HIGH-END CLEANLINESS PROJECT IN GUJARAT

QUALITY COUNCIL OF INDIA
QCI
Creating an Ecosystem for Quality

QUALITY INDIA

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Dear Friends,

The year 2018 has been one of high output years for QCI. Today we have a credible charter of creatively going after problems and delivering quality for our clients across the country. It has been quite successful in its mission of creating an Eco system of Quality in India. The level of activity has grown drastically and we hope to see it accelerates further in the years to come. We managed the required strength as far as human resource is concerned and also expanded our knowledge base to scale up the activities further.

QCI worked on improving the quality of life for 130 crore citizens of the country. The Special Project Group, of which PPID is a part, has come a long way since its inception in 2015. The power of youth has been driving this initiative within QCI. In these years, we have achieved significant growth on the Project delivery and Human Resource front. It is indeed remarkable to see how various projects across multiple sectors undertaken by PPID have created a remarkable impact on quality and sustenance not just on the industry but also on many aspects of quality of life of all citizens. Third-party sampling, testing and analysis of coal for non-power consumers undertaken by QCI has been scaled up. We have already sampled more than 64 MMT of coal. We were appointed by Gujarat Pavitra Yatradham Vikas Board (GPYVB) for "High-end cleanliness project" of their famous 8 Yatradhams. We conducted an independent assessment of 34 airports of the country which are under Airport Authority of India on pre-determined terminal facilities, service delivery and infrastructure. There are several other projects we worked on, like – Quality assessment of erstwhile Restructured Accelerated Power Development and Reforms Programme(R-APDRP); Google Toilet Locator; Performance Rating of Concessionaires, Contractors, Consultants - Ministry of Road Transport and Highways; National Smart Grid Mission; Quality Assessment of Deendayal Upadhyaya Gram Jyoti Yojana- (Rural Power Project); Government e-Marketplace (GeM) - Project Management Unit (PMU); Investigation and monitoring of constitutional safeguards provided for Scheduled Tribes etc. We created more opportunities in the form of new and challenging projects covering assessment and reporting to give impetus to quick implementation of schemes on the ground.

It gives us immense pride to see the organization growing stronger and bigger with each passing year. We have been fortunate to create an ecosystem for young and innovative minds leading transformative changes in a highly critical domain of national policy and governance. With a clear vision and people-oriented approach, we have sailed through many challenges. The tenacity of their resolve as well as their hunger to achieve the unthinkable has been the hallmark of this journey!!

Overall, 2018 has been a growth year for QCI. QCI remains committed to its goal of bringing quality products and services to Indian populace and help industries, including MSMEs, to improve their competitiveness in global market by investing in quality processes and outcomes.Thanks,

Dr. Ravi P. Singh
Secretary General
Quality Council of India

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UNITED NATIONS GENEVA

GUEST SCHOLAR VISIT

The presence of QCI in various forums reaffirmed the leadership position of its India National Platform on PSS amongst other initiatives like Brazil, China and Mexico

United Nations Forum on Sustainability Standards (UNFSS) acknowledged India's active support in furthering the Forum. UNFSS Secretariat mentioned the high-powered launch of its third flagship report on 17th September, 2018 at the ICSTS, New Delhi, organised by QCI in a glittering ceremony with stakeholders from India and other countries

HIGHLIGHTS & IMPLICATIONS FOR QCI

A bilateral meeting was held with FAO, WTO and UNCTAD to highlight QCI's strength in project formulation and implementation for exploring joint projects

In October, 2018, QCI was invited by the United Nations Conference on Trade and Development to send representation for the NTMs Week and the Trade for Sustainable Development (T4SD) Conference. Dr. Manish Pande, Joint Director and Head, PAD Division, QCI, visited Geneva to represent QCI at the events, and various meetings at ITC, WTO and UNCTAD, with the objective of promoting and marketing the competence of QCI to the various organizations in the United Nations and speak at the Trade for Sustainable Development Forum 2018 organized by the International Trade Center of the UN in the session called 'The future of sustainable consumption in emerging markets'. There he also came across international donor agencies such as SIDA to explore funding of trans-national project that QCI can take up for developing and emerging markets.

Dr. Pande attended the Trade for Sustainable Development Conference at ITC Headquarters in Geneva. On the first day, the sessions were on sustainable consumption, role of standards, sustainable production practices in textile, and

the future of sustainable consumption in emerging markets. On the second day, QCI attended T4SD project labs on EU Cities for fair and ethical trade award, and ITC Sustainability Map and GS1 Collaborations, along with a session on Safeguarding Biodiversity.

QCI was invited to the WTO Public Forum at the WTO Headquarters, wherein it attended sessions on Combating Illegal Timber Trade, and Sustainable Trade in the connected future.

QCI was invited to a workshop on Artificial Intelligence for Trade Negotiations held in the Palais des Nations. The DITC's Trade Analysis Branch, jointly with ICC Brazil, organized this workshop to showcase how Artificial Intelligence tools could help trade negotiations.

QCI attended the Green Export Forum, organized by UNCTAD, held in Palais des Nations. The discussion was about the National Green Economic Review with reference to countries such as Senegal, Madagascar, Oman etc. Representatives from UNCTAD explained in detail the initiative and its progress till date.

QCI was also invited to attend the NTMs Week, organized by UNCTAD, including sessions on merging market interests with development interests using voluntary sustainability standards. QCI also spoke in a session on the UNFSS Third Flagship Report, discussing the work of the world's first national platform on PSS which has been established under QCI.

During discussions with Mr Bonapas Onguglo, Chief, Trade Analysis Branch, UNCTAD, it was informed that QCI is going to launch an SDG Mapping service for voluntary sustainability standards and some flagship initiatives of organisations to map their alignment with the SDGs.

FOLLOW-UP ACTION(S)

As an outcome of the discussions that took place with representatives from UNFSS, certain activities and projects will be taken up by QCI in collaboration with UNFSS and other partner national platforms to eliminate the issues in the PSS ecosystem. For these initiatives, the operational framework is to be established by UNFSS. There will be exchange of officials within the Platforms. Training and Capacity Building will be carried out by UNFSS and its partners, and the seed money will also be organized by UNFSS and its partners. QCI will be assisting Brazil National Platform with inputs for the Convention that they are organizing (if requested).

Briefing the Deputy SG, UNCTAD about ICSTS

Speaking at the T4SD

Presenting India PSS Platform

Attending NTMs Week workshop with Ms. Miho, UNCTAD

Networking with Members of UN and Brazil Platform

Receiving appreciation letter at NTMs Week

As panellist at the NTMs Week showcasing activities of the PSS Platform

{ Progress cannot be generated when we are satisfied with existing situations"
- Taiichi Ohno

ZED: Holistic Montage of Quality

The world is undergoing rapid changes in terms of standards of quality, innovation and automation of industries. However, only those few manage to edge others out which remain farsighted in their vision of holistic improvement

Industries, which do not approach improvement techniques in silos, and rather have a definitive vision of overall improvement, tend to succeed better than rival industries.

Toyota was a pioneer in understanding how industries need to improve in a holistic manner and not just remain focussed on the output product. *Jidoka*, one of the concepts of Toyota Production System, was a breakthrough technique by which faults could be spotted at any stage and corrections could be made hence-after, without affecting other processes. Concurrently, Toyota was also focussed on minimising the inventory and introduced the concept of Just-In-Time (JIT), which was all about making what is needed, when it is needed at every stage of production. They also focussed on reducing the time it took to incorporate the production order received into the production line. Concept of *Hoshin Kanri* introduced the concept of goal setting along with means to achieve it, making measurement and monitoring of targets

integral to the possibility of achieving them well within the desired time. With several other concepts, Toyota Production System is still known to be the benchmark standard of production, which companies aspire to learn and adhere to.

Zero Defect Zero Effect (ZED), an indigenous maturity model, takes a leaf from the book of TPS and helps in revolutionising the standards of MSMEs in terms of awareness, productivity and profitability. Let us see how ZED has amalgamated the best methodologies into one single standard and re-defined the approach towards improvement for the MSME sector.

It is well known that the MSME sector, especially in India, is largely labour-intensive. Out of several problems that affect this sector, resource constraint forms a key part. It is hence prudent to extract the maximum out of available resources, human and financial, and enhance productivity.

To start with, any industry, small or large, needs to understand the common principle of "Profit = Earning-Expense." As every industry strives for maximum profitability, it is natural to do any of the following things: either *Maximise Earnings*

or Minimise Expenses. The ideal situation will be to attain both.

Another concept that needs to be understood at this point is the concept of **'unrealised losses'**. Unrealised loss is the surplus amount that could have been earned if systems and processes would have been robust. For example, a clean 36W tube light gives more illumination than a dirty 40W tubelight, and saves electricity by 8-10%. So, basic cleaning of tubelights could have resulted in surplus amount in the operating profit because the 'unrealised loss' of dirty 40W tubelights using more electricity and providing lesser illumination could have been eliminated. ZED mentions 5S as a key metric to focus upon and makes MSMEs aware of the importance of department wise 5S audits to ensure basic hygiene and standardisation of the work place.

