

**The ultimate SME  
implementation guide  
for  
ISO 9001:2000  
ISO 14001:2004  
management systems**

**Section 1  
General  
Version 2005**



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### **Disclaimer**

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*This disclaimer covers all three parts of this publication.*

## **1.2 Foreword**

*This guide for the implementation of Quality Management Systems (QMS) and Environmental Management Systems for the small and middle-sized enterprise, has been developed as an initiative for the members of Euromines.*

*The reason for the development of this guide is that the smaller organisations are also confronted with the requirements of documented and implemented management systems such as ISO 9001 and ISO 14001, they ask for professional and specific knowledge, while resources such as time, manpower and finance are limited.*

*This guide is designed for SMEs that do not have much experience with the implementation of these standards and contains therefore all the needed information. It is designed in such a way that unnecessary paperwork, documentation, and consultant's help can be avoided.*

*The non-experienced user will find a lot of information in this guide and should go through it completely, but for the fast implementer, the Fast Track clearly guides you through the development steps, supported with an explanation of the items from the standards that really matters and without any trivial ballast.*

*An example manual for both standards is also added to this guide, including the main procedures.*

*The core of this guide is the flow chart for implementing the respective management systems. It is advised to follow the steps consequently and conscientiously and then lead the organisation through the management system implementation process. The details about the standards are to inform the implementer about the meaning behind the requirements.*

*The standards itself contains clear requirements. In the text additional comments are made to clarify the matter. This textbook does not replace the standards and does not contain all the text from the standards. The standards are therefore needed to be used beside this guide.*

*With the example manual and other materials, a manual can be designed specifically to the user's organisation. The same applies also for the procedures.*

*The 2000 version of ISO 9001 is requiring much less paperwork than the previous version. The implementation of a QMS or EMS is still a large and time consuming task for an SME, but when using this guide, this task can be managed without the help of an outside consultant or others.*

*The ISO organisation has worked very hard to make both standards compatible and they are, within some boundaries. In theory both management systems could be integrated. Some organisations have done that successfully.*

*However, if you a first time implementer, it is strongly advised to keep the systems separate. It should be realised that the quality management system is designed for the interaction between suppliers, the organisation and customers with as the ultimate purpose, profitability. The environmental management system is designed for a different public. The scope is to minimise risks and environmental damage. The interaction takes place between the organisation, the government, activists and the local community and therefore serves a completely different purpose.*

## How to use this guide?

*This guide is designed for the implementation of a quality management system according to ISO 9001:2000 and for an environmental management system ISO 14001:2004  
The only materials needed besides this guide are the appropriate standards and sufficient resources in means of manpower, motivation and leadership.*

*Quoted text from the applicable standards is marked in **blue**.  
Important text is marked in **yellow**.*

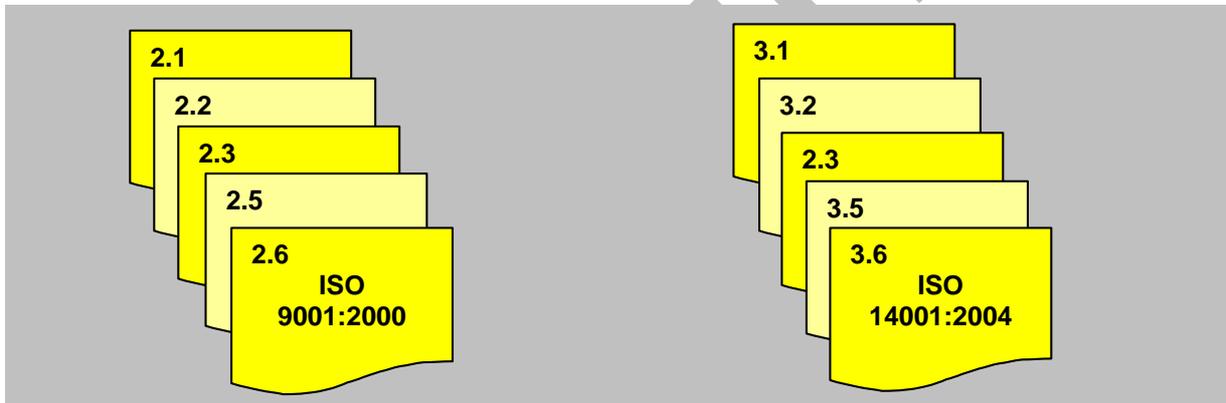
*The non-experienced user, who will implement a management system from almost scratch should go through the general part (one) and through the specific part ISO 9001 (two) or ISO 14001 (three).*

*The more or less experienced users, who want to implement a management system fast and don't need much additional information should use the Fast Track.*

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### For the **Fast-Track** implementation:

*Basically, the following chapters contain the needed information for the fast track implementation.*



*This illustration shows the **Fast-Track** method through the Quality Management System (ISO 9001:2000) information fast,*



*and this green illustration shows the **Fast-Track** method through the Environmental Management System (ISO 14001:2004) information*



### **1.3 What is ISO 9001:2000?**

*ISO certified, who has not seen the advertisements where companies offer their products or services and underline their quality image with ISO certification? What is ISO and what is ISO 9000?*

*The term ISO refers to the International Organization for Standardization and is originally derived from the Greek word ISOS, which means equal. The prefix ISO occurs in many words, such as isothermal, meaning equal process temperatures.*

*ISO is a NGO (Non Governmental Organisation) established in 1947 in Geneva, Switzerland. Today, the ISO organisation has more one than hundred member countries around the world and the word ISO is an understanding.*

*The mission of the ISO organisation is to promote the development of standardisation and the related activities in the global market place, to simplify the international exchange of goods and services and to develop the co-operation in the spheres of intellectual, scientific, technological and economic activities.*

*Because of this, it is possible to order products from all over the world while referring to the appropriate standard and getting exactly what is needed. If not, then the standard will tell who is right and who is wrong and has to correct the product. Also this enables us to draw money from ATM's around the world, and also thanks to ISO standardisation, US standard ammunition fits Belgium manufactured guns and Russian lunar modules on the International space station ISS.*

*Since the establishment of ISO, the organisation has focussed on the development of product related standards. Since the mid 80's however, ISO has worked on system related standards. The ISO-9000 and later the 14000 series are typical examples of this work.*

