex E) are rated from 1 to 5 in accordance with the evaluation criteria indicated in annex D, which elaborates upon the levels of performance and orientation described in UNE-EN ISO 9004:2000.

The detailed evaluation makes it possible to rate the entire quality management system or only certain requirements and guidelines of the standard and may likewise be applied to the entire organization or to specific departments, areas, plants or divisions. For these reasons, this evaluation serves to establish measurable improvement objectives for the entire quality management system or for certain specific areas or requirements of the standard, as well as to monitor the evolution of maturity levels.

The detailed evaluation does not require the use of expert evaluators, although they do require a certain familiarity with UNE-EN ISO 9000 on the part of the evaluator, since although the evaluation questionnaire contains examples of evidence related to the questions, it is necessary to know the standards in order to answer them reliably. For this reason, the evaluator profile fits in with that of technicians or personnel in charge of processes.

The estimated time for carrying out this evaluation may oscillate between 1 or 2 days depending on the size and complexity of the organization, as well as the evaluator's experience and knowledge of it.

The annexes mentioned below may be applied to the detailed evaluation:

Annex B – Relationship matrix between the subclauses of the standard and the principles of quality management (only for consultation purposes).

Annex D – Evaluation criteria.

Annex E – Questionnaire for detailed evaluation.

Annex F – Results sheet of the detailed evaluation.

Annex G – Evaluator's notebook.

NOTE – Mainly due to the degree of detail involved in the evaluation method, it is normal for the results achieved through the detailed evaluation to be lower than those of the management evaluation.

4.3.2 Evaluation Planning. Before starting the evaluation, it is highly advisable to carry out the following activities:

- **appoint a coordinator** to manage all the activities relating to the evaluation;
- **define the coverage of the evaluation** both in what concerns the scope of organizational services (processes, areas, departments, units, etc.) and the scope of the quality system to be evaluated (i.e., the subclauses of the standards to be evaluated);
- **inform the affected areas**, at least, of the scope of the evaluation and the dates of execution.

Example 2 – Filling in the Detailed Evaluation Questionnaire

SUBCLAUSE 8.5: IMPROVEMENT									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING NO.
				1	2	3	4	5	
8.5.1	8.5.1	Is management aware of the importance of continual improvement to company competitiveness?	Evidence of management involvement in improvement (gives impulse to or participates in working groups, allocates resources, etc).		X				
-	8.5.1	Does the organization have a process for identifying and managing improvement measures?	Process for the identification of improvements, etc.		X				
8.5.2	8.5.2	How does management use corrective action to evaluate and eliminate the problems found to affect the functioning of processes?	Procedure for the treatment of non-compliant products, procedures for corrective action and analysis of corrective actions within the Quality Committee			X			

No. of boxes rated				1	1	1							
Value assigned to each box	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.5	5
Points obtained for each column (no. boxes x value)				2	2.4		3						7.4
Final value of the section (sum of all points) / No. of questions applicable												2.4	

4.3.3 Evaluation Method

a) For the detailed evaluation, identify the existing evidence that responds to each question of the questionnaire in the organization being rated (see annex E). As reference for the evidence to look for, the examples of evidence facilitated in the questionnaire may be used. For the purpose of being able to subsequently analyze the causes of possible low ratings, it is convenient to note down the evidence found in response to each question in the evaluator's notebook (see annex G).

In case of doubt regarding the meaning of any question, it is possible to consult that section of UNE-EN ISO 9004 referred to by number for each question in the questionnaire. Likewise, it is possible to consult Clause 3 of this standard.

The final result of the detailed evaluation may be graphically visualized by joining the boxes marked on the detailed evaluation results sheet with one line and tracing another vertical line through the mean value achieved. This way, the lower-rated principles of quality management will appear to the left of the mean and the better-rated principles to the right.

Likewise, the value achieved for each clause or subclause of the standard (arithmetical mean of the corresponding sections) corresponding to the continual improvement cycle (PDCA) may be noted down in the results sheet as indicated below:

- (Plan) Clause 4 Quality management system
- (Plan) Clause 5 Management responsibility
- (Plan) Clause 6 Resource management
- (Do) Clause 7 Product execution
- (Check and Act) Clause 8 Measurement, analysis and improvement

Example 3 – Filling in the detailed evaluation results sheet

DONE BY:		DATE:														
		MATURITY LEVEL														
		1			2			3			4			5		
SUBCLAUSES OF THE STANDARD		ASSIGNED VALUE	1 - 1.3	1.4 - 1.6	1.7 - 1.9	2 - 2.3	2.4 - 2.6	2.7 - 2.9	3 - 3.3	3.4 - 3.6	3.7 - 3.9	4 - 4.3	4.4 - 4.6	4.7 - 4.9	5	
QUALITY SYSTEM	4.1	Managing systems and processes						2.7								Mean: 2.4
	4.2	Documentation				2.2										
MANAGEMENT	5.1	Management responsibility. General guidance				2.2										Mean: 2.2
	5.2	Needs and expectations of the interested parties				2.1										
	5.3	Quality policy					2.4									
	5.4	Planning						2.7								
	5.5	Responsibility, authority and communication				2.0										
	5.6	Management review				2.1										
Points obtained for each column						10.6	2.4	5.4								18.4
FINAL RESULT = (sum of all columns) / no. of applicable subclauses															2.3	

e) **Identifying strong points and areas for improvement.** In the course of the evaluation, strong points and areas for improvement that will enrich evaluation results and increase profitability may be detected. For this reason, and so as to organize the information collected during the evaluation, it will be convenient to reference all those notes that the evaluator may consider opportune in the evaluator's notebook (see annex G).

4.3.4 Preparation of the final report on the results of the detailed evaluation. For the purpose of adding greater value to the results obtained, it is advisable that the final report on results reflects the following aspects:

- scope (what has been evaluated);
- evaluation criteria (UNE-EN ISO 9004:2000)
- evaluation dates;
- composition of the evaluating team;
- summary of results;
- the detailed evaluation results sheet;
- the strong points and areas for improvement identified.

4.3.5 Preparation of the improvement plan. The improvement plan may contain the following elements:

- Establishment of the new maturity level it is desired to achieve in the evaluated area for the entire quality management system or for specific sections of the standard.
- Action for improvement that should be undertaken to achieve the new objectives.

The improvement plan may be based on the contents of Clause 5 of this standard.

5 IMPROVEMENT PLANS

5.1 General

An evaluation does not serve for much if an improvement plan making the organization more competitive is not implemented.

The improvement plan requires careful planning since the resources of an organization are always limited and the possibilities of improvement are abundant. For this reason, it is necessary to establish prioritizing criteria that will make it possible to select those actions that may yield the maximum improvement at the lowest cost as a result; i.e., that will be more profitable for the organization's objectives and strategy.

5.2 Criteria for the preparation of the improvement plan

The following methodology may be followed in order to establish the improvement plan:

1) Analysis of the reasons for the lower-rated areas

The graphic results of the quality management system evaluation [see subclauses 4.2.3 a) and 4.3.3 d)] may facilitate the analysis of the reasons for the lower-rated areas.

Likewise, to facilitate the analysis of the reasons and the definition of improvement actions, it is very important to use the guidelines of UNE-EN ISO 9004 corresponding to the sections with the lowest ratings.

The causes for the low rating of the weak areas should be investigated so as to increase the understanding of the nature of the processes to be improved through the collection, validation and analysis of data. In doing this, the tools for identifying and resolving problems are very useful (cause and effect diagrams, Pareto diagrams, histograms, etc).

2) Prioritizing areas and improvement actions

The results of the evaluation provide information about the weakest points of the quality management system.



Nonetheless, due to the limitation of resources, the improvement plan should be tackled aiming at maximum profitability, i.e., seeking the maximum benefit or impact that can be had at the least investment. For this reason, the improvement areas and the actions to be implemented should be prioritized.

Before prioritizing them, it is possible to select those areas and actions that have a greater impact on:

- the needs and expectations of customers and interested parties;
- the objectives and strategies defined by the organization as success factors;
- the resources available or the capacity of the organization to put the projected actions into operation (cost, timelines, availability of personnel, etc.).

It is advisable for the members of the organization involved in the implementation of these actions to examine the advantages and inconveniences of each proposal, since the success of the implementation depends on the collaboration of all the persons involved.

