

Application of ISO 9000 Standards to Education and training

**Interpretation and guidelines
in a European perspective**

European Centre for the Development of Vocational Training

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to Education and Training
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European perspective

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PREFACE

This report is one of the series of studies elaborated within the context of CEDEFOP's project on quality in vocational training. In conformity with the European Council Resolution of 5 December 1994 on the quality and attractiveness of the VET, CEDEFOP has commissioned and is currently commissioning studies on some key aspects of the debate on quality at European level. It should be clear that the Centre is working both on quality assurance and quality assessment issues. Quality being a multi-dimensional and relative concept, CEDEFOP has started its works on it with a synthesis of ideas and experiences in seven EU Member States complemented by additional information. This publication of "Quality issues and trends in vocational education and training in Europe" is actually available in English, German, Spanish and French.

A second report has been drawn up on one of the main tools for quality assurance and assessment, namely indicators. An overview of the various types of indicators, their scope and implementation with a proposal concerning design methodology for quality indicators is elaborated and it will soon be published in English, French and Spanish.

In relation to quality assessment CEDEFOP has organised jointly with the Greek OAED and the German FHVR-Berlin a conference on "Approaches to the evaluation of European Training, Employment and Human Resource Programmes", aiming to contribute to the definition of priorities so that European Programmes can be more efficiently implemented and evaluation methods improved.

An international and interdisciplinary exchange of views and information on employment policy, vocational training and social policy aspects of the evaluation of European training, employment and human resource programmes took place during the two days of this conference in Athens. The interested reader may find the related papers in CEDEFOP's panorama series in English, Greek, Spanish and German.

Following this, CEDEFOP has proceeded to the analysis of the evaluation practices of quality aspects in vocational training programmes. Five countries have been studied and a synthesis report is in preparation. It will be available in English and French.

Concerning exclusively initial vocational education and quality, CEDEFOP has chosen to limit itself to a comparison of school-based quality concepts and practices in two countries, which are well-advanced in this field: The Netherlands and Denmark.

Two national reports, merged into one under the title "Quality Debate in Initial Vocational Education", have been drawn up. The report, published in English, gives an overview of the policy context on quality and a detailed presentation of the cases of ten schools in both countries, which have adopted different and often complementary approaches to quality assurance.

Based on discussions with experts in the field, CEDEFOP realised that over the last decades the "quality wave" originally started within the manufacturing industry, has also hit the training institutions in Europe. Certification, and especially certification on the basis of the ISO 9000 standards being one of the most sought after certification mechanisms, CEDEFOP has entrusted Mr Wouter van den Berghe, an international expert with a considerable experience in this area, with drawing up the present report on the ISO 9000 standards family in Education and training.

The study does not limit itself to presenting the ISO 9000 standards, and especially the ISO 9001 and ISO 9002, which are the two most relevant ones to highly and less highly regulated training and education providers and institutions, but it also provides for an interpretation of each paragraph of them in a European perspective. It also contains practical suggestions for their implementation and underlines the requirements set up before launching such an operation.

Based mainly on the experience gained by their implementation in the United Kingdom, France, Germany, Belgium, The Netherlands and Denmark, the report underlines the difficulties in adopting ISO 9000 standards in VET, some inherent to the very nature of the educational process and others to the standards themselves.

Now that the ISO 9000 standards are under revision for 2000, CEDEFOP published this report on their implementation in education and training environments in the hope of contributing to the exchange of experience and information on them.

We would like to thank the author, Mr Wouter van den Berghe and all the experts he has consulted for the present work, which – we are convinced – will be useful to the reader.

Tina Bertzeletou
Project manager

Stavros Stavrou
Deputy director

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When I became a consultant for education and training organisations regarding ISO 9000, I learned a lot from the people and organisations I worked with, of which are to be mentioned in particular: Paul Garré and Dirk De Ceulaer (EHSAL), Hans Romaen (Technologisch Instituut), and Valerie McConaghy (May International).

Over the last two years, or specifically for this study, numerous individuals and organisations have forwarded me relevant information concerning ISO 9000 in education and training, often of an internal nature. These include, in addition to the people already listed: Wilfried Bartz and Rüder Keuper, Technische Akademie Esslingen (DE); Karl-Heinz Brehm, Siemens (DE) and ISO; Vincent Calmettes, SISIFE (FR); Søren Casparij, DIEU (DK); Dominique Delferrière, Management Information (BE); Sabine De Ruelle, Vlerick School for Management (BE); L. Jungerius, NCATB-Elsevier Opleidingen (NL); Mr Frances, CESI Languedoc-Roussillon (FR); Peter Hector (†), Aquaforce project (UK); Monika Kegelmann and colleagues, Certqua (DE); Annalis Larsen, Hillerød Technical College (DK); Mr Mol, Aval Lasinstituut (NL); staff from NAACB (UK); Søren Nielsen, DEL (DK); Edgar Sauter, BIBB (DE); Ria Sturm, NS Opleidingen (NL); Eduoard Touboul, CEIFCO (FR). Special thanks also to staff of certifying bodies, in particular Patrick Bellon, ISO 9000 lead auditor with AIB-Vinçotte (BE), who kindly reviewed the interpretation of the Standard in Chapter 4. Staff from DNV (NL) and BSI Quality Assurance (UK) also were helpful in locating additional information and providing lists of certified education and training organisations.

Finally, I wish to thank CEDEFOP and its staff, particularly Tina Bertzeletou, for the support received, but also for the trust and encouragement.

Wouter Van den Berghe

October 1997

1. Introduction

1.1 Context of the report

1.1.1 Background

Over the last decade the topics *Quality*, *Quality Assurance* and *(Total) Quality Management* have become a central preoccupation of hundreds of thousands of organisations in Europe. It was the industrial world which first recognized that much of the growth and economic success of Japan could be attributed to the consistent focus of companies on quality and quality improvement. Since the mid-80s in particular, European firms have started to adopt the concepts and methods of Total Quality Management – in short ‘*TQM*’ – to meet the quality level which customers expect and for improving continuously the quality of products and services they deliver.

One of the more visible features of this ‘quality wave’ has been, particularly in Europe, the *certification* of the quality assurance mechanisms on the basis of the *ISO 9000 Standards*. Despite the fact that the ISO 9000 norms cover only a sub-set of the TQM principles, this form of certification is becoming the *de facto* basic quality standard in many industrial sectors of the more developed European countries. As an example, in the chemical industry in the Rotterdam port area it has become almost impossible for any type of supplier to deliver products or services without being an ISO 9000 certified company. In the United Kingdom, an ISO 9000 certificate has already been awarded to tens of thousands of organisations. Most other European industrial sectors and regions are catching up in this regard. By the end of 1996), over 100 000 organisations in the world had been certified, the large majority of these being European.

The ISO 9000 standards had originally been conceived for companies in the manufacturing industry, in particular subcontractors to large industrial concerns. However, since the early 90s in particular, application of the norms has quickly spread to other sectors of the economy. Indeed, notwithstanding terminology and interpretation problems, most quality experts agree that the requirements set forward in the standards can provide a suitable framework for the quality assurance system of any type of organisation, whether large or small, or whether product or service-oriented. Although this framework is not the optimal one for all types of organisations, and the value of an ISO 9000 certificate differs by sector and country, the developments over the last years have resulted, at least in Europe, in a broad recognition of the value of an ISO 9000 certificate and its function as a quality label.

In this context, it will not come as a surprise that interest for the ISO 9000 quality standards also grew in the education and training world. The first groups to pay attention were providers of continuing education and training for the business world, as well as, to a lesser extent, vocationally oriented schools. Both types of organisations are indeed closer to market needs and business developments than

regular education institutions. Some general education schools and higher education institutions have also taken the ISO 9000 road; a few pioneers have already passed the certification stage. This development is still in its very early stages. It is only since the early 90s that the first education and training institutions in Europe have obtained an ISO 9000 certificate, some of them even for only part of their activities. The numbers are increasing, slowly but steadily, particularly for continuing education and training providers; about a hundred of these had been certified by the end of 1996, mainly from the UK, Germany, the Netherlands and France.

The pace of this development is not dissimilar to trends in other service sectors (and public sectors in general) which have not been as eager as manufacturing to jump on the ISO 9000 bandwagon. Additional hurdles for education and training providers are their limited resources and/or their small size. But even when such – important – practical issues are left aside, for many practitioners the real added value of such a certification process remains doubtful. Information is lacking on the conditions under which ISO 9000 certification can be considered as a viable and, eventually, successful quality strategy for particular types of education or training institutions.

1.1.2 Purpose of this study

Individuals across Europe have recently gained valuable experience regarding the interpretation, application and relevance of ISO 9000 for education and training organisations. These people include staff members of the establishments concerned, researchers, consultants and certified ISO 9000 auditors. So far little exchange of experience has taken place, in particular across borders and language areas; what is known has not yet received widespread attention in the education and training world. Relevant information is often hard to find, specifically in countries where few or no education or training providers have been certified. Moreover, little effort has been undertaken to compare the approaches and results obtained across different European countries.

This report aims at bringing together European experience on the interpretation and implementation of ISO 9000 in education and training environments. At the same time, the document has the ambition to serve as an introductory guide for education or training establishments who might consider certification. Not all aspects could be covered to the same extent. The focus was on:

- the correct interpretation of the ISO 9000 standards specification for education and training providers;
- the experience gained with implementing such a quality assurance system;
- the first results regarding added value, potential benefits and drawbacks.

Originally this study intended considering vocational education and training providers only. In the course of the research, it appeared more appropriate to establish a document report which might be of benefit for all types of education and

training organisations: schools, higher education institutions, adult education providers, private training centres, training departments within firms, etc.

1.1.3 Approach adopted

Ideally, this report should have been based on the in-depth analysis of some twenty or more case studies. Given the considerable geographical spread of certified institutions in Europe and the modest level of support available, a more pragmatic approach had to be taken, however. No *new* cases were investigated, but extensive use was made of the material which was already available or which was kindly provided to the author (cf. Acknowledgements). It was not feasible either to launch and process a European-wide survey on this matter. Despite these limitations, an attempt was made to gather and study as much information as possible. This process included the analysis of:

- existing "interpretations" or clarifications of the use of ISO 9000 in various education and training settings;
- descriptions of case studies or accounts of ISO 9000 implementation stories;
- reports or articles which discuss issues related to the relevance, benefits and problems concerning the application of ISO 9000 to education and training;
- quality manuals of ISO 9000 certified education and training organisations;
- specific checklists used by ISO 9000 auditors.

Almost all the documents referred to (some of which are confidential) were obtained from people and organisations in the United Kingdom, France, Germany, Belgium, the Netherlands and Denmark. Extensive searches were also conducted on the Internet World Wide Web, but on this particular topic, this proved not very successful. The analysis of documents was complemented by oral discussions and interviews (mostly via telephone) with over twenty people in six countries who – as practitioner, consultant or auditor – had been involved in the implementation of ISO 9000 standards in education or training organisations. The research could be undertaken efficiently since the author had a profound knowledge of ISO 9000, provides training on the standards and their application in education and training, and acts as a consultant for several education and training institutes who are working towards (or have already obtained) an ISO 9001 certificate.

After this introductory session, this chapter also recalls the importance of quality concepts in education and training (Section 1.2) and summarizes the key concepts of Total Quality Management (TQM) and its relevance for education and training (Section 1.3).

Chapter 2 provides a short introduction to the ISO 9000 standards. The relationship with quality assurance and TQM is explained, and an overview is given of the main principles of the standards: structure of the ISO 9000 family, underlying principles, main components, and the certification process. This Chapter can be skipped by those who are already familiar with the standards.

The next chapter looks at the context for applying ISO 9000 in an education and training environment. Two main issues are discussed. First, Section 3.1 examines the rationale behind adopting the standards in an education or training organisation: the reasons for seeking certification, the expected benefits, and different considerations by type of education or training organisation. Section 3.2 discusses terminology and interpretation issues. The main interpretation problems are highlighted, the terminology is explained, and a more logical rearrangement of the paragraphs of the standards is proposed.

Chapter 4 is the core of the report. It includes a detailed discussion and interpretation of every paragraph of ISO 9001. Where appropriate, differences by type of education or training organisations are highlighted. Practical suggestions for implementing the requirements are provided throughout the text. Incidentally, ISO 9001 lists in its fourth chapter all its requirements; consequently, the numbering of the sections in this report corresponds exactly with the related sections in ISO 9001 (for instance, Section 4.5 of this report discusses the requirements of section 4.5 of ISO 9001).

Chapter 5 discusses implementation issues. It indicates the minimum requirements before launching a certification exercise (Section 5.1), and summarizes both positive and negative messages emerging from implementing the standards in education and training institutions (Section 5.2). The final section of this chapter gives a qualitative overview of the benefits (or otherwise) resulting from successful certification.

Chapter 6 presents the overall conclusions of the study.

The report does not include a detailed implementation strategy for putting ISO 9000 into practice. The main reason is that implementation varies considerably from one organisation to another. The approach to be adopted depends on factors like: size of the organisation, type of education and training programmes offered, characteristics of customers, degree of standardisation, ancillary services provided, other activities within the scope of the quality system, etc. Implementation strategies will also depend on whether certification is sought for the whole or only part of the organisation. Implementation issues have, however, not been discarded in this report. Section 2.3.4 provides general information about the key steps involved in certification, Chapter 4 includes many suggestions on

how particular requirements of the Standards can be put into operation, and Chapter 5 contains a series of observations resulting from successful implementation.

This report was primarily intended as a guide for education and training organisations, and for policy makers. It does not include, therefore, a critical discussion or in-depth comparison of the differences and interpretations and approaches adopted across Europe. All public and non-confidential sources consulted have been grouped and listed in the Bibliography.

1.2 The importance of quality concepts for education and training

1.2.1 Some observations on quality in education and training

It is not the purpose of this report to discuss the reasons for the increasing emphasis on quality issues in the education and training world – and how governments, institutions and learners are coping with these challenges. These topics are dealt with more extensively in the recent CEDEFOP report "*Quality Issues and Trends in Vocational Education and Training in Europe*". Therefore, only some general points are recalled here.

The first observation is that quality is not a new subject in education and training. Institutions, teachers, administrators, policy makers and learners have always been concerned with quality. Indeed, the quality of an education or training provider eventually depends on the performance of the learners. Even without a formalised 'quality' approach such as *Total Quality Management (TQM* – see next chapter) or ISO 9000, schools and training providers have needed methods, norms, procedures and standards to ensure the quality of their provision. But it is equally true that, traditionally, quality has often been interpreted fairly narrowly, focussing on particular features of the education and training services delivered.

This brings us to the second general observation: in education and training, just like in most other sectors, the dominant quality ethos tends to change over time. The current trend is one whereby quality concerns are increasingly focusing on the total effectiveness of an education provider, whether that is a vocational school, a university or a private training institution. This tendency mirrors the industrial developments where quality considerations are moving towards the *organisational* capacity to deliver high quality goods and services (the systems thinking behind the Total Quality Management concepts).

This leads us to a third important observation: the current concerns for quality in education are no isolated or temporary phenomenon, but are part of broader macro-economic trends. It does not imply that 'older' types of quality considerations (e.g.

didactics) are no longer valuable. Rather, an effective 'Total' Quality strategy in education should be able to incorporate the more traditional quality perspectives.

A fourth general observation is that the 'new' approaches to quality assurance and management in education and training mean something different for each type of education and training. Simply stated:

- a shift in emphasis in schools, from a focus on the quality of the teacher towards the performance of the institution as a whole;
- the introduction of new or additional quality control mechanisms in higher education;
- the creation, for the first time, of quality assurance systems and performance related mechanisms in continuing education and training.

A common characteristic for all types of education and training is the increased concern for the performance of the learner (the effectiveness of learning) and the effectiveness and efficiency of the provider as a whole. This explains also the interest in TQM and quality assurance approaches.

A final observation: notwithstanding the increased emphasis on organisational factors as a prerequisite for quality assurance, it is recalled that no effective learning can take place without high commitment of the teacher or trainer. The corollary is that quality approaches – including TQM and ISO 9000 – are doomed to fail if they do not support the inner motivations of teachers and are able to sustain or increase their commitment.

1.2.2 Emphasis on quality as a result of the dynamics of education and training structures

The current education and training systems in Europe have been shaped by many and different social, cultural, pedagogical, economical and employment factors. All these elements have always been present, but their relative importance tends to change over time and also by type of education and training. The impact of external factors on the education system has also been variable over time. Two important trends may be observed in this regard:

- external demands (from governments, students, employers,...) on the education system are increasing; this puts pressure on the deployment of resources and the efficiency of the organisation
- the continuing education and training sector is becoming a more mature and 'established' economic sector, alongside many other service sectors.

Such trends suggest that the education and training world is losing much of its special status, and is more and more considered like an 'ordinary' economic sector. It also implies that schools, universities and training providers are increasingly expected to perform at high level, behave professionally and provide quality services throughout. The education and training paradigms are changing from supply-driven teaching to demand-led learning. Although many educators do not feel comfortable with such developments, they would seem to be inevitable. Indeed, similar custom-driven trends can also be witnessed in other areas, such as public services.

Amongst the specific factors which contribute to the growing emphasis on quality in education and training, the following may be listed (some of these concern all types of education and training, while other arguments apply only to particular segments of the education and training system):

- When it comes to quality, people increasingly reject the historically grown distinctions between products and services, between profit and non-profit, public and private, and small and large organisations. The broad choice and high levels of product and service quality which are now available in developed countries raise

citizens' expectations and make them critical of low-quality performance anywhere – including in education and training.

- The wide choice available in society gives citizens more power and increases the appetite for change, flexibility and customising. Moreover, people's ways of life and expectations are less uniform than in the past. In education and training this trend is visible through the more complex and variable qualification requirements.
- In this information age, once certain information enters the public domain, citizens tend to expect to get such information in the future as well. Thus, the more information be

comes available on quality and performance results in education and training, the more demand there will be for it.

- Public education institutions are, like most other public services, increasingly called upon to become publicly accountable for what they do and to demonstrate that they deliver a quality service.
- A long term argument for quality in education is that of its own survival, since a well-funded education system can only exist under a flourishing economy. In the current global competitive environment any inefficiency and lack of flexibility, also in education, will be penalized by lower economic growth and hence, eventually, to fewer resources available for education.
- In the relatively stable environment of the past, quality in education and training could almost entirely be attributed to the inherent abilities of the teachers and trainers. Because of the rapidly changing environment, new demands, more complex activities, differentiation, and increased customer involvement, these abilities alone no longer suffice for guaranteeing quality.
- Competition between education institutions is becoming a major issue. For higher and continuing education it is already even crossing national borders. This competition is more and more based on facts and on the real quality of a particular institution, and no longer on its historical standing and reputation. In such a more competitive environment, there is the need to be able to sustain a high quality image with customers, and be able to demonstrate quality on an ongoing basis.
- Many types of education and training organisations, particularly in higher education and most of vocational and continuing education, face an escalation of costs, in order to provide high quality provision. At the same time, public education also faces constraints on public expenditure, which forces governments to find ways to get more for less. Similarly, companies increasingly expect to get more out of their training budget.
- The increased variety and complexity of education and training provision calls for mechanisms to ensure better transparency of the quality on offer.
- The quality trends in continuing education and training are also related to changing attitudes within firms themselves. Companies increasingly recognize the importance of continuing training of their employees as a critical factor for their long term market success. Consequently, optimising this investment through quality assurance arrangements – both within the firm and with the providers – is becoming a necessity.

Thus, there are many factors which, together, call for greater attention to quality in education and training – and hence for mechanisms, methods and systems which can help ensure quality all the time. The above list shows that, while some of these factors are internal to the education structures, most are external. Education and training systems are – increasingly – interwoven with the rest of society, and therefore subject to similar pressures and trends.

1.3 Total Quality Management (TQM)

1.3.1 Introduction

Simply stated, Total Quality Management (TQM) is an organisational strategy and a management approach which involves all employees and is aimed at continuously improving the organisation's effectiveness in achieving customer satisfaction. In this definition, the customer notion is interpreted broadly, and includes also the 'internal customers' within an organisation itself. The concepts and application of TQM originate from Japan, where the systematic use of TQM principles and methods in the production sector made the country an economic superpower in just a few decades. Since the early 80s, the value of TQM has increasingly been recognised by business in the United States and subsequently Europe.

While originally limited to the private sector, and more particularly manufacturing enterprises, the early successes of TQM contributed to the spreading of its principles and methods across other sectors, including public services and non-profit organisations. The main 'logic' behind the adoption of TQM methods is as follows:

- the increasing competition requires continuous improvement of quality and productivity;
- customers determine purchasing choices based on their perception of quality, and hence determine the competitive position of the suppliers;
- an organisation must adopt the TQM paradigm to achieve this customer focus, and to be able to generate high quality all the time at the lowest possible cost.

Empirical evidence confirms, by and large, the validity of these hypotheses. Because of this, TQM has become the predominant approach to quality in the private sector, and increasingly in other areas of economic activity as well.

Although some official definitions of TQM exist, it must be recognised that the scope of 'Total Quality Management' is not very well defined. Each of the leading advocates and 'gurus' of TQM puts emphasis on particular aspects. Since the economy is in constant movement, and needs evolve, the balance between the different components of TQM tends to change over time. Aspects which were central to TQM some decades ago in Japan, may have lost their prominent place today. Thus, TQM is more a catalyst for existing trends and tendencies, than a standard or a precise catalogue of methods and prescriptions.

Over the last years some generic 'models' for Total Quality Management have been developed. In the United States, the first models were based upon the ideas of some quality gurus like Deming, Juran and Crosby. The more elaborated system which has been developed out of this is the set of criteria for the Malcolm Baldrige Award. This has become the standard reference model for TQM in the United States, with adaptations for specific sectors (including education) being piloted.

In Europe, the most important model is that developed for the European Quality Award (EQA), promoted by the industry-led European Foundation for Quality Management (EFQM). The EQA-model covers nine different areas: Leadership, People management, Policy and Strategy, Resources, Processes, People Satisfaction, Customer Satisfaction, Impact on Society, and Business Results. For each area, there are a number of sub-criteria with specific questions for self-assessment. The premise behind the EQA-model is that *"customer satisfaction, people satisfaction and impact on society are achieved through leadership, driving the policy and strategy, people management, resources and processes, leading ultimately to excellence in business results"*. The EQA model has also been at the basis of the criteria of national quality prizes in many European countries. Adaptations of the EQA-model have been made for the education sector, including a sophisticated one for Flemish (vocational) higher education (the so-called 'PROZA'-system).

In addition to such standard models, many specific quality systems have been developed, both at the level of (larger) companies, and for specific sectors. Over the last years, traditional 'inspection based' quality approaches in many European countries have been converted into assessment models which reflect more the TQM paradigm. Some excellent assessment and audit instruments have been developed, particularly in the Anglo-

Saxon world (e.g. the SQMS-system in Scotland). It should be noted that most quality control systems in education are predominantly based on quality assurance principles – which implies that they reflect some of the spirit of ISO 9000 (see next chapter).

1.3.2 Key concepts, principles and characteristics of TQM

When analysing the literature, one will find a broad consensus amongst quality experts about the key characteristics of TQM – although they may not agree as to their relative importance. There are also a number of elements which are considered as part of TQM by some, but not by all specialists. What follows is the author's own synthesis and positioning in these matters.

One may identify a 'TQM-organisation' through four different series of characteristics:

- underlying concepts;
- operational principles;
- implementation characteristics;
- typical results.

These series of characteristics are briefly described below.