*Although many quality standards have been developed since the start of the industrial revolution, it started to be serious in 1959 with the development of the famous MIL standards from the U.S. Department of Defence. A Quality Management System was designed and described in the standard MIL-Q-9858. Later, the different standards were issued under the name AQAP (Allied Quality Assurance Publication) and in use by the NATO and its member countries.*

*Even today some civil companies are using the MIL standard 105d for sample checks, since it is such an understanding.*

*Many suppliers to the defence industry needed to be qualified according to these AQAP standards to be able to supply the military. Also civilian industries wanted to improve their quality systems, and asked the defence organisation to audit their systems. This has stimulated the development of a civilian quality standard, because the military were not able to satisfy the increasing demand for certification of companies, and some were not even working for them.*

*The British Standardisation Institute was the first with a civil QMS, the British Standard BS 5750.*

*Most countries developed over time their own quality management standards which were different from the British standard. Thus the need arose for a universal standard, under pressure from international business and economics and especially the many conglomerates that were operating globally.*

*In 1979, ISO started a technical committee for Quality Management and Quality Assurance under the name ISO/TC 176.*

*It was this committee that developed the ISO-9000 standard, which was issued in its first version in 1987. Compared with the existing quality management standards, ISO prioritised the responsibility of management and the need for sufficiently trained personnel.*

*In Europe, the CEN (Comité Européen de Normalisation) has adopted the ISO standards without any changes. The members of the CEN, the standardisation institutes of the European member countries have all accepted the standard and issued as national standards. Therefore these ISO standards in Europe are known as BS-ISO 9000, NEN-ISO 9000 or DIN-ISO 9000 for respectively the British, Dutch and German standard. Also many countries outside Europe have accepted the ISO standards 9000 and also the 14000 as their national standards. The first issue of the ISO 9000 standards has been a big success and experienced acceptance world-wide.*

*In general, every five years, the ISO standards will be reviewed and renewed. These revisions are needed to keep up with the technological and economical developments, because the requirements on services and goods are constantly changing. Also the way of doing business and managing changes.*

*During the review of 1994, small changes have been made to the standards. It was found that service organisations had difficulties to implement standards that were designed mainly for manufacturing companies. Therefore the word 'product' changed into 'product or service'. The introduction of preventive measures was another important change in the standards. With this it was made possible to continuously strive for improvement of the QMS.*

*After the changes in 1994, the second large change was prepared by the Technical Committee and planned and realised for the end of the year 2000.*

*What are the changes in the ISO 9000:2000 series, compared with the 1994 edition?*

*As mentioned before, the new series of standards is less biased towards manufacturing and therefore more generic. It can be used by all organisations, regardless of type, size or nature and completely independent from the supplied product or service.*

*As in the previous standard, not all the requirements of this new standard may be applicable to all organisations. Since the distinction between the "old" 9001, 9002 and 9003 has been eliminated; an application clause in the new version allows organisations to exclude certain requirements of section 7 that are not relevant.*

*Organisations that developed products or services were to be certified according to ISO-9001. Organisations that just produced, but did not design there products or services were to be certified according to ISO-9002 and organisations that were only trading and not producing, in other words, not added value to a product or service, were to be certified according to ISO-9003.*

*With the new edition of ISO-9001, this standard applies to all organisations, and parts that are not relevant, will be excluded with the application clause.*

*A new process-oriented structure and a logical sequence of the contents differentiate the new standard from the previous one. The new standard still contains a large part of the old version, but the 20 requirements have now been grouped into five sections.*

- *Quality Management System (hereafter QMS)*
- *Management responsibility*
- *Resource Management*
- *Product realisation*
- *Measurement, analysis and improvement*

*The new standard has also significantly reduced the amount of documentation required. Documented procedures have been reduced from 18 to 6, although the organisation may, if required, document other procedures, instructions and forms.*

*The new requirements in the ISO-9000:2000 standard include:*

*Increased emphasis on the role of top management*

*Customer focus to ensure involvement of top management for determining customer requirements*

*Consideration of statutory and regulatory requirements*

*Establishment of measurable quality objectives at relevant functions and levels*

*Establishment of internal communication processes to ensure effective communication of QMS (Quality Management System) objective within the organisation.*

*The ISO family of Quality Management standards consists of four primary standards and several guides for assisting the implementation and understanding.*

### **ISO 9000:2000 Quality Management Systems - Fundamentals and vocabulary**

*This main standard describes the general concept of the QMS and it defines the fundamental terms used in the ISO 9000 series of standards and guides. This standard also includes the eight management principles (see chapter 2.1) in which the QMS, but also the environmental management system must be based on.*

### **ISO 9001:2000 Quality Management Systems - Requirements**

*This standard describes the specific requirements for a QMS whereby the organisation needs to assess, prove and demonstrate its ability to provide products that meet the customers and applicable regulatory requirements and thereby enhance the customer's satisfaction.*

*This is the standard that replaces the former ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994.*

*From now on there is no distinction made anymore between organisations that do their own product development, manufacturing or just trading. The new standard applies to all.*

### **ISO 9004:2000 Quality Management Systems - Guidelines for performance improvements**

*The 9004 standard provide guidance for continual improvement and can be used for performance improvement of an organisation. The purpose of 9001 is to give quality assurance during the manufacturing process to meet customer satisfaction, while 9004 gives guidance for future developments and improvements.*

*The annex A, included in this standard, provides a simple to use guide to determine the degree of maturity of the QMS in an organisation, and to identify the main areas for improvement.*

### **ISO/DIS 19011 Guidelines on quality and/or environmental management auditing systems.**

*This standard provides guidance for the conducting of internal and external auditing on quality and environmental management systems, to verify if the system meets the defined objectives.*

*This standard replaces the former ISO 10011, 14010 14011 and 14012 standards.*

*This brings us automatically to the relationship between the ISO 9000 series for Quality Management Systems and the ISO 14000 series for Environmental Management Systems. ISO 9000 and ISO 14000 is a consistent pair of standards that relate modern management to control of processes and activities of an organisation and the emphasis of the promotion of continual improvement and achievement of customer satisfaction.*

*Some organisations have integrated their quality activities with their activities in the field of environmental issues, and others such as health and safety. Also, their document structure is then integrated.*