It is convenient to set the objectives to be achieved for the next evaluation by fixing numerical results for the principles or sections selected for improvement, and for the resulting average final value to be achieved. Normally, annual objectives aim at the value corresponding to the next box on this evaluation model (three-tenths), or the next highest (six-tenths).

3) Detailing the improvement plan

Towards the end of facilitating the implementation and monitoring of the projected improvement actions, it is advisable to document the improvement plan, detailing, at least, the objectives to be achieved for the selected principles or sections of the standard or the value of the final objective, the prioritized activities destined to achieve these objectives, the projected timeliness for execution, and the persons responsible for implementation.

ANNEX A (Normative)

COMPARATIVE FRAMEWORK FOR DIRECT EVALUATION

- 1) **PRINCIPLE – CUSTOMER FOCUS:** Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

	Description of Maturity Level	Situation of the Quality Management System
1	<p>No formal approach: The activity or process is performed totally or partially but is not adequately documented</p>	<p>The organization acts without necessarily taking customer needs into account Customer and market information is scarce and principally reflects complaints, which are dealt with Isolated nonconformities are resolved but no corrective action is taken Preventive action is not carried out The organization does not know the customer's level of satisfaction Management revision of the system does not take customer satisfaction into account Customer data is used to set objectives</p>
2	<p>Reactive approach: The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>The organization investigates the reasons for its nonconformities and for corrective actions Data relating to the market are taken into consideration in planning objectives Customer requirements are applied to internal specifications to achieve customer satisfaction On occasion, preventive action is taken Management revision of the system takes customer complaints and claims into account</p>
3	<p>Stable formal system approach: The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>The need to identify and cover customer needs is reflected in operative and strategic plans and embodied in terms of measurable objectives Surveys are made or systems applied to efficiently find out the opinion of customers Customer satisfaction is measured and analyzed systematically, resulting in improvement actions to be taken Each organizational process considers the customer as the starting and ending point of activities Management revision of the system takes the level of customer dissatisfaction (complaints and claims) into consideration as well as the level of satisfaction and expectations Quality policies include continual improvement</p>
4	<p>Continual improvement emphasized: The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>The quality management system is oriented not only towards guaranteeing customer satisfaction, but also to increasing it All the company's activities take the needs and expectations of customers and other interested parties into account The voice of the customer and other interested parties is integrated into the culture of the organization, all its processes being subordinated to customer satisfaction The strategic plans and objectives of the organization are focused on satisfying the needs and expectations of customers and other interested parties Management revision of the system takes improvement actions deriving from the analysis of the level of satisfaction of the interested parties Customers and suppliers are directly involved in product designing and revision All activities are focused on giving added value to the customer and interested parties There are effective and efficient communication channels with the customer and other interested parties</p>
5	<p>Best-in-class performance: The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>The organization obtains results from customer surveys and market studies that attest to a very positive, continual evolution that is favourable by comparison with competitors There are product and / or service innovation processes implemented to anticipate customer needs There is an organizational culture of apprenticeship focused on improving the satisfaction levels of customers and other interested parties The quality management system and its results with respect to customers and other interested parties is excellent and innovative by comparison with that of its competitors Quality policies involve customers and other interested parties in continual improvement</p>

3) PRINCIPLE – INVOLVEMENT OF PEOPLE: People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Description of Maturity Level	Situation of the Quality Management System
<p>No formal approach: The activity or process is performed totally or partially but is not adequately documented</p>	<p>The organization's quality policies have been communicated to the personnel At least, the functions and diagram of the management team have been defined There is a descending vertical communication</p>
<p>Reactive approach: The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>Personnel training is planned in relation to the product or service and the organization's quality management system All personnel know their functions in the organization and their position in the hierarchy The documents of the quality management system are systematically revised and updated The personnel know the organization's quality policies and objectives</p>
<p>Stable formal system approach: The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>There is a system for evaluating personnel competences The effectiveness of training programs is evaluated The managers attend to the motivation and involvement of employees and deploy the resources necessary to achieve them There are horizontal, vertical, ascending and descending channels of communication Every person has been given functions and objectives, and these are regularly revised The personnel management system includes the training plan and the evaluation of competences, abilities and experience The quality management system is based on management by process and by objectives</p>
<p>Continual improvement emphasized: The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>The personnel is involved in the continual improvement of its own and of the organization's activities The personnel systematically evaluate the organization and the managers, this information being vital for improvement All process owners acting as leaders in the organization have been identified The personnel is considered as vital by the managers. For this reason, the voice of the employee is taken into account in defining strategy The organization defines individual and group objectives, managing the performance of processes and evaluating the results A culture of quality and personnel involvement in the decrease of environmental impact and safety in the workplace have been included as requirements in all the organization's processes and activities The creation of improvement teams for problem solving is usual, reinforcing personnel creativity and innovation. The personnel contribute suggestions for improvement and opinions and receive acknowledgement for them The planning of training is done considering personnel experience, knowledge, abilities, creativity and innovative capacity The planning of personnel management includes objectives, the necessary resources, the evaluation of the personnel's competence and the measurement of effectiveness and impact on the organization The data resulting from the measurement of training effectiveness is used in the planning of subsequent training</p>
<p>Best-in-class performance: The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>Innovative techniques are applied to achieve personnel involvement Working climate and its results in terms of performance are monitored Personnel evaluation is done through effective systems (for example, 360° feedback) The owners and participants of processes are involved in process improvement and are conscious of the impact of their activity on the overall income of the organization The personnel feel acknowledged and rate their career plans positively The organization uses benchmarking and any other tool that enables it to compare itself with the best-of-class</p>

5) PRINCIPLE – SYSTEM APPROACH TO MANAGEMENT: Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

Description of Maturity Level	Situation of the Quality Management System
<p>1</p> <p>No formal approach: The activity or process is performed totally or partially but is not adequately documented</p>	<p>There are basic and necessary instructions and records for the purpose of making the product or service comply with requirements Some procedures relating to the key activities of the organization have been defined</p>
<p>2</p> <p>Reactive approach: The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>Corrective and preventive actions are provided for The documentation is appropriate for the organization, functional and easy to use The quality policy has been defined and is communicated to the entire organization There is a management representative to coordinate the quality management system</p>
<p>3</p> <p>Stable formal system approach: The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>Management establishes comprehensible, manageable and improvable processes to orient the organization towards customer satisfaction Process information and data are continually being acquired and used There are process control methods The data obtained from the said control method are analyzed to determine the organization's satisfactory performance The documentation satisfies the contractual, legal and regulation requirements as well as customer needs and expectations It is easily accessible to all the members of the organization Objectives based on the quality policies of the organization are set Management defines responsibilities and authorities for the purpose of maintaining an effective quality system Input information for the management system revision takes the level of customer satisfaction into consideration Management allocates the organization all the resources necessary for correct process execution Nonconformities are detected by any person in the organization and revised by the personnel authorized to do this, so as to provide corrective actions, and the information is used as input in the management's system revision</p>
<p>4</p> <p>Continual improvement emphasized: The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>The organization uses methods for evaluating process improvement Management clearly leads in the development, maintenance and improvement of the quality management system for the profit of all the interested parties, through customer satisfaction Management defines methods to measure the organization's performance and determine the scope of the projected objectives Management takes the 8 management principles into account in developing, implementing and managing the system The results of performance measurements are taken into account as an input element for the management system revision in the continual improvement of the quality management system Continual improvement is taken into account in the establishment of quality policies Objectives are systematically revised and modified if necessary The organization records data on nonconformities in order to improve the quality management system The organization effectively controls the identification, segregation and disposal of non-conformity products</p>
<p>5</p> <p>Best-in-class performance: The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>The quality management system includes specific improvement and innovation processes The quality management system contains a criteria of ethics, in the definition of which the entire organization participates Total quality and innovation management models are investigated and followed Communication, systematic teamwork and the elimination of barriers are considered key elements in the functioning of the organization</p>

6) **PRINCIPLE -- CONTINUAL IMPROVEMENT:** Continual improvement of the organization's overall performance should be a permanent objective of the organization.