First of all, there are the *five underlying concepts* – almost dogmas – of TQM:

- *A clear customer focus.* The first priority of an organisation and its staff must be to understand and to satisfy the needs and expectations of the customers and the chosen target group. Furthermore, this customer orientation also embraces the concept of the '*internal customer*' within an organisation. For TQM to become effective, a clarification of the internal customer/supplier relationships within an organisation is needed, to ensure that all internal customers are satisfied by the internal suppliers.
- TQM requires *continuous improvement* in everything an organisation does. Quality is never-ending, and an organisation-wide attitude should prevail whereby the search for improvement always continues, by everyone in the organisation. Such improvements should be guided by a clear understanding of the mission of the organisation, and a vision of what it wants to become.
- *Quality assurance* of internal processes. This implies that standards are set, procedures to achieve them are defined, and adherence to these is guaranteed; problems occurring are remedied in a systematic way. Effective quality assurance contains the seed for continuous improvement (one cannot improve quality without controlling the current situation) – but inefficient quality assurance leads to bureaucracy.
- *Process orientation.* The final quality of a product or service depends on all preceding processes. This principle points to the need for process thinking, for an

integrated approach to the whole development and delivery chain, and for an optimisation of the internal customer/supplier interfaces. It is essential to identify all the critical processes in the organisation.

- *Prevention instead of inspection* to achieve quality. Through adequate preventive measures (appropriate design, decent planning, targeted training, adequate equipment, effective communication, etc.) Fewer quality errors will occur, customers will be more satisfied, and less inspection and control will be needed. The theory of '*quality costs*' shows that the costs and time spent on preventive measures at the planning and design phase will eventually be lower than the costs of inspection, defects, waste and repair.

Secondly, five important *operational principles* distinguish TQM-oriented organisations from the other ones:

- *Management leadership and commitment.* The driving force behind any TQM approach must be the commitment, vision and exemplary leadership of the senior management, which should be carried down to every level of management within the organisation. The leadership of management regarding TQM is essential for building a strong consensus within an organisation regarding quality. Managers should continuously communicate the TQM-message towards their employees.
- TQM requires *teamwork*. The benefits of TQM reside to a large extent in effective teamwork, particularly when involving people from different departments. Effective, cross-functional teamwork needs to be a key operational characteristic of any TQM effort. Such teamwork is both needed by, and the result of, effective TQM strategies. Teamwork also extends in working together with suppliers and possibly customers in addressing issues for improvement.
- *Quality is everyone's job.* Quality is not a functional or departmental responsibility which should be left to inspectors, or quality controllers. Achieving quality – adherence to agreements, meeting customer expectations, avoiding waste – should be the norm in all processes of the whole organisation. This goal requires the involvement of all employees at all levels and in all departments. It must be supported through human resource strategies that recognize and reward quality efforts.
- *Focus on facts.* Discussions and decisions on activities and resource allocations should be based on reliable and relevant information. This applies in particular to everything which relates to the customers, both external and internal (what are their needs, how do they feel about our products/services, etc.?). Of special importance for the development of a more quantitative thinking approach is the use of appropriate *data gathering and analysis* methods (including statistical ones) in order to constitute relevant information in a timely and efficient manner.
- TQM is based on *systematic problem-solving*. This requires the use of appropriate tools and methods for identifying weaknesses and areas for improvement, analysing them, tracing the sources of problems, seeking improvements and, finally, implementing them. In this context, the term 'problem' should be read as 'anything which should be improved'. While some of these tools may be quite sophisticated, most of them are very easy to apply, yet often remarkably powerful.

An organisation which supports these underlying concepts and adheres to the operational principles listed above, is likely to become a TQM-organisation. Whilst there are, in principle, many ways to implement all these principles, the reality shows that most TQM-organisations display the following *implementation characteristics*:

- The formulation of a clear *mission and vision statement*. These are communicated and accepted throughout the organisation, and serve as an anchor for the quality policy and strategy. In larger organisations, such statements also exist at department and unit level. Mission and vision statements include a clear

identification of the customers to be served, and are complemented by the shared values of the organisation.

- The establishment of a *quality manual*, which describes the organisation, its policy, its key processes and the responsibility and authority of staff. In general, such an overall quality manual is complemented by procedural manuals at department level, describing the critical processes in sufficient detail. Access to up-to-date information in quality and procedural manuals is a necessity for quality assurance.
- *Systematic training* of staff throughout the organisation. Training needs are analysed and remedied where necessary, in order to ensure that all employees – from the senior

ior manager until the shop-floor worker – are qualified for the activities they undertake and for the positions and responsibilities they might assume in the future. Training is complemented by human resource policies that reward improvement, professional development and quality achievements.

- *Decision-making* is delegated to the *lowest possible level*. The increased responsibility and authority of employees increases commitment and motivation and encourages mutual trust and support throughout the organisation. In line with this development, the organisation becomes flatter (fewer management layers) and managers become coaches rather than controllers.
- *Customers are asked for feedback* all the time, often through regular *customer surveys* aimed at understanding needs and expectations, checking satisfaction with the quality provided, and detecting new trends. Such surveys are systematically analysed in order to implement changes where necessary. Linked to this, there is an effective system for rapid and effective *complaint handling*. This applies to all kinds of complaints and problems, including those inside the organisation. External customers are often urged to indicate their complaints. Within the organisation, the complaint system should gradually be replaced by a 'suggestion scheme' whereby any individual in an organisation may suggest improvements.

Finally, an organisation which has been working alongside the TQM principles is likely to be able to show the following typical *results*:

- better and more consistent *quality* of products and services provided;
- considerable *reduction of defects*, waste, problems, complaints, delays, etc.;
- regular and timely *innovations* in products and services;
- cost effective and *efficient processes* throughout the organisation;
- a highly *motivated*, qualified and self-confident *workforce*.

Obviously, the nature and the extent of such results will differ strongly across organisations. The extent and speed of achievement depends not only on how the concepts, principles and characteristics listed are put into practice, but also on other factors such as the economic and legal environment, the size of the organisation, and the quality expectations of customers.

1.3.3 What can TQM achieve in education and training?

The fact that possibly a million or so European organisations have adopted some kind of quality or TQM approach (including ISO 9000), implies they must have seen some benefit in doing so. This argument also applies to the education and training organisations who have so far embraced the TQM concepts. One might imagine that the primary reason to move in this direction would have been to improve the quality of their education and training provision. The reality is more complex, however. Based on reported experience and documented case studies, the main rationale behind the TQM approach of the pioneering institutions appears to have been:

- an improved external quality perception and image, thanks to clearer internal policy choices, better customer orientation and more effective marketing;
- a more efficient internal organisation, with more effective management, better motivated staff, and more successful internal communication;
- achievement of professionalism in non-educational services, i.e. the services and activities provided by the institution in addition to the delivery of the course programme (registration, administration,...);
-

raising the quality of the education and training services and products themselves: the relevance of the course programme, the didactic quality of instruction, the effectiveness of the needs analysis,...

This is, actually, also the order in which the benefits of TQM seem to materialize. The fact that the quality of education and training itself is not the central or priority issue may be explained by the strong position of the early adopters in this regard. But it may also suggest that adopting TQM (and ISO 9000, as we will see) does not make a lot of sense if some basic quality level is absent.

2. The ISO 9000 standards for quality assurance

2.1 Introduction

Given the abundance of books available on ISO 9000, there is little added value in providing an extensive description of the norms, their origin and their applicability. This chapter, therefore, only highlights some key issues which are important for a good understanding of the more in-depth discussion on the application of the standards in education and training (Chapters 3, 4 and 5).

"ISO 9000" is the common name for a family of international standards for quality assurance within organisations. Their origin dates back to the development of the American military industry in the early 50s, when the significant expansion of production capacity, increased security requirements, and large-scale use of suppliers made the establishment of 'military' quality standards for suppliers mandatory. In the 50s and 60s similar developments could be observed across the developed world in other areas, such as the nuclear sector, the pharmaceutical industry, and car manufacturing. In general, the system was one whereby the customer (e.g. an automobile plant) audited the suppliers or potential suppliers against the specific standard.

Because this practice led to a proliferation of standards and audits – e.g. a supplier might be subject to several different audits by its major clients – the authorities in the United Kingdom published a 'generic' standard, BS 5750 in 1979. This adoption of this standard provided two main advantages:

- suppliers from a wide range of sectors needed only to comply with one standard, rather than with multiple ones;
- only one audit was required, by an independent body, who subsequently *certified* the supplier company.

Thus, several customer companies no longer needed to undertake different audits themselves, but could rely on the audit and certification by a third party. In addition to the obvious cost-effectiveness of this approach, it also solved the problem of confidentiality regarding the know-how of the suppliers.

The success of this new approach was rapidly observed outside the United Kingdom. In 1987, therefore, the International Standards Organisation (ISO) issued a set of norms, "ISO 9000", which were almost a direct copy of the British standard. Over the following years, the family was expanded with additional norms and guidelines. ISO 9000 became a European standard series for quality assurance (first called EN 29000, now called EN ISO 9000) which was gradually adopted in most European countries. At international level, a first revision of the norms was finalised in 1994, but the modifications were relatively minor. However, a major revision is underway, expected to be ready around 2000. This new version of the standard will be structured differently, will reflect more a TQM than a quality assurance approach, and will use a terminology which is applicable to virtually all economic sectors.

Indeed, with the publication of ISO 9000 a somewhat unexpected phenomenon had occurred. Although initially designed for use in contractual supplier-customer relationships only – and predominantly in the production sector – many different types of organisations started to show interest in the norms as well – first in the UK, subsequently in several other European countries, and finally in the USA and Asia. It was realised that the generic nature of the specifications made the norms applicable to most types of organisations, even non-profit ones – despite the fact that interpretation of some of the sections in a non-manufacturing context was not straightforward. The main reasons for this interest were: (1) the easy recognition by the market of the certificates; (2) the official ‘proof’ by an independent authority of the quality level of the organisation; and (3) the absence of any better or more suitable international norm.

Thus, ISO 9000 has become the *de facto* industry standard for quality assurance for any type of organisation. By 1996 more than 100 000 organisations (predominantly in Europe) had already been certified, and the numbers keep increasing, albeit it at different speeds in different countries. The typical ISO 9000 “waves” in a country are:

- firstly, the manufacturing sector show interest;
- then the service firms directly related to production companies come into the picture;
- and finally organisations from other service sectors get involved, including public services and non-profit organisations.

It should be noted most European countries (with the exception of the United Kingdom) are still in the first wave, although the beginning of the second and pioneers of the third wave can be observed. This – simplified – “wave” model explains partially why providers of continuing education and training are typically the pioneers in the education sector.

2.2 The relation between quality assurance, ISO 9000 and TQM

In the official denomination of the different ISO 9000 standards, there are explicit references to “*quality assurance*”. We have seen before (cf. Section 1.3.2) that quality assurance is an important part of a TQM approach. So, how do ISO 9000, TQM and quality assurance relate to each other?

The term “*quality assurance*” is defined in ISO 8402 – a standard containing official definition of key quality terms – as follows: “*All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality*”.

In practical terms, quality assurance requires an organisation to ensure that:

- quality standards are defined for all activities to which quality assurance applies (a quality standard is a well defined set of minimum criteria which a particular output, product, service or process should meet);
- suitable procedures are available for ensuring that quality standards are met;
- procedures are systematically monitored for conformance, using statistical methods where appropriate;
- causes of the non-conformances identified are analysed;
- causes of problems are eliminated through appropriate corrective action, in order to avoid – or at least minimise – the probability of those problems reoccurring.

When all of this is undertaken – in whatever way – for a set of activities, processes or outputs, it can safely be stated that ‘quality assurance’ is taking place. It should be noted that quality assurance is mainly concerned with the *quality of conformance*, as opposed to *quality of design*, i.e. the quality assurance principle assumes that quality standards have been adequately designed, and that only conformity with these standards needs to be ensured.

Although all of this looks like common sense, the reality in many organisations is often quite different:

- quality standards are vague or ill-defined – or even entirely implicit;
- the existing procedures are incomplete, conflicting or not used;
- inspection or verification of performance is irregular, or happens only when major problems have occurred;
- the real causes of problems are left untouched;
- only short term corrective measures are taken when problems arise, with the risk of the problem reoccurring.

If most of such features apply well to a particular organisation, then it will have to conduct a long and painful exercise to implement a quality assurance system. It should be noted that putting quality assurance mechanisms in place may require several iterations before the whole system becomes stable and normalized.

Although ‘quality assurance’ is only one of the underlying concepts of a TQM approach (cf. Section 1.3.2), it should be recognised that it is closely linked to the other components of TQM (all of which are, in fact, closely linked to each other). For instance:

- the customer orientation should be reflected in the definition of standards;
- continuing improvement is only possible when the current system is well known and under control;
- the effective application of quality assurance requires a process orientation;
- a well functioning quality assurance system reflects a preventive attitude, and will prevent problems.

Thus, effective quality assurance is an important milestone towards a TQM-based organisation; similarly, implementing TQM without adequate attention to quality assurance concepts will eventually fail. On the other hand, it must also be

recognised that excessive focus on quality assurance may yield counterproductive effects, in particular when too much attention is paid to prescribing standards and excessive inspection. Such a "reductive" interpretation – whereby the suitability of the procedures, the analysis of problems and the eradication of problem causes are neglected – would quickly result in a bureaucratic system.

What then about ISO 9000? At first sight, it would appear that the ISO 9000 standards are concerned with quality assurance alone. This spirit penetrates the whole document, particularly through the numerous requirements for documented procedures, document control, quality records, inspection and verification, and corrective measures. However, a closer look shows that the standards cover more than quality assurance alone, and pay attention to other aspects of TQM, such as management leadership, process orientation, and quality improvement mechanisms (through complaint handling, internal audits). In a small enquiry amongst certified education and training providers, conducted for this study, several respondents confirmed that the type of management style needed for a successful TQM approach, does follow almost automatically from an effective and fully operational ISO 9000 system. But the respondents also recognised that ISO 9000 alone is not enough to cover all elements of TQM.

2.3 Main principles of ISO 9000

2.3.1 Structure of the ISO 9000 family of norms

ISO 9000 is really a *family* of norms, consisting of different components. The most important ones to quote here are:

- ISO 9000-1 (version 1994): *Quality management and quality assurance standards – Part 1: Guidelines for selection and use;*
- ISO 9001 (version 1994): *Quality systems – Model for quality assurance in design, development, production, installation and servicing;*
- ISO 9002 (version 1994): *Quality systems – Model for quality assurance in production, installation and servicing;*
- ISO 9003 (version 1994): *Quality systems – Model for quality assurance in final inspection and test;*
- ISO 9004-1 (version 1994): *Quality management and quality system elements – Part 1: Guidelines.*

The other norms of the series concern further guidelines on the use of the standards in specific situations.

Some related standards, such as those on definitions (ISO 8402), on auditing quality systems (the series ISO 10011) and on quality manuals (ISO 10013), are often considered to be part of the ISO 9000 "family".

Certification (see below) of organisations is only possible on the basis of the norms ISO 9001, ISO 9002, or ISO 9003. All the other 'norms' consist of definitions, guidelines or interpretations. For instance, no certification is possible on the basis of the guidelines of ISO 9004-1, a document which reflects to a large extent the characteristics of TQM. Whenever reference is made to "ISO 9000" certification, it actually means certified conformity with the requirements of either ISO 9001, 9002 or 9003.

It is important to understand that the ISO requirements do not concern product specifications, but rather aspects of management, organisation and processes. A product or service can never be 'ISO 9000' certified, but the organisation behind the product may. Where product criteria exist (e.g. impurity levels for food), ISO 9000 certification actually means that a system is in place which ensures that these product criteria are always met.

2.3.2 Main concepts and principles

Thus, the ISO 9000 norms can be considered as generalised specifications for quality assurance, with additional elements borrowed from TQM. The norms do not prescribe how production and management should be organised, but require, simply stated, that an organisation:

- defines and plans its processes,
- documents them properly,
- checks their capability, and
- ensures that they are controlled and reviewed.

Although the ISO 9000 requirements go much more into detail, when these simple principles are adopted in all processes of an organisation, it will be more than 90% "ISO ready".

The ISO 9001-9003 standards consist essentially of a number of management principles expressed in production terminology. The norms' terminology reflects their original focus on situations where suppliers needed to demonstrate to their industrial clients their capability of guaranteeing the conformity to the product specifications. The ISO 9001-9003 norms are heavily process-oriented, with emphasis on thorough planning, documentation and control. The requirements are described in general terms, but the terminology is derived from manufacturing. The principles of the standards can be summarized as follows:

- the organisation has clear quality objectives;
- there are clear agreements between everyone involved;
-

the organisation has the resources to achieve the required quality level (the notion of '*capability*');

- the organisation defines itself which processes and resources are needed for quality;
- all processes and systems are under control, with evaluation and modification when appropriate;
- everything needed for quality assurance is documented;
- quality registrations allow verification and 'proof' of quality assurance

Given the historical development of the standards, some activities receive more attention than others. Some paragraphs are phrased in terms which makes them applicable to virtually any type of organisation, while others use a 'manufacturing' language. Thus, certain parts may need interpretation – or may not be applicable at all. It is recalled that this need for a European interpretation of ISO 9000 in education and training was one of the main rationales for writing this report.

In general, the norms indicate which type of activities need to be documented and controlled (contract, design & development, production, purchasing, delivery, etc.), but do not prescribe exactly how that needs to be done. The standards are more prescriptive regarding the management aspects (quality policy, management review, management representative, ...) as well as for some specific quality assurance measures, such as document control, test and inspection, quality records, corrective measures and internal audits. Implementing all these requirements results in a so-called "*quality system*". Such a quality system will extend beyond the minimal requirements for a quality assurance system.

2.3.3 The content of ISO 9001

ISO 9001 is the most complete standard, and embraces ISO 9002 and 9003. The latest release of ISO 9001 dates from July 1994 and was accepted as a European norm (EN ISO 9001) somewhat later. All Member States of the European Union have since adopted the standard also as a national norm, sometimes with some delay because of the translation. The document consists of 4 'chapters', of which the first three ('Scope', 'Normative Reference', 'Definitions') are very short – together less than a page. Chapter 4, called 'Quality system requirements' is what the norm is all about. It consists of 20 parts, often referred to as 'sections', 'paragraphs' or 'clauses':

4.1 Management responsibility	4.12 Inspection and test status
4.2 Quality system	4.13 Control of nonconforming product
4.3 Contract review	4.14 Corrective and preventive action
4.4 Design control	4.15 Handling, storage, packaging, preservation and delivery
4.5 Document and data control	4.16 Control of quality records
4.6 Purchasing	4.17 Internal quality audits
4.7 Control of customer-supplied product	4.18 Training
4.8 Product identification and traceability	4.19 Servicing
4.9 Process control	4.20 Statistical techniques
4.10 Inspection and testing	
4.11 Control of inspection, measuring and test equipment	

Some of the paragraphs are very long and contain several sub-sections; others consist of a few sentences only. Since Chapter 4 examines and discusses each of these requirements, only some general comments are given at this stage.

Both the length of the different paragraphs, their level of detail and the sequence of the different requirements reflect the historical development of the norms. At present, work is going on within ISO, the International Standards Organisation, for a major revision of the standards, scheduled to be ready around the year 2000. In the new standard, the various sections will be rearranged in a different and more logical order, the terminology used will be less production oriented, and redundancies in the text will be eliminated. On the content side, the process logic will be even more pronounced, and there will be more emphasis on TQM principles (in addition to quality assurance).

At this stage, the requirements of the standards can be grouped into three sets:

- general requirements of a quality system (management responsibility, quality manual and procedures, appointment of a quality manager, availability of qualified resources and staff, ...);
- the need to maintain documented procedures on the key processes of the organisation (design, development, purchase, delivery, etc.) – and implement activities according to the procedures;
- specific quality assurance mechanisms, including test and inspection, keeping quality records, dealing with non-conformities, keeping documents up-to-date, conducting internal audits and holding regular management reviews.

Some of these requirements can easily be implemented in a well run organisation. In an effective, high performance organisation, often the only thing required is to write down, in a formalized manner, the way one is currently operating. However, the specific quality assurance requirements almost inevitably require more work, including the introduction of new activities and processes (particularly document control and internal audits) which often did not exist before.

It should also be mentioned that the ISO 9000 standards are no easy reading. Especially some of the longer paragraphs, and the overlap between some sections, do not facilitate understanding. Moreover, the meaning of certain sentences may not be obvious in a particular context. Consequently, the standards *always* need some interpretation. This has both advantages and disadvantages. The main disadvantage is that it creates an additional hurdle and may reduce confidence in the development of the quality system; it may also lead to excessive control mechanisms. It puts the burden on the organisation of justifying its interpretation of the norm (hopefully, this report may relieve some of this). But this necessity of interpretation also has advantages. For instance, certain sections can be declared inapplicable, whilst for others it may be shown that the requirements are impossible to implement or even illegal, if taken to the letter. In such cases, it is important to demonstrate that, nevertheless, the 'spirit' of the standard is being followed as far as possible.

2.3.4 The certification process

Organisations can be *certified* by an independent body for compliance with either ISO 9001, 9002 or 9003. Several steps are involved in that process. Since education and training institutions are no different in this respect from any other type of organisation, and the implementation process is well described in the literature, only the main steps are highlighted here.

First, the most appropriate standard has to be chosen. Since few organisations get certified on the basis of ISO 9003, the real choice is often only between ISO 9001 and 9002. ISO 9001 is the most complete standard, covering most of the activities of organisations. ISO 9002 is almost identical with ISO 9001, except for the exclusion of design activities. Thus whether an organisation interested in certification should go for 9001 or 9002 really depends on whether it has design and original development activities which are to be part of the quality system. For the education and training sector this implies that ISO 9002 is most suitable for primary and secondary schools (since the programme is often prescribed by the government), while ISO 9001 is more appropriate for higher education and continuing education and training providers (since they design their programmes themselves).

A second important initial consideration is the 'scope' of the certificate desired. Indeed, an organisation can be certified for only part of its activities (e.g. for all activities necessary to produce certain types of products and services). Larger organisations often start with a pilot department before they engage in full certification. Education institutions may wish to exclude ancillary activities from their quality system, because they do not see the added value – or do not have the resources – for setting up quality assurance mechanisms for such activities.

Once the appropriate standard and scope are selected, the organisation will gradually build up the quality system. This may take between 6 and 24 months, depending on factors like the complexity of the organisation, the availability of human resources, the use of external consultancy, and the number of components of

the quality system which are already available. The first part of the work consists in establishing the quality and procedure manuals. Once this activity comes to an end, the 'systems' requirements of ISO 9001 need to be set in operation: internal audits, document control, management reviews, corrective and preventive action, etc.

Most time is likely to be spent on the writing of the quality and procedure manuals. Other time-consuming activities may include the analysis of the different processes, the standardisation of processes, the effective use of new procedures such as document control, internal audits and maintaining quality records, and the training of staff. The time involved in such activities varies greatly from one organisation to the other.

When the whole quality system is fully operational, the organisation should get in touch with an officially recognized certification body (in most European countries, there are several of such organisations). Each certification body uses a slightly different approach, but generally the stages are as follows:

- [sometimes] a pre-audit by the certification body, for identifying gaps in the quality system (such a pre-audit may be undertaken during the preparation process; it is not compulsory and may only be necessary if the organisation has not used a specialised consultant);
- submission of the quality manual and procedures to the certifying body for analysis of conformance with the selected standard (the certifying body will not go any further if it discovers at this stage any major non-compliance);
- audit of the organisation by the qualified auditors of the certifying body; the main purpose is to verify that the quality system is indeed implemented as described in the documentation, and is conform with the requirements of the standard;
- approval of the quality system and award of the certificate;
- interim audits by the certifying body, typically 3 or 4 times over a period of 3 years;
- after 3 years, a new full audit (possibly by another certifying body) is required.

The organisation which wants to be certified has to bear the full costs of the audit and certification; it actually enters into a three year contract with the certifying body. It goes without saying that the certifying body should be independent from the organisation and also from the consultants who may have assisted the organisation.

3. ISO 9000 in education and training

3.1 The rationale for adopting ISO 9000 in an education or training organisation

3.1.1 Main reasons for seeking certification

Improving or maintaining the quality of education or training provision is not the only reason why providers seek to be certified under ISO 9001 or ISO 9002 (ISO 9003 is not relevant). Most of these reasons are similar to those of other organisations. Overall, four types of arguments are put forward:

- promotion of a high quality *image*, high visibility and credibility;
- a response to *external factors*;
- develop a full *quality assurance system*;
- improvement of *specific activities* of the organisation.