*This development brings these activities on a higher level of understanding within the organisation. However, if it is planned to implement a QMS and there is no other systematic activity developed yet on health and safety or environmental issues, it is recommended to keep these activities separate until the QMS and the EMS are established in the organisation. Integration of both systems will be the next step.*

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## **1.4 What is ISO 14001:2004?**

*After the success of the ISO 9000 series of quality standards, the International Standards Organisation has introduced a comprehensive set of standards for environmental management.*

*This series of standards is designed to cover the whole area of environmental issues for organisations in the global marketplace.*

*The ISO 14000 series emerged primarily as a result of the Uruguay meeting of the GATT negotiations and the Rio Summit on the Environment, held in 1992. While GATT concentrates on the need to reduce non-tariff barriers to trade, the Rio Summit generated a commitment to protection of the environment across the world. Since then, the environmental field has seen a steady growth of national and regional standards.*

*After the rapid acceptance of ISO 9000, and the increase of environmental standards around the world, ISO assessed the need for international environmental management standards. In 1991, they formed the Strategic Advisory Group on the Environment (SAGE), to consider whether such standards could serve to:*

- *Promote a common approach to environmental management similar to Quality management*
- *Enhance the organisation's ability to attain and measure improvements in environmental performance*
- *Facilitate trade and remove trade barriers.*

*In 1992, SAGE's recommendations created a new committee, TC (technical committee) 207, for international environmental management standards.*

*The committee, and its sub-committees, includes representatives from industry, standardisation organisations, government and environmental organisations from many countries.*

*The 1996 of ISO14000 standards are designed to cover:*

- *Environmental management systems*
- *Environmental auditing*
- *Environmental performance evaluation*
- *Environmental labelling*
- *Life-cycle assessment*
- *Environmental aspects in product standards*

*A set of international standards brings a world-wide focus to the environment, thus encouraging a cleaner, safer, healthier world for us all. The existence of the standards allows organisations to focus on environmental efforts against internationally accepted criteria. In November 2004 the latest version of ISO 14000 has been issued (ISO 14001:2004).*

*The two standards look similar. However attention has to be paid to the new requirements. Much has been said that there would be no new requirements, but that's not true. There are indeed new requirements which were introduced in order to improve the standard. In this 2005 version of the 'Implementation Guide for QMS and EMS' from Euromines we have added a chapter devoted to these changes and the differences between both standards.*

*At present, many countries and regional groupings are generating their own requirements for environmental issues, and these vary between the groups.*

*A single standard will ensure that there are no conflicts between regional interpretations of a good environmental practice.*

*The fact that companies may need environmental management certification to compete in the global marketplace, could easily overshadow all the ethical reasons for environmental management.*

*Within Europe, many organisations gained ISO 9000 registration, primarily to meet growing demands from their customers. ISO 9000 quality system registration has become necessary to do business in many areas of commerce.*

*Similarly, the ISO 14000 management system registration may become the primary requirement for doing business in many regions or industries.*

*The standards apply to all types and sizes of organisations and are designed to encompass diverse geographical, cultural and social conditions. For ISO 14001, except for committing to continual improvement and compliance with applicable legislation and regulations, the standard does not establish absolute requirements for environmental performance. Many organisations, engaged in similar activities, may have widely different environmental management systems and performance, and may all comply with ISO14001.*

*It is up to the organisations to decide the application of the standards.*

*The organisation has to document the extent of the coverage. However, limiting coverage to a small area may provide competitors with an ideal marketing opportunity.*

*Below an overview is given of the different standards in the new ISO-14000:2004 series.*

**ISO 14000: 2004**                      **Guide to Environmental Management Principles, Systems and Supporting Techniques**

**ISO/IEC Guide 66:1999**            **General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS)**

**ISO 14001:2004**                    **Environmental management systems - Requirements with guidance for use**

*ISO 14001:2004 specifies requirements for an environmental management system to enable an organization to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organization subscribes, and information about significant environmental aspects. It applies to those environmental aspects that the organization identifies as those which it can control and those which it can influence. It does not itself state specific environmental performance criteria.*

*ISO 14001:2004 is applicable to any organization that wishes to establish, implement, maintain and improve an environmental management system, to assure itself of conformity with its stated environmental policy, and to demonstrate conformity with ISO 14001:2004 by:*

*a) Making a self-determination and self-declaration, or*

b) Seeking confirmation of its conformance by parties having an interest in the organization, such as customers, or

c) Seeking confirmation of its self-declaration by a party external to the organization, or

d) Seeking certification/registration of its environmental management system by an external organization.

All the requirements in ISO 14001:2004 are intended to be incorporated into any environmental management system. The extent of the application will depend on factors such as the environmental policy of the organization, the nature of its activities, products and services and the location where and the conditions in which it functions.

**ISO 14004:2004**

**Environmental management systems - General guidelines on principles, systems and support techniques**

ISO 14004:2004 provides guidance on the establishment, implementation, maintenance and improvement of an environmental management system and its coordination with other management systems. The guidelines in ISO 14004:2004 are applicable to any organization, regardless of its size, type, location or level of maturity. While the guidelines in ISO 14004:2004 are consistent with the ISO 14001:2004 environmental management system model, they are not intended to provide interpretations of the requirements of ISO 14001:2004.

**ISO 14015:2001**

**Environmental management - Environmental assessment of sites and organizations (EASO)**

This standard provides guidance on how to conduct an environmental assessment on sites, through a systematic process of identifying environmental aspects and environmental issues and determining, if appropriate, their business consequences.

**ISO 14031:1999**

**Environmental management - Environmental performance evaluation – Guidelines**

This technical report identifies and describes elements and issues concerning environmental declarations and corresponding programs, including technical considerations, declaration format and communication, and administrative considerations for developing and/or using a type 3 environmental declaration.

ISO 14032 contains examples from real organisations to illustrate the use of ISO 14031.

