



IMPLEMENTATION OF AN ISO-BASED INTEGRATED MANAGEMENT SYSTEM FOR MANAGING QUALITY AND ENVIRONMENTAL REQUIREMENTS IN THE CLINICAL LABORATORY

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ABSTRACT

An Integrated Management System (IMS) based on ISO standards is a relatively new approach to manage the continual improvement of processes and quality in the clinical laboratory. The IMS allows the management of two or more ISO standards in a synergistic way. The objective of this work is to present the process of implementation of the IMS at Fleury Diagnostics, a large reference laboratory in Brazil, to manage the Quality and Environmental Systems based on ISO9001:2000 and ISO14001:1996 standards, respectively. The IMS was developed using the PDCA (Plan-Do-Check-Act) cycle in order to define the steps needed to fulfill the ISO requirements. Management principles shared by both guidelines were completely integrated. Measurements of customer satisfaction, definition of personnel competencies, monitoring of management and operational indicators and identification of environmental aspects and impacts were essential tools for the implementation. The Balanced Scorecard (BSC) approach was chosen to monitor management indicators. During 11 months, processes and related activities were evaluated against ISO requirements. As a result, a global measurement of customer satisfaction was performed. 75 basic and specific competencies were determined for 13 different areas. 182 environmental aspects and impacts were identified at the company. 33 environmental programs were established to reduce and control environmental impacts. 136 hours of training were provided to 900 employees. The BSC is currently monitoring 38 indicators. The implementation of an IMS based on ISO requirements is a very good opportunity to improve the quality of all processes in clinical laboratories. The IMS can be considered one of the best ways to assure continual improvement and, as a bonus, it also makes it easier to evaluate management and performance. It suits perfectly the real world of clinical laboratories, making the difficult liaison between the quality-driven nature of laboratory services and the current performance-driven reality of the Health Care System.

Integrated Management System (IMS) is defined as the operation of two or more internationally recognized management system standards in a compatible way. The IMS approach is a growing trend in the Healthcare context and it has been seen as an interesting alternative for laboratories concerned to continual improvement, making it possible to deal with different systems at lower cost, and reducing the time needed for implementation and maintenance after certification. The objective of this poster is to present the IMS implemented at Fleury Diagnostics, a large reference laboratory in Brazil. Fleury has chosen to implement the IMS to manage its Quality and Environmental Systems, based on ISO standards 9001:2000 and 14001:1996, respectively.

ISO (International Organization for Standardization) is a non-governmental organization and one of the most important developers of international standards. It is composed of members from international institutes of more than a hundred countries and its central office is in Geneva, Switzerland. The standards elaborated by ISO are intended to be applicable to industrial and business organizations of all sizes and types. The main purpose of ISO is to develop standards internationally recognized, contributing to make the development, manufacturing and supply of products and services more efficient, safer and cleaner. ISO standards can be generic (used for certification purposes) or specific (guidelines for orientation).

The ISO 9000 series is a collection of good practices related to quality management systems. The ISO 9001:2000 – “Quality Management System – Requirements” presents requirements to the implementation of quality management systems. Its main objective is to increase customer satisfaction by meeting their needs and expectations and also by providing conforming services/products and achieving continual improvement. Its approach can be seen on figure 1. Table 1 indicates the principles and requirements of ISO9001:2000.

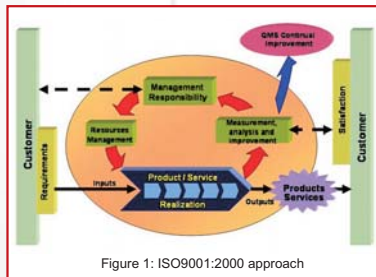


Figure 1: ISO9001:2000 approach

The ISO14000 family grew out of ISO's commitment to support the objective of sustainable development discussed at the United Nations Conference on Environment and Development, in Rio de Janeiro, in 1992.

The ISO 14001 – the standard used for certification purposes, published in 1996 and currently replaced by the new version 2004 – provides organizations with tools to implement efficient environmental management systems, making them able to achieve financial goals in a sustainable way. Based on ISO14001 requirements, organizations are able to improve their environmental performance by controlling the environmental impacts. The number of organizations certified by the standard has increased notably since its publication.

