Quality Mantra
A NEWSLETTER OF INTERNATIONAL CERTIFICATION SERVICES

Station's Highlights

■ **ICS Kanpur :**
has certified following prestigious clients for ISO 9001:2000
- *Kanhaiya Trading Company Kanpur*
- *Rajhansh Gramodyog sansthan Kanpur*

■ **ICS Chennai :**
has certified following prestigious clients for ISO 9001:2000
- *Government General Hospital - A very big government hospital in chennai.*
- *Madras Medical College - one of the top most medical college in India.*
- *Madras Institute of Imaging and Allied Services Pvt. Ltd*

ICS Chennai has achieved a record No. of Certification Audits in a Month - 30 Initial Audits and 30 new registration - Dec. 2004

■ **ICS Pune :**
has certified following prestigious clients for ISO 9001:2000
- Atur India Pvt. Ltd.
- Ekbote's Logs & Lumbers Pvt. Ltd.

Organized Seminar for CE Marking Awareness by Faculty from notification body NEMCO - Mr. Frank Skarpsno on 16th Feb 2005

■ **ICS Nagpur :**
has certified following prestigious clients for ISO 9001:2000
- Suruchi Spices Pvt. Ltd. (Nagpur)

has certified following prestigious clients for ISO 14001:2004
- Koradi thermal power station, M.S.E.B (Nagpur)

■ **ICS Jaipur :**
has certified following prestigious clients for ISO 9001:2000
- Premier Bars Pvt. Ltd.(TMT &CTD bars) Jaipur
- Laxmi Soap Industries-(soaps and detergent)Jhunjunu

■ **ICS Mumbai :**
has certified following prestigious clients for ISO 9001:2000
- DAV International School.

Organized Seminar for CE Marking Awareness by Faculty from notification body NEMCO - Mr. Frank Skarpsno on 19th Feb 2005

Social Commitment for Tsunami

No human being on earth can forget the 26th December 2004. yes! The whole world has come to a grinding halt upon seeing the effects of the nature's one of the destructive arms.

Everyone had joined hands in helping the affected people in India. Organizations came forward to join hands with government. Every one contributed with the great heart of helping them. ICSASIANS have contributed their one day salary for Tsunami relief measures.

The search began in Tamil Nadu where the worst work of nature rendered thousands homeless, childless and so on. Our team identified an area called Kottivakkam Kuppam of Kanchipuram District where the sea and village people shared same platform on the black day December 26th of 2004. The census intimated about the requirements with the help of the local panchayat.

ICS Chennai team immediately went on war footing to obtain the necessary things like utensils, stoves, clothes & groceries. Almost around two hundred people have been distributed with items they needed dearly. Two hundred children were distributed with essentials like Slate, Pencils, note books and a box to carry.

After distribution the team left the area with heavy heart of sufferings they witnessed.

G. Venkataraman

A Bi-monthly News letter is published, printed and Edited by SUNDAR KATARIA on behalf of

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(For Internal Circulation Only)

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March 2005

Vol. III No. 07

Future Issue of Quality Mantra
MAY 2005 Issue : OHSAS Special
JULY 2005 Issue : HACCP Special
SEPT. 2005 Issue : QMS in Service Industry Special

QM Reader's Platform

Thank you for giving me the copy of Quality Mantra. Gone through the QM of January 2005 issue. Good to know about IMS. I have a request that you should include a Question & Answer section in the QM which will make the client more comfortable to ask question regarding any problems faced with respect to QMS, EMS, IMS and get cleared.

Rajeev Jammihal

Thank you very much for the newsletters "Quality Mantra." I appreciate your sincere efforts for a newsletter on ISO activities of your company. I find the contents good ones. Specifically my comments are as follows:

1. Editorial from Mr. Kataria are quite informative. I am looking forward to browse through your book on Integrated Management.
2. Layout: the newsletter is well designed. I would suggest that index & publication information should appear on first page itself. This leaves enough space for readers' comments on second page so that management & customers (readers) are together.
3. Second Opinion: An excellent idea. Please keep it up.

