ISO 9001 Certification Gap Analysis: Case Study of a Libyan Organization

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Abstract — **This work aims to carry out an analytical study of a Libyan organization, analyzing its management system then comparing it with international standard ISO 9001:2000, showing the differences and setting-out improvements of work program taking into consideration the following:**

- **Assessment of the existing system of the selected organization.**
- **Finding-out the weak areas in the QMS of the selected organization.**
- **Setting-out necessary procedures needed for the system improvement showing lack of manpower as well as work procedure.**
- **Identify the difference ratio existing between the organization and the requirements of the international standard.**

This work is expected to enable and improve the selected organization and to qualify it in order to obtain the ISO 9001:2000 certification, presuming that the results and comments have been followed precisely.

Index Terms: **ISO 9001; quality management system.**

I. INTRODUCTION

In the field of integrated management systems for quality, environment and occupational health and safety, several studies and investigations of other researchers were written before and during this study, however, in this study, the focus is on the quality management system (QMS). The QMS can be seen as a system consisting of all the parts and components of an organization dealing with the quality of processes and products. Many organizations have adopted quality management systems developed by the International Organization on standardization (ISO) with the aim of ensuring that quality systems are implemented, leading to continuous improvement in performance and customer satisfaction. ISO management systems, regardless of their release since 1987, have not been undertaken for any research in Libya till 2000's.

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Quality management systems certification is still rising and the literature has suggested many reasons as to why companies seek ISO certification [1], [2] and [3] Improving the efficiency of the quality system appears to be the leading motivator for seeking ISO.

Reference [4] concludes that if ISO 9001 standard is correctly implemented and understood, as opposed to being used just as a marketing and promotional tool, there seem to be significant benefits derived for the organizations that do so both internal and external ones.

In the few years since the turn of the century, the quality movement seems to have matured beyond total quality, new quality systems have evolved from the foundation of Deming, Juran and early Japanese practitioners of quality, and quality has moved beyond manufacturing into service, healthcare, education and government sectors [5].

II. LITERATURE

For many years organizations have been concerned with quality. However, only in the past three decades have they really begun to implement specific measures to achieve an advanced rate of quality in order to achieve competitive advantage [6], [7] and [8]. Quality is vital to the survival of every enterprise. To achieve and sustain the competitiveness; it is principally dependent on delivering advanced quality of products/services to customers [9] and [10]. The establishment of a properly implemented quality management system (QMS) has stood as a system that organizations pursued to ensure quality for all the functional areas including marketing, production, finance and human resources [11] and [12].

Quality Management has gone through several stages of evolvement. Kenya Bureau of Standards [13] outlines those stages as quality inspection stage, quality control stage, quality assurance stage and total quality management stage. Quality management system is associated with the quality assurance stage which focuses on system quality. Implementing a QMS means an organization has to set up a system for controlling its processes which has to be audited by second and third parties to ensure its adequacy. This stage is characterized by among other things the use of quality manuals, procedures, work instructions etc.

The need for International Standards is very important as more organizations operate in the global economy by selling or buying products and services from sources outside their domestic market (ISO 2009). The ISO 9000 family of international quality management standards and guidelines has earned a global reputation as a basis for establishing effective and efficient quality management systems. Reference [14] have identified the mission of ISO as being to develop, promote and publish international standards to which organizations commit themselves voluntarily and its mandate as promotion of the development of international standards to facilitate exchange of goods and services worldwide. As a result ISO has developed several quality management standards that are the basis of QMS. The ISO publications address the implementation of ISO 9001- based quality management systems for small firms in general (ISO, 2002). The QMS is the collection of processes, documents, resources, and monitoring systems that direct the work of an organization regarding product and service quality. The organization needs to establish, document, carry out, and maintain this system to meet the requirements of ISO 9001:2000 [15].