**ISO/TR 14032:1999**      **Environmental management - Examples of environmental performance evaluation (EPE)**

*This technical report identifies and describes elements and issues concerning environmental declarations and corresponding programs, including technical considerations, declaration format and communication, and administrative considerations for developing and/or using a type 3 environmental declaration.  
ISO 14032 contains examples from real organisations to illustrate the use of ISO 14031.*

**ISO 14040:1997**      **Environmental management - Life cycle assessment - Principles and framework**

*This standard specifies the general framework, principles and requirements for conducting and reporting life cycle assessment studies. This standard does not describe the life cycle assessment technique in detail.*

**ISO 14041:1998**      **Environmental management - Life cycle assessment - Principles and framework**

*This standard in addition to ISO 14040, specifies the requirements and the procedures necessary for the compilation and preparation of the definition of goal and scope for a life cycle assessment (LCA) and for performing, interpreting and reporting a life cycle inventory analysis (LCI).  
ISO 14043 provides requirements and recommendations for conducting the life cycle interpretation phase in LCA or LCI studies.*

**ISO 14042:2000**      **Environmental management - Life cycle assessment - Life cycle impact assessment**

*This standard in addition to ISO 14040, specifies the requirements and the procedures necessary for the compilation and preparation of the definition of goal and scope for a life cycle assessment (LCA) and for performing, interpreting and reporting a life cycle inventory analysis (LCI).  
ISO 14043 provides requirements and recommendations for conducting the life cycle interpretation phase in LCA or LCI studies.*

**ISO 14043:2000**      **Environmental management - Life cycle assessment - Life cycle interpretation**

*This standard in addition to ISO 14040, specifies the requirements and the procedures necessary for the compilation and preparation of the definition of goal and scope for a life cycle assessment (LCA) and for performing, interpreting and reporting a life cycle inventory analysis (LCI).*

*ISO 14043 provides requirements and recommendations for conducting the life cycle interpretation phase in LCA or LCI studies.*

**ISO/TR 14047:2003**      **Environmental management - Life cycle impact assessment**  
**Examples of application of ISO 14042**

*ISO/TR 14047:2003 provides examples to illustrate current practice in carrying out a life cycle impact assessment in accordance with ISO 14042. These are only examples of the total possible "ways" to satisfy the provisions of ISO 14042. They reflect the key elements of the life cycle impact assessment (LCIA) phase of the LCA.*

*The examples presented in ISO/TR 14047:2003 are not exclusive; other examples exist to illustrate the methodological issues described.*

**ISO/TR 14049:2000**      **Environmental management - Life cycle assessment -**  
**Examples of application of ISO 14041 to goal and scope**  
**definition and inventory analysis**

*This technical specification provides the requirements and a structure for a data documentation format, to be used for transparent and unambiguous documentation and exchange of life cycle assessment (LCA) and life cycle inventory (LCI) data, thus permitting consistent documentation, reporting of data, data calculation and data quality, by specifying and structuring relevant information.*

*Technical report ISO 14049 provides examples about practices in carrying out a life cycle inventory analysis as a means of satisfying certain provisions of ISO 14041.*

**ISO 14050:2002**      **Environmental management – Vocabulary**

*This International Standard contains definitions of fundamental concepts related to environmental management, published in the ISO 14000 family of International Standards.*

**ISO/TR 14061:1998**      **Information to assist forestry organizations in the use of**  
**Environmental Management System standards ISO 14001**  
**and ISO 14004**

**ISO/TR 14062:2002**      **Environmental management - Integrating environmental**  
**aspects into product design and development**

*ISO/TR 14062:2002 describes concepts and current practices relating to the integration of environmental aspects into product design and development. ISO/TR 14062:2002 is applicable to the development of sector-specific documents. It is not applicable as a specification for certification and registration purposes.*

**ISO 19011:2002**      **Guidelines for quality and/or environmental management**  
**systems auditing**

*ISO 19011:2002 provides guidance on the principles of auditing, managing audit programmes, conducting quality*

*management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors. It is applicable to all organizations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme. The application of ISO 19011 to other types of audits is possible in principle provided that special consideration is paid to identifying the competence needed by the audit team members in such cases.*

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## **1.5 What's involved in implementing QMS/EMS in SMEs?**

### **1.5.1 General**

*About 70% of the world's economy is fed by companies with fewer than 200 employees. This fact initially escaped the attention of the developers of ISO 9000. Today, registrars are scrambling to develop audit plans and fee structures, specifically for these small businesses. The ISO standards developers have been improving the adequacy of the ISO 9000 series and reducing the bureaucracy and paperwork.*

*The small business owner or CEO of a SME, has a lot of different issues and problems to confront in daily life. Besides being the CEO for the company, the job also brings the involvement in its ownership and several other tasks. Therefore, the requirement for an environmental management system or a documented quality management system seems like more time and money.*

*In reality it does not have to be either one.*

*In today's economy having a quality image or being a 'green' company, presents you with a distinctive marketing advantage for the products marketed by the organisation. In addition, the organisation is already faced with numerous regulations related to product liability, health and safety for the employees, quality issues, customer complaint handling and environmental issues.*

*Then, there is always the present need to cut costs, speed to market new products, being leaner than the competition and continuous improvement.*

*Add that to the social conscience some CEO's have, and it is clear that there is a need for a single system that addresses all of these problems.*

*Recent research showed that the major obstacles for implementing a QMS and/or EMS are the cost, the lack of commitment and the dubious benefits for the SMEs.*

*The reason for is that most of the work is subcontracted to consultants. This makes it expensive and the focus will automatically lie on risk reduction, compliance and liability. The link between environmental and quality performance is not being made as well as it could. The lack of knowledge at the SME is another reason. Most SMEs do not have a responsible manager who takes on the quality or environmental task. In many cases these SMEs are even not aware of their legal obligations.*

*The good news is that an environmental management system (EMS), does not have to be a separate entity. Instead, if an ISO 9000 quality management system is already in place, then the infrastructure for an EMS is available.*

*The ISO 9000 family of standards is generic in nature and applicable to all companies, regardless of the type, structure and size of the business, including the small and medium sized enterprises.*

*Also they are applicable to all categories of products whether they are software, hardware, processed material including mining or to services.*

*ISO 9001:2000 specifies what is required to be done by an organisation, but does not indicate how it should be done, thus giving the enterprise a lot of flexibility to run its business with its own knowledge, expertise and insight.*

*The new standard is also appropriated for the SMEs because it demands less paperwork and bureaucracy than its previous version needed. Only six documented procedures are required and the organisation will decide on more procedures or documents when needed. Companies will however, be required to provide objective evidence that the QMS has been effectively implemented and embedded in the organisation.*