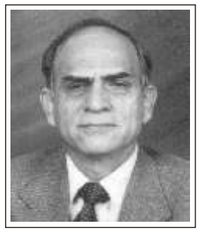
a. November issue carried a question on identifying processes from other clauses. Yes we have to identify processes from other clauses. This is because entire management is a process itself, which means that from section 4 to 8 everything is a process. Also referring to ISO 9000:2001 we find that a process is defined as "a set of interrelated or interacting activities which transform inputs into outputs."& a product or service is defined as "Result of a process". So wherever this happens there is a process. When we start analyzing service sector this definition becomes clearer.

b. Jan issue carried a question on right way for measurement of output of processes? The answers are really good, well thought out. One important aspect is that wherever the measurement matters for the success of enterprise measurement should be done. And as outputs can be tangible or intangible, suitable measurement technique from stable of more than 18 statistical techniques should be chosen and implemented.

4. Integrated Management System is going to be important as organizations implement the standards in all earnestness & start reaping benefits. In such a situation it becomes important that organization becomes lean in case of certification also. Then integrated Management system is the only alternative.
5. Learn with fun is good except some repetition.
6. It is a really good effort and keep it up.

Jayant R Karandikar, Ex. Director OMKAR Consultech PUNE

Editorial



Product/CE Marking Certification System :

Product Certification in India is known as IS Mark as quality mark since long but recent days the concept has been changing to product certification by CE Mark for most of the product. This shift has been forced due to globalization. Although we have signed WTO for the last one decade that should have opened flood gate for Indian Industry. Our expert should have increased to many fold thus helping our country's economy.

Your export to the western countries can only be ensured by improvement of the quality of the product and services. CE Mark/ Product certification is the best tool to assure the quality of the product. Moreover number of countries nearly 50 have joined European Commission who has mandatory requirements for the CE Mark including countries like USA and Japan.

India is developing fast and racing towards developing country. India is today known as one of the largest industrial sector having all necessary and modern manufacturing facility with highly skilled and learned manpower. Why can't we meet the urge of the world by enhancing quality of our product to beat global competition.

International Certification Services realized the above facts and geared up to product/CE Marking Certification. We provider of "total quality solution" by establishing necessary technology , know how and facility. We have number of associations from overseas from the European countries like Nemko, Norway, IMQ-Italy, MedCert-Gmbh and PCBC from Poland to extend notified body and laboratory for the purpose of

Know-how, certification and inspection and testing services.

Certification of the product/ CE Marking is most complex due to number of directives, harmonized standards and local legislative requirements. Therefore in depth knowledge and skill should be available with the Certification Body to cater the certification need so that products manufactured in India and certified as per CE Mark requirements are acceptable to the European and western countries.

ICS has successfully accomplished number of CE Marking products covering machinery, toys, medical devices, construction material, harmonized components, personal safety equipments and white goods, etc.

We have also initiated number of CE Marking training programmes to bring awareness and knowhow to our industry at large and to support and enhance the Indian economy.

Sundar Kataria

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ICS

CE Marking : Awareness

CE marking stands for Value for life, stands for **European health, safety and environmental protection legislations**, which helps in **free circulation of goods** in **EU**(European union) and **EFTA**(European free trade association) total **28 countries**. Abbreviation 'CE' is for French phrase 'Conformite Europeene' which means ' **European conformity'**, which was initially used as 'EC Mark' replaced by **'CE Marking'** officially.

CE marking is also considered to be **'Passport to Europe'** for non-EU products, which indicates to Government officials that the product may be legally placed on the market in their country, because the manufacturer is legally responsible for ensuring that the product confirms to the requirements of the national legislation, also EU legislation makes EU importers liable for the product they import, which has given birth to several product directives. CE marking is also considered to be **'Symbol of Quality'** as it has to meet minimum standards of quality too. The objective of directive is to simplify the movement of goods into and within EU.

What are the advantages and disadvantages of CE marking?

Advantages: 1. **Easy access to** EU+EFTA market as there would be one set of laws and regulations for **entire market place** which guides the designing, manufacturing and labeling of products eliminating multiple conflicting national restrictions on regulated products and ultimately would be cheaper trade.

2. **Reduce damage claims** and liability premium.

Disadvantages:1. New product directives may **exceed the current national laws and regulation** which may **cost manufacture extra** to modify the existing design.

2. Extra costs in obtaining the product **'Certification of registration'** for CE marking. Since directive are guidelines for **evaluation of product for safety aspect,** answer to 'HOW' is Harmonized standards. Product directives contains the 'Essential requirements' and 'performance levels' and Harmonized standards to which product must conform. Harmonized standards are technical specifications(European standards/ Harmonization documents) which are established by European standards agencies such as CEN, CENELEC etc. CEN stands for European committee for standardization. CENELEC stands for European committee for electrotechnical standardization for which SC62 stands for international electrotechnical subcommittee for Medical Device.