Reference [16] asserted that in order to improve the quality the organizations have developed some standard processes in which everyone from employees to customers would be able to participate to improve the quality. Application of a QMS is anticipated to deliver benefits to the organization implementing it, its customers and employees. The ISO 9001 standard generates benefits related to customer satisfaction, such as fewer complaints and improved customer satisfaction, improvement in staff management issues, such as more training for employees and improved efficiency, documentation and clear knowledge of tasks by employees. These results indicate that most firms experience improvement in these issues, due to the fact that the ISO 9001 standard allows them to reduce errors and rework, decrease costs and improve the management of the firm [17]. Reference [18] have acknowledged various benefits that can accrue from Quality Systems that include system efficiency, customer satisfaction, morale of workforce, reduced complaints and costs and reduced time for finishing tasks. In addition some investigators show a positive relationship between certification and results [19], and [20].

III. CASE STUDY

The study at hand investigates applying gap analysis of Ghan Water Factory, the factory was established in Garian which is located 70 km to the South East of the Libyan capital Tripoli at the Ghan valley water dam in 2002. The project was intended as a business investment to save and invest in the natural water resources of the country in order to produce high quality natural healthy drinking water in an easily accessible cost effective and commercially competitive way. The main objectives of the project include:

- Produce high quality bottled water.
- Satisfy customer requirements and exceed their expectations.
- Produce plastic performs for factory as well as other similar plants.

The plant produces two types of water bottles; one in the size of 1.5 liters and the other is of the 0.33 liter. It has the facility and capability to produce different bottle sizes depending on the market needs and this can be done by changing the forms used to produce the plastic performs and through the bottle blowing system. The company has been in operation since 2005 and employs approximately 57 people and its' design capacity is 12,000 units per hour.

Plant policy aims to produce and market bottled water meeting customer satisfaction, these policy is applied through:

- Application of international specification standard ISO 9001:2000.
- Each employee to be responsible for their quality of work.
- The company committed to continually improve its QMS, its products, services and processes to ensure meeting customer requirements and expectations.
- To produce plastic perform (perform is primary form of the bottles consisting of a sealed tube ends with the tube cap spiral produces from PET food grade).

ISO 9001 Gap Analysis and Results

A viable step in any organization is to compare the current QMS in use to the requirements of ISO 9001:2000 standard, this is most commonly called Gap Analysis. GAP analysis compares the actual performance with the potential performance [23]. An organization will define the factors that describe its current state, list down the factors needed to reach its target state and then plan on how to fill the gap between the two states [24]. The first step is to introduce Gap Analysis Checklist [25]. This is a list of requirements in the standard which is written in question format. A Checklist is used to compare QMS in place with the standard requirements, a well designed checklist will provide the user recommendations of what documents to look at, what will meet the requirements and other guidance on auditing to the standard. The checklist should also give the auditor a specific place to document what was observed that did not meet the standard.

When a checklist is used, the objective would be to generate tasks for the implementation planned phase. For each section of the standard, a list of items that need to be implemented, redesigned or documented would need to be ready. Of course the auditor needs to be aware of information required to be documented on the checklist. The following is needed to prepare checklists:

- Notes explaining what practices do not meet the standard
- Notes on where additional documentation is required
- Other observations relating to compliance with standard

- Auditors must be familiar with the standard in order to perform an effective audit

After analyzing and summarizing all data and documents related and comparing them with requirements of QMS (ISO 9000:2000) and series of meeting with the heads of departments, the following results have been reached and are shown in the Table [I] below:

Table 1. Ghan Factory Gap Analysis Results

Element: A-1 Policy & Strategic Objectives		**Present Compliance: 8/10 = 80%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken
A.1.1: Definition of QMS Policy	4/5 = 80%		
Produce a QMS Policy		To document policy in Arabic & English in a separate document	Management & all Departments
Define Commitment of QMS Policy		Risk identification and risk management to be specifically documented	Management & all Departments
A1.2 Promotion of QMS Policy	4/5 = 80%		
Document QMS Policy		Wider circulation & through QMS Bulletin Board, management committee meetings, etc.	Management & all Departments
Document QMS Policy and Objectives		To relate and connect QMS objectives with its business and risks	Management & all Departments