*A SME may find it appropriate to include the description of its entire QMS within a single Quality Manual, including all the documented procedures required by the standard. It makes sense to keep things simple because more involvement from the personnel can be obtained which makes the QMS a lively part of the organisation.*

*The process-based approach given in ISO 9001:2000, will tend to ensure that systems are documented and implemented in a manner that suits the SMEs own way of doing business. This approach makes it easier for SMEs to implement, instead of just taking over an artificial structure of a QMS imposed from the outside or bought as framework software from a consulting firm.*

*It will also be easier to ensure effective internal communication, better and improved utilisation of resources, while people will better understand their roles and responsibilities in the organisation.*

*The new standard has included a provision for deciding on the applicability of certain product realisation processes included in section 7 of the ISO 9001:2000 standard.*

*For example, if the SME has no responsibility for the development and design of the product it provides to the market, then the SME may, giving the reasons behind this argument, exclude this from the quality manual and still can be awarded with certification.*

*The same applies to purchasing, product identification, supplied products by third parties etc. if they are not applicable for the type of products or services provided by the organisation.*

*Implementation of a QMS and/or EMS into an SME is not simple. Smaller organisations have limitations on the resources side, besides that they are often lacking the required knowledge and interest in getting a QMS or EMS.*

*But if the SME will continue to be successful, than it needs to identify and meet the needs and expectations of its customers and other interested parties, such as suppliers, employees, shareholders and the local society in which environment they are operating. The implementation of the ISO 9001:2000 standard can help to achieve these objectives.*

*Often SMEs want to implement a QMS or EMS for the wrong reasons. Many times they start with the objective to improve bottom-line results by implementing these systems.*

*Expectations are for example better efficiency, continual improvement, less waste, repair and rework, consistent control over the key processes and last but not least, better sales by the use of ISO as a marketing tool.*

*This is short-term thinking. Having a good QMS will certainly improve these aspects, but not as a result of the implementation and not immediately. It will take time and effort to get these effects from a QMS. Having an ISO certification is the first step on the road to being a solid and reliable company that is attractive to customers because of the embedded system of continual improvement.*

*On the other side, many SMEs have difficulties with changing their companies around and implementing a QMS and/or EMS for the following reasons:*

- *Too costly to implement and to maintain*
- *Time consuming and little effect on the short term*
- *Difficult to implement*
- *Too much emphasis on documentation and filing rather than on results*
- *Hard to keep up the enthusiasm of the people involved*
- *Organisational resistance to change*
- *Resistance from the staff against change*
- *Customer satisfaction and improvement are not always paying back*
- *The standard is too general and universal, thus not only for manufacturing.*

- *Too many standards in this series*
- *Duplication with ISO 14000*

*Most of the reasoning goes back to a lack of involvement of top management. If they are committed to implement and maintain these management systems, then all the other barriers will dissolve. There is no top management that will accept the resistance of staff or others against a management system or there is something fundamentally wrong in such an organisation. Therefore, it is essential to convince the top management of the SME by sound arguments, that a QMS or EMS is needed to survive as a modern organisation operating in an environment of organisations that know what their suppliers and customers expect and that they are able to fulfil these expectations.*

*The first and most important task for an SME undertaking the implementation of a QMS or EMS, is to establish 'why are we doing it'. If it is done to satisfy local authorities because the operation is exceeding the noise levels or it is done to get entrance to a specific market, then there is the danger that this new-implemented system is simply focusing on the ISO standard and the certificate.*

*The result will not be sustainable and not serve any useful purpose other than draining the company's cash.*

*A system implementation should be driven by:*

- *The improvement of the performance and therefore an increase in bottom line profits.*
- *The effective management of risk*
- *The assurance of quality of product or service to the customer*
- *The basis for implementing is a culture of opportunity.*
- *If required, the acquisition of a symbol of international recognition.*
- *Improve the overall efficiency*
- *Continual improvement*
- *Reduced waste of resources*
- *Consistent control of key processes*
- *Greater marketing appeal and improved public relations*
- *Meeting the requirements for inclusion on some tender lists*

*Basically all aspects of the EMS or QMS must add value to the activities of the organisation in relation to the resources required to implement and maintain each aspect.*

*Added value as described above is:*

- *Reduction of the risk of occurrence of a safety incident or accident*
- *Reduction of the risk of occurrence of an environmental incident or accident.*
- *Improved assurance of specified product or service*
- *Improved product or service quality*
- *Reduction of product or service delivery cost*
- *Reduction of the delivery time of a product or service.*
- *Improved management of resources.*

*These are all good and valid reasons to implement a QMS/EMS, rewarded with a return on the investment.*

## **1.5.2 Implementing QMS/EMS in the mining industry**

*Implementing a QMS or EMS in a small or medium enterprise in the mining industry is difficult. In the previous chapter it is explained why an SME has some back log in comparison with the larger organisation. But its flexibility should make up for it.*

*Being in the mining industry has its own difficulties and this chapter we will try to emphasize on its specifics, so that at the implementation phase these aspects can be build into the system from the start.*

### **1.5.3 QMS**

*Quality management systems in the manufacturing industry are relatively easy to control, because production is done in numbers or volumes and therefore easily related to cost prices per unit.*

*In the mining industry, organisations work with a product of nature and that means that size and volume ratios are always different.*

*That applies also to chemical composition, content of the mined substances and contamination levels.*

*For these reasons it is essential to build the QMS around a very sophisticated system of traceability and record keeping and maintaining. Determining in the earliest stages of the mining process of the production output in qualifying terms and parameters, makes that the right treatment is given in the later production stages (if there are), but also that planning and strategies can be influenced by adequate information.*

*Traceability allows the mining company to determine exactly the value of the product before and after subsequent processing and saves cost. However in many cases it is difficult to use a reliable traceability system on large volumes of mined product, it certainly pays off on the end of the process in predictability, adequate pricing and valuating of stocks.*

*The use of statistical process control (SPC) and applied statistics will allow a reliable data flow that can be used for process control, quality control, customer requirements, planning and for developing new processes.*

*Here the QMS interferes with the EMS, because of the waste stream. Identifying in an early stage the valuable mined materials and minerals, means also that the waste stream is identified and quantified. This registration is essential for operating an effective and adequate EMS.*

*The QMS (extravert) is more an internal tool, to be used to optimise operational activities and assure customer service, the EMS is more an external tool. (introvert)*