Let us move on to another critical inhibitor of profit maximisation: waste. *Waste* is anything that does not add value. It is something that the customer will not pay for. The commonly understood *7 wastes: Transport, Inventory, Motion, Waiting-time, Over production, Over processing and Defects* are hence important to be classified and handled individually.

The 7 wastes

Overproduction • Waiting • Transportation • Over Processing

Inventory • Motion • Rework
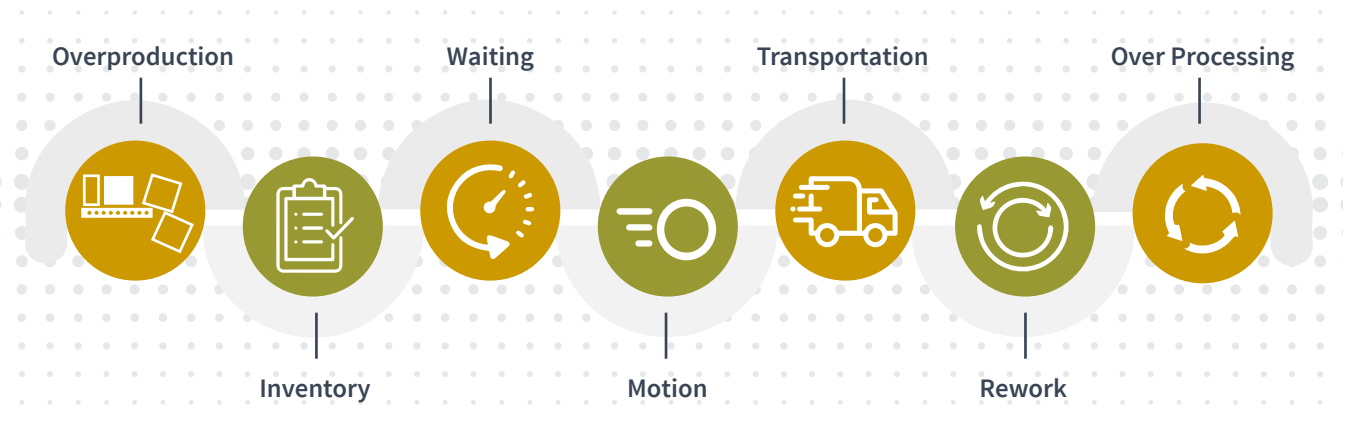
ZED helps MSMEs by making them identify each of these wastes and making them aware of the mechanisms to handle them. Focus on customer feedback, adherence to design requirements, improvising on plant layout, enhancing the system of transportation and storage, regular planned maintenance of machines, implementation of process control and process validation in the ZED model helps MSMEs make the waste visible, be conscious and accountable for the waste generated, helps them measure the waste and finally eliminate them.

Focus on planned maintenance, autonomous maintenance and introduction of concepts like Mean Time To Repair (MTTR) and Mean Time Between Failures (MTBF) to measure effectiveness of maintenance is critical to prevent unnecessary downtime of machines and breaks in process flow. MSMEs are slowly and steadily, through these ZED parameters, making a paradigm shift towards making these improvements measurable. By large-scale implementation of ZED, it thus becomes easier then to track the progress and develop an ecosystem, which can define the maturity growth rate of the MSME sector.

Employees form the backbone of MSMEs

Employees form the backbone of MSMEs and due to lack of resources employees often have to work in a cross-functional domain. This gives them vast hands-on experience about the systems and processes. Also, for this to remain sustainable, employees need to remain motivated at their work place. It becomes

ZED also stresses upon *safety* as an extremely pivotal pillar for sustainable growth of any industry and helps MSMEs in understanding the ways of addressing the safety needs and requirements. It attempts to make MSMEs understand the importance of recording and monitoring accidents, if any, happening in the industry premise. It makes the MSME aware of categorising accidents into Near Misses, Loss Time Injuries, Temporary Disabilities, Permanent Disabilities and Fatal Accidents.

Laying ZED addresses the global call for saving our environment from further damage by helping MSMEs pay attention to the environmental compliances and methodologies of minimising release of untreated emissions and effluents into the environment. With a number of SDG targets linked to the environmental needs and sustainable production, it is worth highlighting the role of MSMEs in contributing towards attainment of those.

As MSME sector forms the backbone of Indian economy, this first-of-its-kind holistic maturity assessment model of ZED will not only standardise the metrics of improvement for this sector, but will be instrumental in putting India into the driver's seat in realising its dream of becoming a manufacturing hub also. It is time we accept the fact that a revolutionary change in manufacturing has already started and that ZED will slowly expand globally to put a stamp of Indian manufacturing ecosystem on the world map. ZED- The Change Begins!

crucial for any MSME to extract maximum output from these experiences. Top management thus needs to involve employees in the bottom line to contribute more in achieving the common goals of the industry. ZED, through its parameters, lays a lot of impetus on employee involvement activities and their proper utilisation. Focus on creation and adherence of skill matrix for employees, engaging employees in Kaizen activities/ quality circles are few of the many areas that ZED looks into to help MSMEs devise a systematic mechanism of utilising the potential of their employees in a much more efficient manner. Involvement of employees through Daily Work Meetings helps the MSME attend to gaps/problems collectively making it simpler to solve it. *Nemawashi*, a TPS concept, stresses on engaging with people and taking their feedback before bringing about a change. ZED also helps MSMEs understand the need of involvement through different mechanism. Similarly, ZED also suggests MSMEs to adapt measures like reward & recognition, etc. to keep the employees motivated.

{ The Modules, while explaining the basic theoretical aspects, emphasize on the applied water pollution areas

A New eLearning Course On Water Pollution Monitoring, Prevention & Control (WP)

Environment Impact Assessment (EIA) Reports are prepared to identify and assess the probable impacts, positive or negative, on the various facets of environment from proposed developmental and industrial projects

Along with the EIA, an Environment Management Plan (EMP) is also prepared which details out the mitigation measures to minimize the negative impacts of the project on the environment. EIA, together with EMP, completes the report. EIA-EMP Reports are required for obtaining environmental clearance for most of the projects in our country as per the EIA Notification of 2006 under the Environment (Protection) Act 1986.

Preparation of EIAs requires knowledge about the concerned Sector of the Industry/ Developmental project and its environmental, ecological and social ramifications. These reports require multi-disciplinary inputs related to land use, air pollution, water pollution, noise and vibration, Geology, Hydrogeology, Ecology, Socio-economy etc. Thus, for preparation of EIAs, experts in 12 areas of expertise called Functional Area Experts (FAEs) are required. The person coordinating the study is called the EIA Coordinator (EC).

National Accreditation Board for Education and Training (NABET), being the national accreditation body, developed an Accreditation Scheme for EIA Consultant Organizations. The Scheme details out the expertise and facilities required by a consultancy organization wishing to conduct an EIA-EMP study and define the criteria of assessment. The Ministry of Environment, Forests and Climate Change (MoEFCC) mandated, first by an Office Memorandum on Dec 2, 2009 and then through a Notification dated March 3, 2015 that only consultants accredited under the NABET Scheme can prepare and present EIA-EMPs to the regulatory authorities for obtaining environmental clearances.

As a part of NABET initiative for capacity building of the EIA Consultant Organizations in the country, the course on Water Pollution Monitoring, Prevention and Control (WP) will exclusively cover relevant knowledge and systematic training to professionals on water pollution and water quality useful from the point of view of EIA. The aim of this course is to develop the understanding about water pollution and water quality among ECs and FAEs. In this course we will discuss the impact of water pollution on human health, animals, monitoring and water quality as per the regulation to minimize the water pollution along with its prevention.

What you will learn?

The Modules, while explaining the basic theoretical aspects, emphasize on the applied water pollution areas. The various issues are explained with examples which will help you understand how the actual field becomes applied. The broad coverage of the 5 Modules are as under:

MODULE 1

Basics of water and waste water, water budget, water audit, water conservation, rain water harvesting

MODULE 2

Rules & regulations applicable to water and wastewater

MODULE 3

Water and wastewater sampling, monitoring, testing/analysis and interpretation of data

MODULE 4

Treatment processes for water and wastewater

MODULE 5

Identification and assessment of impacts including water quality modelling

Benefits of Certification

Going through the Air Pollution Training Modules will:

• Equip the student to appreciate the applied aspects of this field improving his/her chances of employment in the environment profession

• Experienced experts may refresh their knowledge and skill helping them in their professional work even as a freelancer

• Improve his/her chances to be approved as FAE in Water Pollution and quality under the QCI-NABET Scheme

Project Planning and Implementation Division (PPID)

High-End Cleanliness Project in Gujarat

QCI has been partnering with the Gujarat government since October 2017 as a super monitoring agency for maintaining cleanliness and sanitation related services at some of its key Tourist locations and Yatradhams. Details of these are as follows:

Statue Of Unity

Tourism Corporation of Gujarat Limited (TCGL) awarded the contract for conducting high-end cleanliness assessments in and around the world's tallest statue, Statue of Unity, in October 2018.

QCI is conducting assessments at the location twice a month and provides a monthly report to TCGL briefing them about the cleanliness level at the location and areas of improvement, if any.

A location is assessed across three broad categories, namely:

1. Documentation
2. Direct Observation &
3. Public Feedback

There are 18 indicators across these categories which assess manpower deployment, dustbin availability and visibility, records of stock, burning and dumping of waste, swachhta related activities etc.