Element: B-1: Legal and other Requirements		**Present Compliance: 7/10 = 70%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
B-.1. Identification and access of legal and other QMS requirements	4/5 = 80%	Refer to Conclusions and Recommendations	Management & legal Department
Establish and maintain a procedure to identify applicable regulations etc. as the basis of activities that are performed and authorizations that are necessary for the purpose		=======	All Relevant Departments/Divisions
Prepare and a organize formal record of legislative framework		======	====
Organize a list of authorizations and relevant requirements		=====	====
Implementation of procedures to ensure respect and control of requirements		======	====
Make available to the line management the interpretation of the applicable laws and rules and outline procedures to be followed		=====	Management & all Departments
B-1.2. Identify, make available and update the legal and other QMS requirements and the means to ensure compliance	3/5 = 60%		
Establish procedures for systematic identification and review of variations of laws, rules, standards, etc.		Refer to Conclusions and Recommendations	Legal Department
Maintain an appropriate register of the applicable legislation		====	====

Element: B-2: Quality Objectives		**Present Compliance: 11/ = 73%**	
Sub-element	Present compliance	Comments & recommendations to bridge the gap	Action to be taken by
B-2.1 Identification and definition of QMS objectives and targets	4/5 = 80%		
Establish and maintain procedures for defining detailed QMS objectives and performance criteria at relevant levels of the organization		Refer to Conclusions and Recommendations	Management & all Departments
B-2.2 Definition and selection of performance indicators and criteria	4/5 = 80%		
Establish a procedure to set performance criteria activities and tasks		Refer to Conclusions and Recommendations	All relevant Departments & Divisions
B-2.2 Review QMS objectives and performance criteria	3/5 = 60%		
Review periodically the objectives and performance standards criteria in the perspective of continual improvement and further compliance with growing organization expectations		Refer to Conclusions and Recommendations	Management & all Departments

Element: B-3: QMS planning		**Present compliance: 3/5 = 60%**	
Sub-element	Present compliance	Comments & Recommendations to bridge the gap	Action to be taken by
B-3.1 QMS programs, objectives and targets	3/5 = 60%		
Establish and maintain within the organization overall work programs/plans for achieving QMS objectives and targets		Refer to Conclusions and Recommendations	Management & all Departments
Contractors QMS program		Refer to Conclusions and Recommendations	Management & all Departments

Element: C-1 Management responsibilities, management representatives, resources		**Present compliance: 8/15 = 53%**	
Sub-element	Present compliance	Comments & recommendations to bridge the gap	Action to be taken by
C-1.1 Definition of QMS organizational structure	3/5 = 60%	Management decision	Management Committee
Define organizational structure		Refer to Conclusions and Recommendations	Management & all Departments
Identify roles and responsibilities of QMS organizational structure			
C-1.2 Documentation and communication of QMS responsibilities	2/5 = 40%		
Document QMS roles and responsibilities		Refer to Conclusions and Recommendations	Management & all Departments
Include QMS responsibilities in job descriptions		=====	Employees relations department
Setup a QMS communication system		=====	Management & all Departments
C-1.3 Allocation of QMS resources	3/5 = 60%		
Allocate necessary QMS resources		Refer to Conclusions and Recommendations	Management & all Departments

Element: C-2 Competence, Awareness & Training		**Present Compliance: 10/20 = 50%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken
C.2.1: Identification of Competence Requirements.	3/5 = 60%		
From the analysis of activities and the evaluation of hazards and consequences define the positions with critical aspects related to QMS activities		Refer to Conclusions and Recommendations	All Relevant Departments/Divisions
Identification of competence of all personnel with specific requirements for personnel to which QMS critical activities and tasks are assigned.		= = = = =	All Departments
C-2.2 Definition of necessity for training and supply	2/5 = 40%		
Define required training for the operating personnel.		Refer to Conclusions and Recommendations	Training & Development Dept. & all Departments
Analysis of training requirements and inclusion in the budget.		= = = = =	= = = = =
Planning of training activities		= = = = =	= = = = =
Management of training courses		= = = = =	= = = = =
Recording of personnel qualification and of training activities provided.		= = = = =	= = = = =
C-2.3. Personnel competence appraisal.	2/5 = 40%		
Establish procedure for recruitment and selection of personnel for activities with QMS competence requirements (company and contractor)		Refer to Conclusions and Recommendations	Employees Relations Departments & Relevant Departments.
Technical competence appraisal.		= = = = =	= = = = =
QMS competence appraisal.		= = = = =	All Departments
Global.		= = = = =	= = = = =
Recording.		= = = = =	Training & Development Departments & all Departments
C-2.4. Content of courses (General)	3/5 = 60%		
Content of QMS and professional courses for nationals and expatriates.		Refer to Conclusions and Recommendations	Training & Development Department