	Description of Maturity Level	Situation of the Quality Management System
1	<p>No formal approach: The activity or process is performed totally or partially but is not adequately documented</p>	<p>Regular improvements are made on the basis of resolving nonconformities There is no budget defined or personnel especially trained to carry out management improvements</p>
2	<p>Reactive approach: The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>Improvements are made on the basis of corrective and preventive actions Internal quality audits are also a source of improvement ideas, on the basis of detected deviations or nonconformities, which indicate a certain level of improvement systematization and the definition of responsibilities in this area The organization waits for a problem to reveal an improvement opportunity and does not anticipate it</p>
3	<p>Stable formal system approach: The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>Each process defined has a concrete objective, a monitoring indicator, and a person in charge of it who watches over it and proposes improvements in the event of deviation in the indicator Continual improvement, in this way, becomes standardized, ensuring that the processes defined are under control Regular, conveniently formed improvement teams are established for chronic problems or receive their orientation from Management The results of management system revision yield data that are used in the improvement of the organization's performance. The organization has implemented procedures for monitoring, measurement and analysis to prove the product compliance and ensure the compliance of the quality management system The organization records and controls nonconformities so as to improve process effectiveness. The organization analyzes data from different sources to evaluate performance in relation to plans, objectives and other defined goals Data analysis is used as an aid in determining the reasons for existing or potential problems</p>
4	<p>Continual improvement emphasized: The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>There is a continual improvement process for the purpose of improving the organization's quality management system The area of improvement covers quality management, the environment and the system for preventing labour hazards Comparison of results with other competitors through information Procedures are systematized and deployed throughout the organization The best practices are used in the processes of continual improvement Continual improvement is reflected in the quality policies of the organization Management uses the results of the management system revision to identify the organization's performance improvement opportunities The organization has planned and implemented procedures for monitoring, measurement, analysis and improvement that ensure the continual improvement of the quality management system The organization analyzes data from different sources to identify improvement areas, including possible benefit for the interested parties Data analysis is used as an aid in determining the reasons for existing or potential problems and in orienting decisions regarding corrective and preventive actions, necessary for improvement</p>
5	<p>Best-in-class performance: The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>Management continually seeks to improve the effectiveness and efficiency of the organization's processes All the entity's activities are governed by process by the management system Benchmarking activities and comparison with other organizations have been added to the sources of continual improvement. These activities are carried out on a continuous basis, following a concrete method The self-assessment process is based on a total quality model, also used in the design and execution of the yearly continual improvement plan There are systematic activities for process and product innovation</p>

7) PRINCIPLE – FACTUAL APPROACH TO DECISION MAKING: Effective decisions are based on the analysis of data and information.

Description of Maturity Level	Situation of the Quality Management System
<p>No formal approach:</p> <p>1 The activity or process is performed totally or partially but is not adequately documented</p>	<p>Few decisions are made, almost never by consensus</p> <p>Few instruments of information are maintained, and are in no way systematic</p> <p>The environmental impact of the organization's activities is not evaluated</p> <p>Only some obligatory process monitoring of records is maintained</p> <p>There is an updated list of suppliers</p> <p>Information of an administrative character related to personnel functions and the diagram is kept</p> <p>Regular reports are prepared on product or service quality analysis on the basis of customer complaints</p>
<p>Reactive approach:</p> <p>2 The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>There are procedures defining what records and what information are being kept in relation to the quality management system</p> <p>The procedures are used for a better information on suppliers, customers and employees</p> <p>Information is kept on internal nonconformities for their systematic analysis and the generation of corrective and preventive actions</p>
<p>Stable formal system approach:</p> <p>3 The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>Studies and analyses on competitors, suppliers and the market are systematically carried out</p> <p>There is a company plan that generates the corporate mission, vision and values, and which is periodically updated</p> <p>Tools such as SWOT, flow diagrams and brainstorming, etc., are normally used</p> <p>Systematic information from process results is generated through management indicators</p> <p>Data on customer requirements and satisfaction as well as process and product and / or service characteristics are used for the analysis of the management system adaptation</p>
<p>Continual improvement emphasized:</p> <p>4 The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>There is updated input information on quality management scope, environmental management and the prevention of labour hazards, as well as information regarding the organization's product and / or services.</p> <p>The information regarding the results of the different process indicators is evaluated systematically, being considered a priority, and monitored over the integrated balanced scorecard</p> <p>This scorecard is the main tool for management decision making</p> <p>Tools such as affinity diagrams, Ishikawa diagram, Pareto's diagram and other methods are used in meetings of working groups oriented by Management and trained in the analysis and improvement of processes, products and / or services</p>
<p>Best-in-class performance:</p> <p>5 The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>Everything concerning the organization's product and / or service innovation management is also considered as strategic input information in analysis</p> <p>Investigation on ethical and social aspects is also considered necessary</p> <p>The management of knowledge is likewise considered as a source in the evaluation of needs and new product and / or service lines. The organization's intellectual capital is identified and managed</p> <p>There is a clear focus on process, product and / or service innovation of all the areas in the entity</p> <p>Risk analysis is used in every type of activity</p>

8) PRINCIPLE – MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS: An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Description of Maturity Level	Situation of the Quality Management System
<p>No formal approach: The activity or process is performed totally or partially but is not adequately documented</p>	<p>There is a relationship with some suppliers The needs and expectations of suppliers and business partners are not taken into account in product or process planning and revision Said needs and expectations have not been considered in quality policies There is a scarce communication with suppliers and partners in process improvement The organization's purchasing process is not defined</p>
<p>Reactive approach: The activity or process is performed totally and documented adequately with a minimum of data for monitoring purposes and improvement revision</p>	<p>There is a system for managing suppliers that guarantees compliance with specified requirements The purchasing procedure establishes the relationship with suppliers through a system of evaluation and registration Regular meetings are held for the improvement of the product and / or service purchased The best suppliers are rewarded with repeated business</p>
<p>Stable formal system approach: The activity or process is performed and revised; actions deriving from the monitoring and analysis of data are taken. There is a tendency towards improvement in the early stages of the process</p>	<p>The system for managing suppliers ensures the availability of resources, thus ensuring compliance with delivery dates and requirements Regular meetings with the usual suppliers are held for the analysis of the product and / or service purchased, as well as the organization's product and / or service The suppliers know and accept the conditions marked out in the purchasing process Management uses data on the quality of suppliers to make decisions The needs and expectations of suppliers are taken into account in quality policies</p>
<p>Continual improvement emphasized: The activity or process is performed, revised, and action deriving from data analysis is taken. The process is effective and efficient. Tendency to improvement is maintained</p>	<p>The process map identifies the processes related to the suppliers There are effective two-way communication channels as well as business partnerships based on joint value added strategies with suppliers The suppliers participate in the development of the organization's products and / or services The continuous relationship with suppliers gives rise to mutual solutions by consensus to decrease quality, environmental and labour risks Acknowledgment is given to some suppliers The suppliers share quality, safety and environmental objectives, among other things, with the organization Suppliers' contributions are taken into account in the planning of new activities as well as in the revision of activities already planned Infrastructure design provides for the optimization of suppliers' resources Suppliers participate in the validation of new processes Communications systems compatibility is planned between suppliers and the organization to improve the facility of data flow Suppliers' opinions on the organization's supplier management system are regularly solicited, and suppliers are informed of the quality developments in their services Management uses information regarding the results of partnerships in revising its policies and objectives</p>
<p>Best-in-class performance: The activity or process is performed and revised, taking account of what the best players in the sector do. The satisfaction levels of the parties involved are measured and action deriving from revision follow-up is taken. The effectiveness and efficiency of the activity is measured and continually improved so as to optimize it.</p>	<p>A system of acknowledging the best suppliers has been established The suppliers form part of the organization's working teams, both in management and product improvement There are open-door events for suppliers as well as meetings to improve mutual relationships and knowledge Tools are issued in the continual improvement of processes related to purchasing from suppliers The organization carries out benchmarking studies to adapt best practices to its processes</p>

ANNEX B (Informative)