Ranking of locations is done based on the final score and suggestions for improvement are provided to the respective agency.

High-End Cleanliness at 8 Yatradhams

Gujarat Pavitra Yatradham Vikas Board (GPYVB) engaged QCI in October 2017 to conduct monthly high-end cleanliness assessments of their famous **eight yatradhams** *(Somnath, Dwarka, Ambaji, Dakor, Palitana, Girnaur, Shamlaji & Pavagarh)* that attract highest tourist footfall in Gujarat.

Each location is assessed once a month and a monthly report consisting of the performance scorecards, cleanliness indexes, analysis etc. is developed by the team to keep GPYVB informed of the work being done by the cleaning and monitoring agencies at these locations.

With the first year of assessments completed and reports submitted to the GPYVB, the project was extended for another 6 months till March, 2019 to continue the work being done at the locations.

Shree Somnath Jyotirling Temple

"So long as you do not take the broom and the bucket in your hands, you-cannot make your towns and cities clean"

– *Mahatma Gandhi*

Cleanliness Project in **Gujarat**

Cleanliness at 48 Tourist Locations

TCGL engaged QCI in February 2018 as a super-monitoring agency for conducting assessment and evaluation of the cleanliness work being undertaken at 48 identified tourist locations in Gujarat.

Each location is assessed twice or thrice in a quarter depending on its importance and popularity from the perspective of tourist footfall. The findings of the assessments are furnished in the form of a quarterly report and submitted to TCGL for their review.

Study, Analysis and Development of Action Plan based on World Economic Forum (WEF) Ranking System for Travel & Tourism Competiveness Index (TTCI) for India

The World Economic Forum (WEF), for the past 11 years, has engaged leaders in travel and tourism to carry out an in-depth analysis of the Travel and Tourism competitiveness of various economies across the world. The main aim of the TTCI is to create a healthy competition in the travel and tourism sector of various economies by ranking them on the basis of pre-defined parameters. The WEF, every alternate year, releases a TTCI report which ranks various economies based on **14 pillars (categories) which is further subdivided into 90 indicators.**

As the report constitutes a global perspective, the entire methodology is summarised on the basis of two distinct types of research:

1. Secondary data research (Hard Indicators)

2. Impact assessment and opinion-based survey (Executive Opinion Survey)

QCI was engaged by the Ministry of Tourism (MoT) to study the TTCI report of WEF Report 2017 with a mandate to formulate a detailed action plan for respective ministry sensitisation with a focus on increasing India's performance in coming years.

Following steps were followed by QCI for the study of the report:

Step 1: Detailed analysis of the report

TTCI reports for 4 years (2011, 2013, 2015 and 2017) were studied in depth for analysis purpose. Change in sub-indexes, pillars and indicators from year 2011 until 2017 were identified.

Step 2: Estimation of weightages

Weightages for 90 indicators and 14 pillars has been estimated by applying unweighted average formula.

Step 3: Ministry Identification

After mutual discussion with MoT, ministry and their responsible departments were identified for each indicator where for few of the indicators an unstructured questionnaire was used to get more insights about their data source, means of data submission and challenges faced by them. The insights collected here helped further while computing a comprehensive action plan.

Step 4: Benchmarks Identification

Benchmarks were identified for each indicator; countries were benchmarked based on their best policies/strategies that they are implementing to perform better in the respective indicators. These policies were considered as global best practices and were recommended for respective indicators.

Step 5: Calculation of each Indicator Score

Normalization of each indicator's score was done and by using unweighted average formula the countries' score was arrived at. Analytics-driven optimization scripts were then executed to arrive at the accurate formulae specific parameters used hitherto by the WEF in normalizing indicators' scores to a scale of 1-7. Once a relation between the indicator scores and pillar scores was rationalized, a direct impact of change in the score of all given indicators on the country's score was computed.

Step 6: Trend Analysis

Analysis of the trend through study of historic surveys of WEF with focus on evolution of methodology, change of indicators, change in weightages, change of sampling techniques, calculations to arrive at scores etc. was done to bring out action plans for each indicator.

Step 7: Detailed and Focused Action Plan

Detailed and Focused Action Plan with the objective of improving India's rank in the forthcoming TTCI Report was studied indicator wise and improvement expected from the proposed interventions were highlighted.

Health Information System

-Dr Manu Gupta, Accreditation Officer, NABH

Healthcare is undergoing a paradigm shift, moving from 'Industrial Age Medicine to Information Age Healthcare[1]. This 'paradigm shift' is shaping healthcare systems[2] and transforming the healthcare patient relationship[3]. The World Wide Web has transformed the way the public interact with health information.

Sound and reliable information is critical for decision-making in healthcare organizations. An effective health information system is essential in implementation and governance, health research, human resource management, health education and training, health service delivery and financing. Health information system captures the interaction between people, process and technology, which further support operations, and hence improve the quality of healthcare services. The aim of health information systems is to contribute to a high-quality and efficient patient care services.

Health information system captures, stores, manages and transmits information related to the health of individuals or for the day-to-day activities of organisations that work within the health sector such as district-level routine information system, disease surveillance system including laboratory information system, hospital Patient Administration Systems (PAS) and Human Resource Management Information Systems (HRMIS) to provide guidance on planning and gives direction to the activities.

1. Smith, R., The future of healthcare systems, BMJ 314 (1997) 1495–1496, 1997.

2. Haux, R., E. Ammenwerth, W. Herzog, P. Knaup, Health care in the information society. A prognosis for the year 2013, Int. J. Med. Inform. 66 (1–3) 3–21, 2002.

3. Ball, M.J., and Lillis, J., E-health: transforming the physician/patient relationship, Int. J. Med. Inform. 61 (1) 1–10, 2001.

An effective information system is based on the information needs of the organization. The system is able to record, transmit, store, analyze, utilize and retrieve information as and when required for improving clinical outcomes as well as individual and overall organizational performance. Data from various sources are used by multiple users at different levels of the healthcare system, and each user has a specific purpose of the information generated.

At an **individual** level, data about the patient's profile, healthcare needs, and treatment serve as the foundation for clinical decision-making. Healthcare records provide the basis for sound individual clinical care, it can either be a manual/paper-based system or digitalized. **Health facility**-level data, which includes the aggregated facility-level records and from administrative sources such as drug procurement records, enable healthcare managers to determine resource needs, guide purchasing decisions for drugs, equipment, and supplies, and also for developing community outreach. Data from health facilities can also provide immediate and ongoing information relevant to public health decision-making. For example, the public health surveillance system is very useful in case of epidemics. **Population**-level data is important for public health decision-making and generate information not only for those who use the services but also, crucially, for those who do not use them. For example, household surveys have become a primary source of data in developing countries where facility-based statistics are of limited quality.

Health Information System (HIS) is one of the six building blocks of an equitable health system (others being service delivery, health workforce, medical products, financing, leadership, and governance). Cross-cutting components, such as leadership/governance and information systems, lay the foundation for the overall policy and regulation of all the other health system blocks. Availability of accurate and timely information and understanding of how to use them effectively in the health system are critical components for evidence-informed decision-making, which are provided by HIS. The information system works effectively and efficiently when there is consistency and integrity in the interaction among the human, supplies, and process aspects. It is not an independent component of the healthcare system, but rather, it should be designed according to the service delivery system as a whole.

{ Data from health facilities can also provide immediate and ongoing information relevant to public health decision-making

Artificial Intelligence in Manufacturing

**-Dr. Indrajit Bhattacharya, Director, NABET**

Artificial Intelligence (AI) is poised to disrupt our world

With intelligent machines enabling high-level cognitive processes like thinking, perceiving, learning, problem solving and decision making, coupled with advances in data collection and aggregation, analytics and computer processing power, AI presents opportunities to complement and supplement human intelligence and enrich the way people live and work. India, being the fastest growing economy with the second largest population in the world, has a significant stake in the AI revolution.

AI is a constellation of technologies that enables machines to act with higher levels of intelligence and emulate the human capabilities of sense, comprehend and act. Thus, computer vision and audio processing can actively perceive the world around them by acquiring and processing images, sound and speech. **The Natural Language Processing** (NLP) and inference engines can enable AI systems to analyse and understand the information collected. An AI system can also take action through technologies such as expert systems and inference engines or undertake actions in the physical world. These human capabilities are augmented by the ability to learn from experience and keep adapting over time. AI systems are finding ever-wider application to supplement these capabilities across enterprises as they grow in sophistication.