Element: C-3: Communication		**Present Compliance: 6/10 = 60%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
C-3.1. Communication with the company and Contractors	3/5 = 60%		
QMS Communication Management		Refer to Conclusions and Recommendations	All Relevant Departments/Divisions
Workforce involvement.		= = = = =	= = = = =
Communication with Contractors.		= = = = =	All Departments
C-3.2. Communication with External Parties.	3/5 = 60%		
Communication with interested parties		Refer to Conclusions and Recommendations	Management

Element: C-4: Documentation and Its Control		**Present Compliance: 5/10 = 50%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
C-4.1. Implementation of QMS Information System.	2/5 = 40%		
Identify QMS information needs		Refer to Conclusions and Recommendations	Management, Employees & Relation Department & all Relevant Departments
Identify & classify QMS applicable documentation.		======	====
Implement QMS documentation system		=====	====
Establish requirements for QMS documentation.		=====	====
Define responsibilities for documentation management.		=====	====
Address QMS document contents.		=====	====
C-4.2. QMS Documentation Control.	3/5 = 60%		
Review QMS documentation system.		Refer to Conclusions and Recommendations	Management

Element: C-5: Operational Control		**Present Compliance: 15/20 = 75%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
C-5.1. Planning the Operational Control. Conducting activities and tasks according to a procedures and work instruction developed at the planning stage or earlier, in accordance with QMS Policy	4/5 = 80%	O.K.	
C-5.2. Design and Constructions. Define, plan and implement structured control activities during the project engineering design, in order to ensure the respect and compliance with QMS Policy and standards. procurement	4/5 = 80%	Refer to Conclusions and Recommendations	Engineering & Project Department & all Relevant Departments
Define, plan and implement structured control activities during the procurement and construction phase, in order to ensure the respect and compliance with QMS Policy and standards.		=====	====
C-5.3. Operations and Maintenance. Establish and maintaining documented procedures that stipulate operating criteria to cover situations where their absence could leave to deviations from the organization policies and the objectives	4/5 = 80%	Refer to Conclusions and Recommendations	All Relevant Departments/Divisions
Establish and maintain procedures to plan and execute preventative maintenance in order to ensure plant and equipment operations under specific conditions in compliance with QMS Policy and Company standards.		=====	====
C-5.4. Management of Change and Decommissioning. Formally assess, manage, document and approve QMS and other impacts of temporary and permanent change.	3/5 = 60%	Refer to Conclusions and Recommendations	All Relevant Departments/Divisions

Element: C-6: Procurement and Contractors Control		**Present Compliance: 12/15 = 80%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
C-6.1. Qualification of Contractors and Suppliers	4/5 = 80%		
Establish a procedure for qualification of contractors and suppliers		Refer to Conclusions and Recommendations	Management.
Perform a pre-qualification of contractors and suppliers		Refer to Conclusions and Recommendations	Engineering & project dept. and all relevant dept.
Maintained an approval list of a pre-qualified contractor.		O.K.	
C-6.2. Selection of contractors and suppliers	4/5 = 80%		
Establish QMS requirements to be used in procurement and necessary support activities		Refer to Conclusions and Recommendations	Engineering & Project Dept. & all onshore relevant Dept.'s
C-6.3. Control of contractors and suppliers	4/5 = 80%		
Participate in the assignment stages of contract.		Refer to Conclusions and Recommendations	Management, engineering & project dept.'s and all relevant dept.'s
Distribute QMS support documentation to contractors.		=====	With engineering & project dept.'s and all relevant dept.'s/div.'s
Company and contractor's QMS planning of the activities.		=====	====
Perform a QMS audits and inspections on contractor activities		=====	====
Assess contractor's QMS performances.		=====	====
Report contractor's QMS performances.		=====	====
Feedback collection on contractor's QMS performance.		=====	====