**RELATIONSHIP MATRIX BETWEEN THE SUBCLAUSES OF UNE-EN ISO 9004:2000
AND THE 8 PRINCIPLES OF QUALITY MANAGEMENT**

	PRINCIPLES OF QUALITY MANAGEMENT							
	1	2	3	4	5	6	7	8
<div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p align="center">A</p> <p align="center">LEVEL OF RELATIONSHIP</p> <p align="center">No Relationship</p> <p align="center">○ Clear Relationship</p> <p align="center">⊙ Strong Relationship</p> </div>	Customer Focus	Leadership	Involvement of people	Process approach	System approach to management	Continual Improvement	Factual Approach to Decision Making	Mutually Beneficial Supplier Relationships
SUBCLAUSES OF THE STANDARD								
1.- Managing systems and processes (4.1)	○	⊙	○	⊙	⊙	○	⊙	
2.- Documentation (4.2)			○		⊙			
3.- Management responsibility. General guidance (5.1)	⊙	⊙			⊙	○	○	⊙
4.- Needs and expectations of interested parties (5.2)	⊙	⊙	○					⊙
5.- Quality policy (5.3)	⊙	⊙	○		⊙	⊙		⊙
6.- Planning (5.4)					⊙		○	
7.- Responsibility, authority and communication (5.5)		⊙	⊙		⊙			
8.- Management review (5.6)	⊙	⊙		○	⊙	○	⊙	
9.- Resource management. General guidance (6.1)		⊙			○	⊙		
10.- People (6.2)		○	⊙		○			
11.- Infrastructure (6.3)		⊙						○
12.- Work environment (6.4)		○	⊙					
13.- Information (6.5)	○				⊙		⊙	
14.- Suppliers and partnerships (6.6)				⊙				⊙
15.- Natural resources (6.7)		○						⊙
16.- Financial resources (6.8)		⊙			○			○
17.- Product realization. General guidance (7.1)	○		○	⊙		○		
18.- Processes related to interested parties (7.2)	⊙			⊙				○
19.- Design and development (7.3)	⊙			○	○	○	○	○
20.- Purchasing (7.4)					○			⊙
21.- Production and service provision (7.5)	○		○	⊙	○			
22.- Control of measuring and monitoring devices (7.6)						○	⊙	
23.- Measurement, analysis and improvement. General guidance (8.1)			○		○	⊙	⊙	
24.- Measurement and monitoring (8.2)	⊙		○			○	⊙	○
25.- Control of nonconformities (8.3)			○		⊙	⊙	⊙	
26.- Analysis of data (8.4)					○	⊙	⊙	
27.- Improvement (8.5)		⊙	⊙	⊙		⊙	⊙	⊙

ANNEX D (Normative)
EVALUATION CRITERIA

In order to achieve a maturity level in all cases, it is necessary to comply with all the requirements of all the lower levels

Maturity Level	Description of Maturity Level	Level of Application of the UNE-EN ISO 9000 Series
1	<p>No formal approach There is no evident systematic approach; no results, poor results or unpredictable results The activity or process is performed totally or partially, but is not adequately documented</p> <p>Process in development Organization centred on production and rendering the service Quality control system centred on the final stage of production or service</p>	<p>UNE-EN ISO 9001:2000 is partially applied</p>
2	<p>Reactive approach Systematic approach based on the problem and its prevention; minimal data available about the results of improvement The activity or process is performed totally and adequately documented, with minimal data on monitoring and improvement revision</p> <p>Process under control Existence of a quality assurance system</p>	<p>Beginner organization in the use of UNE-EN ISO 9001:2000</p>
3	<p>Stable formal system approach Systematic approach based on process, early stage of systematic improvements; data available on compliance with objectives and the existence of improvement trends The activity or process is carried out and revised; action derived from data monitoring and analysis is undertaken. There is a tendency towards improvement in the early stages of the process</p> <p>Effective processes There is a deployment of objectives and a balanced scorecard</p>	<p>Advanced organization in the use of UNE-EN ISO 9001:2000 and initial experience in the use of UNE-EN ISO 9004:2000</p>
4	<p>Continual improvement emphasized Improvement process in use; good results and constant tendency to improvement The activity or process is performed and revised and action derived from data analysis is undertaken. The process is effective and efficient. Tendency towards improvement maintained</p> <p>Effective and efficient processes There is an integrated system for quality, environmental and work safety management</p>	<p>Advanced organization in the use of UNE-EN ISO 9004:2000. This is applied not only to production and key processes, but also to other auxiliary processes, including those related to the satisfaction of interested parties.</p>
5	<p>Best-in-class performance Improvement process in use; good results and tendency to improvement maintained The activity is performed and revised, taking the best sectorial practices into account and measuring the level of satisfaction of the affected parties. Action deriving from revision follow-up is undertaken. The effectiveness and efficiency of the activity is measured and continually improved in order to optimize it.</p> <p>Excellent processes Sectorial comparisons are made; the organization demonstrates with evidence that it is best-in-class in terms of different results</p>	<p>Organization applies all processes and develops the guidelines of UNE-EN ISO 9004:2000 in such a way that it is considered a model to emulate</p>

ANNEX E (Normative)

DETAILED EVALUATION QUESTIONNAIRE

Subclause 4.1: MANAGING SYSTEMS AND PROCESSES													
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE					RESULT					RATING No.
								1	2	3	4	5	
4.1	4.1	1 Are the organization's key and support processes defined?	Process map										
4.1	4.1	2 Are process owners, input elements, process results and process interrelationships defined?	Process files and diagrams										
4.1	4.1	3 Are indicators associated to the processes defined?	Process descriptions, established and documented indicators, integrated balanced scorecard										
-	4.1	4 Is the method used to measure the processes effective and efficient, and is it revised periodically?	Revisions of control points or process indicators and evidence of the analysis of established indicators										
-	4.1	5 Are processes adapted in the face of possible variations to the product or service?	Process capacity studies										
-	4.1	6 Are the critical points of processes having a greater influence on variability known?	Process files and diagrams										
-	4.1	7 Are processes oriented towards satisfying the requirements of customers and other interested parties?	QFD, surveys, meetings with customers and evidence that the customer's voice is taken into account in the design, planning and development of processes										
4.1	4.1	8 Are preventive measures adopted in the face of possible process failures?	Preventive action, FMEA studies										
4.1	4.1	9 Are the necessary resources available to ensure the development and monitoring of processes?	Evidence of management involvement, ensuring the availability of resources such as management revisions, quality objective programs, process files and diagrams										
-	4.1	10 Is there a systematization of process design and development for the continual improvement of process effectiveness and efficiency?	Data on design revision, process verification and validation and systematic analysis of the results of indicators along with all the information affecting the process, self-assessment, and management revisions										

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for the subclause = sum of all columns / No. of applicable questions

Subclause 4.2: DOCUMENTATION											
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.		
				1	2	3	4	5			
4.2.3 4.2.4	4.2	1 Has Management defined a process for the control of documents and records?	Document, filing list of records, list of valid documents and flow diagram								
4.2.1	4.2	2 Is the documentation defined by Management adequate to the activity and size of the organization, the complexity of its processes and the competence of its personnel?	Analysis of internal and external customer needs and the needs of interested parties, list of valid documents								
4.2.1	4.2	3 Does the documentation of the quality management system include basic documents?	Quality policies and objectives, quality manual, documented procedures required, documents needed (working instructions, specifications, etc.) by the organization to ensure effective and efficient planning, operation and process control, and the required records								
-	4.2	4 Does the control of the documents allow for an effective and efficient management of the system?	Approval and updating of procedures, instructions, plans, etc., availability of applicable versions of the documents at the points of use and distribution and identification (obsolete) of internal and external documents								
-	4.2	5 Does the organization have some system that enables a rapid updating and retrieval of the documents and records?	Computer tools								
-	4.2	6 Is there some security system that prevents the possibility of leaks, plagiarism and appropriation of know-how in the documentation / records of the organization?	Copyright, impossibility of making copies, security locks that impede printing and access to information by level of responsibility								
4.2.4	4.2	7 Have the records been established and maintained in a legible form that is easy to identify and recover?	Different types of records, procedures								