AI Technologies

- Sense
- Comprehend
- Act
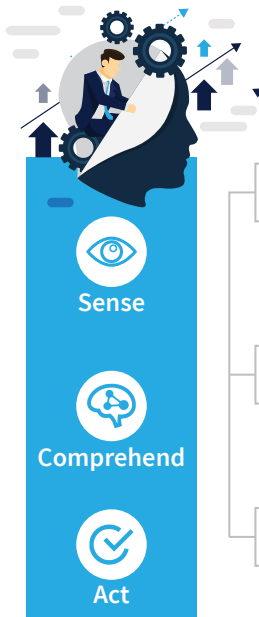
- Computer Vision
- Audio Processing

- Natural Language Processing
- Knowledge representation

- Machine Learning
- Expert Systems

Illustrative Solution

- Virtual Agents
- Identity Analytics
- Congnitive Robotics
- Speech Analytics
- Recommendation Systems
- Data Visualisation

Machine Learning (ML):

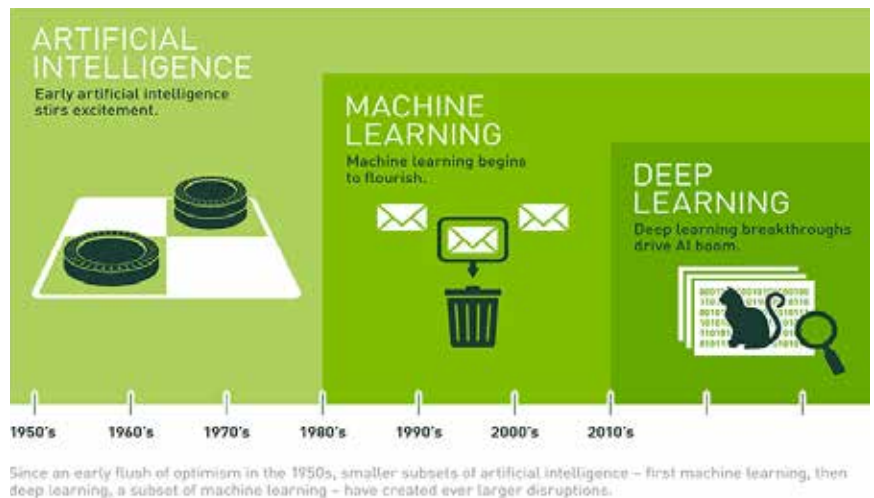Ability to learn without being explicitly programmed

Deep Learning:

Technique for implementing Machine Learning. Inspired by the structure and function of the brain (interconnecting of many neurons)

Artificial Neural Networks (ANNs):

Algorithms that are based on the biological structure of the brain

Since an early flush of optimism in the 1950s, smaller subsets of artificial intelligence – first machine learning, then deep learning, a subset of machine learning – have created ever larger disruptions.

Opportunity: **The economic impact of Artificial Intelligence for India is emerging as a new factor of production, augmenting the traditional factors of production viz. labor, capital and innovation and technological changes captured in total factor productivity.** AI has the potential to overcome the physical limitations of capital and labour, and open up new sources of value and growth. From an economic impact perspective, AI has the potential to drive growth through enabling:

a. Intelligent Automation i.e. ability to automate complex physical world tasks that require adaptability and agility across industries

b. Labour and Capital Augmentation: enabling humans to focus on parts of their role that adds the most value, complementing human capabilities and improving capital efficiency, and

c. Innovation Diffusion i.e. propelling innovations as it diffuses through the economy

AI innovations in one sector will have positive consequences in another, as

industry sectors are interdependent based on value chain. Economic value is expected to be created from the new goods, services and innovations that AI will enable.

Manufacturing industry is expected to be one of the biggest beneficiaries of AI-based solutions, thus enabling **'Factory of the Future'** through flexible and adaptable technical systems to automate processes and machinery to respond to unfamiliar or unexpected situations by making smart decisions. Impact areas include:

- engineering (AI for R&D efforts)
- supply chain management (demand forecasting)
- production (AI can achieve cost reduction and increase efficiency)
- maintenance (predictive maintenance and increased asset utilisation)

- quality assurance (e.g. vision systems with machine learning algorithms to identify defects and deviations in product features)
- and in-plant logistics and warehousing

Adoption of AI by various sectors has been influenced by, among other factors, technical and regulatory challenges, but commercial implications has been the biggest determinant. While technical feasibility, availability of structured data, regulatory barriers, privacy considerations, ethical issues, preference for human relationship have all played their roles in determining the readiness of a sector for large scale AI adoption; compelling business use cases **(e.g. improved efficiency, accuracy, speed, forecasting and accurate decision making)** that lead to direct impact on revenue and profitability have been the biggest driver for companies to pursue accelerated adoption of AI.

Manufacturing sector, primarily automotive and assembly, has been one of the first sectors to implement advanced robotics at scale. The manufacturing sector in India hasn't been far behind, as reflected in a recent study by BCG, where India was ranked 3rd in the world in AI implementation in manufacturing, ahead of nations such as Germany, with 19% of companies in the sector already using AI to a significant extent.

These trends have also been reflected in the nature of investment in research in India, with private sector initiatives such as the Robert Bosch Centre for Data Science and Artificial Intelligence (RBC-DSAI), choosing to focus their efforts in applied research on sectors such as manufacturing analytics and financial analytics.

AI has the potential to add ~1 trillion to India's economy in 2035

India's GVA in 2035 (US$ billion)
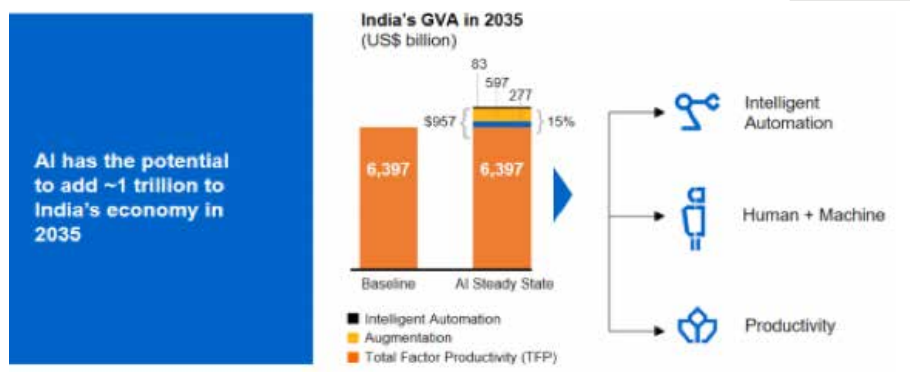
References: Excerpts from Discussion Paper National Strategy for Artificial Intelligence; NITI Aayog, 2018

Lean Implementation in MSME – M/s Balaji Industries, Belgaum, Karnataka

Cluster Name: Automotive Transmission Parts Manufacturing Lean Cluster

About us

- A small unit "**M/s BALAJI INDUSTRIES**" started in the year 1997 by Mr. B H Patil, by procuring a loan from KSFC, started with one lathe, one milling machine & with one operator, has now grown to the tune of few Computer Numeric Controls (CNCs), Vertical Milling Centres (VMCs) and Co-ordinate Measuring Machines (CMMs) with an annual turnover of Rs 1.6 Cr. With limited customer base the unit is processing gear blanks with very high level of accuracy consistently from the last 18 years. It's an ISO 9001-2015 certified unit with Lean Manufacturing activities in place.

- Our mission is to deliver quality products with high level of accuracy by standardizing and modernization. To enhance standard of living of our people and to grow to the tune of Rs. 70 Cr. turnover per annum by 2023.

- This lean road map has taught us how to empower our men to the grassroot, the data excess that we provide to our

men according to their needs to solve problems and empower them to use it, helped us to change their mindset. They no longer simply do what they are told to do, rather they engage in continuously improving work practices to eliminate waste and drive productivity and value.

- Industry 4.0 concept implementation gives us the data required and helps to set up traceability in production and supply, to provide the information needed to ensure that we are operating in a productive, transparent, ethical and sustainable way. Lean activities are people oriented and help to do their jobs better and with ease.

Zone leaders, along with their team, have converted their ideas into more than 45 Kaizens and some of them into Pokayoki's during MBR 3 to MBR 5. Out of these Kaizens we would like to elaborate a few:

- Auto application of rust preventive oil to all finish machined parts.
- SMED trolley for CNC turning centers
- Shadow boards for all measuring instruments and tools
- Industry 4.0 implementation
- Morning meetings
- Work force trainings and review
- Material movements and transfers

Auto application of rust preventive oil to all finished parts of the machine

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Analysis:

Oiling was done manually by hand by helpers. Manpower required was more. There were possibilities of human error and time taken was more which used to lead in parts getting rusty.

Result:

To reduce the issue of parts getting rusty an auto oiling machine is designed in-house. With the help of this machine oiling is done in an easy way. There are less chances of human error. This machine reduced man power and time required for oiling the parts manually.

SMED trolley for CNC turning centers

___

Analysis:

Setting time was very high because of unavailability of material required for setting. Searching time and motion time was more.

Result:

SMED trolley introduced, with all the material necessary for setting like mallet, soft jaws, tooling, setting rings, bolts, spanner etc. kept in one place.

Searching time & motion time reduced and most importantly setting time is also reduced.

Post Implementation Image

Shadow boards for all measuring instruments and tools

Analysis:

No proper place was there to keep instruments, blocks, tools & masters. All were kept in a rack mixed with one another.

Result:

Shadow board introduced and particular item is kept in its specific place neatly & systematically. This reduced the time required for searching an item and also reduced the possibilities of instruments, tools getting damaged.

Morning meetings

Analysis:

Lack of co-ordination among team leaders. Work synchronization was not proper, low production & low through-put yield.