The importance of these arguments is likely to vary strongly depending on the nature of the organisation and their external environment. Let us consider each of the main reasons in turn.

A quality image

Image is important for all types of education and training organisations, because it influences the numbers of pupils, students or trainees – and hence in the long term the survival of the organisation. This reasoning applies whether the organisation is a school, an adult training provider or an internal training department in a company. The image perceived by the outside world depends on the quality of services delivered, as well as on how effective that quality performance is communicated. Being certified under ISO 9001 or 9002 is an easily communicated signal to the outside world that the organisation is committed to quality and that it has been subject to independent external scrutiny.

Circumstances will determine whether ISO 9000 certification on such grounds is justified. The more competitive the environment is, and the more ISO 9000 is understood by the target group of the provider, the more an ISO 9000 label will support or reinforce the reputation. Some of the more specific image-related arguments for ISO 9000 which have been reported in the literature or have been communicated to the author are:

- the need to demonstrate or confirm a leading or pioneering role in a particular market sector (ISO 9000 as a differentiating factor);

- a way to make the quality performance of the organisation visible and easily appreciated by customers (who cannot assess the value of other labels or certificates which may only be known in the training world);
- the willingness of traditional, public education institutions to be considered as an effective organisation which is capable of meeting professional private sector standards (getting rid of a sloppy 'public sector' image) – this applies in particular to public institutions operating in competitive training markets;
- a contribution to maintaining or improving market share;
- credibility of institutions and training providers which teach management, TQM, and ISO 9000;
- the need for a quality label which is easily recognized at international level.

External factors

External demands may not have been the prime reason for launching an ISO 9000 exercise, but they are likely to become the driving factor for certification over the next years. This is because the concern for quality and performance is growing in society, with all organisations being expected to become more accountable to the shareholders or the citizens – depending on whether they are private or public. In addition, clients of education increasingly desire ‘proof’ of the quality promised. Certification is a way of responding to such demands. It is admitted that we are still far away from a situation whereby an ISO 9000 certificate becomes an almost compulsory requirement. But many signs suggest that over the next years an increasing number of European education and training providers (or at least some of their departments) will face the pressure of certification. An example of such developments is the requirement of Vetron, a Dutch association of training providers, which has restricted membership since January 1997 to certified training organisations only.

Examples of the type of external factors which have already forced certain education and training organisations to start the certification process are:

- the explicit demand from a client organisation, often related to the requirements of that client’s own quality assurance system (which requests quality guarantees from suppliers);
- the current or anticipated demand from governmental bodies (e.g. for public tendering);
- the implicit or announced expectations from major client organisations;
- the pressures because of certification of main competitors;
- the demand from a sectoral training organisation (entry request);
- for training departments in firms: the extension of existing certification from other departments (e.g. production); or a requirement by the mother company;
- a compulsory requirement for being granted the right to deliver certified or accredited training;
- a mechanism to avoid state regulation or accreditation (e.g. in continuing training or higher education).

In the private, commercial education and training sector, such external factors still lead to positive differentiation with competitors. However, over time, they will become ‘negative’ motivators: merely being certified will no longer provide any particular advantage, but not meeting the external demand might have drastic implications in terms of market share. It is as yet unclear whether such arguments might also apply to public institutions – since in any foreseeable scenario, the number of public education institutions who may become certified over the next decade will remain a small minority. One factor – not very probable though – which may spur ISO certification in this area, would be the desire for achieving some kind of European compatibility of quality management and quality assurance arrangements.

Quality assurance and internal organisation

An obvious argument for going the ISO 9000 route is the need and willingness to establish a quality assurance system which covers all critical areas of the organisation. One might have expected this to be the first and most important reason for certification, but so far the 'image' and 'external demands' arguments seem to prevail. An exception may have been the University of Wolverhampton (the first university to be certified), where the unifying and systemic arguments appear to have been the predominant driving force. But from the information gathered for this study, this does not seem to apply as yet to many

other organisations. Maybe this is a temporary situation: most of the education and training organisations which pioneered certification were convinced that they had a good system already – this may be less the case in the future.

If an education or training organisation is looking for a comprehensive quality assurance approach, then the principles and requirements of ISO 9001 or 9002 are to be considered seriously. Indeed, most traditional quality assurance methods in education and training are based on a classical typology of a provider who delivers particular courses and programmes to students. This facilitates the analogy with industrial production and mass services – and hence the quality philosophy adopted there. One might even argue that the ISO 9000 standards can more easily be applied to education and training activities than to other services, such as health care, personal care, consulting or research.

Additional, related arguments which have been put forward by certified education and training organisations are:

- ISO 9000 provides a visible, understandable and verifiable focus for the internal quality improvement efforts of an organisation;
- the perspective of a certificate and formal recognition of the efforts undertaken is important for the motivation of staff;
- unlike traditional quality approaches in education and training, the ISO 9000 standards consider education or training activities not as isolated processes, but in the context of the organisation's quality objectives;
- ISO 9000 obliges the organisation to formalise its quality level, and develop procedures to avoid deterioration in the future;
- the certificate also helps as regards internal recognition of quality efforts, and provides reassurance and pride about the current performance;
- the compulsory requirements avoid the use of a 'TQM à la carte' with no clear milestones;
- independent of the rhetoric on 'quality assurance', education and training organisations may just seek the benefit of being sure that their internal organisation becomes more effective, efficient and consistent;
- documenting and operating a quality system is seen as an excellent means for maintaining quality levels in organisations with a high turn-over of staff (e.g. some higher education institutes) or who use external teachers and trainers.

Specific quality improvements

Some organisations have sought to introduce ISO 9000 to improve specific functions or activities. This may be related to a general concern of ensuring high customer satisfaction, or to the willingness to attain specific quality levels. Some examples related to education and training institutions are:

- improvement of the logistical and support processes;
- better control of external trainers;
- development of a thorough procedure for design and development of training and education programmes and courses;

- quality assurance of the examination and evaluation of students.

Putting the arguments into context

The previous paragraphs listed many arguments which an education or training provider may examine when considering ISO 9000 certification. Although many items are listed, it should be pointed out that, in general, most certified education and training organisations singled out only a few of these. Indeed, the belief in the importance of only one or two

main reasons for certification, gives a clear focus and may hence yield the necessary motivation and commitment to bring the whole exercise to an end; this may not be achievable if the goal of certification is diluted across a wide range of objectives.

Several of the possible arguments in favour of ISO 9000 also apply to other quality approaches and certification, accreditation or recognition arrangements. There is no doubt that several of these approaches are better tailored to the education and training world. Why then, still opt for ISO 9000? The main arguments which have been put forward in this regard are:

- ISO 9000 has high visibility outside the education and training sector, and also at international level – which a national quality scheme seldom has;
- much external expertise, advice and training on ISO 9000 is readily available; this is often lacking for other quality approaches;
- last but not least, ISO 9000 should not be seen as competing but rather complementing other quality control arrangements: existing standards, evaluations, documents and methodologies can relatively easily be integrated into a quality system that meets ISO 9000 requirements.

It should also be mentioned that the reasons for seeking certification in the education and training world, do not differ fundamentally from those of other organisations. An in-depth UK survey "*ISO 9000 – Does it work?*" conducted in 1995 by the Manchester Business School on behalf of SGS (see Bibliography), found eight reasons for seeking certification which were each listed by at least half of the respondents to the survey (in decreasing order of importance):

- future customers likely demand for ISO 9000;
- increase consistency of operations;
- maintain/improve market share;
- improve service quality;
- customer pressure;
- use as a good promotional tool;
- make operations more efficient;
- improve product quality.

The survey also found that "*small companies principally sought the standard to improve market share and for promotional purposes. (...) The larger the organisation, the more likely it was to cite customer pressure as a reason for certification. The service sector emphasised the importance of increasing market share and the need to improve consistency of operations and quality of service (...)*". These results, when interpreted in an education and training context, are consistent with our findings regarding education and training providers.

3.1.2 Problems and disadvantages

Arguments in favour of certification should, of course, be balanced against the counter-arguments and disadvantages. These are numerous as well and – in the

light of the limited number of certified education or training institutes – still outweigh the positive arguments. Again, several groups of possible disadvantages can be listed:

- interpretation problems;
- insufficient relevance;
- inappropriate standardisation;
- time consumption and cost;
- specific problems.

Interpretation problems

Application of the ISO 9000 standards is not straightforward. The requirements and even the underlying concepts have to be ‘translated’ or ‘interpreted’ into a language which an education or training provider can understand. It is this very problem which was one of the main reasons for writing this report.

Since Section 3.2 and the whole of Chapter 4 will cover this issue in depth, only the main categories of interpretation problems are listed here:

- the terminology used in the standards;
- the sequence and interrelationships of the different clauses;
- the methods and extent of quality assurance required;
- the product definition to be used;
- the mapping of the education and training processes onto the requirements of the standard.

Thus, anyone in education and training interested in ISO 9000 needs to take this first, considerable hurdle. There are many who have stopped considering using ISO 9000 after reading the norms, wondering about how these could be applicable to their situation. While the overall philosophy behind the norms may become clear after some time, the interpretation of some clauses might remain obscure. Even ‘specialists’ – i.e. people and organisations who have published interpretations or guidelines on ISO 9000 in education and training – do not agree entirely on all interpretation issues.

Insufficient relevance

Many education or training experts, particularly from the public education sector, criticize ISO 9000 at its core, as being of insufficient relevance for education and training institutions. It is true that the norms were neither designed nor optimised with education or training institutions in mind. The following fundamental arguments are often heard:

- there is no obligation in the ISO 9000 norms to adhere to any minimum standards; in fact, organisations set themselves the quality levels for which they are satisfied (with the risk, of course, that they set low standards);
- ISO 9000 is not the best way towards TQM in an education and training institute; there are other approaches which facilitate the introduction of TQM;

- many critical aspects of education and training institutions and their services are not explicitly listed in the standard (and may hence not be covered);
- the complexity and multiplicity of objectives and purposes of education do not fit very well with the standardisation resulting from ISO 9000;
- ISO 9000 imposes mechanisms on education and training institutions (e.g. document control, quality records,...) with little or no added value.

It would lead us too far here to discuss each of these criticisms in depth. There is some truth in all of them, but some objections are based on a misconception of the purpose and usage of the standards. Whether the risks pointed out might materialize or not, will depend on how the quality system is implemented. As of today, and in as far as the available information makes a full assessment possible, none of these potential weaknesses seems to have occurred with the first education and training organisations which have been certified. For instance, none of these institutions has set low standards. It is recalled that certified organisations will set their standards at the level required by the clients, and that the dynamic of the quality system (with its audits and corrective measures) will ensure that standards are set at an appropriate and sustainable level.

However, when ISO 9000 spreads across an increasing number of education and training organisations, the risk will become real that inappropriate and insufficiently relevant quality systems might be created.

Inappropriate standardisation

Since the ISO 9000 standards were originally conceived for medium-sized to large companies in the manufacturing sector, it is legitimate to query its appropriateness for education and training organisations, which are in many ways similar to small SMEs from the service sector (the main exception to this analogy are higher education institutions, but even these are service organisations).

Because of their less standardized operations, service organisations encounter problems in meeting the ISO 9000 requirements, when these are taken literally. Every service operation is unique and no service activity can be 100% controlled because of the involvement of external, unpredictable factors – in the first place the reaction of the customer, who is in general actively involved in the delivery of the service itself. This is quite obvious in an education and training environment, where it is well known that the quality of teaching and learning depends to a large extent on the interest, commitment and initial qualifications of the learners.

When writing procedures for education and training organisations, it is often not straightforward to find the appropriate level of abstraction. On the one hand, procedures should demonstrate compliance with the requirements of the Standard, but on the other hand they should allow for a certain level of variability. Education and training institutions should avoid excessive paperwork and prescriptive rules – but at the same time they ought to be able to control the quality of delivery. For that reason, they need to clarify for themselves what are the critical aspects of their delivery – which need rigorous control – and those elements where more freedom and variability will not lower quality standards, or are indeed a real necessity for assuring quality all the time. This is even more important since the staff involved has in general high qualifications, and excessive prescription and standardisation might be neither desirable nor productive.

When there is a lack of understanding of the desirable degree of standardisation, there is a serious risk of creating a bureaucracy with a focus on procedures, records and control. Education and training organisations should therefore seek appropriate advice in order to minimise such risks.

Time consumption and cost

The cost and time-consuming nature of the implementation of ISO 9000 requirements are probably the most serious obstacle to the generalised use of the standards in education and training institutions – and this is likely to remain so for the coming years. There is always an important direct cost, consisting of the cost of certification. In most cases, there are additional expenses for guidance and training

by specialised consultants. Both cost factors vary in relation to different parameters, such as:

- the size of the organisation;
- the number of fundamentally different services – and their underlying processes (this has an impact on the number of procedures);
- the ‘quality culture’ which prevails;
- the appropriateness and completeness of existing documentation (procedures, forms, checklists,...);
- the existing evaluation and monitoring arrangements;
- the experience with quality assurance.

The cost of certification is, in general, mainly related to the size of the organisation and the number of procedures. The extent of need for training and external guidance will, however, depend on all the factors mentioned. Typical cost ranges (excluding very large or very small organisations) for certification are in the range of 3 000 to 10 000 ECU, while consultancy (training, advice, pre-audits,...) may vary from 2 000 to 20 000 ECU. To such figures should be added the salary costs and overheads of the staff working internally on the set-up of the system. Again this will vary considerably, but it is likely to represent the equivalent of between 4 manmonths (for a small, very well and focused training organisation) and several manyears. Typical implementation schedules – from initial decision to certification – last between 9 and 24 months.

Once certification is obtained, there is also the cost of the 3-4 interim-audits over a three year period (1 000 to 2 000 ECU/audit) and the maintenance of the system – which may require about 30% of the staff resources needed for the initial implementation.

Obviously, ISO 9000 comes at a price. This may be an insurmountable barrier, particular for small training providers and public education institutions. Few of these seem to be willing to take such a financial risk, unless they feel strong pressure to do so. Nevertheless, the cost issue should also be put in its proper context:

- other quality assurance arrangements (e.g. government based inspections) or Total Quality Management approaches also require considerable resources – with a cost structure which is often hidden (e.g. the real cost for inspecting a school may be higher than that for an ISO 9000 audit);
- expenditure for training, advice and pre-audits should diminish over time, as more experience becomes available;
- the cost of certification should be considered as a long term investment, to be depreciated over several years;
- while cost is the most visible barrier, experience to date suggest that the time consumption is actually the biggest obstacle: many organisations cannot release full-time staff for such an exercise, which implies that implementation happens in phases and is often interrupted because of other priorities.

Specific problems

Some other problems which have been reported include:

- the certification process does not lead to the publication of a public audit report – governments are therefore reluctant to encourage the use of the system in public institutions for accountability purposes;
- the audit rhythm which follows the certification may fit badly with the annual school cycle or the academic year;
- the length of the implementation process – up to two years – requires a formidable commitment from both management and staff – in particular since it is almost certain that unexpected problems will arise and that the external environment might change;
- cost and cost-effectiveness issues are not considered in ISO 9000.

Overall assessment of the importance of problems and disadvantages

Some of the above mentioned problems are likely to continue to persist in the future – unless the standards themselves change. Thus, it must be recognised that the ISO 9000 approach has some inherent weaknesses for education and training, which require skill and creativity to address. The cost and time implications are a real hurdle, and the risk of creating a bureaucratic system is always present. Besides, in the author's opinion there seems to be no justification for the objection, expressed by some education and training experts, that ISO 9000 would be fundamentally inappropriate for education and training

institutions. The reality is that most institutes have not yet reached a level of quality assurance and control which would make the implementation of the standard feasible.

By way of comparison, we list the most important problems with certification as reported by the already mentioned survey by the Manchester Business School:

- time required to write the manual;
- high volume of paperwork;
- high cost of implementation;
- time required to complete implementation;
- high cost of maintaining the standard;
- lack of free advice;
- lack of consistency between auditors;
- time spent checking paperwork prior to audits.

Only the first of these drawbacks was mentioned by over 30% of the respondents; the last item by 16%. The survey concluded on this point that *"The high cost of implementation – in terms of time, volume of paperwork and money – were seen as the major problems related to ISO 9000 across all groups. Small organisations generally considered drawbacks to be more significant, when compared to the benefits, than did large organisations. The same pattern was seen in concerns with ongoing maintenance of the standard (...)"*.

3.1.3 Differences among education and training organisations

For practical reasons, the previous paragraphs did not list the advantages and drawbacks for each different type of education or training provider. In a European report like this one, it would have proven to be an impossible exercise anyway, since categories of education and training organisations display different characteristics across countries. However, it is useful to compare briefly the relevance and applicability of ISO 9000 by grouping education and training providers in different ways:

- Compared to the suppliers of 'initial' education (schools and higher education institutions), the providers of continuing education and training (CET) are more likely candidates for ISO 9000. This is because CET provision is much more subject to competition and the laws of supply and demand than initial education. The first education and training institutions to be certified – and by far still the majority – were all CET providers (including training departments of international concerns, e.g. IBM Germany).
- When comparing 'general' education with vocational education and training (VET), it is obvious that VET providers are more suitable candidates for ISO 9000. Indeed, VET institutions – whether public or private – need to have a clear client focus (the professions and sectors for which they educate) and they are more subject to external pressures regarding the relevance of what they offer. It should be no surprise that the first ISO 9000 certified schools in the different European

countries were technical and vocational schools [e.g. Sandwell College (UK), Hillerød Technical College (DK), Technisch Instituut Glorieux (BE)].

- ISO 9000 is more likely to be appropriate for 'larger' than for 'small' institutes. The main arguments are that the larger education and training organisations: may have sufficient resources available, may already have or need a lot of standardized operations, can benefit most from a TQM approach for internal efficiency improvement, and are forced to have a medium and long term perspective. Often, it is the larger organisations in their sector who are the first to obtain a certificate [e.g. DIEU (DK), Technische Akademie Esslingen (DE), NCATB-Elsevier Opleidingen (NL)].
-

The more varied and customised the provision of education and training is, the more time it will take to obtain an ISO 9000 certificate – simply because the volume of documented procedures per person is much higher. Thus, organisations who only provide training "à la carte" face more hurdles than institutes using essentially the same approach for most of their education and training delivery. Thus, surprisingly maybe, while ISO 9000 standards may be less relevant and needed for a primary school than for a provider of customised training, the school would proceed much faster in implementing the quality system requirements – in particular when it operates in a heavily controlled environment. In many schools much of the required quality documentation already exists, but lacks consistency and control.

- As to the higher education sector, it is difficult to identify clear patterns. Only a few full higher education institutions have been certified (University of Wolverhampton (UK), Luchtvaarthogeschool (NL), EHSAL (BE), ESIG (CH),...). There have also been some cases where units and departments of universities were certified – typically in the management, engineering, facility management or continuing education areas [e.g. Department Industriel Beleid of the KULeuven (BE)]. It seems likely that the number of such certified departments and units will increase over the next years, but whether this trend might also apply to full universities and other higher education institutions remains to be seen. ISO 9000 is met with much scepticism in academic circles, and the standards also face competition with existing or new audit, quality assurance or accreditation arrangements.
- A special category which merits attention are the training providers which depend directly of other organisations, such as training departments or semi-independent training units of large firms. Here we can see a mixed bag of developments. In some cases such training centres have taken the lead in ISO 9000 (e.g. the training department of the Dutch Railways), but in other cases they have followed, with some delay, the corporate company policy on ISO 9000 certification (e.g. different departments of CESI in France). Whether it makes sense to certify separately the training departments within companies, will to a large extent depend on their operational, financial and decision-making autonomy. If autonomy and scope are limited, then the quality system of the training department ought to be integrated in that of the firm as a whole.

This brief overview underlines the fact that the choice for ISO 9000 is not just a matter of balancing potential benefits and drawbacks. A decision also depends to a large extent on the particular environment in which the organisation operates.

3.1.4 Conclusion

The ISO 9001 and 9002 standards are suitable frameworks for the implementation of a quality assurance system with providers of education and training. The tangible and often compulsory requirements (quality policy, quality manual and procedures, regular audits,...) provide an overall, measurable framework for quality efforts, as opposed to less systematic and more qualitative improvement approaches. The main

advantages of the ISO 9000 arrangements – compared to other quality assurance approaches are that:

- ISO 9000 certification combines four aspects at once: a comprehensive quality system, a credible assessment of it, formal certification and recognition, and a guarantee of ongoing maintenance and improvement;
- the value of ISO 9000 is appreciated by the different customers of education and training;
- ISO 9000 is easily recognized internationally.

There is, at present, no other international system with the same characteristics. At the same time, it must be recognised that the ISO 9000 norms are certainly not the best imaginable quality standards for education and training, and need to be complemented by content-related criteria. But the biggest drawback remains the considerable cost – in terms of both direct expenditure and input of human resources – of implementation. As of today, only education and training organisations with high quality standards and sound financial management can safely engage in ISO 9000 certification.

3.2 Terminology and interpretation issues

3.2.1 Main interpretation differences of the ISO 9001 requirements

The requirements of ISO 9000 always need some interpretation. In most service sectors, many of the specifications laid down in the standards need careful analysis and adequate interpretation before they can be applied in a particular education or training context. This interpretation relates to both the terminology – which is relatively easy – and to the processes concerned – which is often not straightforward. Also, the order of the different paragraphs will appear ‘unnatural’ or even ‘illogical’ to many people from the education and training world.

This section highlights some general interpretation issues, preparing the ground for the more detailed discussion of the clauses of ISO 9001 which is provided in Chapter 4. When interpreting the standard, the author had to make some choices. These are believed to reflect the most logical and consistent approach for a wide variety of education and training environments. It is recognised, however, that for certain aspects other interpretations can be defended – or that in a particular context another interpretation might be more suitable.

Maybe the most fundamental difference in interpretations of ISO 9000 standards for education and training is the definition of the ‘*product*’: is it the ‘learning’ or the ‘learning process’, or rather the education or training programme which is offered? This is not just an academic problem, but one which has implications throughout the standard. Based on comparisons with other service sectors, the real difficulty of controlling the learning process, and the choices made by many certified education and training organisations across Europe, the author has opted for the ‘product’ as being “*the education and training services offered by the organisation, including associated products, tools and services*”.

This choice has many implications when interpreting a number of Clauses of ISO 9001. For instance, when ‘learning’ is taken as the ‘product’, then the ‘testing and inspection’ requirements concern assessment and evaluation of students and trainees. However, when ‘the course (programme)’ or ‘training’ is considered as the product – as is done in this report – then the ‘testing and inspection’ requirements refer to the evaluation of a course or training session by students, trainees and/or their employers.

The main interpretation differences – as derived from an analysis of available documents – are summarised in the next table; the column ‘Interpretation adopted’ is the one that is the basis for comment in Chapter 4. The full titles and contents of the clauses can be found in Chapter 4 as well.