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for the subclause = sum of all columns / No. of applicable questions											
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Subclause 5.1: MANAGEMENT RESPONSIBILITY. GENERAL GUIDANCE (Evid)									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
5.1	5.1.2	14 Does top management consider the results and data obtained from its management in the revision of the system?	Record of system revision, analysis of nonconformities and approval of improvement plans						
-	5.1.2	15 Is there a table of indicators for measuring compliance with all the set objectives?	Map of indicators, complete balanced scorecard and record of monitoring of objectives						
-	5.1.2	16 Is the future of the organization and management of changes planned?	Strategic plans, SWOT diagram						
-	5.1.2	17 Are risks identified and managed and are improvement opportunities taken advantage of?	Identification of risks, SWOT diagram						
-	5.1.2	18 Does top management formulate radical changes in processes as an element of continual improvement?	Examples of changes in process due to process re-engineering						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for the subclause = sum of all columns / No. of applicable questions													
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Subclause 5.2: NEEDS AND EXPECTATIONS OF INTERESTED PARTIES									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
5.2	5.2.2	1 Are regular meetings held with the customer that make it possible to work together with him in order to be more familiar with his surroundings, his expectations, his problems, etc?	Minutes of meetings						
5.2	5.2.2	2 Is information about customer claims and complains systematically collected?	Reports of claims and complains						
-	5.2.2	3 Is information about the market collected either by the organization or by other organizations in the sector?	Market study reports, SWOT diagrams, reports from associations and from the sector						
-	5.2.2	4 Are the products / services of other organizations analyzed?	Comparative studies and reports about the situation of the competition						
5.2	5.2.2	5 Is customer satisfaction periodically measured?	Customer surveys, results of surveys and plans of action						
--	5.2.2	6 Is there a system for identifying all the interested parties?	Documents that identify the interested parties						
-	5.2.2	7 Are the needs and expectations of the interested parties expressed and communicated?	Files on needs and expectations of interested parties, communications of needs and expectations, dissemination talks, requirement specifications						
5.2	5.2.2	8 Are the customer's latent needs investigated (innovations on existing products, application of technologies used in other sectors, tendencies in other countries, etc?)	Customer surveys, participation in sectorial fairs, innovations introduced and research on customers' needs						
-	5.2.2	9 Is training in which the management and the persons affected participate periodically planned, and are reports made on the results obtained?	Training plan and participants in its preparation						
-	5.2.2	10 Is there a personnel management system with activities to undertake for personnel development in which the persons affected participate?	Personnel management document, career plans						

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Subclause 5.2: NEEDS AND EXPECTATIONS OF INTERESTED PARTIES							RATING No.	
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT				
				1	2	3	4	5
-	5.2.2	11 Is personnel satisfaction measured periodically?	Surveys (acknowledgment, satisfaction in work and personal development), results of surveys and actions taken					
-	5.2.2	12 Are personnel evaluated, promoted and given incentives on the basis of their involvement in improvement?	Procedures on promotion and incentive system					
-	5.2.2	13 Is there a long-term relationship with suppliers in line with the strategy and plans of the organization itself?	Partnerships, contracts with suppliers					
-	5.2.2	14 Are programs promoted in which suppliers participate in the development phase of new products?	Reports of meetings with suppliers and records of the participation of suppliers in new products					
-	5.2.2	15 Is there an exchange of information with suppliers on methods and / or technologies used?	Reports of meetings with suppliers					
-	5.2.2	16 Are cost reduction programs established jointly with suppliers?	Reports on cost reduction					
-	5.2.2	17 Is assistance given to the supplier to increase its capacity?	Reports on visits to suppliers					
-	5.2.2	18 Are agreements made with suppliers on investments that may improve the characteristics of the products / services?	Reports on agreements with suppliers					
-	5.2.2	19 Are techniques for rationalizing production used in agreement with suppliers?	Reports on agreements with suppliers and JIT concerted quality agreements with suppliers					
-	5.2.2	20 Is there a system of acknowledgment for achievements and involvement in the improvement of suppliers?	System of acknowledgment and report on the acknowledged suppliers					

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Subclause 5.2: NEEDS AND EXPECTATIONS OF INTERESTED PARTIES (End)									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
-	5.2.2	21 Does the organization actively participate in sectorial as well as general associations and organizations for the purpose of being up to date on the tendencies of the sector?	List of associations in which the organization participates and records of its participation						
-	5.2.2	22 Are shareholders / owners informed about the strategic plan and the financial results, and is information obtained from them by way of feedback on the strategic plan?	Shareholders' reports						
-	5.2.2	23 Is an identification and evaluation of the present, past and future environmental aspects of the products, processes and activities of the organization carried out, and are plans established for the minimization or improvement of the environmental impact?	Reports of studies made and action taken						
-	5.2.2	24 Does the organization participate in social activities with the community in which it resides, encouraging workers' collaboration, and does it cooperate with educational institutions for the training of workers?	Activities done and type of cooperation undertaken						
-	5.2.2	25 Have the organization's work hazards been evaluated and have prevention plans been drawn up?	Prevention plans, evaluation reports on work posts and action taken						
-	5.2.3	26 Are the legal and regulation requirements applicable to the processes, products and activities of the organization identified and are they taken into account in making plans?	List of legal and regulation requirements applicable and strategic plan						
-	5.2.3	27 Is compliance with the applicable legal and regulation requirements evaluated?	Evaluation of compliance and actions deriving from the evaluation of compliance						
-	5.2.3	28 Does the organization have a code of ethics or conduct defining the principle of legality and the correct way of acting in order to comply with it?	Code of ethics or conduct						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for the subclause = sum of all columns / No. of applicable questions

Subclause 5.3: QUALITY POLICY										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
5.3	5.3	1 Are all the necessary requirements provided for in the standard taken into consideration in setting the policies?	Quality policies							
-	5.3	2 Do the personnel participate in the preparation of the quality policies?	Participants in the preparation of the quality policies, type of participation and minutes of the quality committee							
5.3	5.3	3 Is there a system of communication and understanding regarding quality policies?	Minutes of meetings, management communiqués, existing communication channels and type of consultations done							
5.3	5.3	4 Is there a process for the revision of quality policies before their approval and dissemination, and does this revision take place after changes to the mission, vision and strategies, as well as with a set periodic regularity?	Revision process followed, management revision, and previous quality policies							
5.3	5.3	5 Do the quality policies include a commitment to the continual improvement of the effectiveness and efficiency of the organization's performance and its compliance with requirements?	Document of the quality policies							
-	5.3	6 Do the quality policies include a commitment to provide the necessary resources to establish a structure based on continual improvement?	Document of the quality policies							
-	5.3	7 Do the quality policies support the creation of improvement working groups?	Number of functioning working groups and reports on improvements achieved							
5.3	5.3	8 Is there consistency between the quality policies and the organization's general objectives?	Documents on quality policies, strategic plans, general objectives and quality objectives							

No. of boxes scored	1	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box												
Points obtained per column (no. of boxes x value)												

Final rating for the subclause = sum of all columns / No. of applicable questions

Subclause 5.4: PLANNING (End)									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
-	5.4.2	10 Is the planning of the organization in the definition of processes necessary to comply with the quality objectives and the requirements of the organization coherently aligned with the organization's strategy?	Quality plans, strategies and policies of the organization						
5.4.2	5.4.2	11 Does the input information for planning reflect all the requirements of the Standard?	Comparison with input factors of subclause 5.4.2 of UNE-EN ISO 9004, Quality plans						
-	5.4.2	12 Does Management take on the responsibility of systematically revising the results of planning to ensure the effectiveness and efficiency of the processes?	Meetings on revision of quality planning results. Comparison with the results in Section 5.4.2						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for the subclause = sum of all columns / No. of applicable questions													
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Subclause 5.5: RESPONSIBILITY, AUTHORITY AND COMMUNICATION (End)									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
5.5.3	5.5.3	10 Has top management ensured that effective and efficient communication processes have been established in the organization?	Intranet, e-mail, bulletin boards, meetings with management, internal team meetings, internal newsletters, suggestion boxes, employee surveys and measurement of the effectiveness of communication processes						
5.5.3	5.5.3	11 Are quality policies, requirements, objectives and achievements communicated?	Verify that the contents of communications coincide with what is asked for in the established channels of communication						
5.5.3	5.5.3	12 Does Management actively promote feedback and communication from organization personnel to enable employees to participate?	Channels of participation established, systems of suggestion						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final rating for this subclause = sum of all columns / No. of applicable questions