Result:

All zone leaders assemble every day at a particular time in the morning & discuss, review, suggest about production details, quality and daily whereabouts. This, in turn, giving good results in terms of co-ordination, through-put yield, quality orientation, new ways to eliminate wastes, 3M and optimum utilization of resources and of course meeting targets set by the organization with ease.

Work force trainings & review

Analysis:

Random working style, lot of quality & production issues.

Result:

Training the operators is leading to disciplined way of working, rejection PPM levels have come down, lot of SOPs developed, involvement of work force enthusiasm, morale improved. 5S, TPM, Kaizens, 3M activity trainings have led to change of mindset.

Material movements & transfers

Analysis:

Transportation of material from one shed to another was difficult and time consuming. Needs more man hours and energy.

Result:

Introduced custom made transport auto, bins and pallets. Now only one person can transport more number of parts within a stipulated time which eliminates Muda & Muri.

M-01
Speed	Feed Rate
0	0

Program: B

M-02
Speed	Feed Rate
1600	288

Program: O0157

M-03
Speed	Feed Rate
0	0

Program: B

M-04
Speed	Feed Rate
0	0

Program: B

M-05
Speed	Feed Rate
1300	236

Program: O0853

M-06
Speed	Feed Rate
1300	0

Program: O0851

M-09
Speed	Feed Rate
1050	0

Program: O0807

M-10
Speed	Feed Rate
1000	403

Program: O0808

CVM 640
Speed	Feed Rate
0	0

Program: B

Left Form

6	MANPOWER – PREVIOUS DAY							SHIVAKUMAR V.J	05Min
	CNC	/9	LATHE	/5	VMC	/4	QUALITY: /3 HELPRS /7		

REASON :

7	QUALITY ISSUE AT CUSTOMER END PPM (PREVIOUS DAY)	NILESH P.	05Min

FAIL :
REASON/ ACTION

8	QUALITY ISSUE IN HOUSE PPM (PREVIOUS DAY)	NILESH P.	1Min

INHOUSE REASON/ ACTION

9	MAINTENANCE	1Min

Monday Preventive Maintence :

1st Monday monthly Preventive Maintence :

10	REQUIRED FORGING & BAR STOCK	QTY	REQUIRED FORGING & BAR STOCK	QTY

11	STOCK (FORGINGS) [Inhouse – Every Monday]								1Min
	PART	LATHE	CNC	VMC	TOTAL	PART	LATHE	CNC	VMC	TOTAL
	2400TST					2005 00001				
	2400TST					Axle shaft				
	TST Kane					Adaptor				
	20040 0TST					VT500 001				

12	LEAN ACTIVITIES [Every Monday]			SHIVAKUMAR V.J	25Min
	5'S %	Red Tag	PPP	WPP	

REMARK :

8 Wastes :	3 M :	Kaizen :
SMED :	SOP :	VSM :

13	E-MAILS [Inward And Outward]

14	POSITIVE THOUGHTS

15	ATTENDANCE	
	1 E. H. PATIL	6 NILESH P.
	2 SHIVAKUMAR V.J	7 SHRIDHAR K.
	3 RAVI M.	8 BASUF
	4 P. SUNDKAR	9 NARAYAN P.
	5 S. HIREMATH	

Right Form

BALAJI INDUSTRIES	REV NO : 02 DATE : 16.6.18
MACHHE INDUSTRIAL AREA, MACHHE, BELAGAVI, KARNATAKA	DATE : 8 Feb-19
	TIME : 11:30 AM

1	PLANNED & ACHIVED			RESPONSIBILITY	TIME
	PREVIOUS DAY ACTIVITIES		SALES	PRODN	SHIVAKUMAR V.J	05Min
		TARGET :	XXX	XXX		
		TILL DATE :	XXX	XXX		
		BALANCE :	XXX	XXX		
		TODAY'S TARGET :	XXX	XXX		

2	TODAY DISPATCH					BASU P.	1Min
	PART NAME / NUMBER	QTY	AMOUNT	PART NAME / NUMBER	QTY	AMOUNT	

3	OEE (ACHIVED AT PREVIOUS DAY)					SHIVAKUMAR V.J	2Min
	CNC	PERCENTAGE	VMC	PERCENTAGE	LATHE	PERCENTAGE	

Reasons For less Percentage :

How to resolve :

4	TOMORROW'S PLANNING				RAVISH, HIREMATH	05Min
	M/C NO	PART NAME/NUMBER	QTY	M/C NO	PART NAME/NUMBER	QTY	

5	PRODUCTION PLANNED & ACHIEVED (YESTERDAY 1st & 2nd SHIFT)									RAVISH & HIREMATH R SUNDKAR	2Min
	CNC / VMC				RTB SECTION			VENDOR			
	PLANNED		TARGET	ACHIEVED	ITEM NAME	TARGET	ACHIEVED	ITEM NAME	TARGET	ACHIEVED	
	M/C	PART									
	M02										
	M04										
	M05/06										
	M09/10										
	M101										
	M102										

Testimonials: Lean Manufacturing Competitive Scheme (LMCS)-Katwe Industries, Belgaum, Karnataka

Cluster Name: Automotive Transmission Parts Manufacturing Lean Cluster

Katwe Industries started in the year 1989 with fabrication activities, later on moved into providing machining services to companies like Hindalco Industries Ltd., Belgaum; Weir BDK Valves, Hubli & Fairfield Atlas Ltd., Shinoli etc. Machining capacity consists of CNC Machines, VMC Machine, Cylindrical Grinding Machines and Conventional Lathe Machines. It also caters Structural Fabrication services to Hindalco Industries.

Based on the requirement from customers, Katwe Industries started manufacturing own products: Butterfly and Balls Valves. Further, in the field of structural engineering and precision component manufacturing through continuous improvement, in all processes, efficient utilization of resources and good working environment.

Lean Implementation Journey

The Lean Journey started from Aug 2017. During these 18 months of journey Katwe Industries learned about OEE (Optimum Equipment Effectiveness), Capital Productivity, Labour productivity, Elimination of hidden wastages, Reduction in Lead Time with the help of Value Stream Mapping (VSM) and new ideas converted to Kaizens. It also learned to educate and train its

employees to make cultural and behavioral changes in attitude of the employees. After implementation of Lean Principles, the company has grown and saved Rs.14.00 lakhs only through elimination of wastes & improvement in its processes. This has helped directly/ indirectly in the growth of customers (through Reduced PPM) .

Katwe Industries is very happy to be associated with QCI and MoMSME through whom we are able to achieve what we could not all these 25 years. We are very much thankful to Govt. of India's Lean Cluster program, our customers Fairfield, Atlas , Shinnoli and Mahindra & Mahindra , because of whom we are a part of LMCS of GoI program. They are a focused team of self-motivated individuals, post lean implementation journey.

Katwe has eliminated 93 number of Non Value Added process, introduced 36 no's Kaizens with the help of team members. Some of the Kaizens as follows:

Centralized Coolant System

Project Problem

Filling coolant manually to all CNC machines - Resulting in wastage of 3 Man Power for 3Hrs daily

Action Initiated

Kaizen

Problems Details

Previously we used to top-up/refill the coolant manually. A 200- ltr barrel was kept outside the CNC shop and used to mix coolant and water by stirring with a stick. The mixed coolant was then taken to individual machines manually by buckets for refilling/topping it up. For this refilling we used to spare 3 Persons for 3 Hrs each day. After implementation of Lean tools and techniques, we observed that unnecessary movement and minor stoppage of machines for refilling activity. This was costing the organisation annually Rs. 1,17,000/-, so it wanted to eliminate this waste and hence the KAIZEN.

Kaizen Theme

500-lit capacity tank is fitted on top floor of the building & pipe- line is laid all along the machines. For water inlet to tank piping is done. The outlet to each machine is fitted with a Ball valve and flexible hose. The required quantity of soluble oil is filled manually and water with pumpset. Now as the coolant is ready in overhead tank, the operators are able to top-up/refill the coolant into the machine by just opening and closing of the valve, without stopping of the machine.

Kaizen Idea

Centralized Coolant System

Before

After

Investment Cost

Tank & Pipe Lines	6620.00
Ball Valves	3460.00
Labour Charge	1500.00
Total Amount	**11,580.00/-**

Resulting Benefits

No need of additional man power for refilling the coolant into the machine. Operators can easily refill the coolant up to required level without machine stoppage. Unnecessary motion of helpers and minor stoppage of machine is eliminated. The saved manpower (3 man power 3 hrs daily) is utilized to carry-out other works.

> *After implementation of this KAIZEN, Katwe saved Rs. 1,17,000/- annually*

Introduction of Four-Jaw True Chuck in lieu of Face plate

Project Problem

Butterfly Valve body clamping on face plate and making outer diameter true w.r.t bore was difficult and more setting time required.

Problem Details

While machining (size:200mm to 300mm) the Butterfly valve bodies, the butterfly valve bodies were butted on face plate, clamping with bolt nuts and adjusting the outer diameter true w.r.t bore was difficult and only skilled operators could do it. The setup time required was more and hence delay in lead time. The time required for machining 2 bodies was 8 hours with all these setup.

Action Initiated

Kaizen

Kaizen Theme

Four-jaw true chuck is procured and started using to hold the outer diameter of the body enabling bore to be automatically true with respect to Outer Diameter. Here the time required to Machine 2 bodies is 3.20 hours (earlier for 2 bodies we used to take 8 Hrs).