Clause	Interpretation adopted	Other possible interpretations
General	Product = the education and training services offered, including associated tools and services	Product = the acquisition of learning Product = the student, trainee, pupil Product = the degree, qualification obtained
4.3 (Contract)	Contract review only covers agreements with customers	Contract review also covers contracts with suppliers, sub-contractors or external trainers
4.4 (Design)	Design does not include (or only marginally) development of education and training (<i>designs stops at the specification of programme content</i>)	Design includes substantial elements of development, up to close before delivery stage
4.4 (Design)	Design validation of a course happens just before it is released	Validation of the course design happens after the first run of the course
4.5 (Document)	External documents need minimal document control, unless when they critically affect the quality of the education or training	Most external documents should be controlled much the same way as internal documents
4.6, 4.10 + others	Part-time teachers should be considered as other staff (<i>unless their input is very limited or irregular</i>)	Part-time teachers are to be considered as sub-contractors
4.7 (Customer's product)	Supervision of students, welfare, care is not to be considered under this Clause (where relevant, this falls under Clause 4.9)	Supervision of students, welfare, care should be considered under this Clause
4.8 (Identification)	Identification and traceability refers to the education and training services	Identification and traceability applies to the student/learner
4.9, 4.11 (Calibration)	Calibration is only required for the equipment of which the accuracy is critical for the learning process, and for any equipment needed for testing the performance of trainees	Calibration is needed for all equipment used for the purpose of developing and delivering education or training

4.10 (Inspection)	Test and inspection concerns the monitoring and evaluation of the education and training services offered, including tangible items produced for it (assessment of students is covered under 4.9)	Test and inspection cover all aspects of assessment which take place, including those concerning students. Test and inspection only refer to the tangible items used for the education and training service
4.10 (Inspection)	Receiving inspection is impossible for services; these aspects may only be applicable for certain goods purchased	Receiving inspection and test cover the need to establish the level and needs of incoming students
4.12 (Test status)	Inspection and test status refers to the stage at which education/training programmes (and all their components) are	Inspection and test status only applies to equipment Inspection and test status also applies to learners
4.13 (Nonconformities)	The definition of non-conforming 'product' should be extended to include the services as well	The control of non-conforming products only refers to faulty tangible items
4.15 (Handling)	Only applicable to tangible goods (in as far as these are used)	This clause should also be interpreted for services, and thus cover items like student care, counselling etc.
4.20 (Statistics)	For simple statistics (sums, averages, tables) evidence of the correctness of the figures is OK; for more advanced computations evidence is needed of understanding of the techniques adopted	This clause applies to all stages where at least sums or averages are computed

At first sight, this list may appear excessively long. Surprisingly however, many of these interpretation differences do not necessarily lead to considerable variations in the implementation of quality systems. This is a direct result of the overlap and redundancy of the requirements of ISO 9001. This ensures that certain quality assurance arrangements which are, in a particular interpretation, not covered by a specific clause, need to be undertaken anyway because of the requirements of another clause. In particular the general clauses 4.2 (Quality system) and 4.9 (Process control) are formulated in such a way that quality arrangements must be in place for *all* critical processes, whether these are covered by a specific clause of the norm or not.

There is a second, more challenging type of interpretation problem. This concerns the assessment of how the requirements can be addressed effectively with minimum overhead. Indeed, in many situations it is often not straightforward to say whether or not the requirement of ISO 9001 is entirely fulfilled. Consider, for instance, the need

to define and analyse ‘design input factors’ during the design process (Clause 4.4). It will be a matter of judgement by the institution and the auditor of the certifying body to decide whether all critical input factors are being considered. Another example: the requirements for purchasing goods and services from suppliers, where the organisation has to decide on the appropriate level of quality control. It is not obvious on what basis such specifications are acceptable or not. A third example: are slides and overhead transparencies used by trainers to be considered as ‘controlled documents’ or not?

The answer to such questions has major consequences for the implementation and maintenance of the quality system. The ISO 9000 standards contain many parts which need subjective assessment for education and training providers. Chapter 4 contains guidelines about what is necessary or desirable for most types of institutions, but it is stressed that every case is different and needs its specific interpretation. This is, actually, both a strength and a weakness of ISO 9001.

A third, related type of interpretation difficulty concerns the rigour and extent to which the requirements have to be followed, such as:

- the level of detail needed for documents (particularly procedures and work instructions) – which has considerable implications for document control;
- the nature and quantity of quality records – often the biggest stumbling block in the effective maintenance of the quality system, and the seeds for a bureaucratic, paper based system;
- the specificity of the quality policy and objectives;
- the frequency of internal audits and management reviews;
- the scientific validity of the evaluation and assessment methods used.

No authoritative guidance exists on such issues. Some auditors, consultants and quality managers go much further than others in these matters. It is risky to generalize here, since what needs to be done depends on the complexity of the organisation, the demands from customers, and the educational attainment of the staff. In the report, a plea is made for minimal bureaucracy, but one ought to check that the certifying body agrees with the interpretation adopted.

3.2.2 Using ISO 9000 terminology in an education and training context

In line with the interpretation choices made in this report, it is possible to draw a table which ‘translates’ some of the key terms found in the ISO 9000 standards into more common education and training terminology.

ISO 9000 term	Interpretation for an education or training organisation
Supplier	Developer or provider of education or training
Customers	Students/pupils for education; employers or trainees for training

Product	Course, education or training programme; education or training material
Executive Management	General Director/Headmaster/Rector/Committee of Directors/...
Contract	All types agreements with customers – also implicit ones – from the registration of students for a course, to a negotiated agreement for custom-made training
Design	Definition of education/training specifications; design of course programmes and curricula; specification of the content of education/training material; design of assessment and evaluation instruments for students/pupils/trainees
Purchasing	Acquisition of necessary goods and services, including the use of temporary, free-lance or external teachers/trainers/lecturers
Processes	Refer to the development, planning, delivery of education and training, including any assessment of students/pupils/trainees
Inspection and test	The assessment and evaluation of the courses/programmes/ materials by the students/pupils/trainees/employers
Calibration	Refers mainly to the assessment of the validity of the assessment and evaluation tools used
Nonconformities	Any problem occurring during the development and delivery of education and training
Training	Training and professional development of the staff of the education or training organisation

The next chapter provides more details on these terms. It should be noted that several words used in ISO 9001, e.g. *'procedure'*, *'document and data control'*, *'internal quality audits'*, or *'quality records'* have a particular meaning in the Standard. For that reason, they are not included in the Table, but their meaning will become clear in Chapter 4.

Finally, a terminology problem is recalled which is often neglected: the translation of the norms into the different European languages. Although these translations are authorized, they have often been made with a particular type of organisation in mind. This translation may, in turn, facilitate or not the 'interpretation' for education and training purposes. Some key terms of ISO 9000 are actually not easy to translate, such as:

- management
- control
- procedure testing
- review
- contract
- design
- purchasing
- data
- inspection and

- audit
- records

- system
- verification

- training
- servicing

The author of this report has encountered cases where the translation of the terms 'inspection and testing' led people to believe that the clause concerned the testing of students or an external inspectorate system.

3.2.3 Rearrangement of the requirements of ISO 9001

When reading the different requirements of ISO 9001 or 9002, one is likely to be puzzled by the particular sequence of the different requirements (which are grouped in 20 sections or Clauses). The order does not appear logical – which presents an additional hurdle for education and training organisations in finding their way through the norm. Moreover, the length of the clauses varies considerably from a few lines to a whole page. Some clauses have been subdivided in many sub-clauses, while others consist of a single paragraph. Surprisingly, moreover, the length of the Clauses or the number of sub-clauses are not correlated with their importance – in particular not in an education and training context. The varying degree of detail in the specifications and the overlap between certain sections may further add to the confusion of those who are not yet familiar with the standards.

One way to resolve this problem, is to read and analyse the requirements of the standards in a different sequence. For education and training organisation, this will be particularly useful if they read at the same time the interpretation provided in Chapter 4 (since that chapter was meant as a reference document, the sequence of the different clauses and sub-clauses has been rigorously followed). The next paragraphs suggest a different sequence, which may be more appropriate for education and training organisations. The titles used are those of the norms. The figures (e.g. 4.2) refer to the corresponding (sub-)clause.

General principles of the quality system

- 4.2.1 Quality system – general
- 4.1.1 Quality policy
- 4.1.2.3 Management representative
- 4.1.2.2 Resources
- 4.1.2.1 Responsibility and authority

These clauses list the general requirements of a quality system, including a quality manual, a clear quality policy, the appointment of a quality manager, allocation of sufficient resources and the definition of responsibility and authority of staff.

General requirement for the implementation of the quality system

- 4.2.2 Quality system procedures
- 4.2.3 Quality planning
- 4.18 Training
- 4.5 Document and data control
- 4.6 Control of quality records

These clauses specify the general requirements for the implementation of the quality system: document processes in procedures, undertake quality planning where required, make sure that all staff is appropriately trained, and control documents, data and records.

General principles of process control

- 4.9 Process control
- 4.10 Inspection and testing
- 4.20 Statistical techniques
- 4.7 Control of customer-supplied product
- 4.8 Product identification and traceability
- 4.12 Inspection and test status

These are general quality assurance requirements which apply to all critical processes, in order to ensure that these processes are under control and will yield the required quality outputs. These requirements are stated in fairly general terms; some aspects are not applicable to education and training. For several processes (see below), there are more specific additional requirements

Specific requirements for particular processes and activities

- 4.3 Contract review
- 4.4 Design control (*does only apply to ISO 9001*)
- 4.6 Purchasing
- 4.11 Control of inspection, measuring and test equipment
- 4.15 Handling, storage, packaging, preservation and delivery
- 4.19 Servicing

These clauses elaborate, for some processes, further the general quality assurance requirements. The applicability of the different paragraphs varies considerably (see Chapter 4 for more details).

Maintaining and improving the quality system

- 4.13 Control of nonconforming product
- 4.14 Corrective and preventive action
- 4.17 Internal quality audits
- 4.1.3 Management review

Together, these clauses create a feedback loop which ensures that problems are solved, causes of problems are removed, improvements take place continuously, and the whole quality system is regularly and thoroughly reviewed.

Reading the interpretations of the clauses of ISO 9001 in this sequence might help an education or training organisation to understand better the real implications and requirements of the standard.

4. Interpretation of ISO 9001 requirements for education and training organisations

Introduction

This chapter is the core of this report. It contains a detailed discussion of all requirements of ISO 9001 and their interpretation in an education and training context. Since ISO 9002 is a subset of ISO 9001, no separate discussion is provided on ISO 9002. An attempt has been made to pay attention to all types of education and training organisations – from schools, through higher education institutions, to providers of continuing education and training. Thus, for any particular organisation, some parts of the discussion will not be applicable; in general this will be obvious from the text.

An important limitation of the chapter should be mentioned. Many education and training organisations undertake activities which may not be directly linked to education, such as child care, accommodation of students, consultancy, research, etc. Although such activities are occasionally mentioned, no specific interpretation or guidance is provided on such matters.

The starting base for writing this interpretation was the author's own expertise in assisting education and training organisations with regard to ISO 9000. This was considerably enriched through the analysis of a large number of documents from all over Europe, produced by standards organisations, certifying bodies, researchers and certified providers of education and training themselves (see Bibliography). The author was moreover given the possibility to analyse internal documents of certified organisations and certifying bodies.

For some general aspects of interpretation and the terminology used, please see Section 3.2. Please note that certain concepts, such as 'customer' need to be interpreted differently for different types of organisations. In order to avoid continuous reference to "ISO 9001 and ISO 9002", the text uses most of the time the term 'the Standard'. The word "Clause" is used to refer to one of the twenty numbered requirements of the Standard, or sometimes to a well-defined subsection of one of the requirements. Although it may appear cumbersome, the term 'education or training organisation' is used fairly systematically – it may refer to a school, a university, an adult education institute, a training department within a firm, a private training provider, etc. Only when no misunderstanding may occur, more specific terms (e.g. 'school') have been used.

In the text, the interpretation choices which were mentioned in Section 3.2 have been followed consistently. Occasionally, however, some reference is made, *in italicised text*, to the implications of other possible interpretations.

A final warning when using these guidelines: every organisation has different characteristics – and thus the interpretation of the ISO 9001 requirements will need to follow suit. There are also many different ways in which the requirements can be met. Any quality system is unique, and the guidelines which follow should never be followed blindly. There is no substitute for a proper analysis of the activities and operation, before any ISO 9000 exercise takes off.

4.1 Management responsibility

4.1.1 Quality Policy

The education or training organisation must have a Quality Policy statement, in order to comply with the requirements of this first clause of the Standard. The statement should clearly demonstrate the organisation's commitment to quality towards its customers. The quality policy of publicly regulated education institutions should also be relevant to the legal, social and national context.

The quality policy should include or refer to specific quality objectives to which the organisation is committed. Such objectives should be relevant to the needs and expectations of customers (employers, students, trainees,...). They should give substance to the main messages of the overall quality policy, which is often phrased in general terms (e.g. 'We provide high quality education to students'. 'We deliver an excellent service to all our clients'. 'Our mission is to develop customized training which meets the needs of our customers'). Some examples of specific quality objectives of an education and training organisation are:

- 90% of trainees are satisfied or very satisfied with the training courses;
- all governmental standards and regulations are met or exceeded;
- failure rates of students will be below 15% by a certain date;
- success in obtaining a particular certificate, prize, award,...

The quality objectives can also be related to organisation and performance of the quality assurance system itself, for instance:

- all agreed deadlines are met;
- each process is subject to at least one internal audit per year;
- all course programmes are reviewed every three years by independent experts;
- all trainers have certain content-related and didactic qualifications;
- verifiable learning outcomes will exist for all courses by a certain date;
- all criteria for a quality prize or award will be met by a given date.

When defining quality objectives for substantiating the overall quality policy, one may also identify goals which implicitly refer to the achievement of a particular quality level, such as: increasing market share, low turn-over of staff, the amount of internal training, commitment of parents and students, spontaneous congratulations, winning of tenders, employability of graduates, etc.

The definition of the Quality policy is the responsibility of the senior manager(s) with "executive responsibility" – what is meant is the chief executive/head teacher/director/general manager/rector etc. This responsibility should not be delegated. The quality policy should be issued, communicated and made known throughout the organisation. Indeed, the Standard requires this policy to be "*understood, implemented and maintained at all levels*". The quality policy and related objectives should be included in the Quality Manual and should be publicly accessible (e.g. on

public display). In larger organisations, middle management has an important role in communicating and supporting the quality policy. All full- and part-time staff (including external experts and free-lance trainers) involved in both educational and support activities should receive the same quality message from management. Sub-contracts with third parties who may affect the quality of the service (in particular external teachers and trainers) should refer to the quality policy of the education or training institution.

It must be possible to show how the quality system of the organisation is consistent with the Quality Policy and the stated quality objectives and intents. Moreover, all statements relating to quality which are given in documents, training manuals, promotional material, etc. must be consistent with the quality policy.

There should be evidence of the intent to deliver against these objectives. This could be done by establishing an annual action plan for quality improvement which is linked to the Quality Policy and its specific objectives. Larger organisations need to have such plans and goals for each major department.

As the aims of the organisation change, and needs and expectations of customers evolve, the quality policy and objectives will require adaptation. These changes and the necessary implications for the quality system should be examined at management reviews (Clause 4.1.3) and documented. Changes must be issued in a controlled manner (see Clause 4.5) and properly communicated to all employees.

4.1.2 Organisation

4.1.2.1 Responsibility and authority

The responsibility and authority of all staff who can influence quality should be documented. In most organisations, including in the education and training sector, all staff have an effect on the quality of the service (including part-time or external teachers and trainers, support staff and subcontract staff). It is up to the management of the organisation to decide on the responsibility and authority for particular tasks and duties.

The requirement of this clause may be fulfilled by including a full organisational chart in the quality manual (Clause 4.2.1), complemented by other statements in the quality or procedure manuals (e.g. task allocations as part of procedures). The quality system documentation could also include references to existing descriptions of duties (e.g. in staff contracts or public regulations). Sometimes, responsibility might need to be assigned to a team, committee or council (such arrangements are often found in higher education). Descriptions of responsibility and authority should be clear, complete, and consistent across the organisation.

These documents, charts and descriptions of duties are to be considered as 'controlled documents' (see Clause 4.4). This implies that they should always be up-to-date, authorised and available to those who need access to them.

Special care should be given to defining the responsibility and authority for critical quality system aspects, particularly:

- the management review (Clause 4.1.3);
- the management function responsible for Quality (Clause 4.1.2.3);
- the responsibilities and authority for the maintenance of the Quality system (several Clauses);

- inspection and verification (Clause 4.10 and others);
- quality system non-conformances (several Clauses);
- corrective and preventative actions (Clause 4.14);
- quality records (Clause 4.16 and others);
- internal quality audits (Clause 4.17).

In an effective quality system, defining responsibilities for such activities is in general fairly straightforward.

4.1.2.2 Resources

This clause expects an education or training organisation to ensure that adequate resources are provided to allow the effective and efficient operation of the quality system. With 'resources' are meant: people, facilities, equipment, education and training materials, supplies, services, etc. This requirement covers all management, work performance, and verification activities which are part of the quality system. All resources needed must be adequately identified; this demand is restated for several specific processes in other clauses of the Standard.

In education and training, particular attention should be paid to the adequate definition of the necessary competences of teachers/trainers (see Clause 4.18). All staff need to be appropriately qualified for the tasks for which they are responsible. The Standard, in addition, underlines this need for those people undertaking the critical functions of verification of the quality of work and the internal auditing of the quality system (Clause 4.17). Where a division of responsibility exists between the performance of tasks and the assessment or verification of these tasks, this should be clear, and both functions should be appropriately resourced.

Appropriate training should be provided to ensure people are and remain qualified for their jobs (this applies in particular for verification and auditing functions). Training records should be maintained to provide evidence that suitable training has been provided (see Clause 4.18). Such training records are to be processed as Quality Records (see Clause 4.16).

4.1.2.3 Management representative

The education or training organisation needs to identify a member of the management team as the person who has a clearly defined responsibility and authority for implementing and maintaining the requirements of the Standard. This person, referred to in the Standard as the 'management representative', may be called 'Quality Manager' or 'Quality Coordinator'. Responsibility and authority must be fully documented. He or she may have other responsibilities dependent on the size of the organisation and the complexity of the quality system. In larger organisations, it may be useful to appoint a deputy quality manager, and to create a 'quality management unit' headed by the quality manager. In very small organisations, the quality manager is often the director/head of the institution.

Formal reporting mechanisms should exist between the Quality Manager and the management team regarding system, process or service failures. The Standard also suggests that the quality manager be a liaison person with external parties. He or she thus becomes the focal point for the quality system, and has a central role in the continuous improvement of the system. It is recalled, however, that all staff bear responsibility for the quality of their own activities, and that the ultimate responsibility for quality and performance is with the senior manager.

4.1.3 Management review

According to this clause, senior managers have to assess regularly the suitability and effectiveness of the quality system, so that they may identify areas where improvements can be made. The review process, called the 'management review', should be described in the quality manual and take place at defined intervals (at least once a year). It should

ensure that the quality system continues to meet the needs of the organisation, its customers, and the requirements of the Standard. Other staff may attend this review meeting when appropriate.

The management review is in general based on an overall report of the quality manager and may include such items on the agenda as:

- an analysis of the quality policy and its implementation;
- the state of development of the quality system;
- the results of internal quality audits;
- an analysis of customer complaints;
- the status of documented systems;
- outcomes of evaluations and customer satisfaction surveys;
- the effectiveness of corrective and preventive measures taken;
- evaluation of improvement programmes.

The review must at least consider the quality policy and the key characteristics of the quality system, and determine whether quality objectives are being achieved. This requires the preliminary specification of objective targets for quality system improvements (e.g. the specific quality objectives mentioned in Section 4.1.1) and assessment at a later stage if these have been achieved.

Evidence should be available that reviews are planned and effective. Minutes of management review meetings must be maintained and be treated as quality records (Clause 4.16). Those records should show what decisions were made, what preventive, corrective or other follow-up action were to be undertaken, and who was responsible for their implementation. There should, of course, also be evidence that these decisions have effectively been implemented and/or re-assessed in a subsequent management review.

4.2 Quality system

4.2.1 General

A quality system consists of a coherent set of standards, procedures, activities, feedback mechanisms and management actions which together ensure the quality of the products and services delivered. Since most activities in an organisation, particularly in education and training, influence quality in one way or another, the quality system will need to encompass virtually all activities and processes of an organisation (with the possible exception of financial tasks, certain marketing and public relation activities, part of internal information and communication, personnel administration, environmental measures, etc.).

It is useful to recall here that an organisation can be certified for part of its services (e.g. a consultancy office only for its training activities; or a school only for its regular education programmes). In such cases, the quality system will only need to cover

those activities, functions and factors which could affect the quality of the education and training for which certification is sought.

Not any type of system of work organisation is a quality system; to qualify as a 'quality system' under ISO 9000 all requirements of the Standard need to be fulfilled. Clause 4.2 lists some of the main principles; more explicit requirements are developed in the other clauses. Overall, the clauses provide a framework for a quality system (e.g. with a quality policy, documented procedures, internal audits, quality records, etc.), with strong emphasis on effective quality assurance mechanisms. The detailed implementation of the quality system is not prescribed in the Standard. There are, for instance, no detailed instructions on how procedures have to be written, on the format of quality records, or on the frequency of internal audits. What matters is that the quality system is appropriate to the type and size of the organisation.

The establishment of a quality manual is a mandatory requirement of the Standard. The manual should include at least:

- the organisation's quality policy and objectives;
- a short description of the organisation and its activities;
- the main responsibilities and functions of staff;
- an outline of the structure of the quality system documentation;
- a cross-reference between the procedures (and other elements of the quality documentation) and the requirements of the Standard.

The relation between the organisation's policies and the documented procedures should also be obvious from the quality manual.

In a small education and training organisation it may be possible to include the full quality documentation as part of the quality manual; if not, at least references to the procedures should be made. In larger organisations, these documents are typically compiled into one or more procedure manuals (there is no formal obligation to do so).

It may be useful for education and training bodies to explain in the manual how the 'production terminology' has been interpreted in the education/training/ learning environment, and to justify on what grounds certain clauses (or part of them) were not considered applicable, or interpreted in a particular way.

4.2.2 Quality systems procedures

A 'procedure' is a formalized and often standardized description of a process. A process consists of a series of tasks undertaken by two or more persons. Most of these tasks are sequential, but some of these could occur in parallel and/or be repeated within the same process. The description of one or more sequential task undertaken by a single person is often called a 'work instruction'; a procedure may

contain or refer to one or more work instructions. In practice, there is no strict boundary line between both concepts. There are also no strict guidelines on the complexity and length of procedures; for maintenance and document control reasons, it is often appropriate to keep procedures relatively short.

It should be noted that the Standard uses the term '*procedure*' fairly often. In fact, the term in ISO 9000 corresponds with both the concept of a procedure as defined above, and with a work instruction. In this report, the term 'procedure' is only used for the description of a process.

Sub-clause 4.2.2 of the Standard requires that 'procedures' exist for describing the processes within the quality system. These procedures should be consistent with the Quality Policy. Some of the procedures required concern the core processes which are common to any type of education or training organisation, e.g. delivery of courses, recruitment of staff, registration of students/trainees, etc. Other procedures will be specific to certain organisations, e.g. assessment of students or development of learning material. A third group of procedures is related to the specific requirements of the Standard, e.g. internal auditing, document control.

The number, length, and level of detail of procedures should reflect the complexity and variety of the processes within the organisation. Another important factor is the competence level of staff. With highly qualified staff (which is often the case in education and training institutes) detailed procedures and work instructions are not mandatory. In such circumstances, the organisation should be able to provide evidence (e.g. through quality records showing few non-conformities) that more details are not necessary. For lower qualified administrative and support staff more detailed procedures and work instructions may be necessary. Thus, documented procedures should include sufficient detail to enable qualified staff to understand what has to be done and by whom. But procedures must be written in such a way that the quality system can be audited effectively and efficiently. This excludes procedures written at a high level of abstraction.

Writing procedures, work instructions and other associated documents (e.g. forms) can be a tedious task. Education and training bodies should, whenever possible, develop these on the basis of existing documents, but ensure that these are suitably and consistently identified and referenced. Most of the documents which publicly funded education institutions are legally required to have can often be 'recycled' or simply be used as such. While it is still common practice to document the quality system on paper, the procedures, work instructions, forms or other related documents might also be available (possibly exclusively) electronically – or even in any other accessible form, e.g. on audio or video cassettes.

4.2.3 Quality planning

The term '*quality planning*' may be misleading, and should not be confused with 'quality plans'. 'Planning' refers to a method, a 'plan' to the result. This clause requires that quality planning is carried out to ensure that quality policy and objectives (Clause 4.1.1) are met, and to define methods of implementation for meeting the customer needs. Basically, an organisation should undertake such planning in a systematic way. Since most agreements with customers include the execution of standard sequences of tasks, such tasks will already be documented in procedures. For many education institutions with a regular provision of the same types of programmes, all aspects of quality planning may be covered by standard procedures included in the documented quality system itself. This would exclude, however, that a non-standard activity (e.g. a new, customized course) to be part of the quality system covered by the certificate.

