



THE QUALITE'

Unifying the quality

The Qualit'e is now quarterly publication brining updates in the world of quality.



FROM THE EDITORS DESK

Dear Readers,

It gives me immense pleasure to promulgate that the Qualit'e has now turned into a quarterly Publication. Thank you for your overwhelming response to make Qualite a success. I also, thank URS team, for creating a platform for readers to update them with new happenings.

The Qualit'e shall focuses on Latest updates in Quality, its concepts, technologies etc.

This Issue covers latest standards ISO 21930:2007 and ISO 23600:2007 in the market and how they encourage sustainability in building construction and make street safer for disabled persons respectively.

This Issue also covers new trends in Biological evaluation of Medical Devices. ISO 10993, Biological evaluation of medical devices, Part I, Evaluation and testing (2003), provides guidance on how to perform a biological evaluation of a device. The general biological evaluation of medical devices standards include basic evaluation and testing, sterilization residuals and the preparation of samples / reference materials for testing.

Further, This Newsletter highlights happenings in URS- News, its New Members and major clients certified by URS during the period.

I look forward to your proactive participation to make the Qualit'e reach apex.

I invite your articles for publications in our Magazine , to send articles email at editor@thequalite.com

Vasudha

Visit: www.thequalite.com



New standard encourages sustainability in building construction.

A new standard will help to ensure that urbanization, which is a global trend, develops in an environmentally friendly manner.

ISO 21930:2007, *Sustainability in building construction – Environmental declaration of building products*, will be a very helpful tool for the designers of buildings, manufacturers of building products, users of buildings, owners of buildings and others active in the building and construction sector who are increasingly demanding information that enables them address environmental impacts of buildings and other construction works”, declares Jacques Lair, leader of the team of ISO experts that developed the standard.

For details visit www.iso.org

New standard will make crossing the street safer for disabled persons



The aim of ISO 23600:2007, *Assertive products for persons with vision impairments and persons with vision and hearing impairments - Acoustic and tactile signals for pedestrian traffic lights* is to ensure equivalent information worldwide at intersections equipped with pedestrian crossing signals.

The standard sets out the requirements, technical specifications and performance criteria for acoustic and tactile signals for pedestrian traffic lights and will help to ensure major benefits such as:

- Harmonized criteria for manufacturers and designers
- Safe, reliable and functional products
- Enhanced compatibility between products

For details visit www.iso.org

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SCHEMES

Management System

- ISO9001
- ISO14001
- OHSAS18001
- TS16949
- AS9100
- ISO22000
- ISO27001
- ISO10002
- ISO13485
- TL9000

Product Certification

- CE MARK
- GOST-R

Compliance Audit

- RoHS
- GMP
- WRAP
- C_TPAT

Inspections

Trainings

- Lead Auditor
- Internal Auditor
- Capacity Building Programs.

TREND



New Trends in Biological evaluation of Medical Devices.

More extensive material characterization and increased determination of toxicological risks are now required when evaluating new medical devices. The new requirements together with other changes in the ISO 10993 series described here suggest how companies can adjust their approach.

Biological evaluation and risk

The purpose of a biological evaluation of a medical device is to ensure that the device is safe, from a biological and toxicological perspective, for the patient and the user. The most effective way of making a biological evaluation is to examine all materials and fabrication processes. The biological reactivity with respect to the intended use of all the substances and processes involved should be investigated. ISO 10993, Biological evaluation of medical devices, Part I, Evaluation and testing (2003), provides guidance on how to perform a biological evaluation of a device. However, because biological evaluation is part of the risk management process of the device, ISO 10993-1 should be used in connection with ISO 14971, Medical devices, Application of risk management to medical devices.

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NEWS

➔ **URS held its Annual Conference on 5-6th Jan 08.**

URS organized its annual conference on 5-6th January 2008, at Badhkal Lake, Faridabad with a theme "Meet & Mingle".

The conference was a huge success, acquainting people at URS about the latest developments and scheme knowledge.

➔ **URS welcomes the following new members in its family**

Mr. Mohd. Ansari, *Mumbai* Ms. Cheenu Sharma, *Delhi*

Mr. Amit Kumar, *Delhi* Mr. Arun Kumar, *Chennai*

Mr. Suman Chattopadhyay, *Kolkata*

Visit: www.thequalite.com

URS CERTIFIES

1. Mumbai International Airport for ISO10002(Complaint Management System)
2. Oberthur Card System Private Ltd.
3. Pragati Green Meadows & Resort
4. Jaypee Vasant Continental
5. Chkitsa Medicare Centre Pvt.Ltd
6. Nagpur Municipal Corporation
7. Golaya Progressive Public School
8. Maharashtra State Electricity
9. Aurangabad Central Prison
10. Office of DY. IG Prisons

For more log onto www.ursindia.com

FEATURED ARTICLES

THE COST OF QUALITY

It's a term that's widely used – and widely misunderstood.

The “cost of quality” isn't the price of creating a quality product or service. It's the cost of NOT creating a quality product or service.

Every time work is redone, the cost of quality increases. Obvious examples include:

- The reworking of a manufactured item.
- The retesting of an assembly.
- The rebuilding of a tool.
- The correction of a bank statement.

In short, any cost that would not have been expended if quality were perfect contributes to the cost of quality.

Total Quality Costs

Quality costs are the total of the cost incurred by:

- Investing in the prevention of nonconformance to requirements.
- Appraising a product or service for conformance to requirements.
- Failing to meet requirements.

Ashish Bhargava

To read more visit www.thequalite.com

Editorial Board Members

Ms. Vasudha, Mr. Ashish Mukherjee, Mr. Tarun Gulati, Mr. K.G Misra, Mr. Deepender Agarwal.



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