Kaizen Idea

Four-Jaw True Chuck

Investment Cost

Four-Jaw True Chuck – Rs 21,690.00/-

Resulting Benefits

Setting time waste is eliminated
Reduction in Lead time
Reduced operator fatigue
Production increased

> *By this KAIZEN, Katwe saved Rs 64,800/- annually*

Before

After
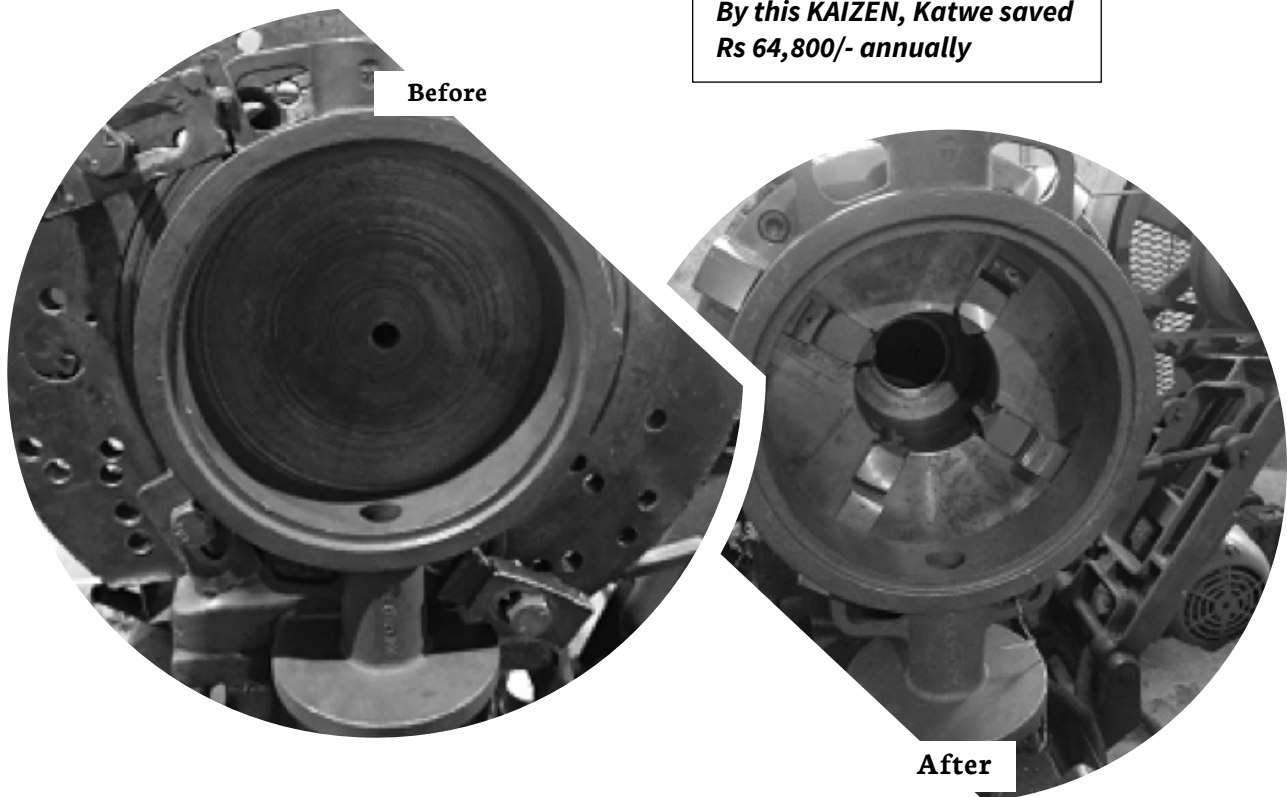
Lathe Machine fitted with Retrofit Controls

Project Problem

Lathe section operator's absenteeism, less output, rejections and rework issues facing since last 5 years.

Action Initiated

Kaizen

Problem Details

Since last 5 years we were facing the lathe operator's absenteeism, less output, rejection and rework issues. Skilled operators were on leave intermittently, were unable to dispatch the finished goods as per customer requirement. Also when skilled operators were on leave, rework/rejection percentages were more.

Kaizen Theme

The lathe machine is retrofitted and operator is able to handle two machines. As the machine is fitted with numerically controlled unit, the required programme can be made and the programme will take care of the correctness of dimensions.

Rework and rejections that would happen earlier is eliminated now. Operator skill is not required here. Only he has to load and unload the jobs.

Since one operator is able to handle two machines, there is saving in man-hours and also cycle time is reduced & the productivity increased.

Investment Cost

Retrofit Machine installation costs Rs 3,75,000.00/-

Resulting Benefits

Un-skilled Operators can work on this machine, Productivity increased, Efficiency increased, Reduced operator fatigue, Reduced Quality issues.

Material deliver on time, Annual Savings Rs.1,81,920/-

Before

After
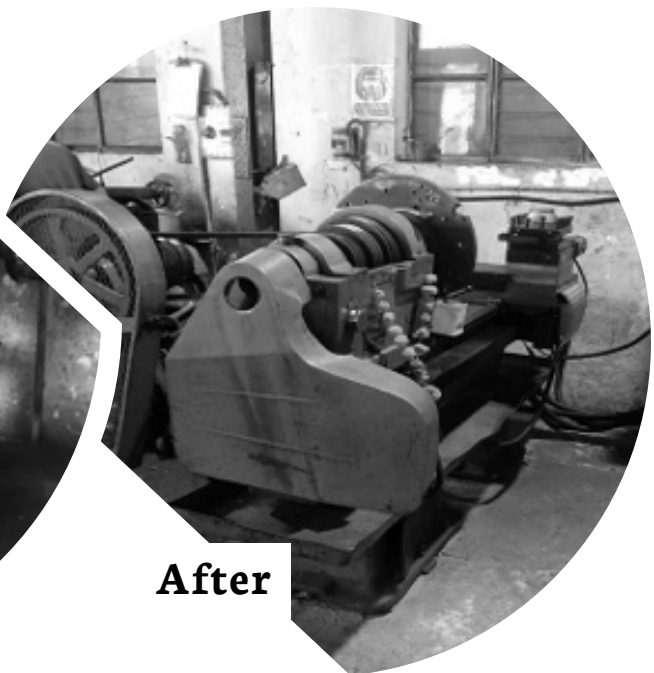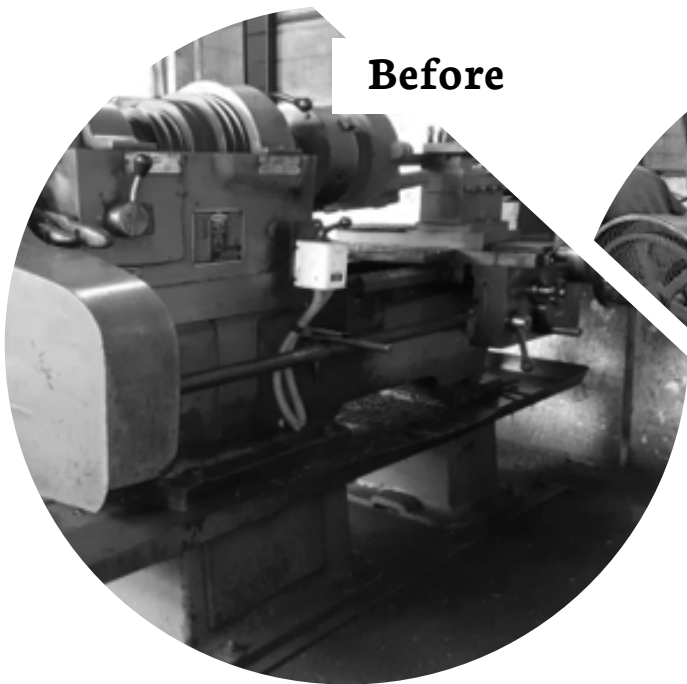
SMED Methodology Applied in Machining of Ring Gear D2500001 Component: Lean Manufacturing Competitive Scheme (LMCS) – Implementation by M/s Beejay Enterprises, Balgaum, Karnataka

Cluster Name: Automotive Transmission Parts Manufacturing Lean Cluster

Before starting

Our production team took up the challenge and executed a plan so that our company can get benefit from changeovers through SMED project in Lean Manufacturing.

The actual "Gold" standard for manufacturing performance data is measuring OEE (Overall Equipment Effectiveness) with an additional breakdown of OEE loss categories into the Six Big Losses and a detailed breakdown of OEE Availability losses into Downtime Reason (sixteen losses- including tracking changeover time).

The first priority team ensured that there is a clear understanding of where productive time is being lost, and that decisions on improvement initiatives are made based on hard data. That means putting a system in place to collect and analyse manufacturing performance data, thus our team started collecting that and took video recording of each and every activity and started to generate records. System is set for measuring manufacturing performance to collect data for at least two weeks to gain a clear picture of where productive time is being lost.