For most other education and training organisations, the Standard provides in this clause a list of activities which should be considered for quality planning, and which may be integrated in the quality planning for 'non-regular' activities. This process may be limited to creating a sheet of paper showing the specific requirements of the customer, the appropriate (parts) of procedures which are to be applied (by whom and when), possible exceptions, and any other extra information needed to ensure that the needs of the customer are met. There should be evidence that quality planning occurs and that it is effective.

4.3 Contract review

4.3.1 General

The word '*contract*' is used within ISO 9000 in a general way, meaning any type of agreement between the education or training provider and its customers (students, trainees, employers, etc.: anyone who receives services from the organisation). Thus, a '*contract*' refers to an agreement to deliver education, training or other services; it may be actual or implied, written or verbal. In principle, the '*contract*' may cover all activities at the customer/supplier interface. In education and training, these contacts are likely to be frequent and interwoven in the other processes (design, delivery, evaluation,...). Since such processes are well covered by the requirements of other clauses of the Standard, one can limit the scope of this Clause to the initial '*agreements*' made with the customers.

This clause does not prescribe what an (initial) agreement should contain. Rather, it states that every agreement with a customer should be '*reviewed*' – which means that an assessment is made on whether one can deliver what is promised. The bottom line is that a provider of education and training services should have verified that the organisation is capable of fulfilling the '*contractual*' requirements.

Many education and training providers offer pre-designed courses or programmes, to which students or trainees can enrol. The registration establishes a '*contract*' between the provider and customer; often, many features are implicit. This '*contract*' is usually not negotiable: the student, trainee or employer has only the choice to accept or reject the offer made. In all such cases, '*contract review*' is not really applicable to the individual registration of students/trainees, but applies to the general conditions and promises of the provider. '*Contract review*' comes down to a regular review by the provider of:

- the suitability of standard conditions offered to students, employers,...;
- the accuracy of the promotional information (e.g. a course prospectus);
- the up-to-dateness and appropriateness of the information provided in advance of a course (including pre-enrolment guidance);
- the implicit expectations generated (e.g. what a parent expects from a school; or the quality of the facilities in an expensive top management course).

Where custom-made training is to be delivered – in particular for continuing education and training – this Clause should be interpreted like in most other business sectors: both customer and provider must know what they agree, and there must be clear evidence of a review of terms and conditions. There will be need for evidence that every custom-made agreement has been reviewed.

Contract review also applies to the conditions imposed by grant-awarding bodies: no grant for an education or training project should be accepted if the provider is

incapable of meeting those requirements. If legal constraints apply to certain types of education or training provision, customers should be informed of these.

Please note that some experts also include the agreements with sub-contractors, particularly external trainers, under this clause. This line of thought is not followed here, since this aspect is sufficiently covered by Clause 4.6 and the control mechanisms included elsewhere in the Standard.

4.3.2 Review

Before a 'contract' is concluded, both customer and supplier need to understand what education and training services are being offered. They should be deliverable by the education or training organisation, and evidence should be available that the resource implications have been taken into account. This clause requires that such aspects have been formally considered before a final contract is agreed (this is what is meant by 'review'). Examples of elements which may need to be reviewed are:

- the suitability of existing training courses for re-use or adaptation;
- the availability of know-how (content related, didactic, methodological,...);
- the availability of qualified staff (at the required moment);
- the feasibility of the proposed planning and the time schedule;
- the technical feasibility and the availability of resources and equipment.

Particular attention should be paid to those situations where the final agreement is different to what had been offered or required initially.

An almost inevitable implication of this Clause is that verbally made agreements imply some positive confirmation in a written or electronic form. This may be achieved using fax confirmation messages, confirmation by letter, or logging verbal orders and confirming them back to customers over the phone.

For many education and training organisations – particularly those using standard conditions for their courses – the procedure or work instructions to be established to meet the requirements of this clause will be fairly simple. In more complex situations, there might be the need to have separate procedures for:

- preparing a quotation or a draft contract;
- reviewing and approving a quotation and/or a contract.

4.3.3 Amendments to contracts

Between the start and the end of the contractual period, the agreements made initially may have to be amended. This applies in particular to long education and training programmes, or to the development of comprehensive education or training materials, where changing circumstances may require modification of the programme. Such changes would normally be covered by other clauses of the

Standard, particularly Design (4.4), Process Control (4.9), and Control of non-conforming product (4.13). Thus, it is possible to limit the scope of this clause to modifications which occur just after the agreement has been concluded, and before any design or development work has begun. A typical example is a sudden programme modification because of unavailability of a trainer. Another example is the rescheduling or cancellation of course. Such events could be documented in a separate procedure or work instruction (if they occur regularly), as an explicit part of other procedures (e.g. on the conduct of courses), or through the generic arrangements for dealing with non-conformities (see Clause 4.13).

What matters is that both the provider and all customers concerned are aware of the changes in the agreements and their implications. Thus, the provider should have good communication channels with all customers affected, as well as a mechanism for internal communication of all contract amendments and their implications. This is particularly important for larger education and training organisations, where several departments may need to be informed and to act accordingly.

4.3.4 Records

A written contract is to be treated as a quality record in itself (see Clause 4.16), but there should also be evidence of the contract review process itself (e.g. minutes of meetings, list of changes made). Such evidence should also be kept and maintained as quality records.

4.4 Design control

4.4.1 General

The correct understanding and application of this clause on 'design control' is crucial for the application of the Standard to education and training programmes. The main purpose of the design parts of the quality system is to develop education and training services which start from identified needs and objectives. The first paragraph of this Clause is an introductory one, highlighting the need to have appropriate procedures for the design and the verification of the design, and to ensure that all design requirements are satisfied.

Clause 4.4 is only appropriate if the programmes or courses developed are to some extent unique or customised, in e.g. subject matter, delivery method or assessment method. When there is, within the scope of the quality system, only marginally original design activity, then this Clause does not apply and ISO 9002 is applicable instead of ISO 9001. This applies for instance when

- the provision of education or training is based upon standard syllabi
- education or training is predefined within explicit requirements (either requested by customers or prescribed by the state, like in schools)
- when the programme is compiled by assembling modules of standard programmes or courses.

Any marginal design activities left could then be covered under Process Control (Clause 4.9). Practice to date indeed confirms that schools and highly regulated adult education bodies, subject to external prescription of educational content, are indeed certified on the basis of ISO 9002, while continuing education and training providers and higher education institutions aim for ISO 9001, since their capacity to design their programmes themselves is a critical quality characteristic.

Anything which requires an original design is covered by this clause. For education and training providers this may include:

- curriculum design and development;
- course design and development;
- design of course syllabi;
- design of learning materials (including software based materials);
- design of assessment materials and methods;
- design of assessment/examination questions;
- definition of work placements;
- preparation of guidance and tutoring of students;

and possibly:

- preparation of course visits;
- planning of teaching/training schedules;
- design of extra-curricular activities;

- design of other services delivered and developed by the provider (e.g. consultancy, research, training needs analysis,...).

Whether activities such as preparation of course visits fall under this clause or rather Process Control (Clause 4.9) depends on the 'design originality'.

For education and training activities, the interpretation of the different paragraphs of this clause is often not straightforward, for several reasons:

- There may be several, but related design processes: programme design, course design, development of syllabi, guidance, etc. For each of them there should be documented design methodologies which comply with the different requirements of the clause – which may be difficult or even impossible.
- The design process in education is often based on subjective grounds and/or its quality may be difficult to assess.
- For education and training courses, particularly the relatively short ones, it is often impossible to distinguish between elements of design, development and planning. For longer programmes, (re-)design might even take place during the period of delivery.
- The appropriateness of the design can often only be assessed after the education or training has been delivered; for a course which is only run once, it implies that certain verification and review steps required by the Standard are either impossible to implement or do not give full guarantee of quality of delivery (this characteristic also applies to many other services).

It should also be noted that ‘design’ of education may have two components:

- The first is the definition of education and training goals and objectives. When these are predefined by the state or the customer, this aspect does not need to be considered. However, when the provider has a certain degree of freedom in setting the goals and objectives, the processes of identifying these learning objectives could be so important (e.g. on the basis of training needs analysis, market research, comparisons with other programmes) that they merit a procedure in its own right.
- The second, more ‘traditional’ type of design in education and training is when identified learning goals serve as the basis for the development of programmes, courses and learning materials. The focus of the discussion below will be on such forms of design.

The different sub-clauses of Clause 4.4 define different stages of the design process. A common requirement is the clear definition of responsibility for each aspect of the design process. This should be documented in procedure(s).

It is recalled that some education and training bodies also provide ‘non-educational’ services and products (e.g. research). Such design activities are not considered here.

4.4.2 Design and development planning

This second paragraph of the clause basically states that all design and related development activities (for curricula, courses, training materials,...) should be carried out in a planned way. One needs to specify:

- all the critical tasks which need to be done;
- the output of each task;
- the staff who need to carry out the activities.

Staff assigned to design should be qualified to do so; adequate resources need to be available. It goes without saying that standard procedures should be available to avoid that a new plan has to be established for every new design activity.

4.4.3 Organisation and technical interfaces

This sub-clause applies in particular to larger education and training providers where different people and/or different departments jointly contribute to the design (of a curriculum, a course syllabus,...). The responsibility and authority of all the staff involved in the design process (including lecturers, course directors, programme managers, tutors, external trainers), and their interfaces, should be clearly defined and documented. Appropriate communication channels and coordination mechanisms should exist to provide all relevant parties with correct information at the right time.

4.4.4 Design input

'*Design input*' refers to all the information elements which are necessary (and may reasonably be expected to be obtainable) for the design of a particular education/training output. The final goal of this first step is to arrive at a sufficiently detailed specification which will guide the design process itself.

Design input elements may vary significantly from one type of design to another; they may include:

customer and course related elements

- the overall learning goals, objectives and outcomes to be achieved;
- the requirements for assessment of learning (e.g. the type of examinations);
- how and to what extent the quality of the output should be evaluated;
- the desirable period and the number of hours available for learning;
- the financial possibilities of the customer.

learner related factors

- educational profile, existing qualifications, entry-level of learners;
- other characteristics of learners (age, sex, working environment,...);
- familiarity of learners with particular types of learning (face-to-face, distance learning, etc...);
- types of support available to learners (e.g. tutor, line manager, additional learning support materials, self-assessment methods, library, equipment,...);
- restrictions on place and time for the learning.

internal factors

- internal rules resulting from the quality policy and the quality system;
- commitments made in programme prospectuses and course announcements;
- rights and promises given to students/trainees;
- availability of resources (staff, place, equipment,...) at the required moment;
- competence and qualifications of available trainers/teachers;
- the design or content of similar, existing outputs;
- outcomes of previous design and programme reviews;
- financial or resource constraints of the provider.

external factors

- legal requirements and constraints which are applicable;
- external quality standards or criteria which are adhered to by the provider;
- requirements of external examining or certification bodies;
- requirements needed for a particular certificate or external award;
- outcomes of appropriate market research;
- opinions of particular bodies representing the customers (e.g. professional associations suggesting requirements for certain graduates).

Furthermore, the design input information should include the results of any contract review activities which are not included in the above list. The input requirements considered have to be documented, since they will be used for review and comparison with the design output (see below). The design input elements have to be reviewed; incomplete, ambiguous or incompatible requirements must be resolved with those who have issued them (this may even require an amendment of the contract).

In order to obtain some of this input information, it may be necessary to carry out market research, analyse appropriate literature, discuss practical issues with customers, or conduct a training needs analysis. An efficient way to deal with all these requirements is to work on the basis of one or more checklists where all the possible input requirements for a particular design process are listed.

4.4.5 Design output

The '*design output*' information contains the final outcome of the design process. For many education and training development processes it is difficult to define where 'design', 'development' and 'delivery' stops. If any 'development' is excluded from 'design', then the 'design output' data might not differ much from the 'design input' data, the main difference being that some choices have been made between different options available (e.g. choice of a particular training method, an assessment methodology, a particular trainer). When, on the contrary, 'design' includes most of the development process, then the design output might almost resemble the final education product (finalised courses, syllabi, programme schedule, etc.).

When putting the 'design output' stage in the early phase of the development process, one may identify the following types of design output elements:

- detailed objectives of every module;
- a definition of the knowledge, skills and attitudes the learners should acquire;
- the didactic approach to be adopted;
- resources and staff to be used for development and delivery;
- scheduling of modules or lessons;
- teacher and trainer manuals (or outlines of these);
- overview of the format and content of the learning support materials;

- external or internal validation criteria of the courses or materials;
- the evaluation and assessment methods and tools to be used;
- planning and guidance for the development, highlighting critical aspects.

The distinction between design 'input' and 'output' is not always clear-cut, particularly for relatively modest designs following a standardized approach. In education and training there is also a tendency to specify design input requirements in output terms. Once the type of design output has been defined for a particular design process, one should check that the requirements this sub-Clause states are met. The design output should:

- be documented properly;
- conform to all appropriate regulatory requirements;
- be formulated in such a way that a comparison with design input is possible;
- be verified and validated on the basis of the design input requirements (see 4.4.7 and 4.4.8 below);
- contain or reference criteria for the acceptance of the final outcome of the service (development or delivery);
- highlight critical factors for development and delivery of outputs.

Although, in the end, most of these rather technical requirements boil down to common sense, this step is a formal requirement and should take place in every design process (could be at the verification stage).

4.4.6 Design review

The sub-clauses 4.4.6 (design review), 4.4.7 (design verification) and 4.4.8 (design validation) are closely interrelated. For short and simple design processes in education and training, the requirements will almost entirely overlap. For more significant designs the stages will differ, but remain closely interrelated.

The main purpose of the '*design review*' is to evaluate suitability of the design process itself. This requires an education or training institute to:

- check whether the design input elements are still relevant;
- review the capability of the design process to meet those requirements.

Representatives from all units of departments involved in the design process (or the particular design stage under scrutiny) should be involved in this review. Other competent staff should join where this is felt appropriate (e.g. an expert might be asked to give his independent opinion).

A design review can, in principle, be conducted at any stage of the design process, preferably towards the end of every major stage. It is up to the education and training organisation to determine the frequency, timing, format and thoroughness of the design review. This will mainly depend on the complexity of the design, the number of people involved and the uniqueness of the design methodology under review. For instance, if a continuing education institute always uses the same design

methodology for short courses, then the design review can be 'light' and often been subsumed in the verification stage (see 4.4.7). On the other hand, for major design processes such as the creation of a complete curriculum or the production of comprehensive learning materials, several thorough reviews might be necessary. Such reviews are likely to take place as part of progress meetings attended by all parties concerned.

Whatever approach is taken, the design review activities should be planned in advance. Problems identified through the review activities should be given appropriate solutions. Records of the design review process (e.g. minutes of meetings) should be kept.

4.4.7 Design verification

'*Design verification*' is a necessary step to ensure that an acceptable design is obtained. In essence, verification activities should compare the output of the design process with the design input requirements. Given the intangible nature of education and training, defining proper and affordable verification mechanisms may prove to be difficult. Possibilities include:

- pilot courses/programmes (trial runs), if a course is run more than once;
- comparing the design with similar designs;
- external comments from examination bodies, experts,...;
- feedback and/or agreement from customers;
- self-assessment on the basis of an appropriate checklist.

Records of the verifications should be kept.

In principle, the verification of a course design is not the same as the verification of the course itself. In reality, it may only be possible to verify fully the appropriateness of the design after the course has taken place (covered by the requirements of Clause 4/10, Inspection and Testing). On the other hand, verification of learning materials before finalisation and delivery, is often feasible – and indeed desirable.

When a design is complex and consists of different phases (e.g. the adaptation of a new curriculum), the verification should be conducted at each stage. On the other hand, design verification for a typical short custom training course may require no more than asking the customer for confirmation that the design corresponds with what he needs.

4.4.8 Design validation

'*Design validation*' is the formal approval that the design process has been completed and that development and/or delivery can go ahead. In principle, validation should follow successful design verification. When designing education

and training programmes, it may not be possible to undertake validation at all, or only at earlier stages in the design process. This applies in particular when full verification is only possible after delivery of the service. In such cases, 'validating a course' implies then that at least the 'controllable' aspects of the course design have been reviewed and verified; validation then coincides with the verification.

This clause is only fully applicable to the design of tangible items (learning materials, assessment tools, assessment questions,... – where the validation requirement can easily be implemented) and to the development of course programmes or other educational services which will be undertaken several times. In such cases, it would appear most appropriate to validate the course after the first trial run: only then one is in a position to check whether all user requirements have been adequately addressed. Of course, all precautions have to be taken to ensure that such a trial run also meets the requirements of the customer.

4.4.9 Design changes

There should be documented mechanisms for dealing with changes which inevitably arise during the design processes, particularly longer ones, and for programmes which are run more than once. One should have a mechanism for identifying when changes are needed, for implementing and recording them. These changes could affect the overall objectives, and be either customer driven or resulting from internal evaluations or voluntary improvements.

For courses which are only run once, for occasional handouts, this clause does not really apply, except for longer programmes where a mid-term review could indicate the need for changes.

4.5 Document and data control

4.5.1 General

In education and training organisations, many documents which are needed for a quality system exist already. Often lacking are, however, standardisation of documents, descriptions of some processes, and a system to 'control' such documents. The purpose of this clause on '*Document and data control*' is to make sure that everyone in the organisation

has – or has access to – up-to-date copies or electronic versions of the documents and data they need. Clause 4.5.1 states that there should be documented procedures for document and data control. There are two main processes to be controlled: approval and issue of documents (Clause 4.5.2) and modifications and changes of documents (Clause 4.5.3).

The requirements of this clause apply, in principle, only to the documents and data which are used within the quality system itself; for education and training organisations this means that relatively few documents are excluded. Documents to be considered include

- the quality manual;
- procedures and procedural manuals;
- work instructions, forms, lists – whether these are printed, in electronic form, handwritten, etc.;
- training materials, course syllabi (in particular when they are used more than once).

It could be argued that agreements, monitoring and evaluation results, reports, project and course files, minutes of meetings, filled-in forms, letters, etc. also fall under this definition. However, such documents or data are either specifically covered by other Clauses of the norm, or by the general requirements of the 'Quality records' clause (4.16). For this reason, we will exclude these from the discussion and focus on documents and data which serve as an input to, or description of, the quality system. To illustrate the difference: the design and adaptation of a form falls under this clause, while a filled-in form falls under Clause 4.16, 'Quality records'.

Document and data control also concerns externally generated documents which have an impact on the quality of education and training, such as:

- all external documents referred to in the quality and procedural manuals;
- information and prescriptions from customers which are necessary for producing the required education and training;
- legislation, government circulars affecting the delivery of education and training;
- requirements of external certification, accreditation or other relevant bodies;
- external course syllabi or training materials used as part of the provision (however, this requirement is also covered by other clauses in the Standard);
- relevant handbooks and user manuals (e.g. on software).

Of course, the organisation cannot itself modify such external documents (as required in Clause 4.5.3), but they still need to be appropriately codified, issued and distributed to those who need them. If external documents are not automatically forwarded to the organisation (such as government circulars), arrangements should be in place to ensure that the latest edition of such documents are immediately acquired (e.g. through a subscription to an appropriate publication service). If an external document is modified, obsolete copies have to be removed in a similar way as internally controlled documents (Clause 4.5.2).

If the document and data control system is partially or totally electronic, then:

- sufficient hardware should be available to facilitate access
- security measures should be in place to avoid unauthorized modification
- backup measures should be appropriate to avoid unintended loss
- printing should be restricted to avoid spreading of obsolete documents.

The essence of Clause 4.5 is that anyone who issues a '*controlled document*':

- is authorized to do so;
- has approved the latest version;
- knows who has access to the document;
- is confident that obsolete copies have been removed;

and that any user of a document

- knows which version he or she is using;
- is confident that it is the latest, authorised version.

4.5.2 Document and data approval and issue

This sub-clause requires the following to be part of the procedure(s) for document control:

- identification of all documents which are to be '*controlled documents*' (this includes course material, when it is likely to be re-used);
- instructions on how and by whom controlled documents may be prepared;
- instructions on how controlled documents are to be uniquely referenced;
- mechanisms to ensure that all controlled documents have been checked by approved personnel before they are issued and released;
- distributions lists of the persons who need to receive controlled documents;
- mechanisms for making controlled documents available to the people on the distribution lists;
- a master list or equivalent set of documents identifying the current revision status of all controlled documents.

Moreover, there should be an effective mechanism to ensure that obsolete documents:

- are either immediately deleted
- or, when archiving certain obsolete documents is needed for legal or other justified reasons, that they are removed and protected from unintended use.

Please note that '*access*' or '*availability*' does not require that everyone has a personal copy; rather that people know the controlled documents which may affect them and can consult these at an appropriate location. For instance, education and training organisations may make available only one set of documents for a whole department, a unit or for (groups of) teachers and trainers. Although such arrangements facilitate document management, they also require extra attention for communicating to all staff all changes which have occurred in the documents that affect them (Clause 4.5.3).

4.5.3 Document and data changes

The following elements need to be in place:

- all persons who are authorized to make changes to controlled documents should be identified;
- if these persons are not the same as the original issuers, then they should have adequate access to all relevant background information;
- the nature of change should be indicated (on the document itself, on a separate list, in the communication attached to the revision,...);
- there should be a system for recording the changes which have been made to documents.

Please note that these principles apply, not only to procedures and work instructions, but to all controlled documents, except for external documents, where only the nature of the changes can be recorded.

It is common practice to indicate a small revision by a version number increase like 1.1, 1.2, 1.3 etc., while major revisions are indicated by starting at the next integer number, e.g. 2.0, 3.0, etc.

4.6 Purchasing

4.6.1 General

This clause covers the '*purchase*' of all goods and services which are critical to the quality of education and training services offered. Purchasing includes:

- acquisition of goods;
- leasing or renting equipment, services;
- sub-contracting of services;
- use of external trainers or teachers (see below);
- recruitment of interim or temporary (short-term) staff;
- external professional assistance (consultancy, translation,...).

All such products and, particularly, services are to be 'purchased' to a defined specification and from reviewed source.

This clause deserves particular attention for all education and training organisations which use external teachers and trainers, since the institute-trainer interface is critical to the delivery of quality education and training. Examples of such 'externals' are: 'free-lance trainers', 'independent trainers', 'interim' or temporary teachers, invited academic or professional experts, etc. When such 'external' trainers deliver substantial amounts of education or training for an organisation on a regular basis, it seems more suitable to consider them – for the application of the Standard – on the same basis as regular staff, whatever their employment status might be.

Other sub-contractors for which the requirements of this Clause may apply are:

- external experts who advise on education and training issues (e.g. on course content, multimedia development, quality assurance,...);
- external tutors, guidance providers, assessors or examiners;
- other education or training organisations to which whole or part of the design, development or delivery of programmes and courses is sub-contracted;
- persons and organisations who develop tools, forms or other documents used (e.g. for training needs analysis, evaluation,...);
- temporary staff for administrative support;
- desktop publishing and translation services;
- interpretation services;
- transport services;
- mailing and courier services;
- providers of accommodation (particularly classrooms) or catering;
- providers of relevant equipment, software and/or audio-visual material;
- publishers or editors of books and learning materials; bookshops;
- printing or copy services of promotional and course material;
-

companies and organisations providing work placements, equipment or facilities which are an integral part of a course programme;

- certification, awarding or accreditation body services.

This list includes possible sub-contractors for education and training related services. When education and training organisations develop other services (e.g. research, supervision of pupils, sport and cultural activities,...), other types of sub-contractors might also need to be considered.