Element: D-1: Monitoring and Measurement		**Present Compliance: 10/15 = 66%**	
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
D-1.1 Monitoring of activities and operations	4/5 = 80%		
Establish a procedure for monitoring activities and operations.		Refer to Conclusions and Recommendations	All relevant dept.'s/div's.
Plan monitoring activities.		=====	====
Carry out monitoring activities		=====	====
Calibrate and maintain monitoring equipment.		=====	====
Record the results of monitoring activities.		=====	====
D-1.2. Measurement of QMS performance.	3/5 = 60%		
Develop a set of key performance indicators.		Refer to Conclusions and Recommendations	All relevant dept.'s/div's
Measure regularly QMS performance.		=====	====
Collect Measures to assess QMS performance.		=====	====
D-1.3. Verification of compliance	3/6 = 60%		
Establish a procedure to verify the conformance to the applicable rules		Refer to Conclusions and Recommendations	Legal dept. with all relevant dept.'s
Determine the compliance to the applicable rules		=====	====
Report the results of monitoring activities.		=====	All relevant dept.'s/div's

Element: D-2: Non-Conformance, Corrective and Preventive Actions		**Present Compliance: 8/15 = 53%**	
Sub-element	**Present Compliance**	**Comments & Recommendations to Bridge the Gap**	**Action to be taken by**
D-2.1 Management of non-conforming situations.	3/5 = 60%		
Establish responsibilities and authorities in management of non-conforming situations.		Refer to Conclusions and Recommendations	Management, employees & relation dept. & all relevant dept.'s
Establish a procedure for the management of non-conforming situations		=====	All relevant dept.'s/div's
Maintain records on non-conforming situations and on actions undertaken.		=====	====
Share lessons learnt across personnel		=====	====
D-2.2. Implementation of corrective actions	3/5 = 60%		
Investigate causes of incidents		Refer to Conclusions and Recommendations	All relevant dept.'s/div's
Plan suitable corrective actions		Refer to Conclusions and Recommendations	All relevant dept.'s/div's
Review proposed corrective actions		=====	====
Implement approved remedial actions		=====	====
D-2.3. Monitoring of corrective actions	2/5 = 40%		
Apply controls to monitor corrective actions implementation, their effectiveness		Refer to Conclusions and Recommendations	All relevant dept.'s/div's
Record status of corrective actions.		=====	====
Verify the effectiveness of corrective actions.		=====	=====

Element: D-3: Internal Audit.	**Present Compliance: 9/20 = 45%**		
Sub-element	**Present Compliance**	**Comments & Recommendations to Bridge the Gap**	**Action to be taken by**
D-3.1 Auditing Planning.	2/5 = 40%		
Establish a QMS Audit Plan.		Refer to Conclusions and Recommendations	Management.
Establish a procedure for auditing		=====	=====
Define responsibilities in the audit process		=====	====
Provide adequate training for auditors		=====	Training & Development dept.
Prepare internal audit report		=====	Management.
D3.2. Internal auditing	2/5 = 40%		
Conduct objective and periodic internal audits.		Refer to Conclusions and Recommendations	All relevant dept.'s
Identify audit team members.		=====	====
Plan internal audit activities.		=====	====
Carry out internal audit activities.		=====	====
Prepare internal audit reports.		=====	====
D-3.3. Audit Contractors/Suppliers.	2/5 = 40%		
Conduct audits at contractors /suppliers when necessary.		Refer to Conclusions and Recommendations	All relevant dept.'s/div's
Identify audit tem members.		=====	====
Plan audit activities		=====	====
Evaluate the QMS system for contractors/suppliers		=====	====
Prepare audit report		=====	====
D3.4. Management of corrective actions.	3/5 = 60%		
Implement corrective actions.		Refer to Conclusions and Recommendations	Management and all relevant dept.'s
Monitor corrective actions.		=====	====
Record status of corrective actions.		=====	====
Review the effectiveness of corrective actions.		=====	====