STEP 1

Identified Pilot Area - Initially target area for the pilot SMED program is selected. The ideal equipment /Jig/Fixture which will have the following characteristics:

In order to create a wide base of support for the SMED project, include the full spectrum of associated employees in the selection process, and work hard to create a consensus within the team to target equipment choice. After election of equipment, recorded a baseline time for the changeover in activity chart. Changeover time is measured as the time between production of the last good part (at full speed) and production of the first good part (at full speed).

Item	Description
Duration	Initial changeover is long enough (89.64 minutes) to have significant room for improvement, but not too long to be as to be overwhelming in scope
Variation	There is large variation in changeover times (e.g. changeover times range from one to two hours).
Opportunities	There are multiple opportunities to perform the changeover each week (so proposed improvements can be quickly tested).
Familiarity	Employees familiar with the equipment (operators, maintenance personnel, quality assurance, and supervisors) are engaged and motivated, through Lean management trainings.
Constraint	The jig/fixture/equipment is a constraint/bottleneck – thus improvements will bring immediate benefits. If constraints equipment is selected, minimize the potential risk by building temporary stock and otherwise ensuring that unanticipated downtime can be tolerated.

Step 2

Identify Elements (viz, 3Ms)

The team worked together to identify all the elements of the changeover in an effective way of doing this to videotape the entire changeover and then worked from the videotape to create an ordered list of elements, each of which includes:

- Description (what work is performed)
- Cost in Time

Item	Description
Elements Activity Record	For typical changeover 30 to 50 elements being documented. Noted a series of activities that are stuck to a wall in the order they are performed during changeover.
Man and Machine	Captured both "human" elements (elements where the operator is doing something) and "equipment" elements (where the equipment is doing something).
Other Notes	While videotaping, the changeover had observers taking notes. Observers also had noticed things that are missed in videotape.
Observe	Only observe – let the changeover take its normal course.

STEP 3
Separate External Elements

Activities of the changeover process that are being performed with little or no change while the equipment is running are identified and moved "external" to the changeover (i.e. performed before or after the changeover). Since it is not unusual for changeover times to be cut nearly in half with this step alone. Thus categorize the activities as external and move it before or after the changeover, as appropriate.

Examples of activities for such treatment include:

Item	Description
Retrieval	Retrieval of parts, tools, materials, and/or instructions
Inspection	Inspection of parts, tools, materials, and/or materials
Cleaning	Cleaning tasks that can be performed while the process is running
Quality	Quality checks for the last production run

After this step the team made an updated list of changeover elements that are split into three parts: External Elements (Before Changeover), Internal Elements (During Changeover), and External Elements (After Changeover).

Item	Description
Retrieval	Retrieval of parts, tools, materials, and/or instructions
Inspection	Inspection of parts, tools, materials, and/or materials
Cleaning	Cleaning tasks that can be performed while the process is running
Quality	Quality checks for the last production run

Step 4
Convert Internal Elements to External

The current changeover process is carefully examined, with the goal of converting as many internal elements to external as possible. Cost as measured by the materials and labour needed to make the necessary changes.

Benefit as measured by the time that will be eliminated from the changeover. Once the list has been prepared actual work begins on making the necessary changes.

Item	Description
Advance Preparation	Prepare setup parts and tooling in advance for the changeover
Jigs	Use of jigs/fixture (e.g. to perform alignment and other adjustments in advance of the changeover)
Modularize	Modularize equipment – Jigs/Fixtures replaced with one single plate
Modify	Modified existing setup elements

STEP 5

Streamline Remaining Elements

The remaining essentials are reviewed with an eye towards streamlining and simplifying so that they can be completed in less time. First priority is given to internal elements to support the primary goal of shortening the changeover time.

Techniques that are used to streamline essentials are:

The deliverable from this step: A set of updated work instructions for the changeover (i.e. created Standardized Work instructions) and a significantly faster changeover time!

Item	Description
Release	Eliminated Jigs/Fixtures bolts (e.g. use quick release mechanisms or other types of functional clamps)
Adjustment	Eliminated adjustments (e.g. use standardized numerical settings; convert adjustments to multiple fixed settings; use visible centerlines etc.)
Motion	Eliminated motion (e.g. reorganize the work space)
Waiting	Eliminated waiting (e.g. make first off parts inspection a high priority for QA)
Standardizing	Standardized hardware, tools are fixed in tool turret of VMC (e.g. Single plate and fewer tools are needed)
Operations	Created parallel operations (e.g. activities on multiple operators working on the same equipment with close attention to potential safety issue etc.)
Mechanize	Mechanize (normally this considered a last resort)

Accelerate Progress

When implementing SMED project, it was helpful to us to recognize that there are two broad categories of improvement:

Human (achieved through preparation and organization) and Technical (achieved through engineering)

Experience has taught that the human elements are typically much faster and less expensive to improve than the technical elements. In other words, the quick wins are usually with the human elements. Avoid the temptation, especially with technically proficient teams, to over-focus on technical elements. Instead, focus first on the human elements.

In general, the following chart illustrates this principle, showing areas of opportunity and improvements for SMED projects.
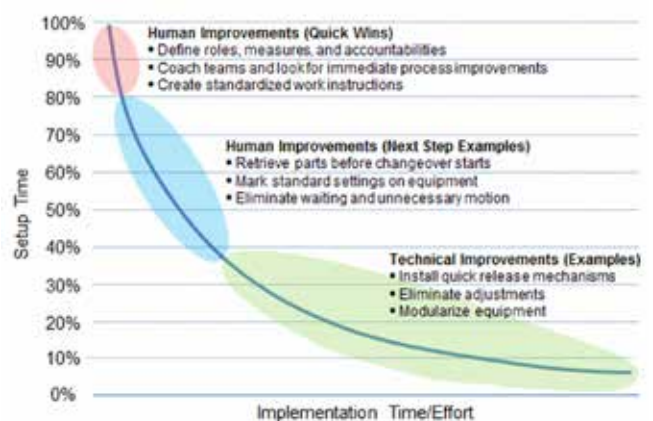
Benefits of SMED

- Lower manufacturing cost (faster changeovers mean less equipment downtime –elimination of sixteen losses)
- Smaller lot sizes (faster changeovers enable more frequent product changes)
- Improved responsiveness to customer demand (smaller lot sizes enable more flexible scheduling)
- Lower inventory levels (smaller lot sizes result in lower inventory levels)
- Smoother start-ups (standardized changeover processes improve consistency and quality)

Summary of achievements through SMED Projects

Item	BEFORE	AFTER
Asumed Setting Time	86.84 min	27.74 Min
External Setting Time	19.32 min	3.97 Min
Internal Setting Time	67.52 min	24.67 Min
Actual Setting Time At Video Shooting	89.64 min	30.04 Min

Cost Saving through SMED	
Before Changeover time	89.64 Min
After Changeover time	30.04 min
Saved/Setting (i.e. 59.60 X M/c Hour Rate Rs. 7.5/min)	Rs. 447.00
Annually Saving (48 Setting's)	Rs. 21456.00

Horizontal deployment for other products	
Ring gear - 300500001	Rs. 21456.00
Spindle - 706	Rs. 18000.00

We thank QCI for their valuable inputs on successful implementation of Lean Management in our organization. We have learned many valuable concepts through real-time examples, and will continue to apply what we learned beyond the classroom.

It has created an environment in which we feel free to ask questions and are always available for help with backup team. We have learnt to share knowledge, cross learning across the clusters. LMCS has given us training beyond syllabus and taught our team the importance of self-motivation and determination.

Our Social Media Presence
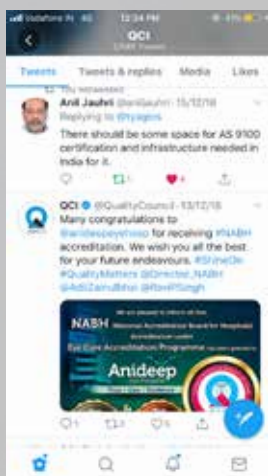
QCI
QUALITY COUNCIL OF INDIA
Creating an Ecosystem for Quality

NABET
National Accreditation Board
for Education and Training

"StandOut From
TheCrowd"

WHY CERTIFICATION BODIES SHOULD GO FOR **ACCREDITATION?**

Assures their competence and reliability

Promotes consistency and demonstrates equivalence of assessments

Is an indicator that the CB desires a competitive advantage by undergoing a voluntary evaluation

Greater quality awareness and enhanced communication as part of accreditation process

Sustained continual improvement through assessment of system effectiveness, efficiency and competence

Working towards the goal of "certified once – accepted everywhere."

Encourages confidence in all stakeholders because of regular, impartial, independent assessments by an Accreditation Body with international membership

Quality Council of India | National Accreditation Board for Education and Training
ITPI Building, 6th Floor, 4 – A, Ring Road, I P Estate, New Delhi – 110002

National Accreditation Board for Testing and Calibration Laboratories

Board Updates

f **@QualityCouncilofIndia** 🐦 **@QualityCouncil** 📷 **qualitycouncilofindia**

INTERNATIONAL PARTICIPATIONS & UPDATES

IAF-ILAC JOINT ANNUAL MEETINGS 2018

International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) joint Annual Meetings were held in Singapore from 22nd Oct to 1st Nov, 2018

These meetings involved strategic planning to ensure that broader community and market place continue to gain benefits of accreditation. It provided a valuable platform for interaction and communication with other accreditation bodies, regional accreditation cooperation, stakeholders etc. CEO, NABL along with NABL officials participated in the meetings.