When the number and type of such sub-contractors is limited, then it is often possible to cover all the requirements of Clause 4.6 in one single procedure (with different annexes per type of sub-contractor) or include parts or all of the requirements within other procedures (for instance, provision of training rooms or catering could be embedded in a procedure on the delivery of a training course). For use of external trainers, a separate procedure is recommended.

To summarize, the purchasing process can vary between being fairly important – especially for continuing education providers who use external trainers, and for higher education institutions offering many services – to rather trivial – e.g. with schools offering regular education programmes in their own premises, exclusively with own staff.

4.6.2 Evaluation of subcontractors

For each pertinent type of sub-contracting, the principles of quality assurance should be applied. The first step in this is to assess potential sub-contractors on their capability to deliver the quality level expected.

For all external trainers and teachers (and by extension, for organisations who provide such persons or provide training services on a sub-contract basis), the following needs to be present:

- a clear definition of competence requirements, related to the nature and type of teaching and training to be delivered;
- evidence that the persons selected meet those requirements (based on track records, academic qualifications, professional experience, previous performance, trainer certificates and awards, evaluation by trainees, recommendations by peers or clients, etc.);
- evidence that the persons selected understand the operation and conditions of the part of the quality system which affects them;
- a controlled list of teachers and trainers who have proved to be suitable for certain types of education and training.

It is strongly recommended that a special 'recruitment' procedure is established which deals with such 'purchasing of teachers/trainers' and which includes the above elements. Even education and training organisations with a long history of

collaboration with external trainers, are likely to require a higher degree of formalisation in the selection of trainers and monitoring their performance. These people should be monitored (on the basis of classroom observation, feedback from trainees, regular discussion,...) to establish whether they should be re-used in the future, and for what purposes.

For the other types of pertinent sub-contracting the following needs to be in place:

- identification of the relevant quality standards, specifications or other requirements; the level and degree of detail will depend on the nature of the sub-contract and the extent of impact on the education/training service;
- sub-contractors should only be selected if they can be shown to be able to meet those requirements (for existing sub-contractors this might be on the basis of documenting previous experience; for new ones, on the basis of a documented formal assessment or audit on the basis of the identified requirements);
- sub-contractors need to understand the requirements of the quality system, be able to demonstrate adherence with requirements and keep whatever records needed to prove conformity with the quality system;
- the performance of selected sub-contractors should be regularly reviewed (possibly with audits);
- quality records (Clause 4.16) should be kept regarding the performance and monitoring of sub-contractors;
- a list of approved sub-contractors should be maintained, and available where such purchasing may be initiated;
- only approved subcontractors should be used, except in emergency situations (where there should be strict authorisation).

Through such mechanisms, it is ensured that all sub-contractors have the capability of supplying materials or services of the required quality.

Monitoring of subcontractors may involve some of the following activities:

- recording of any problems, defects, incorrect delivery, poor service, errors, etc.; such records are to be reviewed regularly;
- reviewing of performance on a regular basis;
- carrying out audits.

The procedure(s) should identify how action will be taken if a subcontractor does not meet requirements. This may eventually include removal from the approved subcontractors list.

4.6.3 Purchasing data

Essentially, this sub-Clause requires that all 'purchasing documents' (order information, agreements, letters and related documents) are fully explicit as to what the organisation wants to purchase and to what standard. Such documents should be reviewed and approved by the organisation before they are released.

Agreements with external trainers should include the specific contributions required for a particular course, but also (possibly under the form of a reference to other documents) information about the general requirements of the quality system for trainers.

For the other sub-contractors, this sub-Clause requires making sure that the order information is unambiguous and sufficiently detailed. Orders could in principle be verbal, but then at least a documented record should be created.

4.6.4 Verification of purchased products

This sub-Clause may apply to situations where the education or training organisation and/or its customer wish to verify the suitability of e.g. external training facilities, residential accommodation, work placements, etc., after the sub-contractor has been selected. A customer may also want to meet or observe a particular trainer before accepting him or her. Such aspects should be suitably arranged with the sub-contractor, and do not modify the organisation's overall responsibility for ensuring the quality of service.

4.7 Control of customer supplied product

In manufacturing the external customer may sometimes provide materials for incorporation in products they ultimately buy back. In services, particularly education and training, this is rarely the case. Examples include:

- the provision of accommodation by the customer;
- the provision of equipment and materials (manuals, software, video tapes,...) to be used for learning purposes;
- background information, reports, specific know-how;
- case studies, examples to be integrated in a course.

In schools, particular attention should be given to tangible items pupils bring with them: these should be fit for purpose, safeguarded against loss (if feasible) and protected from damage (in as far as the school sees this as its responsibility). Something particular which may be considered under this clause are educational credits and exemptions from courses which students carry with them.

Essentially, this Clause states that where such situations occur and may influence the quality of the service, the organisation should:

- check the quality and the suitability of what has been supplied;
- store and maintain it carefully (record it in the case of credits);
- report to the customer any loss or damage.

Where such processes apply, they should be documented. This could be done as part of other procedures.

4.8 Product identification and traceability

There are three more or less tangible 'products' of education and training providers to which identification and traceability applies:

- learning materials, in particular books and syllabi;
- course programme content and structure;
- awards given to the learner.

This clause requires the appropriate *identification* of such 'products'. This boils down to keeping records of courses which are being or have been taught (course name, by who, for who, when, where, how,...) and linking these with the written specifications and agreements. It requires every course and associated elements (syllabi,...) to have a unique name and/or coding. When courses, syllabi or awards vary over time, then identification needs to extend to include the version, the year or anything else which makes it possible to identify each different course offering. Of course, these codification and naming conventions should be used consistently within the organisation.

Traceability refers to the need to be able to tie each learner to the particular education and training programme followed. Traceability is not mandatory, only needed when agreed at contract stage. However, it is something which most education and training organisations can already provide based on existing learner records.

Note: interpretation of this clause is different if the product is taken to be 'the learning' or 'the student'. Such an interpretation would put more emphasis on student/ trainee records, in particular their development of attainment. However, even with the adopted interpretation (the product is the provision of education and training), there is need to control student/trainee records, at least because of the requirements of Process Control (Clause 4.9). In either interpretation, maintaining staff records is necessary, but does not need to be covered under this Clause, since it results from the combined requirements of other clauses (including 4.1, 4.6, 4.9 and 4.18).

4.9 Process control

This Clause is the heart of ISO 9000. It encompasses all education and training related processes which are not covered explicitly somewhere else in the Standard. Depending on the type of organisation and the education and training services offered, this may include one or more processes from the following categories:

development and preparation

- conduct of training needs analysis of trainees (could also be covered by Clause 4.4);

- development of a particular course module (may fall partially under 'design');
- development and finalisation of a learning material;
- educational software development;
- translation, adaptation and editing of learning materials;
- desktop publishing and finalisation of course materials;
- printing/copying of education and training materials;
- planning and scheduling of the course provision [see also the clauses on 'design' (4.4) and 'quality planning' (4.2.3)];
- cancelling and rescheduling of courses; replacements of teachers.

administration and support

- individualised and/or mass mailing of information, course prospectus, etc.;
- development and maintenance of the mailing list and address data files;
- management of the computer services (could be several procedures);
- distribution of appropriate information and materials to teachers;
- provision of practical information to students/trainees/employers on course schedules, classrooms, requirements, etc.;
- distribution of course materials to students/trainees/pupils;
- registration of students/trainees.

learning related activities

- teaching and delivery of classroom training;
- provider-led conduct of practical exercises, software simulations, laboratory work, workshops;
- tutoring, monitoring and providing feedback to students (for courses, project work, exercises, theses,...);
- provision of educational guidance to students (at several stages throughout the programme);
- supervision of on-the-job training and work experience placements;
- provision and use of library resources (may include several procedures);
- adjusting courses and programmes during delivery;
- educational-oriented visits and tours.

organisation of education and training sessions

- facility management during a course;
- provision of appropriate equipment and didactic material;
- catering and accommodation;
- recording attendance of students/trainees;
- supervision of pupils (in schools);
- reward or discipline measures (in schools).

assessment and evaluation of learners

- verification of student/trainee ability and entry qualifications;
- intake discussions of students or trainees;
- development of test and examination questions;
- assessment of students (tests, examinations);
- awarding of degrees and certificates.

Note: most education and training organisations (particularly schools and universities) provide other services to students (accommodation, social services, transport, administrative services...) or to customers (e.g. research, consultancy,...). Although these are not discussed in this report, such activities are in general to be documented according to the requirements of this Clause. This also holds for 'generic' services such as health care availability, career guidance counselling, safety and security arrangements, transport, etc. – whenever these can be considered as part of the (sometimes implicit) agreements with the customers.

In principle, all such processes need documented procedures. This may be a daunting task, but the reality is less frightening. First of all, in most education and training organisations, only a subset of these processes exist and/or are critical to the quality of the service (for instance, most schools do not develop their own materials, and most private training providers do not formally assess trainees). Thus, part of the list can immediately be abandoned. Secondly, some processes may be so simple and straightforward that it makes sense to group several of them within a single procedure – or subsume the activities in other procedures. Finally, some of the processes listed may be sub-contracted. Thus, the number of procedures to be documented in order to comply with the requirements of this clause, will in most cases be far shorter than the long list above may suggest.

In principle, Clause 4.9 need not apply to those education and training related activities covered elsewhere in the Standard, such as:

- contract negotiation (4.3);
- design and development of courses and learning materials (4.4);
- purchasing of goods/services and use of external staff (4.6);
- monitoring and evaluation of the education and training programme (4.10-4.13);
- training of staff (4.18);
- servicing after the course (4.19).

However, in an education or training context the requirements of these clauses often reflect the same principles of quality assurance as laid down in Clause 4.9. This implies that procedures, work instructions, document control, quality records, etc. can be approached from the same perspective. One can, therefore, give a consistent look to all procedures and related documents which are part of the quality system. There is no need to give the procedures which have 'their own Clause' a 'special place' in the quality and procedure manuals. Rather, the structure of the various processes documented in the manuals should reflect the internal logic of the organisation. The only processes which may merit a special place – since they affect virtually everyone and are specific to ISO 9000 – are the 'generic' quality assurance procedures, i.e. those concerning the diffusion of the quality policy and management review (4.1), document and data control (4.5), corrective and preventive action (4.14), control of quality records (4.16), and internal quality audits (4.17).

Clause 4.9 lists several requirements which need to be fulfilled, some of which translate badly to education and training processes (and to service processes in general). However, clause 4.9 states in its penultimate paragraph "*where the results of processes cannot be fully verified by subsequent inspection and testing (...) the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met*". This applies to most of the processes to be considered. Thus, evidence should be available of the incorporation – where feasible – of the *principles of 'controlled processes'* to any process falling under this Clause:

- documented procedures and/or work instructions, including sufficiently detailed criteria or guidelines for the operation of the process;
- suitable, approved and well-maintained equipment and an appropriate working environment;
- availability of qualified staff, with specifications of the required competences (in particular for critical activities);
- compliance with any applicable norm, standard, quality plan, or other procedures;
- monitoring of progress (if possible through measurable indicators); records of these monitoring activities should be kept for a reasonable period.

This is really common sense for anyone concerned with quality in education and training. The challenge is, however, to manage all of this in a systematic way for all pertinent processes.

Since these processes are to be controlled, the organisation should be able to provide evidence that the procedures have been followed. A system of records (many of which often exist already) and regular checks (through internal audits, lack of complaints about non-delivery or defects) may suffice for most of the processes. Test and examination results may provide further evidence. What matters is that an organisation can demonstrate that adequate standards and procedures have been defined, and that these are in general followed (mechanisms for identifying and correcting problems are discussed later).

In most of the processes listed, the quality of competence of staff is critical. This reinforces the importance of setting standards for staff and making sure to recruit qualified staff and external teachers/trainers who meet such standards. That is a far more productive approach than defining a process control procedure with endless checks and routines. In as far as staff recruitment has not already been covered by complying with the requirements under one of the other Clauses (e.g. 4.1, 4.2, 4.6 or 4.18) it makes sense to have a procedure for staff appointment which respects the requirements of Process control, i.e. includes:

- standards for different types of staff (qualifications, experience, skills, attitudes,...);
- how potential new staff members are assessed against those standards before recruitment;
- how the continuing relevance of staff competence is monitored (see also 4.18).

Process control is also the area where most of the work instructions are to be written down, since this is the core operation of education and training organisation. Caution is necessary, since this is not common practice in many education and training organisations. Once appointed, most education institutions leave teaching staff a high degree of freedom to get on with the job. For ISO 9000 certification this is clearly insufficient, but one should equally avoid the temptation to overprescribe how teaching and other educational activities are to be carried out. One approach to this difficult choice is to consider what type of promises are given to customers, or what expectations are raised (or might be expected) with students/trainees. Procedures and work instructions should contain enough information, guidelines and monitoring mechanisms to make sure that these promises and expectations can be fulfilled.

Whether a particular work instruction is needed or not, also depends to a large extent on the qualification of the staff member. The higher qualified, the less need there is for detailed work instructions. However, through the system of internal audits (Clause 4.17) it should become quickly obvious in which areas work instructions are lacking, and in which ones they are superfluous.

To summarize, process steps and minimal standards need to be identified and documented for all critical processes. The process must be carried out in a controlled way, so that plans, procedures and instructions are available, staff and equipment used are adequate, and that the general conditions are appropriate to achieve the plans.

4.10 Inspection and testing

4.10.1 General

There are a number of interpretation and applicability issues concerning this Clause. When course programmes and other learning opportunities offered to students and trainees are considered as the 'product' in the context of the Standard, 'inspection and testing' refers to the monitoring and evaluation of the development and delivery of those services. Logically, under this interpretation, assessment of learners (tests, examinations,...) is not covered by this Clause, but by the requirements of Process Control (Clause 4.9.).

This view is not shared by all experts involved in the certification of education and training establishments. In practice, however, whether assessment of learners is related to Clause 4.9 or 4.10 does not make much difference for the quality manual, procedures and quality records.

A second problem is that the different stages at which, according to the Standard, inspection and testing are supposed to take place (receiving, in-process, final stages) may either coincide or simply not exist. Moreover, it is often not possible to use 100% reliable inspection and test methods, given the intangible nature of services. In such situations it will be important for the organisation to show that the

spirit and the purpose of this Clause are adhered to as much as possible. The problem of applicability of the Standard also holds for Clause 4.12 and even more for Clause 4.11.

Overall, the Standard requires under this Clause to inspect all incoming 'products' (if these are critical for the end-quality), to check training and education products and services while they are under development, and to check the output for conformance to specifications (if possible) before they are released for use. Other clauses (notably 4.13) also require to set aside non-conforming 'products' so as to prevent their accidental use.

Education and training services consist of tangible items such as learning materials, and the non-tangible teaching and assessment processes and related activities. Some experts have argued that teaching and assessment is already fully covered under process control, so that Clause 4.10 need only be applied to the tangible items which are used or produced for the education or training service. In such a narrow interpretation, the requirements of this Clause could apply to the following types of products:

- purchased learning materials (textbooks, software, equipment, audio/visual items,...),
- assessment and other tools,
- supplies, specific material used in courses,

always, of course, in as far as these are critical for the quality of the output.

In a broader interpretation the Clause "inspection and test" also covers teaching and related activities, to the extent that the specific requirements are applicable (e.g. 'incoming product'-inspection is in general impossible) and/or are not yet covered by other clauses. This broader interpretation is adhered to in the sequel. Simplified, the spirit of the set of requirements laid down in this Clause is that an education or training provider can demonstrate that the development and delivery of education and training services is checked, monitored and reviewed at appropriate intervals and with suitable methods – all in order to ensure that what has been required and promised will be delivered.

A range of different methods and approaches can be used in order to comply with these 'test and inspection' requirements, such as:

- course and programme evaluations by learners during, at the end and after the education and training delivery;
- self-assessment by teachers and trainers;
- monitoring of effectiveness of the education and training by programme coordinators, customers, independent assessors;
- statistical analyses of student performance, including trend-analyses;
- indirect measures of quality (e.g. motivation of learners, complaints,...);
- opinions expressed by customers and people who have completed a course;
- comparisons with related programmes, benchmarking;
- comparison with existing standards.

What type of evaluation is most appropriate, which method is to be preferred, and at what intervals evaluations need to be conducted, will depend on the circumstances and the particular type of provision: the organisation must be able to show that the evaluation mechanisms are appropriate to ensure the continuous quality of the education and training services provided.

The first paragraph of this Clause 4.11 explicitly lists the requirement to have documented procedures for test and inspection in order to ensure that specifications are met. These inspection and test activities must be part of either standard procedures or specific quality plans; the results should be considered as quality records (Clause 4.16).

From a practical point of view, the assessment, evaluation or review of individual items of a programme (e.g. a particular course, a syllabus, a practical training period, project work,...) may be documented as part of the general procedure(s) which cover their development and delivery, i.e. those procedures that need to exist in order to comply with the requirements of Process Control (Clause 4.9). On the other hand, for comprehensive education and training services, for the overall didactic and pedagogical approach, and/or for a course programme as a whole, it may be more appropriate to document the evaluation mechanisms in a separate procedure.

Where education and training organisations deliver other types of services (e.g. guidance, research, supervision, etc.), it will also be necessary to comply with the requirements of this Clause. Although such processes are not discussed here, the interpretation to be given to the inspection requirements might often be similar, mutatis mutandis, to what applies to education and training. It is indeed a common characteristic of services that inspection can not take place before delivery, but only during the service or after it.

4.10.2 Receiving inspection and testing

This sub-Clause requires to inspect or test all incoming goods and services before they are put to use (4.10.2.1), by taking into account the quality control mechanisms already used by the supplier to avoid unnecessary double checking (4.10.2.2). In urgent cases, when no inspection has been possible, the products concerned need to be clearly marked and identified (4.10.2.3). In education and training, three cases can be considered:

- tangible products which are critical for the education or training provision;
- education and training services provided by external trainers or organisations;
- other services supplied by sub-contractors.

By their very nature, services (including education and training) cannot be 'inspected upon receipt'. One possible exception is when trial runs of courses have taken place:

such trials could be used for 'receiving inspection' – but it seems more logical to consider this as part of the design requirements (Clause 4). Since formal assessment of sub-contractors (including external trainers) is already covered under Clause 4.6.2, the requirement of this sub-Clause 4.10.2 can be safely ignored for education and training services.

Please note that, when 'learning' or 'student' is considered as the 'product', there would be a compulsory requirement to test their entry level and qualifications – unless, of course, the customer does not want this to happen. In reality, whenever such action is to be taken, it will need to be documented; in the interpretation followed in this report, this would be covered by process control (4.9).

When critical, tangible products are acquired, they need to be inspected prior to use. Special care should always be taken when purchasing complete learning packages, courses and textbooks from external sources (this concerns both the publishers and the authors). Obviously, the inspection can be reduced if effective preventive techniques are employed, such as purchasing items from approved subcontractors where high confidence levels have been established. In such cases, all that may be required is that the teacher or trainer checks at the beginning of a course that all items used are OK (for long programmes, this may have to be repeated several times during the overall period of activity).

In any case, some kind of record has to be made of the inspection which has been carried out, demonstrating that the goods were judged to be suitable for their intended use.

4.10.3 In-process inspection

Purchased goods (e.g. a course handbook, an assessment tool) are most often used unaltered, so there is no need for any type of process-inspection. If they are modified, inspection of the adaptation may occasionally be necessary, to avoid problems jeopardizing the timely and effective development of the training or education service for which the product is being modified.

For education and training 'products' which are developed by providers themselves (e.g. a course syllabus), in-process inspection becomes relevant as soon the development time (the period between the initial design and the final delivery) is substantial. This should, in principle, already have been documented following the requirements of Design (Clause 4.4) and Process Control (Clause 4.9).

The same observations apply to the development of the services (educational and others). The typical example is the development of a new curriculum. But in addition, "in-process" inspection also applies to the delivery itself, since that is part of the service process. For courses which last more than one day, it is often desirable and appropriate to have one or more interim evaluation. These should comprise at least the checks carried out to ensure compliance with the planned programme (e.g. on

the basis of student and staff records, student assessment, course evaluation,...). Whether other services delivered merit such type of in-process inspection, will have to be considered in the light of their contribution to the quality of the programme. Again, one would expect that appropriate "in-process" checking mechanisms have been built into the procedures established following the requirements of Process Control (4.9).

4.10.4 Final inspection and testing

Final inspection and testing is always applicable:

- for goods it concerns a final check before release;
- for services, particularly education and training itself, it may concern the verification of a test course or prototype (if applicable), but – above all – it applies to the evaluation of the services after they have been delivered.

The evaluation of education and training activities is not only important from the perspective of this Clause. It also serves as an input or verification for the requirements of many other Clauses of the Standard, including:

- Contract Review (4.3 – Were specifications appropriate? Were they met?);
- Design (4.4 – Was it appropriate?);
- Process Control (4.9 – Was delivery as specified?);
- Corrective Measures (4.14 – What should be changed?);
- Internal Audits (4.17 – Where should we improve?).

The requirements of this crucial sub-clause refer, for education and training, to all types of assessment, monitoring, test or evaluation activities (including evaluations some time after the course) which are used to analyse the performance of the programme. All these together should provide an overall picture which makes it plausible that the quality requirements have been met.

A minimum requirement in higher education and continuing education and training is a quality assessment by students/trainees, preferably on standardized evaluation forms. Where relevant, this should be complemented by evaluations by teachers themselves, by programme coordinators or employers. In schools, assessment by pupils may not be possible or relevant, but it could be replaced by teacher self-assessment, opinions of other teachers (in particular those who 'receive' the pupils at a later stage), a review of the results of examinations and assessment of pupils, opinions of education institutions or employers who take on the pupils, etc.

In cases where evaluations can be conducted entirely before the final release of a course or material (e.g. trial runs of courses, review of the quality of course syllabi by independent experts), the evaluation results must be acceptable before the delivery can take place.

4.10.5 Inspection and test records

The procedures which cover all the checks, assessments, reviews and evaluations mentioned, should include:

- the requirement to maintain quality records of such evaluations;
- the records should show whether activities have been satisfactorily conducted;
- if records show problems or non-conformities, procedures for dealing with 'non-conforming products' (Clause 4.13) should be applied.

4.11 Control of inspection, measuring and test equipment

4.11.1 General

Although this is one of the longest clauses of the Standard, the applicability to education and training is fairly limited. This holds both for the services delivered, and for any education and training products supplied. It has already been highlighted that provision of education and training cannot easily be measured, and that the instruments to do so are not 100% reliable.

This clause states that documented procedures must exist which ensure that the evaluation, test, assessment and checking methods, software, equipment and tools are sufficiently reliable to ensure that the education and training provision conforms to specifications.

This Clause may therefore apply:

- in the first place, to any instrument, software, tool or method used to ensure that learning is taking place in the way which was planned and agreed (such approaches being required by Clause 4.10);
- but also – when applicable – to any inspection, measuring and test equipment used by learners as part of a learning process where such measuring is critical to the learning process (this is not a very frequent situation, mainly referring to learning situations where the use of calibrated equipment is important).

When an education or training organisation also undertakes other activities for which it also seeks certification (e.g. research, carrying out surveys, publishing,...), the full requirements of this Clause may apply.

The thrust of this Clause concerns predominantly the evaluation tools used during the development and delivery of education and training. These may include:

- forms for recording assessment information,
- reference standards and norms,
- checklists,
- questionnaires,
- specific software,
- audit methods (internal and external),
- benchmarking procedures,

- assessment of performance methods by externals,
- external awarding systems (for labels, certificates,...).

Following the requirements of this Clause, an education or training provider must be able to show the reliability of the test methods and tools used:

- the outcomes are valid;
- evaluation results can be safely compared from one course (or other product) to another;
- the same method is applied consistently throughout the whole organisation.

Of course, this reliability has to be proven within reasonable limits (any judgement in education and training is likely to have some subjective component) and in as far as the application of the methods is under the full control of the provider (for instance, abuse of questionnaires by students can never be completely eliminated). The organisation has to demonstrate that reliability and effectiveness of evaluations are taken seriously and that all reasonable efforts have been made to obtain outcomes which can be trusted. No organisation is expected to take steps beyond those that are customarily accepted by the education and training sector as relevant. Often, the acquisition or modification of existing, commonly accepted external evaluation methods may suffice.