### **1.5.4 EMS**

*Expansion within the mining and metallurgical sector is central to the development and economic growth of many developing and developed countries. The products of the sector are not only essential for construction activities and many industrial processes, but are also often a valuable source of foreign exchange earnings. However, mining operations frequently involve a high degree of environmental disturbance which can extend well beyond the extent of mineralized areas.*

*The impacts of a mining operation commence with exploration activities, extend through extraction and processing of minerals, and may continue post-closure of the operation, with the nature and extent of impacts varying throughout the stages of project development. In comparison with many other sectors, the potential social and environmental issues*

*associated with mining and mineral processing operations are both highly significant and complex to manage. The fixed location of the mineralized zone of interest imposes constraints on all aspects of mining developments including the method of mining, location of mine facilities, requirements for new infrastructure and services (or conflict with existing infrastructure), and the suitability of waste management or disposal methods. This in turn profoundly influences the environmental, social and health impacts of mining developments, as well as the economic viability of developing a given mineralized zone.*

*Mining operations may be categorized as either surface or underground. Surface mining may be broadly defined to encompass open pit, open cast, quarry, strip, dredging and placer (hydraulic) mining. Underground methods include pillar-and-stope, shrinkage-stope, block caving and long-wall mining. Most mining operations (whether surface or underground) share a number of common stages or activities, each of which can have potentially adverse impacts on the natural environment, social and cultural conditions, or the health and safety of mine workers or communities in the environs of the mine.*

*With the introduction of an EMS in the mining industry, there is a valuable tool that helps controlling the business and the environment. Having an EMS means in the first place a pro-active step towards the community, showing that all what can be done, will be done to protect the environment from a more or less serious impact. Within the standard a procedure is required to maintain this pro-active communication and it is proven to be most valuable for the mining company.*

*The EMS allows adding certain branch specific requirements such as the Cyanide Code in use at gold mining*

*Other important aspects that play a role in the mining industry and that are not translated automatically in the EMS are;*

- *Decision making about abandoned mines and mining sites. If possible the rehabilitation of it, in co-operation with the local government.*
- *Drainage problems during mining can have an effect on the direct surroundings. It is a well-known phenomena and a pro-active approach is usually very effective.*
- *Contamination of ground water is an aspect that should be adopted into the EMS when this is relevant to the mining company.*
- *Waste reduction and identifying waste streams is not specifically mentioned in the EMS, but must be part of the operation and the proper and adequate use of it must be laid down in an EMS procedure.*
- *Determining and monitoring soil quality and ground quality.*
- *Assessment of soils and grounds contaminated by hazardous substances.*
- *Comprehensive monitoring of waste disposal grounds.*
- *Chemical and bacteriological and radiological monitoring of municipal and industrial sludges and waste waters, discharged into surface water, underground waters and grounds.*
- *Testing and controlling of emissions and immisions of atmospheric air pollution.*
- *Determination of pollutants in the geological environment.*
- *The save and trained use of explosives or other mining equipment*
- *The testing and controlling of radioactive contaminations caused by industrial activities*
- *Monitoring and controlling of noise and vibrations in the mines and mining pits and related work areas and municipalities.*
- *Monitoring and controlling of surface-related hazards in mining areas in respect of shallow voids and the assessment of efficiency of their liquidation.*
- *Monitoring of hazards originating in areas of closed mines.*

## **1.6 Aspects of certification**

*The process to become certified to ISO 9000 and/or ISO 14000, after the successful implementation of the system, and how to maintain this status once the organisation has achieved it, is given in the steps below.*

### **The selection of a certification body.**

*Organisations that desire to obtain a certificate, need to submit an application to the certification body of their choice. The issues to consider when selecting such a certification body include the following:*

- *Whether accreditation by a accreditation body is desired.*
- *Whether the nature of accreditation of the certification body is acceptable in the market to which the organisation wants to export.*
- *The image of the certification body in the specific market and in general.*
- *The cost for certification and periodical surveillance audits.*
- *The fact that the National Accreditation Body has been accredited by the certification body.*

*An accredited certification body has been given formal recognition of its competence to carry out ISO 9000/14000 certification and registration. Most registration bodies has been accredited.*

*Accreditation is a part of a hierarchy of assurance. It is granted to a registration body as recognition that it meets and continues to meet internationally accepted criteria that cover integrity and technical competence to access companies to the ISO 9000 and 14000 standards.*

*The accrediting authority ensures that the registration body, conform to these criteria, which include the qualification and experience of auditors, the time spent on auditing and surveillance and the need for impartiality.*

*These days well known registration bodies offer certification while the National Accreditation Board does not recognise the certification. The reason for this is the debatable role of the accreditation board in relationship with the cost involved. In these specific cases, the certification body and the customer decide to install their own 'accreditation board' mainly consisting of independent experts, members of the branch organisation and delegates of the certification body. This is certainly an acceptable solution, on the condition that the 'accreditation board' remains independent from the organisations who are subject to auditing. Please be warned – do not work together with certification bodies that are not registered at all by the national accreditation boards.*

### **Preparing for the assessment**

*Under ISO 9001:2000 and ISO 14000:2004, the first requirement is to define the organisation's processes that affect quality or environment, so that the first step is that the auditor from the certification body meets with the organisation's management to gain understanding of its processes.*

*Normally speaking, the certification audit starts then with the review of the organisation's management system manual and the procedures by the auditor, to ensure that the management system manual covers the requirements of the standard. This is known as the 'adequacy audit' or document review audit.*

*The auditor conveys any gaps (non-conformities) found in the documents to the organisation for necessary actions and re-submission of the documents, if required. The certification body*

also examines, where relevant, the justification included in the quality manual for not including certain product realisation processes. Such exclusions should be acceptable to the certification body.

### **Auditing**

After the satisfactory completion of the document review, the auditor will undertake the second part of the audit process at the organisation's location at a mutually agreed time and date, because certification audits are not surprise visits. The audit at location begins with an opening meeting.

During this meeting, the auditor will explain to the management how the audit will be conducted and when and how the findings will be conveyed to the management.

The auditor will collect evidence of conformity and non-conformity through observation of activities, examination of procedures, records, observation of conditions of housekeeping, through interviews with the concerned managers and personnel of the organisation, on a sampling basis. The information gathered through interviews is verified and tested by the auditor by acquiring the same information from other sources, such as physical observations and measurements performed on the product and the related records.