Element: E-1: Management Review.	**Present Compliance: 4/10 = 40%**		
Sub-element	Present Compliance	Comments & Recommendations to Bridge the Gap	Action to be taken by
E-1.1 Review Planning and Documentation preparation	2/5 = 40%		
Review Planning		Refer to Conclusions and Recommendations	Management. Committee
QMS review committee		=====	=====
Collection of documentation		=====	Management. Committee
E-1.2. Management Review Meeting	2/5 = 40%		
Documentation evaluation.		Refer to Conclusions and Recommendations	Management. Committee
Proposal approval and meeting close-up		=====	=====

IV. CONCLUSIONS AND RECOMMENDATIONS

A. Conclusions

Based on the gap analysis results, it can be concluded that the company showed nearly 80% compliance with the QMS requirements in policy and strategic objectives. This percentage is quite high as the company has the basic QMS requirements including quality manual, work instructions and operational procedures. Approximately 70% compliance with QMS in legal and regulatory requirements, a 73% compliance with QMS quality objectives, a 60% compliance with QMS in planning, a 53% compliance with QMS in management policy, a 50% compliance with QMS in training awareness and competence, a 60% compliance with QMS communication, a 50% compliance with QMS in documentation and its control, a 75% compliance with QMS in operational control, a 80% compliance with QMS in procurement and contracts, a 66% compliance with QMS in monitoring and measurement, a 53% compliance with QMS in non-conformance, corrective & preventive actions, a 45% compliance with QMS in internal auditing, and 40% compliance with QMS in management review. The overall compliance of Ghan water bottling company with QMS was 61%. This percentage is quite low due to the lack of implementation of QMS, and the awareness of its employees about QMS.

Even though the percentages are low, based on ISO 9001:2000 preliminary gap analysis checklist, the

company is in a position to implement QMS (ISO 9001:2000) [24].

B. Recommendations

Based on the gap analysis the company should:

A. Policy

A.1 Define and document QMS policy(ies) and clearly state its overall QMS strategic objectives

B. Planning

B.1 Update all legal and other QMS requirements and the means to ensure compliance

B.2 Establish detailed QMS objectives and performance criteria at relevant levels

B3. Establish and maintain QMS program(s) for achieving the objectives and performing criteria

C. Implementation

C.1 Define, document and communicate the roles, responsibilities, authorities, accountabilities and interrelations of personnel who manage, perform and verify activities having it's effect on the activities, facilities and processes.

provide the necessary resources (human, technical competence, technology, financial) to actualize and control the QMS.

C.2 Ensure all personnel, both Organization's and Contractor's, are competent, trained and are aware of implications of their activities for QMS purposes.

C.3 Ensure communication of QMS information, consistent with Policy and with applicable legislation and regulation.

Ensure reception and response to communications from interested parties.

C.4 Establish and maintain appropriate information to describe the core elements of the QMS and their interaction and to provide reference to related supporting documentation.

C.5 Plan operational control activities to include all aspects of the exploration and development cycle (including maintenance), in order to endure that such activities are carried out under specified conditions to manage identified risks.

C.6 Evaluate and select contractors based on their ability to meet the specified requirements and those of reference standards, and to operate a QMS that is consistent with the requirements and provisions of the reference models and that is compatible with the QMS of the organization.

Define and implement controls that ensure contractors confirm to specified requirements and to those of reference standards.

D. Monitoring

D.1 Routinely monitor and measure the most important characteristics of activities and operations that may have a significant adverse effect on QMS performance.

Monitor actions setup to achieve the assigned objectives.

Periodically verify the conformance to the applicable laws and internal standards.

D.2 Ensure adequate treatment and corrective actions to solve non-conforming situations and remove causes of no conformance, including incidents and quasi incidents, by determining the causes, planning adequate corrective actions and timing for implementing, defining responsibility for that, applying controls for their monitoring, verifying effectiveness of actions undertaken.

D.3 Plan and execute audits as suitable intervals to:

- Determine level of application and effectiveness of QMS.
- Verify compliance with legislative and other applicable requirements and standards.
- Verify areas of improvements for QMS.
- Review the results of previous audits.

E. Review

The company should

• Review, at appropriate intervals, the adequacy, suitability and continuing effectiveness of QMS and its performance, the policy(ies), procedures and performance results, versus the requirements of the reference standard and other subscribed requirements including the strategic objectives and targets.

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