Interpretation of control requirements for tangible control equipment used within a learning context is briefly discussed under the next paragraphs.

If agreed with the customer, the evaluation, test or assessment results must be delivered to the customer.

The methods for assessment of students are not included under this Clause since these do not measure the 'product'; they fall however under Process Control. A well established examination system where the quality assurance principles of Process Control apply will include mechanisms to ensure that assessment is reliable and consistent to a reasonable degree. Therefore, the spirit of Clause 4.11 will be present.

4.11.2 Control procedures

As regards the evaluation methods of education and training activities, this sub-Clause states that these should be well justified, documented, and the outputs should be recorded. This does not add any new requirements to those already discussed above. Let it just be recalled that:

- the extent of evaluation should be determined in advance
- appropriate evaluation tools should be identified and used in a consistent manner
- evaluation methods and frequency should be documented and implemented
- evaluation should take place under suitable circumstances

- results of evaluations should be reliable
- quality records are to be kept of all evaluations.

There are cases – particularly in courses with a considerable technology content or those concerning metrology as a subject – when tangible measurement and test equipment needs to be used and whereby its accuracy impacts on the quality of the course (e.g. when low accuracy may provide students with wrong information). This equipment may concern, for instance:

- weighing scales,
- electrical and electronic meters, oscilloscopes,
- chemical measurement instruments,
- ECG equipment,
- any equipment used during assessment, where the calibration can affect the learner's score.

In such cases, the Standard requires the organisation to:

- identify all equipment where calibration is necessary;
- define the accuracy needed for such equipment;
- select appropriate equipment;
- check and calibrate the equipment at regular intervals and under suitable conditions;
- let qualified staff undertake the calibration;
- calibration itself must be based on predefined methods and on appropriate reference standards;
- keep quality records of these calibrations;
-

- recalibrate and re-assess non-calibrated results when appropriate;
- avoid deterioration of control and measurement equipment.

In addition, for equipment used for other services (e.g. commissioned research, surveys, consultancy,...) the case for calibration must be carefully thought through; procedures should be documented accordingly.

4.12 Inspection and test status

This clause expects an organisation to know what tests and evaluations of the education and training products and services (at development and delivery stage) have been applied and what the result was. The information available should indicate whether and to what extent the test results were satisfactory; if they were not, appropriate action has to be taken (see Clause 4.13.2). The clause applies to all services and goods which undergo one or more test or evaluation process.

For most education and training organisations, this requirement will be relatively easy to fulfill, provided all evaluations can easily be linked to the relevant programme activities – and vice-versa. Adequate documentation and filing of programme records will normally suffice to meet these requirements. A useful tool is a standard checklist which is filled in for every regular type of activity, where all evaluations scheduled can be ticked off and commented on as needed.

This clause is of particular relevance for:

- long programmes which consist of many modules and learning materials (in order to know for each component to what extent it has been evaluated);
- programmes with trial runs or which are run for the first time;
- provision of education and training by using learning materials which are not fully finalised (e.g. software in 'beta-version').

4.13 Control of nonconforming product

4.13.1 General

'*Nonconformance*' refers to any feature of the quality system where performance or outcomes are not in line with what had been planned and agreed. This clause requires an organisation to have procedures for undertaking immediate action to prevent such non-conformities adversely affecting the quality of the service.

More specifically, this sub-clause states that the following general requirements are to be met:

- (timely) identification and recording of non-conformities;
- assessment of the impact of the non-conformities on quality;

- isolation of non-conforming items to avoid inappropriate use (when feasible);
- notification to the appropriate people;
- immediate remedial action when needed.

Some of these requirements are further developed in the next sub-clause.

For education and training organisations, non-conformities may thus appear in such diverse processes as the development and delivery of the programme, the practical ar

rangements for students and trainees, the sub-contracted services, students/trainees performance (when due to the provider), learning materials, etc. Thus, this clause applies not only to faulty items and defects in tangible products used in teaching, such as:

- defective audio-visual equipment,
- damaged books and other learning materials,
- teaching materials (e.g. slides, OHPs,...) which are not consistent with the course syllabus,
- ill-functioning demonstration or simulation material

but also to problems, errors, omissions, etc. relating to the services provided, e.g.:

- late or non-arrival of a teacher/trainer,
- poor coverage of planned subject matter,
- improper didactic materials,
- scheduling errors,
- inappropriate accommodation,
- low validity of examination results,
- poor performance of teachers,
- irrelevant programme content,
- loss of documents.

Not all non-conformities have the same importance. For services, three typical cases can be considered:

- the non-conformity is of minor importance (e.g. will not affect quality and/ or is unlikely to be repeated): in such cases no further action is required;
- the non-conformity indeed affects quality, but cannot be remedied anymore (e.g. behaviour of teachers, incomplete coverage of subject matter): in such cases customers should be informed, and the information should be fed into the procedure for Corrective Action (Clause 4.14) to prevent it from re-occurring;
- the non-conformity indeed affects quality, but immediate remedial action is possible (e.g. reschedule a module; update the learning materials): this is covered by the next sub-clause.

4.13.2 Review and disposition of nonconforming product

This sub-Clause concerns the actions to be taken as a result of any type of non-conformance (where such action makes sense – cf above). Requirements for the documented procedures include:

- definition of responsibility and authority for dealing with nonconformities;
- assessment of the non-conformity and decision of action to be taken (rework, accepted as such, used in another context, completely rejected,...);
- seek agreements with customer for continued use of any nonconforming product;
- re-assess conformity of any reworked product;
- keep quality records of these reviews.

Such requirements are fairly obvious for tangible products, e.g.

- labelling them 'out of date', '1996 only', etc.;
- storing them in a separate location, marked e.g. as 'non-current learning materials'.

However, the requirements need suitable interpretation for the intangible education, training and related services. What matters is that an organisation always takes timely and appropriate action whenever a problem occurs. Such action should, moreover, be recorded in one way or another to allow for continuous improvement [following from the requirements of Corrective and Preventive Action (Clause 4.14) and Internal Audits (4.17)].

One may consider having a separate procedure for 'Control of nonconforming product', but one could also include the mechanisms in place as part of the specific procedures.

4.14 Corrective and preventive action

4.14.1 General

This clause is, combined with Internal Audits (4.16) and Management Review (4.1.3), crucial for ensuring the continuous improvement of the quality system and the quality of the services delivered. While the 'Control of non-conforming product' (Clause 4.13) concerned the immediate steps to be taken when problems occur, this clause on '*corrective and preventive action*' requires documented procedures for adapting the quality system in order to systematically prevent or reduce the non-conformities. Such measures will often lead to an amendment of procedures or related documents.

The difference between 'corrective' and 'preventive' action may not always be clear-cut, in particular when the provision is subject to considerable change: a corrective measure to one course is at the same time a preventive measure for another. In as far as it is necessary to make the distinction, corrective measures are always a response to a problem or a non-conformity, while preventive actions are to be taken to avoid problems occurring, before any problem has arisen.

This Clause does not stand on its own, but is related to, and overlaps with, many other requirements of the Standard:

- corrective and preventive measures could be both an input to, and an output of the Internal Audit (4.17) process;
- modifications in procedures resulting from these measures have to be controlled (4.5);
- the data used should have been recorded as quality records (4.16) following the Control of nonconforming product (4.13);

- corrective measures may result from action undertaken as part of the design verification (4.4) and inspection and testing (4.10) activities.

It should be noted that this first sub-Clause states that the nature and extent of corrective or preventive action should be related to the importance of the problem and the risks involved – a common sense requirement.

4.14.2 Corrective action

This sub-Clause exclusively concerns corrective measures and requires that documented procedures cover:

- a system for handling complaints;
- the effective and timely dealing with reports and records concerning nonconformities;
- the analysis of the causes of nonconformities;
- recording the results of such analyses;
- decisions regarding the appropriate corrective action to eliminate the causes or reduce their impact (whenever feasible);
- monitoring of the implementation of corrective actions.

These requirements can be met by education and training organisations in different ways. As a minimum there should be a procedure for effectively dealing with all kinds of complaints from customers, students or trainees. It is often useful to extend such a procedure to include complaints from staff, as well as to broaden it to a 'suggestion scheme' for quality improvements.

One may, in addition, create either a 'generic' procedure for corrective action, or instead incorporate the requirements of this sub-clause in other procedures. If the quality system is modest in scope and the control of processes is well documented, some or all of this may be covered under the Internal Audits procedure (4.17), making it unnecessary to have a separate 'Corrective Action' procedure, except for the complaints handling. However, the quality manual should at least refer to the corrective action arrangements which are in place and where and how these are documented. What matters is that the organisation uses a systematic method of:

- investigating nonconformities or noncompliances and their causes;
- scanning the available data and records in such a way that worrying patterns or trends may be detected;
- defining methods for analysis (e.g. statistical techniques, quality improvement projects,...);
- implementing and monitoring all corrective measures.

It is recalled that records should be kept of problems, defects, the investigation of their causes and any follow-up corrective actions implemented; these should be used as part of the internal audit process (4.17).

Education institutions which provide certificates and degrees when pupils/students have successfully passed examinations, will also need to foresee a specific appeal and complaint procedure concerning the examination process. In general, such a requirement is often already documented under the form of a 'student charter' or a document listing the 'examination rules and principles'.

4.14.3 Preventive action

The principles are similar to those of the previous sub-Clause. The Standard requires an organisation to use all relevant information sources in order to prevent problems and non-conformities occurring. Possible sources (in addition to those used for corrective action) are:

- market research and training analysis reports;
- progress reports;
- management reports;
- surveys, evaluations;
- internal and external audits and assessments;
- statistical analyses of student/pupil/trainee performance;
- trend analyses of data (e.g. on student performance, trainee complaints,...);
- feedback from former students.

Based on the timely analysis of such information, preventive actions should be implemented in similar ways as the corrective actions (see above). Preventive actions are closely linked to the outcomes of internal audits (4.17); the outcomes should also be discussed as part of the Management review (4.1.3). Of course, the effectiveness of the preventive measures should be monitored.

The organisation must be able to show that reasonable efforts are undertaken to prevent nonconformities occurring, and that these efforts are based on appropriate information and analysis, and the use of suitable methods. Again, it is important to be able to show that the analysis undertaken has led to suitable preventive measures. If the quality system is fully operational (including corrective measures, internal audits and regular management reviews) there may be no need to have a separate procedure for preventive measures – but the organisation will still have to be able to give evidence that preventive measures are systematically applied. Again, the quality manual should at least refer to the arrangements which are in place and to how and where they are documented.

4.15 Handling, storage, packaging, preservation & delivery

Since it is difficult to cross-refer the individual headings of this Clause to education and training activities, they are discussed together.

4.15.1 General

4.15.2 Handling

4.15.3 Storage

4.15.4 Packaging

4.15.5 Preservation

4.15.6 Delivery

This is a clause where the term 'product' has to be interpreted literally as a tangible item, excluding services. Most of what is stated in the clause about products is often not critical for education and training, and does, therefore, not justify elaborate procedures. Products where parts of this clause may apply to might be:

- learning materials, in particular open learning materials;
- books, journals, other documents and audiovisual materials in libraries;
- materials on which learners work (e.g. wood);
- computing equipment and software;
- language lab equipment;
- other tools and equipment used in the learning process;
- assessment and examination papers;
- informative documents, guidelines.

Overall, the requirements are straightforward:

- all critical aspects of handling, storage, packaging, preservation and delivery of products should be documented as part of procedures;
- items should be properly marked so that they can be identified if needed;
- the handling, location and storage method of critical products should be such as to prevent damage or deterioration – even after final inspection (this may relate to cleanness, humidity, temperature, light, etc. of rooms);
- storage areas should be appropriately secure (this applies e.g. to exam papers, library documents);
- there should be appropriate methods for logging such materials in and out the storage areas;
- the quality and condition of the products in stock should be assessed at appropriate intervals;
- packaging should be implemented according to the agreed specifications;
- items waiting to be checked before use should be separated from items ready for use;
- when agreed with the customer, the protection of critical items should also include the delivery to destination (e.g. for open learning).

Often, for the education and training services provided, all that needs to be done is to include one or more paragraphs or work instructions within the procedures for purchasing, product development or delivery – and only for the products and stages where this is critical. Larger institutions, for instance with extensive library facilities, or those disseminating learning materials, will need to ensure that the requirements of this clause – particularly 4.15.1 (general), 4.15.3 (storage) and 4.15.6 (delivery) –

are properly documented in separate procedures or integrated in the procedures required for Design (4.4.), Purchasing (4.6) and Process control (4.9).

If students are considered as the 'product', then the coverage of the Clause has to be extended. Under this interpretation, services like health care availability, career guidance counselling, safety and security arrangements, transport, also need to be covered. In the interpretation followed in this report, such activities are – if considered critical for the quality of the service – to be documented under Process control (4.9).

4.16 Control of quality records

The obligation to keep 'quality records' is stated at numerous places in the Standard. Minimum requirements listed explicitly in a particular clause of the Standard are quality records for:

- management review (4.1.3);
- contract review (4.3.4);
- design review (4.4.6);
- design verification (4.4.7);
- evaluation of sub-contractors (4.6.2);
- verification of purchaser supplied product (4.7);
- identification and traceability (4.8);
- qualified processes, equipment and staff (4.9);
- release of incoming products before verification (4.10.2.3);
- inspection and test records (4.10.5);
- checking of test hard- and software (4.11.1);
- calibration of inspection, measuring and test equipment (4.11.2e);
- accepted non-conformities and repairs (4.13.2);
- investigations of the cause of nonconformance (4.14.2);
- results of internal quality audits (4.17);
- follow-up activities of internal audits (4.17);
- records of training of staff (4.18).

The requirement to keep a record of particular information is also an explicit or implicit requirement of several other Clauses (e.g. for document control (4.4), corrective and preventive action (4.14), etc.), although the term 'quality record' is not used.

Clause 4.16 extends the definition of quality records to cover the full set of records which can "demonstrate conformance to specified requirements and the effective operation of the quality system". Thus, the minimum requirement is the establishment and maintenance of a set of records which together provide the documented and objective evidence of the smooth operation of the quality system at all stages, and of the conformance to the procedures and quality plans.

A number of general remarks apply:

- such 'quality records' may exist on paper, in electronic form or even otherwise (e.g. indications on a planning board or a wall);
- the output of a process itself can be a quality record: filled-in forms and checklists, letters, planning schedules, minutes of meetings, reports, internal memos, etc.;
- it follows from the above that in a well organised education or training organisation, many of the necessary quality records will already exist (although they may not be standardized and not maintained properly).

Thus, an education or training institution will need to identify which existing records could serve as quality records, and which additional ones need to be created in order to comply with the requirements of the standard. Some creativity is needed in order to minimize the number of records necessary, e.g. by trying to:

- draw together several types of quality records on one paper (e.g. by using checklists);
- modify existing outputs so that they may also serve as quality records (e.g. slightly adapt a form used for accountancy purposes).

Again, the prime purpose must be to be able to provide evidence of the proper functioning of the quality system – nothing more.

For quality records identified by the organisation, this clause requires to:

- identify and codify them appropriately;
- gather and collect them;
- have appropriate filing and storage arrangements;
- define access to them;
- maintain them during a predefined interval;
- dispose of them after the retention period.

None of these requirements is difficult to implement (although retention periods are often ill-defined); however the challenge is to apply the rules for all quality records consistently. Simplification can be obtained by treating several quality records together: for instance, all quality records concerning a particular student, or a particular training course, are kept in one file together: this will simplify storage, access, maintenance and disposal.

Retention periods could vary and should be defined in the light of the requirements of the law and the quality system. Some examples:

- records of non-conformities could be kept for one year – or until the next internal audits;
- data on courses, students and staff could be kept for about 5 years;
- information on degrees awarded should be kept for much longer.

During the retention period, records should be protected from theft, damage or deterioration (including data corruption of electronic records).

The term '*quality record*' may lead to the misconception that new, special records have to be created for the quality system. In reality many existing day-to-day records are suitable as quality records. Whether or not certain information is appropriate for that purpose depends on its critical contribution to the evidence that procedures are followed and the quality system operates well. The following is a checklist which may help in establishing a list of suitable records:

- all types of documents (forms, reports, lists, minutes,...) used for evaluations, audits, tests, assessments, reviews,...;
- external or internal reports of reviews, tests, screenings, audits, benchmarks;
- letters, notes, memos;
- minutes of meetings;
- quotations, contracts, agreements;
- invoices (if sufficiently detailed);
- registers;
- complaint forms;
- a log-book of courses and events;
- student/trainee records (courses followed, results obtained,...);
- staff records (particularly qualifications and performance – including for guest lecturers and external trainers);
- lists of (possible) suppliers or sub-contractors;
- internal or external reports, studies, analyses, surveys, statistics,...;
- filled-in forms and checklists;
- computerised files (appropriately protected);
- exam questions and papers;
- video recordings of training;
- computer logs;
- documents produced by quality improvement projects;
- documents produced in relation to staff training;
- lists of certificates awarded.

This list might provide some inspiration on how existing records could be used as 'quality records' – as such or after minimal adaptation (e.g. by making sure that minutes of meetings always contain certain standard information). Rarely, all these documents will be needed to provide evidence of the quality assurance system in operation. On the other hand, not all records are to be considered as quality records either: they are only quality records when:

- the requirement to keep the records is specified in a procedure; some of these records are a compulsory requirement of the Standard, and
- the records meet the aforementioned requirements for labelling, retrievability and retention.

It may be necessary to control records maintained by a subcontractor, if these are needed to demonstrate conformance to specified requirements or the effective operation of the quality system.

When keeping records on persons, or other sensitive data, legal requirements regarding the storage of data and privacy have to be respected.

4.17 Internal quality audits

This clause on internal quality audits does not need special interpretation for education and training organisations. Nevertheless, the requirements are fairly new for most of them. Even in well organised, prestigious and recognized education or training institutes, internal audits were rather uncommon before the arrival of ISO 9000. Fulfilling the requirements of this Clause, together with those on document control (4.5) and quality records (4.16), make the real difference between a good functioning organisation, and one with a quality system based on the Standard.

The requirements of this Clause are easy to understand. There need to be documented procedures which cover the following aspects:

- a schedule should exist which ensures that all activities which are part of the quality system are audited at appropriate, regular intervals;
- the audits should be carried out to schedule;
- internal auditors should be appointed;
- these auditors should have the skills necessary to undertake internal audits; appropriate training should be arranged;
- the audits should be carried out by persons who are independent from the activities being audited;
- the audits should verify the compliance with procedures and quality plans;
- the audits should also analyse and determine the effectiveness of the quality system;
- audit reports should state the deficiencies and problems observed and recommend improvements where necessary;
- audit results should (at least) be communicated to those who are responsible for the area audited;
- follow-up corrective actions should be carried out promptly;
- the implementation of corrective actions should be verified and recorded;
- audit records are to be treated as quality records;
- results of audits should serve as an input to the management reviews (4.1.3).

It is obvious that these requirements impact on the whole organisation.

In general, it suffices to write one procedure which specifies how the organisation is going to run its internal audits. Some requirements (training, quality records, corrective action, management review) could be incorporated into other procedures. Some general remarks and observations on the audit process:

- the frequency of auditing should be determined in the light of the importance of the processes; once or twice a year is often a good starting basis, to be adapted in the light of experience;
- the requirement that auditors are independent of the area being audited, may be difficult to comply with in a small training company; in such cases the auditor should pay extra attention to objective analysis;
- auditing of quality management systems is a skill: there should be appropriate training (1-2 days + some trial runs) to make sure that auditors are well prepared, undertake their job in the right mind set and are accepted by colleagues;
- auditing should focus on the process and the activities, not on the people; this approach helps to overcome resistance and hiding of problems;
- the auditor should have access to all relevant information (including quality records, corrective action and previous audit reports), and be able to ask any question considered relevant to knowledgeable staff;
- care should be taken to identify both conformity and nonconformity, to ensure auditing is a positive process; the better the quality system, the more internal audits will be welcomed as opportunities for improvement, rather than exam-type judgement processes;

- the need for and the type of corrective action is best agreed between the auditor and the auditee; this will facilitate implementation.

Given their size and limited resources there will be few education or training organisations with full-time internal auditors. It is best to create a small pool of motivated people. This implies that for most of them, auditing will only take a few days per year of their time. Since auditing can be an interesting learning experience, such an arrangement also facilitates the distribution of knowledge and experience across the organisation.

4.18 Training

Various sections of the Standard require that all activities which may affect the quality of the service are to be carried out by competent and qualified staff. This clause expands on this by requiring that training needs of staff – both current and new – should be analysed systematically, so that at all times they have the knowledge and skills they need. In particular, there should be documented procedures regarding the training of staff which include:

- analysing the training needs of staff;
- providing training in order to fill any training gap identified in the training needs analysis;
- ensuring, through appropriate education, training, learning or experience, that all staff members who undertake activities which affect quality, are qualified and competent to do so;
- keeping records on the training of staff and their qualifications.

Please note that these requirements may also apply to regularly used external trainers – in as far as such requirements have not yet been covered by Clause 4.6 (purchasing of training services).

Training needs may be assessed on the basis of regular surveys, as part of the annual staff appraisal, or following analysis of deficiencies in the quality system itself. Special care is needed for the analysis of training needs and the updating and re-training of teachers and trainers. Although the Standard allows an organisation to set its own requirements – corresponding to the quality levels expected by its customers – it is often useful to specify qualification requirements and re-training activities in three areas:

- didactic competences (which should be related to the typical target group of the organisation, e.g. adult learners);
- subject-related competences;
- programme related knowledge and skills (e.g. concerning the specific approach used in a particular course, the quality policy of the provider, etc.).

Evidence of current qualifications of staff could be provided by maintaining up-to-date CV's.

The concept '*training*' should be interpreted broadly, including induction of new employees, guidance, and staff development. This affects all staff, including managers, teachers/trainers and support people. In order to develop an active training policy, it may be useful to specify general competence requirements, qualifications, and desirable experience for all functions and tasks within the organisation. A useful document could be a qualification matrix, showing which teacher or trainer is qualified to provide certain subjects or courses. One should be aware, however, that qualification requirements change over time and that such documents must be controlled.

An obvious case where all staff will need some additional training concerns the introduction of the quality system itself and the changes in the operation caused by it. Particular attention may need to be paid to:

- the understanding and use of procedures;
- implementation of corrective measures;
- quality records;
- internal audits.

For the more specific functions of the organisation (e.g. purchasing) no extra training may be necessary if the staff concerned have themselves been involved in the establishment and review of procedures. Whether training is sufficient or not, can often only be assessed after the training. If a quality system operates well, and few problems can be attributed to errors from staff, then there is an indirect proof that the staff is qualified and well trained.

In public education institutions, the qualifications required from teachers are often prescribed by law. From a legal point of view, these could be considered as sufficient. In such cases, the institution may not have the legal freedom to impose higher standards.

It is finally recalled that within education and training, teachers and trainers often carry out their tasks with minimal contact with the rest of the organisation. This situation requires well-established communication lines to make all staff aware of the (changing) requirements of the quality system, to detect new training needs in time, and to be confident that all staff will contribute actively to the maintenance of the quality system (e.g. by spotting deficiencies and suggesting improvements).

4.19 Servicing

'*Servicing*' refers to any activity undertaken after delivery of the product and service. This clause says that, if servicing is specified in the agreement with the customer, that arrangements must be in place to ensure that the organisation can carry out these activities according to requirements. If no servicing is agreed or needed, then an education or training organisation can safely ignore this clause.

Possible types of servicing are:

- support of students and trainees after completion of the programme (e.g. help line);
- mailing of learning materials, proceedings, corrected exercises, assessment results, etc. to students and trainees after a course has been conducted;
- providing a detailed review report of a training programme to a customer;
- conducting an additional assessment or effect measurement some time after a course has been delivered (e.g. to assess relevance for a job);
- providing job-seeking services, special facilities for retraining, social activities, etc. for alumni;
- providing refresher courses.