Subclause 5.6: MANAGEMENT REVIEW										
		QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
9001	9004									
5.6.1	5.6.1	1 Does the management team set periodic meetings to review the system?	Agenda, minutes or plan of action, process defined and record of reviews							
5.6.2	5.6.2	2 Does the management representative inform top management about the degree of effectiveness of the QMS?	Report of the management representative about the degree of effectiveness of the QMS and minutes of meetings reflecting the information given by the management representative about the degree of effectiveness of the QMS							
5.6.2	5.6.2	3 Does the management representative inform top management about any need for improvement in the QMS?	Report of the management representative about proposals for the improvement of the QMS and minutes of meetings reflecting the information given by the management representative about proposals for the improvement of the QMS							
5.6.2	5.6.2	4 Is the need for input information in review analyzed by Management?	Minutes of quality system reviews by management. Information system							
5.6.2	5.6.2	5 Does Management review use the results of analyses on nonconformities?	Records of nonconformities of the system and reports on system review and corrective actions. Data analyses							
5.6.2	5.6.2	6 Does management review use the results of quality audits?	Audit reports and records of system changes or reports on system revision							
5.6.2	5.6.2	7 Does management review use a system of quality indicators?	A balanced scorecard of indicators and statistical documents on evolution of indicators							
5.6.2	5.6.2	8 Does management review use a system of management indicators containing among them quality indicators?	A balanced scorecard of indicators and statistical documents on the evolution of the indicators							
5.6.2	5.6.2	9 Is the result of the indicators analyzed during the review, and is it compared with objectives?	Report or record of system review, record or table of process indicator monitoring and plan of action deriving from the review							
	5.6.2.	10 Does the management review use information about competitors' results as input information?	Report of audits and records of system changes or reports on system review							
	5.6.2	11 Does the management review use information available from exchange activities and fora?	Record of input documentation for the review							

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Clause 5.6: MANAGEMENT REVIEW (End)										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
5.6.2	12	Does the management review use benchmarking activities undertaken as input information?	Record of input documentation for the review							
5.6.3	13	Are the results of the system review used to identify opportunities for improvement in the organization's performance?	Minutes of the Management's quality system review. Corrective actions open. Improvement plans. Data analyses							
5.6.1	14	Is the effectiveness and efficiency of the organization's processes evaluated?	Indicators used							
5.6.3	15	Do the minutes of revision include decisions and actions on the need for resources and the improvement of the product in relation to the requirements of customers and other interested parties?	Minutes of the Management's quality system review							
5.6.3	16	Does Management promote the collaboration of other interested parties (customers and suppliers) in the improvement of the system?	Minutes of meetings with customers and suppliers							

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final value for the subclause = sum of all columns / No. of applicable questions

Subclause 6.1: RESOURCE MANAGEMENT. GENERAL GUIDANCE								
QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
		1	2	3	4	5		
9001 6.1	9004 6.1	1 Is the allocation of resources consistent with the strategic plans established, the mission and vision of the company and its quality policies?	Mission, vision and quality policies of the organization, strategic plans, program of objectives, management revision and budget allocations					
6.1	6.1.2	2 Are the necessary resources for the achievement of the objectives proposed in the organization allocated?	See the program of quality objectives and seek out the allocation of resources such as personnel, infrastructure, human and physical conditions, information, suppliers and business partners, natural and financial resources					
6.1	6.1.2	3 Are the necessary resources projected during the pre-established moments, such as management reviews, revisions of objectives, quality planning, or new expectations or needs of interested parties?	Management reviews, planning, monitoring and revision of objectives and goals, quality planning, planning of compliance with new expectations or needs of interested parties (for ex., training plans, design and development plans, calibration plans, etc.)					
6.2		4 Are resources systematically updated to the extent that environmental situations or objectives change?	Evolution of resources during the last few periods. Measurements of their degree of use					

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7
Value assigned to each box												
Points obtained per column (no. of boxes x value)												

Final rating for the subclause = sum of all columns / No. of applicable questions

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Subclause 6.2: PEOPLE							RATING No.			
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT						
				1	2	3		4	5	
6.2.2	6.2.2.1	1	Is the professional profile of personnel performing functions that affect quality defined?	Quality manual, catalogue of work posts, organizational manual or any other document in which responsibilities are defined						
6.2.2	6.2.2.1	2	Is the system for updating profiles in accordance with the evolution of work posts defined?	Redefinition of work posts and profiles						
6.2.2	6.2.2.1	3	Is the system for updating personnel training in accordance with the evolution of work posts or change of post due to new business activities, changes in process, tools or organizational teams defined?	Training plan and personnel files						
6.2.2	6.2.2.2	4	Is the system for ensuring that the personnel is aware of the consequences of their possible errors defined?	FMEA of processes. Awareness campaigns						
6.2.2	6.2.2.2	5	Is there an adequate management of performance to verify that the level of personnel competence is the required level?	Documentation on the performance evaluation done on personnel						
6.2.2	6.2.2.2	6	Is the effectiveness of training evaluated?	Examinations, interviews with trained personnel, evaluations of personnel in charge						
	6.2.1	7	Do the persons in charge and the authorities defined facilitate decision making?	Quality manual or any other document where responsibilities are defined						
	6.2.1	8	Does the deployment of objectives reach and affect all the organization's personnel?	Objectives and their deployment into specific goals						
	6.2.1	9	Are working teams created for the improvement of the effectiveness and efficiency of the organization?	Formation of improvement teams						
	6.2.1	10	Are personnel initiatives and needs taken into account?	Suggestions of personnel and resulting responses or actions						
	6.2.1	11	Is there a management system for personnel safety and health in the workplace?	System documentation						
	6.2.1	12	Is there an active participation in the setting of objectives, and are these deployed at all levels of the organization?	People in the different areas of the organization must have participated in the preparation and deployment of the objectives directly affecting them						

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Subclause 6.2: PEOPLE (End)										
QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.			
		1	2	3	4	5				
9001	9004									
6.2.1	13 Is personnel perception of the acknowledgment and reward system, as well as the criteria that they understand should be considered of greater value in their work station measured?	Surveys								
6.2.2	14 Is the selection and reassignment of personnel consistent with the profiles of work posts?	Examples of recruitment or personnel changes and their consistency with the profile of the work post in each case (personnel competence)								
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No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7
Value assigned to each box												
Points obtained per column (no. of boxes x value)												
Final value for the subclause = sum of all columns / No. of applicable questions												

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Subclause 6.3: INFRASTRUCTURE										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
6.3	6.3	1	Is infrastructure defined by the Management on the basis of the requirements of all the interested parties?	Strategic (infrastructure) plan						
6.3	6.3	2	Is the maintenance plan of the infrastructure defined in accordance with all the requirements?	Maintenance plan						
6.3	6.3	3	Is there adequate information to contrast the projected infrastructure with objectives and other requirements?	Indices of infrastructure use in relation to objectives						
6.3	6.3	4	Is there an emergency plan that contemplates existing risks to the infrastructure, the persons and the objectives of the organization?	Emergency plan						
6.3	6.3	5	Is the suitability of the infrastructure revised in view of any changes in the organization's objectives?	See revisions to the plans and contrast them with the general objectives of the organization						
-	6.3	6	Are aspects of safety, cost and protection contemplated?	Risk studies						
-	6.3	7	Are the environmental aspects associated to the infrastructure contemplated, reducing them as much as possible with respect for the environment?	Environmental impact studies, work hazard assessment, list of environmental aspects identified and annual environmental program						
-	6.3	8	Are all the required licenses on hand?	Licences for activity, works and the like						
-	6.3	9	Are all the applicable legal rules and regulations available and updated?	Legal regulations						
-	6.3	10	Do the infrastructure and its function comply with all the legal regulations?	Technical inspection reports by the authorities or regulating agencies						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7
Value assigned to each box												
Points obtained per column (no. of boxes x vale)												

Final rating for the subclause = sum of all columns / No. of applicable questions

Subclause 6.5: INFORMATION										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
-	6.5	1	Has management identified its information needs?	Documents identifying the information necessary to the organization						
-	6.5	2	Are the sources of internal and external information needed by the organization defined and accessible?	Subscriptions to magazines, applicable legislation or standards, membership of the appropriate associations, committees or fora, existence of diverse channels of information (fax, e-mail, telephone) etc.						
-	6.5	3	Is the available information kept in a manner that ensures that only authorized personnel have access to it?	Classification of information when necessary (secret, confidential, etc.), access profiles and levels, patents transacted						
-	6.5	4	Does Management use information, data and knowledge in the establishment of the organization's strategy and objectives?	Inclusion of the necessary data in the planning of strategy and objectives						
-	6.5	5	Is monitoring carried out regarding the use of information to improve the management of information and knowledge?	Management revision						
-	6.5	6	Does the system established for the management of information allow for the "accumulation" of knowledge about key aspects for the organization?	Data base for the management of knowledge						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final value for the subclause = sum of all columns / No. of applicable questions