There are more than 22 product directives such as low voltage directive(LVD), Electromagnetic compatibility (EMC), Medical device directive(MDD), Toys directives etc. and more than 300 Harmonized standards which are published by EC(European commission) in official journal/ gazette of the European communities. Few new directives coming up are WEEE 2002/96/EF (Wastage of Electrical, electronics equipments); ROHS 2002/ 95/EF(Restriction of hazardous substances as, Hg, Pb, Cd etc)

The European commission nominates 'Notified Bodies' which serves as independent test labs and performs steps called by directive. These Notified bodies could be private or Government agencies which must have necessary qualification to meet the testing requirements set forth in the directives.

For obtaining CE marking on product there are general steps to be followed depending on product and nature of risk the product presents.

1. Identifying the purpose or intended use of product.
2. Determining applicable directive(s) and Harmonized standard(s).
3. Determining extend to which product complies with the essential requirements for design and manufacturing in the applicable directive(s).
4. Choose the 'modules' for **'conformity assessment procedure'** which is again guided by directive depending on risk involved.

Eg: Module A:Internal production control.
Module Aa :Intervention of a notified body.
Module B :EC type Examination.
Module C :Conformity to type.
Module D :Production quality assurance.
Module E :Product quality assurance.
Module F :Product verification.
Module G:Unit verification.
Module H: Full quality assurance.

Conformity Assessment Procedure could be **self declaration; Voluntary certification or Mandatory Certification.**

Self Declaration: Assessment is done by manufacturer, Technical file is kept with manufacturer, and manufacturer issues DOC(declaration of conformity)and mark CE . Examination by Notified body is not required.

Voluntary Certification: Assessment by Notified body, Technical file is kept with Notified body, and EC body issues the certificate and approval mark.

Mandatory certification: Assessment by Notified body, Technical file is kept with Notified body. Examination is done by notified body and issues certificate and approval mark.

5. Depending on risk involved and conformity assessment procedure(where Greater risk), appoint the Notified body and establish the **European Authorized Representative** who will represent the manufacturer to deal with the CE marking vigilance authorities, helps in getting **'Certificate of registration'** for product (certificate of registration stands valid for one year and needs updation), who keeps manufacturer away from understanding the complex European product regulation also who stands as lawyer representing manufacturer in court.
6. Preparation of Technical File and Declaration of Conformity.
7. Assessment & Examination.
8. Issue of certificate and approval mark.
9. Affixing CE marking.

There must be a systematic approach for selection of electrical ratings and characteristics of the component. Mechanical supporting elements, critical load bearing elements and high-speed components must have sound characteristics. Selection of the characteristics of such elements must be based on some calculation and estimates required for the purpose.

Design review and risk assessment
This is a systematic approach to analyse the product for likely hazards considering the life cycle of the machine, likely consequences, and a positive approach to minimize the hazard. It includes mainly risk analysis, evaluation, reduction and proper documentation

All possible hazards are analyzed systematically considering the life cycle of the products and a conclusion is made whether the design is safe or additional safety measures need to be incorporated. The safeguards to be provided, if necessary, must not be easily defeatable and its use shall not de-motivate the operator from using it. In other words, product use without safeguards must de-motivate the user from doing so.

In many cases manufacturers use the best suitable components available in market and try to incorporate good techniques. However, while integrating such components in the products, they ignore or underestimate the critical issues of such components explained in their respective manual. When higher level of safety or reliability is the destination, integration of the components for specific application is still critical even if the component is a proven one in the market. If configured wrongly or not taken care by adequate (recommended) precautions, it may prove to be not suitable & may fail in critical situations for which it is recommended.

Therefore, a designer or an expert must evaluate for design parameters systematically to meet the directive of higher safety level and demonstrate that it is in conformity with the requirements of the European union directives.

Changes in design parameters based on risk assessment
The risk assessment may enforce for some constructional changes like addition of guards or incorporation of the interlocks. If it is so, then manufacturer must change accordingly & construct the machine incorporating the new requirements and update the instruction manual.