The auditor will visit and verify compliance with the QMS or EMS in all departments and functions within the scope of the management system.

The new standard will require significant changes in auditing methods for both internal and external auditors. Auditing will become more subjective and less objective, relying more upon questioning and less on hard evidence.

In order to carry out a process audit, the auditor will start with the inputs, follow the process through its various stages to examine how it is controlled and verify that the output meet with what is required.

Such a process may be, for example, the actions required by the organisation on receipt of a customer order, and the steps taken to convert that order into something that will allow a product ordered to be manufactured. The input here would be the customer order, and the output, the organisation's internal documents, resources and materials that allow the manufacture of the product.

Another example of a process could be those steps that an organisation would take to procure chemicals required to dissolve metals. The output would be the receipt of the chemicals from the supplier.

Thus the auditor will need to look at the process, determine the inputs, examine how it is controlled, and look at the outputs. The way the process is controlled may require an examination of mechanisms other than documented procedures.

Such control mechanisms could be, for example, control charts or process flow diagrams. Whatever the means by which organisation decided to control the process, the auditor will seek evidence that the control of the mechanism is indeed effective.

The ultimate test of effectiveness is an examination of whether the end result of the process is in accordance with the inputs.

An example of a buying process end result could be the receipt of chemicals. If the purchase order did not contain sufficient information to allow the correct product to be supplied or was deficient in some way, then the output would not be acceptable.

The customer may not get the chemicals that were required. Thus the process would not be giving the output required. Some changes to the process would need to occur in order that the chemicals required were indeed received, thereby making the process output acceptable.

*Auditing processes should result in a logical audit of the activities of organisations in carrying out the various functions required to supply customers with a product or service, which meet their needs.*

### **Non-conformities**

*The evidence collected by the auditors is compared with the audit criteria (the company's policies and objectives, manuals, procedures, instructions and contracts) and the audit findings including the non-conformities if any, are clarified and reported to the management at the end of the site audit in a formal meeting with the management, called the closing meeting. The non-conformities (NCs) are graded by the auditor as major or minor. Observations are also noted.*

*A 'major non-conformity' indicates that:*

- *The company has failed to implement any one part of or the full QMS*
- *Any specific department of the company has failed to implement the QMS as applicable to the department*
- *A number of minor non-conformities in the same QMS requirement are found.*

*A 'minor non-conformity' means an isolated incident of a failure to comply with a defined process or QMS requirement.*

*An 'observation' indicates that if the situation as found during the audit is not addressed, it may lead to a non-conformity in the future.*

*Where a major non-conformity is found, the recommendation for certification is deferred until corrective action on the same is verified through a follow-up audit.*

*After obtaining the organisation's timetable for corrective action, recommendations for certification are given by the lead auditor (the leader of the audit team), and these recommendations are conveyed to the organisation in the closing meeting itself.*

### **Award of the ISO 9000/14000 Certificate**

*Based upon the recommendations of the lead auditor and after independent review of these recommendations by the certification body, the latter issues a certificate to the organisation. The certificate is issued for a specific scope of the business and the products and services for which the organisation has implemented the QMS. It is important to make sure that the right scope is put on the certificate. Decide on time what the scope is that should be mentioned on the certificate.*

### **Surveillance audits**

*The certificate is initially awarded for a period of three years. During this time periodic surveillance audits are carried out by the certification body on mutually agreed dates. An audit plan for three years indicating the scope of the audit in each surveillance audit is transmitted to the organisation in advance by the certification body.*

*These audits are planned in such a manner that all aspects of the QMS are audited over a period of three years.*