Subclause 6.6: SUPPLIERS AND PARTNERSHIPS									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
-	6.6	1 Has Management established some system of two-way communication that facilitates rapid problem-solving with suppliers?	Appointment of persons in charge and establishment of contact telephone numbers. Computer applications that permit rapid communication between both organizations						
-	6.6	2 Is the service rendered analyzed?	Standards of service, follow-up and communication with the suppliers having the capacity to deliver compliant products						
-	6.6	3 Are suppliers made to involve themselves in customer needs and expectations?	Information / training on new products and meetings with suppliers to analyze customer complaints and satisfaction						
-	6.6	4 Does Management carry out actions with suppliers that make it possible to eliminate redundant verifications as well as to encourage suppliers to implement improvement programs?	Quality policies, concerted quality and other similar agreements and cooperation with providers in the validation of process capacities						
-	6.6	5 Are suppliers given support in the adoption of new technologies and working methods?	Technical and organizational assessment and economic support for the incorporation of new technologies						
-	6.6	6 Are suppliers' and business partners' efforts and achievements evaluated, acknowledged and rewarded?	Suppliers' participation in the organization's profits (rebates, etc.), reduction of payment timeliness and the organization of congresses / meetings in which they are informed of business perspectives, new products, better suppliers and business partners, etc						
-	6.6	7 Are suppliers made to involve themselves in the organization's design and development activities in order to share know-how and effectively, efficiently improve execution processes and delivery of compliant products?	Meetings or working groups held with suppliers / business partners						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final value for the subclause = sum of all columns / No. of applicable questions

Subclause 6.7: NATURAL RESOURCES										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
-	6.7	1	Is the availability or substitution of natural resources planned for the purpose of preventing or minimizing their negative effects on the organization's performance?	Contingency plans to ensure the availability or substitution of these resources, standards of action, revision of availability and substitution of these resources						
-	6.7	2	Are natural resources used in accordance with the regulations in force?	Fines, complaints, demands and control over environmental resources						
-	6.7	3	Are alternatives to the use of natural resources evaluated?	Studies of costs and analysis of technologies						
-	6.7	4	Are non-renewable resources reused and recycled?	Environmental policies and evidence of recycling						
-	6.7	5	Is the risk associated to the use of natural resources in all the phases of the product life cycle calculated?	Consumption measurement and savings plans						
-	6.7	6	Are the environmental aspects associated to the use of natural resources such as water, gas, energy, etc. evaluated?	Report on environmental impact						
-	6.7	7	Are customers informed of the possible risks in the event that appropriate alternatives for certain natural resources are not available, in case these may be scarce, and are they sensitized regarding alternative solutions that would produce less impact on the environment?	Minutes of meetings, other communications, project plans and alternative proposals						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final value for the subclause = sum of all columns / No. of applicable questions													
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Subclause 7.3: DESIGN AND DEVELOPMENT									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
7.3.1	7.3.1	1 Does the organization determine the stages of design and development and the revision, verification, validation and persons responsible for each stage?	There is a format for design and development planning and monitoring in which stages are defined <i>a priori</i> along with the revisions, verifications and validations necessary for each stage and their specific authors and persons in charge						
7.3.1	7.3.1	2 Does the organization plan and monitor the organization of the design and development of all its products?	Identification of any product with its analysis of design and development by the organization, and the drawing up of a report on the planning and control of the design and development associated with all of its products						
	7.3.1	3 Are the risks and effects of possible product or process design flaws evaluated?	Design revisions, FMEA						
7.3.2	7.3.2	4 Does the design and development of products take account of the needs and expectations of all interested parties?	Existence of a specific heading on the needs and expectations of customers and interested parties (customers, suppliers, users, persons from the organization) in the planning and control report						
7.3.2	7.3.2	5 Are input elements for design and development determined and recorded?	Existence of a specific heading on input elements (needs and expectations of customers, suppliers and users; regulations, standards, policies and objectives, previous experiences, existing products, etc.) in the planning and control report						
7.3.2	7.3.2	6 Have the input elements been formulated such that the product is verified and validated effectively and efficiently?	Evidence of verification that the input elements are formulated in such a manner as to enable verification that design and development results satisfy the input elements using the least possible resources (product, process, materials and test specifications; training and purchase requirements; user information, etc.)						
7.3.3	7.3.2	7 Do the results of design and development permit verification with respect to input elements?	Evidence of verification that the input elements are formulated in such a manner as to enable verification that design and development results satisfy the input elements using the least possible resources (product, process, materials and test specifications; training and purchase requirements; user information, etc.)						
7.3.3	7.3.2	8 Are design and development results approved before passing on to the next phase?	There is a format for design and development monitoring in which this is verified						

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		Subclause 7.4: PURCHASING					RATING				
							No.				
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.		
				1	2	3	4	5			
7.4.1	7.4.1	1 Has a purchase process been defined to satisfy the needs of all the interested parties?	The persons from the organization use the process with a high degree of satisfaction; there is a very small percentage of non-conforming purchased products; products with a limited environmental impact are purchased at a reasonable cost, etc								
7.4.1	7.4.1	2 Are all requirements that may affect the quality of the products supplied defined beforehand?	Product specifications, costs, subsequent verifications, special processes to undertake, stock rotation, cost studies on storage and application of some warehousing technique (JIT, FIFO, etc.), product conservation, etc								
7.4.1	7.4.2	3 Has top management established criteria for the processes of selection, evaluation, recognition and revalidation of suppliers, and are these adequately managed?	Instructions and recording of suppliers. List of suppliers and their classifications, periodic meetings for the analysis of detected incidents, study of trends and market developments in search of more competitive suppliers and a descriptive document of the purchasing process and its level of compliance								
7.4.1	7.4.2	4 Are criteria as well as products that are purchased and services that are contracted revised and updated to ensure their conformity with specifications?	Evolution of changes in acceptance criteria, purchasing process, purchases or products								
7.4.1	7.4.2	5 Is the capacity of suppliers to provide the required products evaluated?	Analysis of historical service data, joint development of organization / process and product supplier, concerted quality agreements and other strategies with suppliers, list of competitors, results of audits done on suppliers, suppliers' financial capacity, minutes or reports of meetings with suppliers in relation to agreements, abridged improvement plans, etc								
7.4.1	7.4.2	6 Are suppliers made to involve themselves in process and innovation improvement working groups, and is there a system of acknowledgment for suppliers?	Minutes of meetings with suppliers for the development of new products and technologies and reports on the resulting improvement plans. Minutes of the internal board and proposals for acknowledgments								

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Subclause 7.5: PRODUCTION AND SERVICE PROVISION									
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
				1	2	3	4	5	
7.5.1	7.5.1	Are the processes for the manufacture of the product or the rendering of the service monitored in such a way as to result in the compliance of requirements as well as the obtention of benefits for all the interested parties?	Documents and records of process control in production or service rendering. Records that give evidence of compliance of requirements or the satisfaction of the interested parties owing to the productive process						
7.5.2	7.5.1	Is there a process validating system (that only applies in these cases in which no verification activities, such as inspections and testing, may be done) that includes the criteria applicable to equipment, personnel, environmental conditions and any other factor that may affect quality, and is there a specific documentation for it?	Validation documents and records						
7.5.2	7.5.1	Have the requirements of customers and the other parties interested in all the processes above, from which inputs to manufacturing processes derive, been taken into account?	Documentation of processes, personnel suggestions, non-compliances or environmental complaints, etc						
7.5.2	7.5.1	Is the information deriving from the monitoring and measurement of manufacturing processes used for effectiveness and efficiency improvement?	Measures deriving from the monitoring and measurement of processes, such as waste reduction, personnel training, infrastructural improvement, prevention of problems						
7.5.3	7.5.2	Are the identification and traceability of products or services used to track their status or history employed as a tool for preventing errors?	Labelling, marking, identification of products / services, corrective and preventive actions						
7.5.4	7.5.3	Does the organization have any control over the property of the customer and other interested parties?	Records of inspections upon the acceptance of products that are the property of interested parties, adequate identification, conservation and prevention of incorrect use						
7.5.5	7.5.4	Has a process been implemented to avoid damage, deterioration or misuse during suppliers' delivery, handling, packaging, internal storage and conservation and the delivery of the product to the customer?	Procedure and records of the process						
7.5.5	7.5.4	Have the necessary resources to avoid damage, deterioration or misuse throughout the product's life cycle been identified and communicated to the interested parties?	Instructions for use, conservation, and disposal of the product after its useful life						