Table 2 indicates the principles and requirements of ISO14001:1996

ISO 9001:2000 eight Management Principles	ISO 14001:1996 Principles
Customer focused organization: understand current and future needs	Identification of Environmental aspects - elements resultant from activities, products or services of an organization that can interact with the environment.
Leadership: establish unity of purpose, direction and internal environment of the organization to achieve the expected results	Evaluation of Environmental Impacts - modifications of the environment caused by environmental aspects
Involvement of people: full involvement of employees enables their abilities to be used for the organization's benefit.	Analysis of legal environmental requirements: the company must achieve compliance to local, state and federal environmental legal requirements.
Process approach: related resources and activities managed as a process	
System approach: managing a system of interrelated processes to a given objective contributes to efficiency	
Continual improvement: permanent objective of the organization to improve the overall performance	
Factual approach to decision making: effective decisions are based on the logical analysis of data and information	
Mutually beneficial supplier relationships: enhance the ability of both organizations to create value	
ISO9001:2000 Main Requirements	ISO14001:1996 Main Requirements
4. Quality Management System Requirements	4.1 Environmental Management System Requirements
5. Management Responsibility	4.2 Environmental Policy
6. Resource Management	4.3 Planning
7. Product Realization	4.4 Operational Control
8. Measurement, Analysis and Improvement	4.5 Checking and Corrective Actions
	4.6 Management Review

TABLE 2: ISO 14001:1996 - Principles and Requirements

The implementation of the IMS at Fleury Diagnostics took 11 months. A pre-existent Quality System implemented according to ISO 9001:1994 principles was used as the basis for the IMS. Common management system requirements shared by both guidelines were integrated, such as corrective and preventive actions, internal audits, calibration and maintenance of equipment and control of documents and records, as shown in Figure 2.

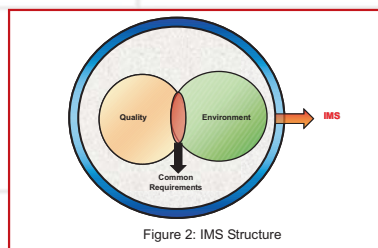


Figure 2: IMS Structure

The PDCA Cycle was used to define the steps needed to implement the System and fulfill the standards' requirements, including the achievement of continual improvement, as seen in figure 3.

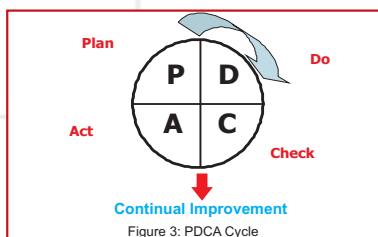


Figure 3: PDCA Cycle

An integrated Management Policy was defined to state the mission of the laboratory in terms of quality and environmental management.

Fleury's Integrated Management Policy

To perform and develop, with technical excellence and ethics, customer services and medical procedures, committing itself to the continual improvement of the services provided by:

- Implementation and maintenance of the Integrated Management System (IMS)
- Respect to the environment and prevention of pollution by complying with the applicable legislation and by treating the waste produced

The Balanced Scorecard (BSC) approach was used to define five strategic objectives and monitor management indicators related to patient safety and satisfaction, according to the four perspectives defined by this methodology (Financial, Customer, Internal Business Processes, Learning and Growth), as shown in Figure 4.

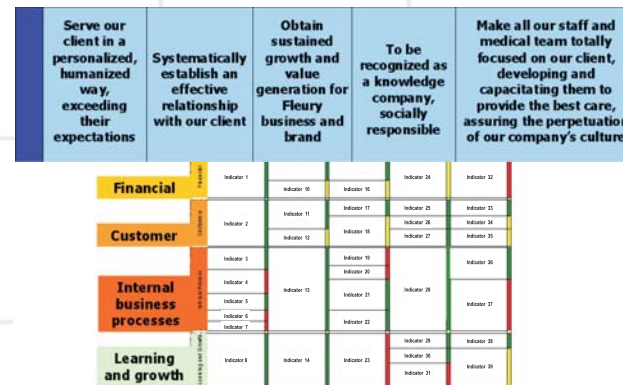


Figure 4: BSC Approach

Documents, non-conformities reports, environmental aspects and impacts and environmental programs were elaborated. These materials were available for consultation in the Intranet, accessible to any employee in the company.