Instruction Manual preparation
Manufacturer must compile an instruction manual for safe use of the product. It shall content information about the product, technical specifications, intended application, installation, operation, and maintenance in detail. It must be stand alone and complete in every respect

Testing of the product to the applicable standards:
The product need to be tested to the applicable standards as discussed above. The testing work can be awarded to the independent test laboratories having good credentials. Testing by independent laboratory may not be essential if the manufacturer has good test facility and expertise to compile the test data in totality. However, preference is always given to the third party independent test laboratory due to higher acceptability of the test results.

Preparation of Technical File:
After having gone through above activities, it is expected that the manufacturer prepares a Technical file containing at least following

- EC Declaration of Conformity
- A general description of the product
- Design and production drawing and diagrams
- An overall drawing of the machinery together with drawings of the control circuits
- Full detailed drawings, accompanied by any calculation notes, test results, etc required to check the conformity of the machinery with the essential safety & health requirements
- Detailed technical data for essential aspects of the product
- A list of the essential requirements of the EC directive
- Standards applied and other technical specifications, which were used when the machine was designed
- Report of calculations & tests that have been carried out

Affixing of CE Marking
Once the declaration is signed by manufacturer or his local agent, CE marking on the products can be affixed

Authors can be reached for any further information at
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Learn with Fun

QMS-1994 EDITION

QMS-2000 EDITION

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Second Opinion

Quality mantra asks three leading consultants, to give their opinion on the typical problem asked by any of our clients on QMS/ EMS every issue.

Typical problem of this issue is as under:-
We have been trying to decide on how best to address, or whether we are addressing the CUSTOMER SATISFACTION CLAUSE (8.2.1) of ISO 9001:2000.
It is understood that this merely means sending out a few questionnaires as well as considering customer complaints.

Would this approach be correct?

Dr. R.R. Lakhe, Nagpur
Customer satisfaction is the foundation of ISO 9001:2000 as it envisages it through continual improvement. According to ISO 9000:2000 customer satisfaction is customer's perception of the degree to which the customer requirements have been fulfilled. Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction. Even when customer requirements have been agreed with the customer & fulfilled, this does not necessarily ensured high customer satisfaction. The common practice of getting feedback through questionnaires slightly fulfill this requirement. However, the questionnaire survey & customer complaints are not enough to indicate satisfaction as most of the customers do not bother to give their true opinion and feel the questionnaire as mere formality. Also the research has indicated that only 10% of unsatisfied customer complaints & out of these very few gets recorded by the organizations. More appropriate indicators would be no/volume of orders received from the customers, prices of product accepted by customers, no. of new customers added, no. of visits to customers & the sales volume of business. The methods of determining & reviewing requirements of the customer (clause 7.2.1, 7.2.2), customer communications (7.2.3) and care exercised in handling customer property (7.5.4) are to be screened during audit to get a proper perspective of fulfillment of customer requirements and customer satisfaction thereof.

Dr. R.R. Lakhe, Nagpur
B.E(Mech), M.Tech (Prod), DBM, Dip. Training and Development, MA(Public Admin), M.A(sociology) , doctoral Fellow of NITIE, LA (QMS, EMS), More than 20 years of experiaence & have published many books & journal.

Mr. Yogesh Jain, Indore
Clause 8.2.1 says: "… the organization shall monitor information relating to customer perception…. The methods for obtaining & using this information shall be determined." The customer feedback questionnaires and analysis of customer complaints is limited approach and is lip service paid to customer satisfaction measurement. Other avenues to measure customer perception should be employed as most of the times even customer feedback is just not available (hardly in 15% of times).

Companies must work out Market share analysis, improved sales growth, retention of regular customers through repeat sales analysis, sales through referred leads, customer returns to measure customer satisfaction. Study of competitor's strategy, surveys, response to advertisements and customer contact programs should also be documented to arrive at some measure and should factor in Customer Satisfaction Measurement.

Customer Satisfaction Measurement should not be limited to Quality Control or M.R. function; it should be well supported by Marketing and Management and be linked to their performance indicators. It should be thoroughly discussed in Management Review to bring seriousness. Efforts should be made to collect data from various sources and map it on company's operational area to judge improvement in customer satisfaction.

If possible the same can be extended to intra-company customer satisfaction index & verbal input / feedback should also be documented for better results.

Such measures are very helpful in service industry i.e. Retail Outlets, Insurance Companies, Banks, etc. besides regular manufacturing set up.