No. of boxes scored	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Value assigned to each box													
Points obtained per column (no. of boxes x value)													

Final value for the subclause = sum of all columns / No. of applicable questions

Subclause 8.1: MEASUREMENT, ANALYSES AND IMPROVEMENT. GENERAL GUIDANCE

9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
8.1.	8.1.1	1	Is continual improvement an organizational purpose integrated into the organization and inculcated from the highest level of management?	Quality policies, quality strategy and quality objectives						
8.1.	8.1.1	2	Does the organization establish systems for measurement and analysis to ensure its performance and that of the interested parties?	Evaluation of products, services and the satisfaction of customers, employees and other interested parties						
8.1.	8.1.1	3	Does management periodically re-establish and revise the parameters to measure on the basis of their usefulness in decision making?	General objectives of the organization, quality criteria / production requirements and balanced Management scorecard						
8.1.	8.1.2	4	Is there a communication system that permits the knowledge and use of the results of the measurements made for any part of the organization that may benefit from it?	Internal communications strategy and Management communiqués						
-	8.1.2	5	Is the effectiveness and efficiency of this communication revised in turn?	Revisions made that are on the record						
-	8.1.2	6	Are these documented in a plan that may be periodically revised, and which includes the measurements projected, their frequency, and objectives or annual goals with a vision of continual improvement?	Quality plan						
-	8.1.2	7	Is objective measurement given impulse by Management as a measure of effectiveness and efficiency and as part of the organization's culture for the continual improvement of all activities and results, even participating in its cascaded definition?	Management communiqués, seminars, courses held with the participation of Management and managers, minutes of the management committee and minutes of the quality committee						
-	8.1.2	8	Is the periodic character of measurements taken into consideration in assessing the relationship between obtainable advantages and the degree of difficulty of the measurements?	Quality committee minutes and quality plan revisions held under these criteria						
-	8.1.2	9	Are measurements contrasted with objectives or goals that are variable in time, achievable but ambitious for the continual improvement of the activities and the results of the organization?	Quality indicators (history) and annual goals						
-	8.1.2	10	Are the results of the measurements taken into consideration in decision making?	Minutes of the management committee and the quality committee						
-	8.1.2	11	Are the results of the measurements in the evolution of management and employee performance taken into account?	Career plans and criteria followed in evaluations and career plans						

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9001		9004		QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.
						1	2	3	4	5	
8.2.1	8.2.1.2	1	Are customer expectations verified with respect to the products and services of the organization?	A list of expectations that is periodically updated							
8.2.1	8.2.1.2	2	Is customer satisfaction with the products and services of the organization verified?	Results of surveys / interviews / meetings with customers and sectorial studies							
8.2.1	8.2.1.2	3	Are customer claims monitored in a centralized way?	Number of claims, their causes and the results of measures taken in view of each claim							
8.2.1	8.2.1.2	4	Is customer information (satisfaction, claims, suggestions) used as a source for improvement?	Use of this information in the design or modification of products							
-	8.2.4	5	Are owners' / shareholders' expectations verified?	Method for finding out and gathering people's expectations							
-	8.2.4	6	Are key suppliers' expectations verified?	Method for finding out and gathering people's expectations							
-	8.2.4	7	Are employee expectations verified?	Method for finding out and gathering people's expectations							
-	8.2.4	8	Are the expectations of the community in which the company operates verified?	Method for finding out and gathering people's expectations							
-	8.2.4	9	Are the expectations of interested parties taken into account in the organization's processes?	See process input elements and results							
-	8.2.1.3	10	Is there an effective and efficient procedure of internal audits to evaluate the strengths and weaknesses of the quality management system?	Reports on internal audits							
8.2.2	8.2.1.3	11	Does Management ensure that measures are taken in response to the results of internal audits?	Measures taken							
-	8.2.1.4	12	Are the costs of quality and non-quality compiled and evaluated, and is action taken in consequence?	Reports of total cost of quality and non-quality and improvement measures							
8.2.3	8.2.1.5	13	Does Management directly participate in the self-assessment of the quality management system using some kind of method?	Number of managers participating, method of self-assessment used and list of improvement measures approved by Management							
8.2.3	8.2.2	14	Are measurements carried out to assess process performance?	Files on process indicators, monitoring graphs in the evaluation of indicators							
8.2.3	8.2.2	15	Are these measurements used in the management and improvement of processes?	Measures deriving from the monitoring and measurement of processes							

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Subclause 8.2: MEASUREMENT AND MONITORING (End)										
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT					RATING No.	
				1	2	3	4	5		
8.2.4	8.2.3	16 Are measurements and monitoring of the product characteristics carried out, and is action taken in consequence?	Records of monitoring and measurement of the product and actions taken on the basis of the measurements							
8.2.4	8.2.3	17 Does the organization revise the methods used in measuring its products, so as to consider any improvement opportunities deriving there from?	Records of revision and improvement opportunities found							

No. of boxes scored	1	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5	
Value assigned to each box	1	1.4	1.7	2	2.4	2.7	3	3.4	3.7	4	4.4	4.7	5
Points obtained per column (no. of boxes x value)													
Final value for the subclause = sum of all columns / No. of applicable questions													

Subclause 8.3: CONTROL OF NONCONFORMITY							RATING No.			
9001	9004	QUESTIONS	EXAMPLES OF EVIDENCE	RESULT						
				1	2	3		4	5	
8.3	8.3.1	1	Is there a documented procedure relating to controls, responsibilities and authorities regarding the treatment of nonconforming products?	Procedure for nonconformities and the treatment of nonconforming products Procedures for corrective measures						
8.3	8.3.1	2	In the event that non-conforming products are detected and there is a doubt that such have been turned over to the customer, are measures decided upon to inform and / or take back the product?	Procedure for dealing with nonconforming products and product tracking system						
8.3	8.3.1	3	Are corrected nonconformities recorded in the normal course of work?	Records of nonconformities, corrective and preventive measures and procedures for nonconformities						
8.3	8.3.2	4	After detecting a non-conformity, is there a system to follow with reference to the product or process?	Procedure for dealing with nonconforming products						
8.3	8.3.2	5	Is the identification of nonconforming products controlled to avoid their unintended use?	Procedure for dealing with nonconforming products						
8.3	8.3.2	6	Are the nonconformities of key processes, strategic processes and support processes identified?	Records of nonconformities and corrective and preventive measures						
8.3	8.3.1	7	Is there a record of non-compliances along with their disposal? Is this information used as a source for process improvement?	Record of nonconformities and corrective and preventive measures, report on revision by Management and record of the monitoring of nonconformities and corrective and preventive measures						
8.3	8.3.1	8	In the case of recovered products, are the phases and controls that are carried out documented?	Procedure for dealing with nonconforming products and records of recovered products						

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ANNEX F (Informative)

DETAILED EVALUATION RESULTS SHEET

DONE BY:		DATE:														
		MATURITY LEVEL														
		1			2			3			4			5		
		RATING ASSIGNED	1 - 1.3	1.4 - 1.6	1.7 - 1.9	2 - 2.3	2.4 - 2.6	2.7 - 2.9	3 - 3.3	3.4 - 3.6	3.7 - 3.9	4 - 4.3	4.4 - 4.6	4.7 - 4.9	5	
QUALITY SYSTEM	4.1	Managing systems and processes														Mean:
	4.2	Documentation														
MANAGEMENT	5.1	Management responsibility. General guidance														Mean:
	5.2	Needs and expectations of interested parties														
	5.3	Quality policy														
	5.4	Planning														
	5.5	Responsibility, authority and communication														
	5.6	Management review														
RESOURCES	6.1	Resource management														Mean:
	6.2	People														
	6.3	Infrastructure														
	6.4	Work environment														
	6.5	Information														
	6.6	Suppliers and partnerships														
	6.7	Natural resources														
	6.8	Financial resources														
MANUFACTURE	7.1	Product realization														Mean:
	7.2	Processes related to interested parties														
	7.3	Design and development														
	7.4	Purchasing														
	7.5	Production and service provision														
	7.6	Control of measuring and monitoring devices														
ANALYSIS AND IMPROVEMENT	8.1	Measurement, analysis and improvement														Mean:
	8.2	Measurement and monitoring														
	8.3	Control of nonconformity														
	8.4	Analysis of data														
	8.5	Improvement														
Points obtained per column																
FINAL RESULT = sum of all columns / No. of applicable subclauses																

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