*A re-certification audit is carried out after three years.*

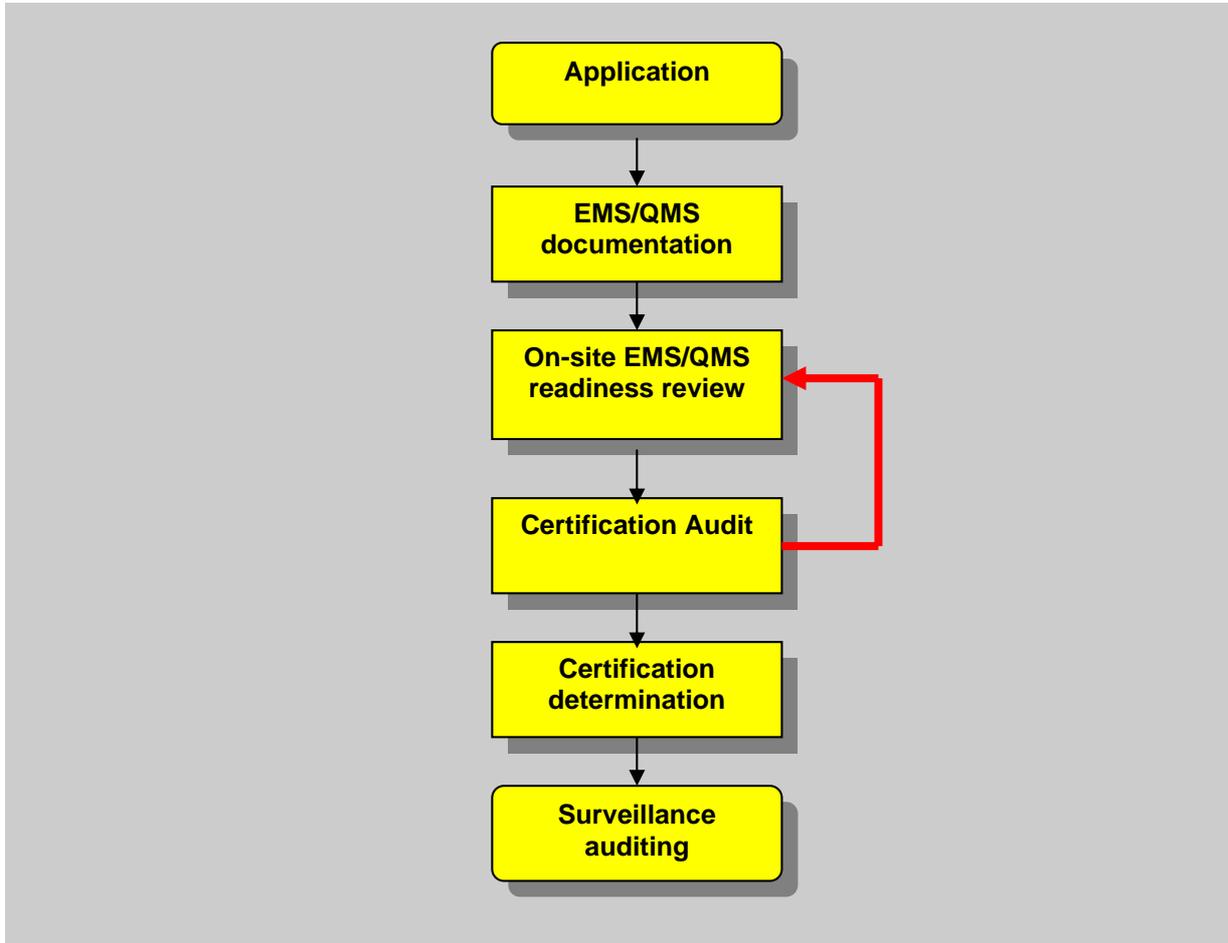


Figure 1.1, The QMS/EMS certification process

euromines

## **1.7 Initial review**

*The fundamental concept of the ISO 9001 and 14000 standards is the continual improvement of quality and environmental performance. But before the planning of improvement, the current status has to be determined.*

*The initial review is in itself, a simple but needed time consuming step by the implementation of a management system. No organisation starts from scratch. Each organisation has already acted in the field of quality or environmental issues.*

*The initial review includes each standard used at the organisation, each specification, including policy, legal requirements, training, objectives and targets, operational control systems, document control, management review and the corrective action.*

*The review should take into account the culture, products, marketing strategies and other specifics of the entire organisation. In all cases, consideration should be given to the full range of operating conditions, including possible incidents and emerging situations that may be encountered or situations with severe out of control products or services.*

*The ability of suppliers and subcontractors to comply with the organisations QMS and/or EMS program and the applicable regulatory requirements should be evaluated. It is strongly recommended that the initial review consider customer complaints, internal audits, management reviews, energy use, financial accounting and information systems so that these issues may be integrated in the management system.*

*To effectively start the initial review, several things must be done. First, the management should issue a company-wide announcement of intent and endorsement. This should include estimates of the time required to complete the initial review and time required to complete the full project.*

*Second, the project leader should be identified and vested with sufficient authority for completion of the project.*

*The initial review is a review of all pertinent documents, from which an accurate plan is designed for the management system gap analysis. All information from the initial review, including deviation from regulatory requirements and adverse impacts on quality or the environment, should be identified along with policies, programs, procedures, training and work instructions and operational controls.*

*A part of the project team should begin to assemble a registry of appropriate regulations and requirements identified during the initial review. All pertinent national, state, local, customer and self-designed requirements should be assembled. They should be compared with the identified management system impacts for quality or environmental issues.*

*An initial review is also important in ensuring that the management system design is compatible with all current organisational management structures and operations wherever possible. This is important where the management system interfaces with the operation's safety, accounting or other management programs.*

*The focus will be to achieve operational efficiencies that assure improvements and maximise cost reductions.*

*The initial review will produce:*

- *A management system analysis that details where existing management procedures must be further investigated to determine conformance to the standard.*
- *A review of the organisation's overall quality or environmental management strengths/weaknesses.*
- *A schedule of events for the gap analysis.*

*The gap analysis allows for a quick comprehensive assessment of the organisation's existing management practices and procedures, and compares them with the requirements of the standard.*

*To perform the gap analysis, a standard template tailored for that purpose is used.*

*The template is a questionnaire based on the standard. Each standard item is checked according to the actual situation. The result can be 'yes', the organisation complies, 'no', the organisation does not comply completely and 'none', the organisation does not comply at all. In the right column remarks can be made about the status and findings.*

*The score from this questionnaire identifies which areas of the management system might be enhanced to improve performance and comply with the standard.*

*Based on the results of the gap analysis, the project planning and design may require modifications. Using the results of the gap analysis, the management system development process can start.*

*This may involve modifying existing procedures, adapting other business practices. At a certain point new procedures will be required.*

*Prior to embarking on management system development, it must be noted that the more flexible the management system is, the easier the implementation will be and also the future adoption.*

*Chapter 2.5 contains the Gap analysis template for ISO 9001:2000.*

*Chapter 3.5 contains the Gap analysis template for ISO 14001:2004.*

## **1.8 References**

*EN ISO 9001, Quality management systems – Requirements (ISO 9001:2000)*  
European Committee for Standardisation, Brussels

*ISO 14001 Environmental management systems – Specification with guidance for use. 2004*  
International Organisation for Standardisation, Geneva, Switzerland

*ISO for small businesses, What to do, ISO/TC 176 2002*  
ISO Central secretariat, Geneva, Switzerland ISBN 92 67 10363 6

*Overstappen op de nieuwe ISO 9000 serie. Louise van Bergenhenegouwen 2001*  
Nederlands Normalisatie Instituut, Delft, Netherlands ISBN 90 5254 087

*Quality Management System ISO 9001-2000* Mike Nasser 2001

*Quality systems in the small or medium sized enterprise (SME)*  
Institute of Quality Assurance

*An introduction to ISO 9000:2000*  
International Trade Centre UNCTAD/WTO

*ISO 14001 Implementation and operation through document management and workflow.*  
Natalie Soroka and Michael Gordon, American Management Systems, Inc. 2000

*Environmental management experts identifying obstacles to ISO 14001 implementation in SMEs and suggest ways to overcome them. INEM, International Network for Environmental Management. 2002*

*Introduction to the ISO 14000 family of environmental standards, Poul Buch Jensen*  
INEM, International Network for Environmental Management. 2002-11-01

*Modern methods for quality control and improvement, Harrison M. Wadsworth*  
John Wiley and Sons, 1985.

*Environmental Policy, Hecla Mining Company.*

*ISO 14001:2004 – ISO has finished their job, now it is with you (and us), Tse Chun Ho, BVQI*

*Summary of key changes between ISO 14001:1996 and ISO 14001:2004, CSA Technical Committee on Environmental Management Systems*