Mr. Yogesh Jain: B.E. (Mech.) and M.Tech. (Futures Studies & Planning), is in the field of consulting since 1998. He has got certification of known units of Central India. He is working in ISO 9001:2000, HACCP, WHO-GMP, TS 16949 Standards He has also executed service sector clients of School, Colleges, Hospitals and Petrol Pumps.

Customer's Platform

Certificate Presentation Ceremony of Maitraya Services Pvt. Ltd. (Dairy Division) at Dhule, Maharashtra.

Have you ever used or found useful any of the advice given by the consultants in second opinion. If so, we would like to hear from you. Please write to editors at uday@icsasian.com

Diary Notes

From	To	Place	Training course	Contact details
02/ 03/ 05	06/ 03 /05	Delhi	Lead Auditor Course (5 days) QMS	Ms Mamata 011- 22042106/2107 icsapld@ndb.vsnl.net.in
09/ 03/05	10/ 03/05	Jaipur	IQA training Course (2 days) QMS	Ms. Simran 0141-2610291 ics_jpr@icsasian.com
18/ 03/ 05	22/ 03/ 05	Chennai	Lead Auditor Course (5 days) QMS	Mr. Venkatraman 044-24719070 icsapld_chennai@vsnl.net
18/ 03/05	19/ 03/ 05	Daman	IQA training Course (2 days) QMS	Mr. Rajesh Pandey 0260-3091135/2433400 ics_vapi@icsasian.com
11/04/05	12/04/05	Pune	IQA training Course (2 days) QMS	Mr. Ashok Ohol 020-25455206 ics_pune@vsnl.net

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Corporate News

MD Addresses Associates Meet at Ahmedabad on 28th January 2005

ICS has been organizing meets at various stations from time to time to keep our business associates abreast on the growth and development, new standards, requirements, revisions, needs of the nations including our strategy to safeguard, life, safety and environment.

Such meets were recently organised at Ahmedabad on 28th Jan, 2005 and Mumbai on 11th February, 2005. ICS plans to organise more such interactive meets with our business associates and consultants on regular basis.

Sheetal Kataria (Director, ICS) Weds Vishal Thomas on 27th December, 2004.

Feature

CE Marking of Machines An overview

By
Krishna Murari, Additional Director
Gokul R. Mahajan, Joint Director

Scope:

This document describes briefly the modalities & procedures involved for evaluation of the product to the requirements of European Harmonised standards so that it can be self-declared by the manufacturer or his representative and CE Marking may be affixed.

The scope of this article is applicable for the products, which are falling under the self-certification module.

Who should read this document?

It is intended for the technical decision-making authorities concern with the manufacturing unit. When decision-making authority is fully aware of the formalities and other concerns, the ultimate objective of testing to the requirements of the European standards & placing the CE Marking of the product is easy and complete with full knowledge & consequences.

Determination of applicable Directives:

With the general guidelines, it is easy to come to a conclusion that most of the products where electricity is being used, Low Voltage Directive (73/23/EEC) and Electromagnetic Compatibility Directive (89/336/EEC) are invariably apply. If the product employs hazardous mechanical movement, powered by other than human efforts then Machinery Directive (98/37/EC) is also applicable.

When high-pressure accessories are used such as reservoirs then one may have to refer to Pressure Equipment directive (97/23/EC) partially or fully.

Determining applicable directive seems an easy task but in some cases it may prove to be a tough going job & any error or ignorance may prove that the product is wrongly placed in to the market without meeting the applicable directives requirements. Therefore, it is equally important to decide the applicable directive in association with the test laboratories or an organization, which has adequate knowledge and working experience in this field.

Determining the suitable standards under applicable directives:

Every directive contents numerous harmonized standards, which are published in the official journals of the European Union, and it is presumed to meet the conformity once they are applied to the extent applicable. Selection of the applicable standards for LVD and EMC directive is relatively simple due to good experience gained by the laboratories in the testing field, however selection of applicable Product Specific Standards under Machinery Directive may still need some focused attention. The very fact that under MD many new & new Product Specific (Type C) Standards are coming up & one need to apply the most suitable standards instead of applying the Generic Standards which were available few years before. In view of this an expert advice may be necessary to select appropriate European harmonized standards for a particular equipment or machinery

Designing of the Product to meet the requirements

Manufacturer designs the products taking care of Essential Health & Safety Requirements (ESHR) stipulated in the new European standards. It is understood that manufacturer has good design data pertaining to the product. Protective devices installed & selection of the setting must correspond with the actual requirement of the product being designed.