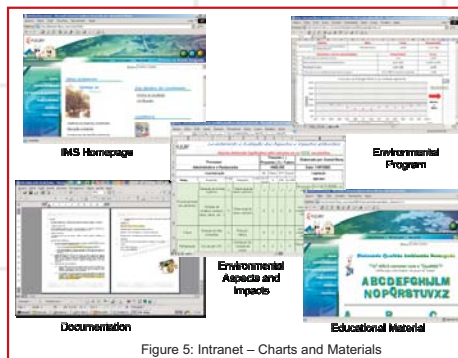


Figure 5: Intranet - Charts and Materials

Educational actions were taken to reduce the production of residues, especially non-hazardous waste. In order to communicate the requirements of the standards and internal procedures, user-friendly, cartoon-style folders and other creative educational materials were elaborated and provided to all employees. Examples can be seen in Figure 5.

Results of the IMS implemented at Fleury in the year of 2004 for General, Quality and Environmental requirements are summarized in Tables 3,4 and 5.

ISO 9001:2000	ISO 14001:1996	IMS of Fleury Diagnostics
4. Quality Management System Requirements 4.1 General Requirements 4.2 Management Responsibility 4.3 Resource Management 4.4 Product Realization 4.5 Measurement, Analysis and Improvement	4.1 Environmental Management System Requirements 4.2 Environmental Policy 4.3 Planning 4.4 Operational Control 4.5 Checking and Corrective Actions 4.6 Management Review	4.1 Environmental Management System Requirements 4.2 Management Responsibility 4.3 Resource Management 4.4 Product Realization 4.5 Measurement, Analysis and Improvement 4.6 Environmental Policy 4.7 Planning 4.8 Operational Control 4.9 Checking and Corrective Actions 4.10 Management Review

Table 3: Results IMS - Common requirements

Table 4: Results IMS - Quality Management Requirements

Table 5: Results IMS - Environmental Management Requirements

In summary, the implementation of Quality and Environmental Systems based on ISO standards has many advantages:

- It is applicable to the laboratory as a whole, including administrative and financial areas
- It can be used as a management standard to help the organization to achieve all expected results
- It can be used as the basis to standardize processes before applying a more specific standards:
- The IMS has a generic approach and for this reason it can be used as the basis for more specific accreditation standards (CAP, JCAHO) and also as the basis for other Quality and management tools like Lean and Six Sigma, as shown in Figure 6.
- The implementation of an Integrated Management System using the ISO 15189:2003 requirements for accreditation and ISO 9001:2000 for certification is a very good opportunity to improve the quality of internal processes and achieve the best results in clinical laboratories.
- The application of an IMS based on both standards can also better harmonize the technical and managerial approaches of the clinical laboratory, clearly helping the difficult transition from the conformance-driven nature of laboratory services to the new, performance-driven reality in the Health Care System.

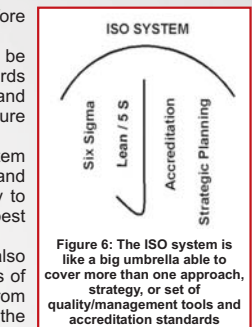


Figure 6: The ISO system is like a big umbrella able to cover more than one approach, strategy, or set of quality/management tools and accreditation standards

At Fleury Diagnostics, the main benefits accomplished by the implementation of the IMS were:

- Better integration and effective management of related processes and departments
- Processes standardization
- Better control of documents and records
- Pollution prevention
- Cost reduction
- Effective monitoring of processes
- High level of top management involvement with the System
- Focus on customer satisfaction enhancement
- Continual improvement

Besides the benefits usually brought by ISO Integrated Management System – cost reduction, process optimization and document simplification – the IMS implemented at Fleury Diagnostics has been essential to verify and assure the quality of internal processes and reduce environmental impacts. By facilitating the evaluation of the overall performance of the laboratory, the IMS can be considered one of the best ways to assure continual improvement in a clinical laboratory.

ISO 9000:2000 Quality management systems - Fundamentals and vocabulary
 ISO 9001:2000 Quality management systems - Requirements
 ISO 9004:2000 Quality management systems - Guidelines for performance improvement
 ISO 14001:1996 Environmental management systems - General requirements with technical specifications and support techniques
 ISO 14004:2004 Environmental management systems - Guidelines for performance improvement
 ISO 15189:2003 Medical laboratories - Requirements for quality and competence
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