If such activities are part of the quality system and formally agreed with customers, then the general principles of quality assurance – as found throughout the Standard – have to be adopted.

4.20 Statistical techniques

4.20.1 Identification of need

The first sub-Clause asks an education or training organisation to identify which statistical techniques – if any – are needed for the proper function of the quality system. This applies in particular to the verification, analysis and evaluation activities.

In general, these needs are limited for education and training organisations. They could concern, for instance:

- processing of assessment and evaluation results;
- summarizing and categorizing data on complaints, deficiencies, defects,...;
- construction and analysis of performance indicators such as pass rates, cycle times, achievement records, customer satisfaction scores;
- trend analyses of data.

Such elements could be specified as part of the relevant procedures.

It is mentioned that statistical techniques are important for research and some other activities (e.g. surveys) which education or training organisations might conduct.

4.20.2 Procedures

The ultimate purpose of this clause is to guarantee that statistical information is reliable and comparable over a time period. Therefore, appropriate mechanisms should exist to ensure that the statistical techniques are used in an appropriate way. This implies that it is possible to demonstrate their suitability for the purpose and that qualified staff apply them.

5. Implementation of a quality system based on ISO 9000 standards

5.1 Introduction

5.1.1 Purpose of this chapter

Interpreting and analysing the requirements of ISO 9001 for an education or training organisation may intellectually be the most demanding task. The real challenge and most of the work, however, will be the implementation of the quality system itself. In this chapter we provide a short overview of some of the key issues which are to be considered in this regard. The text is essentially based on implementation stories reported in documented case studies, articles, some surveys, telephone interviews and the author's own experience. It does, therefore not claim to be complete, but rather provide an opportunity for those interested in ISO 9000 to learn from others.

5.1.2 Conditions to be met before launching a certification exercise

Section 3.1 highlighted the possible advantages and drawbacks of developing a quality system according to the ISO 9000 requirements. An organisation should consider such arguments before it decides to implement the Standard or not. This is, however, only part of the story. Some organisations benefit from much better 'starting position' than others, and will have far less difficulty in implementing the requirements. Thus, the relevance of the Standard should not only be considered in terms of advantages or drawbacks of the quality system, but also in the light of the complexity and risks of implementation. After all, establishing a quality system is not merely adding a few bells and whistles to an existing organisation, but is an important 'change process' which will have an impact on the whole organisation. It is well known from management consultancy experience that the implementation of change processes is always difficult and risky, and that resources are often underestimated. This also applies to the whole certification process, from the initial decision on adopting the Standard to the final award of the certificate. Interestingly, unlike many other types of change processes, few ISO 9000 exercises seem to be abandoned once they are initiated. One reason more to ensure that one is well prepared.

Although it is dangerous to generalize about the 'ideal' starting requirements for ISO 9000, we suggest to consider the following ten conditions:

- the organisation is already well organised;
- there is a (sometimes implicit) quality policy, with standards which are taken seriously;
- the organisation has been and is likely to remain fairly stable in terms of activities and personnel (no other important change, expansion or streamlining operations are going on);
- there is a good understanding of all internal processes;
- many standardized documents exist already (*even more to be preferred: procedures and a quality manual*);
- the organisation is financially sound;
- a qualified, motivated and credible (highly regarded) person is available to coordinate the implementation;
- the senior management believes in the value of certification and is committed to it;
- the number of significantly different types of customers, products and services is limited (*note that this has little to do with the customised or individualized nature of the products and services*);
- the organisation is small with only a few departments and maximum a few dozen staff members.

If most of these conditions are met, the organisation can safely engage in an ISO 9000 exercise. But if none or only a few apply, then it is likely that the journey towards certification will be long and paved with obstacles. A bonus in both cases would be the easy access to professional advice and to the experience of similar organisations who have already implemented the requirements.

5.1.3 What is the minimum quality documentation?

The most visible aspect of the fulfilment of the ISO 9000 criteria, is the existence of the controlled 'quality documents' (quality manual, procedures, work instructions, forms,...). In a well-established quality system, the volume, structure and complexity of this documentation should be a true reflection of the complexity of the organisation. Therefore, no specific guidelines can be given as to the desirable size and volume of the quality documentation. It remains useful, however, to pinpoint those aspects which should always be documented as part of an ISO 9000 compliant quality system. These minimal requirements are:

- A specific quality policy and specific quality objectives, which are consistent with the quality system and with the ISO 9000 requirements.
- Description of responsibility and authority of all staff.
- Procedures (with corresponding work instructions, forms, criteria, lists,...) which cover the quality assurance requirements of the Standard:
 - controlling and maintaining of the quality documentation (including the modification of procedures and related documents);
 - conducting internal audits;
 - dealing with complaints and problems (including self-assessment); corrective measures;
 - training and professional development of staff;
 - holding regular management reviews;
 - controlling quality records (*this could also be part of other procedures*).
- Procedures (with corresponding work instructions, forms, criteria, lists,...) which cover the processes and activities which are explicitly mentioned in the Standard:
 - systematic review of all agreements with customers (including registration of students/trainees);
 - design and planning of courses, programmes, education and training materials (*only for ISO 9001*);
 - purchasing of goods and supplies;
 - recruitment of staff; use of external trainers (*when applicable*);
 - monitoring and evaluation of education and training programmes.
- Procedures (with corresponding work instructions, forms, criteria, lists,...) which cover the other processes not already addressed, such as:
 - development and adaptation of courses, programmes, education and training materials (*when applicable*);
 - delivery of education and training programmes (enrolment, teaching, practical organisation);
 - assessment and examination of trainees (*when applicable*).

For small organisations with a regular and standardized provision, this may just suffice; it may in some cases even be possible to group some of these processes into a single procedure, while certain items of this list may not apply. All the other requirements of the Standard (e.g. product identification and traceability) can easily be incorporated as part of the procedures mentioned. Thus, about 15 procedures would appear as the minimum for ISO 9001.

This minimalistic approach is, however, more the exception than the rule. For small education and training providers, which essentially always use a standardized approach, about 20 'procedures' seems a more realistic number – at least if the full scope of the activities is included in the quality system. The larger an organisation becomes, the more the number of procedures is likely to increase, up to 100 or more (for higher education institutions). The rate of growth is not so much dependent on the number of staff or the turn-over, but rather on the number of different processes which take place. A small higher education institution, with its many different activities and services to students, may need more procedures than a large continuing education provider.

It is recalled that providing numbers of procedures is always somewhat problematic. Quite different practices exist for the writing of procedures: in certain organisations they are very general, leaving much of the detail to separate work instructions and other related documents; with others, the procedures are much more detailed, with less reference to annexes. It goes without saying that, the more details a procedure contains, the more there will be a tendency to split it up into smaller procedures, in order to keep the maintenance practical. With such an approach, the number of procedures tends to rise. This should be balanced against the fact that usually fewer annexes are needed in such cases.

Another parameter in the numbers game is the required level of detail of procedures and work instructions, which is linked to the qualification level of the people concerned. The higher skilled and educated staff are, the less necessary it will be to use lengthy and very detailed procedures and instructions. Since most education and training organisations have fairly highly qualified staff, it is often possible to leave out details, since it can be safely assumed (and demonstrated by the running of the quality system) that the omission of such details will not negatively affect quality. The fact that fewer details are needed, often allows some streamlining and merging of procedures as well.

With such considerations, we have entered into the area of individual tailoring of a quality system to the needs of a particular organisation. It is not really possible to make any further generalisations on such matters in a report of this kind. What should be retained is that some creativity is needed for creating a quality system with minimal quality documentation, but which remains fully compliant with the Standard.

5.2 Implementation of the quality system

5.2.1 Generic issues

The implementation of a quality system (compliant with ISO 9001 or 9002) is different for every organisation. Nevertheless, the following stages can often be identified:

- preliminary investigations regarding the relevance and cost-benefit ratio of certification;
- decision by the senior management, possibly including the selection of an appropriate consultant;
- analysis of the existing situation: type of customers, outputs, processes, documents available; choice of the appropriate standard (ISO 9001 or 9002);
- awareness building, training (on the standards, writing of procedures), project planning;
- drafting the components of the quality documentation: procedures, quality manuals, instructions, forms, etc. (*this is the most resource intensive phase*);
- training on document control and internal audits (*may start in the previous phase*);
- revision of the quality documentation;
- start of operating the quality system (including document control, internal audits, corrective measures, management reviews, etc.);
- external audit and, if successful, certification;
- maintenance of the quality system with 3-5 external audits over a period of 3 years.

It is recalled that the whole process from decision to certification for a typical education or training organisation is often in the range of 12 to 18 months. The reader is also reminded of the fact that a certificate is only valid for 3 years.

5.2.2 Positive messages from implementation experiences

A rudimentary analysis of the experience of education and training organisations which have already been certified, shows the following positive results:

the ISO 9000 certification process

- assists in a better understanding of the outputs delivered and the internal operation of the organisation;
- contributes strongly to the generalisation of process thinking, and the acceptance that every process in the organisation contributes to the final quality;
- quickly introduces a culture where keeping to the procedures is seen as an asset, and not a bureaucratic prescription (*this depends heavily on the common sense used when designing procedures*);
- makes people aware that many of the requirements are already fulfilled and that many of the documents needed already existed;
- adds a new dimension and dynamic to the existing quality culture;
- provides a real aid to systematic procedural development;
- is often less difficult to implement than initially anticipated;

- quickly demonstrates its applicability and relevance.

These positive messages result from successful, pioneering cases. Whether they will remain valid when more organisations become certified remains to be seen.

5.2.3 Negative messages from implementation experiences

Even ISO 9000 enthusiasts in education and training recognise that implementation of a full quality system is not an easy affair. Some negative experiences from those already certified in education are listed below:

- there is a considerable direct cost and also an indirect cost which is sometimes underestimated;
- some managers pay only lip-service (they see only the marketing potential) but do not commit sufficient resources;
- there is lack of official guidance on several interpretation issues, and the extent of acceptable variability (the norm is seen as 'education-unfriendly');
- there are no accepted references for the level of standards on which the quality system has to be built;
-

- work for certain requirements is underestimated (e.g. design, calibration,...);
- customers often have no explicit ideas of what they need and want;
 - the implementation process starts slowly because of insufficient expertise;
 - for many people, learning to think in process terms is challenging;
 - most people lack the skills to write good procedures for their own activities;
 - training and raising awareness of own staff takes more time than expected;
 - it takes time before a culture of self-reflection and self-assessment emerges;
 - the resistance to changing attitudes and way of thinking of staff is often greater than expected;
 - people find it difficult to be both critical (even when things are OK) and constructive when problems arise;
 - staff members' time constraints make it difficult to progress rapidly, keep on schedule, and ensure continuity in the implementation;
 - differing internal attitudes amongst staff (active and less active people, drivers and lazy people) slow the implementation process down;
 - there is an almost irresistible tendency to overload the quality and procedure manuals with details, which requires extensive streamlining at a later stage;
 - the finishing touch for getting all processes under control often gets postponed;
 - once the quality documentation is completed, getting used to the paperwork takes time and effort;
 - initially, the quality system cannot keep up with the pace of change;
 - the launching of the document control procedure quickly results in a bureaucratic system;
 - there is insufficient consistency with regard to other quality requirements (e.g. from the inspectorate).

In order to put such negative experiences in context, it is recalled that most of these have been reported by certified education and training organisations. These are, despite their critical comments, in general positive or even extremely positive about their experience. When preparing this report, managers of about a dozen certified education or training organisations confirmed to the author that, with hindsight, they would do it again.

5.3 First results of ISO 9000 certification in education and training

5.3.1 A marginal phenomenon

At the time of writing of this report, only a few hundred education and training organisations had obtained an ISO 9000 certificate (of which over half in the UK). Even though this figure is likely to increase significantly over the next years, it remains small, both compared to the number of organisations already certified (over 100 000 now), and the several hundred thousand education and training organisations in Europe. So, by all standards, ISO 9000 certification is still a marginal phenomenon in the education and training world, and will remain so for the

next years – with the possible exception of certain segments of the training market in some European countries (United Kingdom, Netherlands).

For that reason, the results of ISO 9000 certification which are presented hereafter, should not simply be generalized. Indeed, those organisations which were the first to obtain certification can hardly be considered to be representative for the whole sector. Overall, such organisations report favourably about their experience, but in the author's impression, many of them already had a well developed quality assurance or TQM cul-

ture before they engaged in certification. Thus, more research over a sufficient time scale would be required in order to examine whether the benefits reported continue to outweigh the drawbacks, and under what assumptions the experience may be transferable to other education and training organisations. More analysis is also needed on:

- the cost-effectiveness of certification, and the period over which the investment should be depreciated;
- methods and tools to keep bureaucracy at a minimum;
- the real impact of ISO 9000 standards on the improvement of the content of education and training;
- alternative quality assurance models, systems and strategies which might be more appropriate and more cost-effective than ISO 9000.

The education and training sector is not unique in facing such issues. Similar questions also apply to many other areas in which the long term implications of ISO 9000 certification remain unexplored.

Notwithstanding these critical remarks, it is useful to list the main results which have been reported by a whole range of certified education and training organisations across Europe. Below follows an overview of the key messages, resulting from an analysis of the literature available, the author's own experience, and some telephone interviews conducted for this study. It goes without saying that all results do not apply to all organisations.

5.3.2 Benefits of certification for education and training

The main benefits of ISO 9000 based quality systems, as reported by certified education and training providers, can be grouped into four categories: external recognition of quality level, an improved quality culture amongst staff, streamlining of the internal organisation, a dynamic of continuous improvement, and more consistent quality outputs for specific processes.

External recognition of quality level

In the cases where ISO 9000 certification is a mandatory requirement, its acquisition is of course a major benefit. Apart from this, still a rare requirement for education and training institutes, other reported external benefits include:

- an easy external appreciation of the certificate as a real quality label, which helps in marketing and instilling confidence;
- improved access to large companies (applies particularly to continuing education and training providers);
- recognition of leadership in a particular sector by peers (will apply less in the future);
- enhanced credibility of the quality claims made (in particular because of the independent auditing);

- recognition by competitors in the training world.

An improved quality culture amongst staff

Many of the reported benefits relate to an improved quality awareness and commitment of staff:

- the development and maintenance of the quality system provides a clear focus for internal quality improvement by all staff;
- staff have a better understanding of their duties and responsibilities;
- TQM-concepts like "internal clients" and 'Aprocess orientation' are more easily understood and applied;
- certification provides greater internal visibility of quality efforts and reassurance for staff;
- quality issues are better understood and more efficiently and effectively discussed by staff;
- there is a higher quality awareness when purchasing goods and services from third parties;
- staff have more confidence in themselves;
- staff become more critical of themselves and more constructive in seeking performance improvements;
- staff is fully prepared and committed to continuous improvement.

An interesting – but not unexpected – observation is that the improved quality culture is found more amongst managers and support staff than with teachers and trainers.

Improvement and streamlining of the internal organisation

Here there are two series of benefits. On the one hand, the new quality assurance mechanisms, like document control, internal audits, corrective measures and management reviews are quickly seen as contributing to more efficiency, effectiveness and quality improvement (even when these new arrangements initially meet some resistance).

On the other hand, the quality system contributes to a tangible organisational change, in particular a more streamlined organisation:

- overall, a more rational and transparent organisation emerges;
- all policies and procedures become more in line with each other;
- responsibilities of staff are more clearly defined, with no grey zones left;
- management practice is improved at all levels (leadership is encouraged);
- most processes are conducted in a standardized manner, resulting in more efficient and effective operations;
- internal communication throughout the organisation is greatly enhanced.

Some cases even mention a reduction of bureaucracy – but it is not obvious that such findings could be generalized.

A dynamic of continuous improvement

Certified education and training organisations, in particular those who have been certified for a number of years, report positively about the emergence of a dynamic of continuous improvement throughout the whole organisation, noticeable through:

- regular changes and improvements across the whole quality system;
- a more flexible and dynamic organisation (one called it an 'oiled' system);
- a high value added from the internal audits, assisting in the move towards a learning organisation;
- early and better identification of problems and weakness, followed by a fast and adequate response;
- emergence of various spin-offs, such as generalisation of team work and inter-departmental coordination.

More consistent quality outputs

Most certified organisations report on a more consistent meeting of process standards and strongly reduced variability of outputs, including:

- the design and development of curricula and training specifications;
- the development and finalisation of education and training materials;
- the use of external trainers and teachers;
- the running of the administrative support functions;
- the different interface points with clients (students, trainees, employers,...);
- more focus on the needs of internal clients throughout the different people;
- streamlining (up to re-engineering) of specific processes (e.g. purchasing of goods and services).

Overall, most certified organisations are able to show increased satisfaction among students, trainees or employers.

Comparison with other sectors

In the already mentioned study by the Manchester Business School for SGS (see Bibliography), the UK organisations surveyed listed the following as the top ten benefits of ISO certification (in decreasing order of occurrence):

- better management control,
- improving awareness of procedural problems,
- using the standard as 'a promotional tool',
- improving customer service,
- facilitating elimination of procedural problems,
- improving efficiency,
- keeping existing customers,
- increasing customer satisfaction,
- aiding induction of new staff,
- improving market share.

All of these benefits were reported by at least one out of two organisations. One can easily verify that these benefits are broadly similar to those listed for education and training organisations. The study reported also that *"69% of respondents felt that their expectations had been met or exceeded. (...) The majority were also satisfied with the impact of ISO 9000 on their organisation. (...) Comments made by respondents suggest a clear link between management commitment to improvement and satisfaction with ISO 9000."*

5.3.3 Drawbacks of certification

A mixed bag of problems

Even education and training organisations who are overall very positive about ISO 9000, recognize a number of problems and drawbacks in the operation of the

system. In addition to numerous implementation hurdles (see Section 5.2.3) the problems most frequently mentioned are:

- the continuous volume of paperwork involved;
- the cost of certification and the ongoing cost of maintenance (this is particularly a concern of publicly financed education institutions);
- the risk of evolving towards a bureaucracy focused on procedures and registrations;
- the difficulty of implementing changes fast.

Other criticisms mentioned include:

- ISO 9000 certification does not yield a quality assessment report (which makes it unsuitable for public accountability purposes);
- at least part of the staff may not be motivated to support the quality system;
- there is a danger of thinking one is perfect once the certificate is awarded;
- some risk of 'forgetting' the requirements of the quality system until the next external audit arrives;
- certification does not yield an increase in market share.

These and other problems should not be generalised, since they are highly dependent on particular circumstances.

Some education and training institutions mentioned some 'problems' of an entirely different nature:

- jealousy and even straight rejection of the value of the certificate by peers;
- lack of interest by the press (which has got so used by 'ISO 9000 News' that they see no news value in reporting about another certificate).

Putting the drawbacks into context

Quoting again from the SGS study, the main issues raised by certified UK organisations across all sectors of the economy as 'being a major problem' were:

- the time required to write the manual and to complete implementation,
- the high volume of paperwork, and
- the cost of implementation and maintaining the standards.

Other complaints concerned the lack of free advice, inconsistency between auditors (raised by larger companies), the time spent on checking paperwork prior to audits, the vagueness of the standard, and the difficulty of interpreting the standard. The study also found that *"those least satisfied with the standard had been motivated much more by pressure to keep existing customers and to use ISO 9000 as a promotional tool. (...) Small organisations generally considered drawbacks to be more significant, when compared to benefits, than did large organisations. The same pattern was seen in concerns with ongoing maintenance of the standard"*.

5.3.4 10 tips and conditions for success

ISO 9000 is not an appropriate goal for any organisation in any circumstance. Neither can anyone engage in the certification process with a reasonable chance of success. Below are 10 tips for successful implementation of ISO 9000 certification by education and training organisations. Most of these are necessary conditions for successful certification:

An education or training organisation interested in ISO 9000 should:

- know very well why it wants to be certified;
- have fully committed managers who are prepared to implement a quality system;
- be convinced of the relevance of the standard (*not only of the certificate*);
- take all (interpreted) requirements of ISO 9000 serious (unlike TQM, you cannot pick what you like!);
- have a long term vision on quality issues;
- have already high quality standards for its key services;
-

- be well organised;
- not be in the middle of another major change project (e.g. restructuring, take-over,...);
- be capable of committing sufficient staff time;
- start from a sound financial situation.

If an organisation fails to meet more than half of these conditions, it is unlikely to benefit quickly from its ISO 9000 journey.

6. Conclusion

The research underlying this report has shown that certification on the basis of ISO 9000 standards can provide a valuable framework for the quality efforts of education and training organisations. Experience so far indicates its capability as a mechanism for improved customer service, high levels of quality assurance and a dynamic of continuous quality improvements – the three cornerstones of TQM.

ISO 9000 is not in contradiction with any sound educational standards or practice, and can easily complement other quality approaches (in particular those focussing on input- or output-factors). Obtaining a certificate enhances the organisation's quality image and underpins its quality claims in an increasingly competitive environment. It may enable an education or training provider to fulfill or exceed externally imposed quality criteria.

These positive outcomes come at a price. First of all, obtaining an ISO 9000 certificate requires considerable commitment and resources, in particular when the starting conditions are not optimal. Only a fraction of education and training providers seem currently in a position to engage in such an effort – if they are convinced of its cost-effectiveness. Secondly, ISO 9000 is in itself not sufficient for achieving quality of the content of education and training programmes – in particular in situations where the customers are not in a position to specify or influence the content (including learning objectives, quality criteria, indicators, and evaluation mechanisms). This situation applies to most regular education provision, and to some areas of continuing education and training. From that perspective, ISO 9000 is merely a tool for assuring quality of education and training provision, while the definition of content will have to be derived elsewhere.

It should be mentioned that many of the arguments which have been put forward against ISO 9000 certification of education and training providers – such as the possibility to set low content quality standards, unnecessary paperwork, and the irrelevance of several of the standards' requirements – have so far not proven to be justified. Indeed, such issues appear to have been anticipated and been addressed creatively. But it must also be recognised that the first certified education and training organisations were not necessarily representative either.

What remains unresolved is the question of cost-effectiveness of the certification process and the maintenance of the quality system. More research is needed on the impact of ISO 9000 certification, its relevance, its cost-effectiveness, and the coherence with traditional quality concepts and mechanisms used in education and training.

An international ISO 9000-'like' standard, which would be specifically developed for education and training organisations, would seem to be an attractive option. No international movements in this direction are taking place. There are, however, some

interesting developments going on in other corners of the quality world: an 'education' adaptation of the criteria for the European Quality Award, internationalisation of (higher) education assessments, international accreditation schemes (also mainly for higher education). It is unclear whether any such initiatives will gain sufficient momentum. In contrast with ISO 9000, they suffer from a narrow focus on particular types of education and training institutions, and from low visibility externally.

Maybe the education and training world will wait until it sees the fully revised version of ISO 9001, scheduled to be available by 2000. This new release will be structured better, use a more generic terminology and will be based more on TQM concepts. That sounds

like a more attractive option for education and training organisations – and in any case one which is likely to meet less resistance.

In conclusion, even the increasing number of ISO 9000 certificates is unlikely to put an end to the vivid debate about quality assurance and quality management in education and training institutions. Eventually, it will be the market which will decide whether the cost of certification is worthwhile, whether its benefits will outweigh the drawbacks, and whether any other national or international quality scheme is more appropriate.

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Most of the following list of books, reports and articles deal specifically with the application and implementation of ISO 9000 in education and training environments: guidelines, interpretations, case studies, critical comments, etc. One should be aware that many of these documents concern a particular type of education or training organisation; some documents are also somewhat biased by the national context or the particular experience of the organisations reported on. The bibliography further includes references to several ISO 9000 standards, as well as to some general books on ISO 9000. It may be useful to note that the ISO 9000 series exists also as European norms (series EN ISO 9000, previously EN 29000) and that authorized translations of these norms exist in many European languages, issued by the national normalisation bodies.

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