Training on ISO/IEC 17025:2017: For APLAC Member

NABL participated in the training for the new version of ISO/ IEC 17025:2017. The training was conducted for APLAC members from 13th to 15th Nov 2018 at Hong Kong.

South Asian Expert Group on Accreditation (SEGA) Meeting and attached training on Cooperation of Accreditation Bodies and Regulatory Bodies, Goa

Under the framework of SAARC PTB Cooperation, PTB Germany in cooperation with NABCB organized South Asian Expert Group on Accreditation (SEGA) Meeting and attached training on Cooperation of Accreditation Bodies and Regulatory Bodies at Goa from 4th -7th December 2018.

During the meeting, the future of SEGA as a self-sustainable body was discussed and regional accreditation activities viz. regional proficiency testing in SAARC region for 2019 was planned.

In the 2-Day training program, possibilities and challenges of the cooperation between accreditation bodies and regulatory bodies were discussed.

Establishment of Asia Pacific Accreditation Cooperation (APAC):

Amalgamation of Asia Pacific Laboratory Accreditation Cooperation (APLAC) and Pacific Accreditation Cooperation (PAC) – two former regional accreditation cooperations

APAC, a new regional accreditation body association, came into existence on 1st January 2019 by merger of two former regional accreditation cooperations -- APLAC and PAC. This alliance foresees to serve the members of both the organizations with higher efficiency. There will be unity in purpose and synergy in engagement with members, regulators and stakeholders.

APAC's primary role is to manage and expand a Mutual Recognition Arrangement (MRA) among accreditation bodies in the Asia Pacific region. The MRA facilitates the acceptance of conformity assessment results (e.g. test reports, test certificates, inspection reports, and certification) across the region and with other regions around the world. Conformity assessment results that are produced by Conformity Assessment Bodies (CABs) that have been accredited by one APAC MRA signatory are accepted by all the other APAC MRA signatories. This mutual recognition and acceptance of conformity assessment results reduces the need to undertake duplicate testing, inspection or certification, thus saving time and money, increasing economic efficiency and facilitating international trade (reference from APAC website)

Further information on the new APAC is available on its website: www.apac-accreditation.org.

AWARENESS PROGRAMS

Awareness Programme in association with IGS Local Chapter, Bangaluru

NABL, in association with Indian Geotechnical Society (IGS) Local Chapter, conducted an Awareness Programme in Bangaluru on 18th November 2018. The occasion was graced by Mr. Raje Gowda, QC in-charge, PWD, Government of Karnataka as Chief Guest and Prof. Shivapullaiah, Pro-Chancellor of GITAM University as Guest of Honour who emphasised on the importance of NABL accreditation for all Geotechnical labs in the country. They also cited the challenges faced by the lack of accredited laboratories in the area of Geotechnical testing. Dr. Sivakumar Babu, IGS President; Prof. Ramesh H N, Chairman, IGS Local Chapter and Joint Director, NABL were few other dignitaries present.

The program was attended by 40 representatives from IGS, Laboratory and State Government who appreciated NABL initiatives and assured their support to NABL in terms of providing technical expertise for enhancing laboratory accreditation.

Awareness Program on "Salient Features of Specific Criteria for Calibration Laboratories in line with ISO/IEC 17025:2017"

NABL launched PAN India Awareness Program on "Salient Features of Specific Criteria for Calibration Laboratories in line with ISO/IEC 17025:2017".

The seminar was focussed on familiarising the participants with the new version of ISO/IEC 17025:2017, related changes in specific criteria for calibration laboratories, its impact on laboratory & quality management systems, updates in the field of Calibration viz. Mechanical (Mass, Pressure, Force, Dimension) Thermal and Electro-technical etc.

2-Day awareness program for Northern Region was organised in New Delhi on 20th-21st Dec 2018. The program was graced by Mr. Anil Relia, CEO, NABL; Dr. D.K. Aswal, Director, National Physical Laboratory (NPL); Dr. Sanjeev Agrawal, Scientist, Central Pollution Control Board (CPCB), and Director NABL.

Director, NPL, Chief Guest of the program, emphasized on the role of National Metrological Institute (NMI) and importance of traceability in calibration. CEO, NABL addressed the participants and apprised them with the efforts put in by NABL in building quality network throughout the nation. Dr. Agrawal elaborated on the significance of calibration in Ambient Air Monitoring Equipments.

NABL received an overwhelming response and anticipates similar programmes in future.

Awareness Program at TATA Motors, Pantnagar

In continuation with the Awareness Program conducted by NABL on 8th September 2018 for the suppliers of Tata Motors Ltd., Pune, a similar program was conducted at Pantnagar on 26th December, 2018.

The program was designed to cover the aspects related to quality infrastructure, NABL accreditation and its benefits, brief on the requirements of ISO/IEC17025 and how to avail services from the accredited laboratories followed by an Open Forum for discussion.

The target audience was more than 100 in number and majority of them comprised of quality assurance personnel of various supplier companies of TATA Motors.

PARTICIPATION IN NATIONAL CONFERENCES & SEMINARS

Seminar on Analytical Science at National Centre for Compositional Characterisation of Materials (NCCCM), Hyderabad

NCCCM Hyderabad conducted 2-Day seminar sponsored by Department of Atomic Energy-Board of Research in Nuclear Sciences (DAE-BRNS) on Analytical Science from 30th Nov to 1st Dec, 2018.

NABL participated in the seminar wherein a talk on "NABL Accreditation and Current Status in Food and Pharma Sector" was delivered. The talk detailed about benefits and importance of accreditation, NABL & its international linkages, present accreditation scenario in Food and Pharma Sectors.

Annual Conference (Indian Geo-Technical Conference) IGC-2018, Bengaluru

NABL participated in the Annual Conference IGC-2018 organised by Indian Geotechnical Society (IGS) at Bengaluru from 13th to 15th December 2018. The conference was attended by more than 600 delegates from academic & scientific backgrounds along with technocrats from soil testing laboratories.

The Secretaries of local chapters, IGS from Indore, Delhi, Guwahati, Surat, Bhubaneswar, Hyderabad, Pune, Cochin,

Coimbatore and Chennai in discussion with Joint Directors, NABL conversed on enhancing the quality of testing laboratories pertaining to Geo-technical investigations. The participants were also apprised about the importance of soil stabilization, interpretation of results and new techniques.

Mega camp for strengthening the Eco system of MSMEs, Panipat

The need of service from NABL accredited laboratories in Panipat region called out for an outreach program. In line with this, a 'Mega Camp for Strengthening the Eco System of MSMEs' was conducted on 21st December 2018 at Panipat. Ms. Sumedha Kataria, IAS, Deputy Commissioner, graced the occasion wherein MSMEs were appraised about NABL accreditation and its benefits.

Approx 60 participants, including manufactures and representatives from local textile industry, attended the program. They were encouraged to establish laboratories in the region and get them accredited by NABL. The participants were also acquainted with NABL website and its search options to find accredited laboratories.

NDE 2018 Conference and Exhibition on Non-Destructive Evaluation, Navi Mumbai

Indian Society for Non-Destructive Testing organized an annual event comprising of conference and exhibition at Navi Mumbai from 19th-21st December, 2018. Many eminent speakers from the field of Non-Destructive Testing (NDT) delivered talks on the subject matter and the exhibition brought together all the conventional and advanced NDT technologies under one roof for the benefit of delegates. Live demonstration on NDT equipments was also witnessed by the delegates. More than 75 exhibitors across the globe participated in this event.

A special session on accreditation was inaugurated by Director, NABL wherein participants were apprised with the process of NABL Accreditation; technical requirements of accreditation for NDT Labs for Metal & Alloys, Building Materials; Metrological traceability and the requirements for Proficiency testing and Inter laboratory comparisons.

Over 1000 delegates from all over the world attended the event which provided an ideal platform to delegates to share and discuss their work with experts and colleagues working in NDT and related fields.

TRAININGS

Following training courses were organised by NABL:

5-Day Assessor Training Course as per ISO/IEC 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories" at Gurugram from 10th to 14th October 2018

4-Day Training Program as per ISO/IEC 17043:2010 "General Requirements of Proficiency Testing" at New Delhi from 23rd to 26th October 2018

4-Day Training Program as per ISO/IEC 17043:2010 "General Requirements of Proficiency Testing" at New Delhi during 13th to 16th November 2018

5-Day Assessor Training Course as per ISO/IEC 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories" at Bengaluru from 17th to 21st December 2018

National Accreditation Board for Hospitals and Healthcare Providers

NABH

Board Updates

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NABH Programs and Trainings

Achievement in last three months (October 2018 to December 2018):

During the period of October 2018 to December 2018 following work has been accomplished:

S.No.	Program	New Application Received	Accreditation Granted
1.	Accreditation Program	117	85
2.	Certification Program	617	426
3.	Empanelment Program	90	53
	Total	**824**	**564**

Programs on Implementation (PoI) & Education Workshops:

Program on Implementation training conducted in various cities on NABH Accreditation Standards of Hospitals, AYUSH, Blood Bank and Nursing Excellence, Pre Entry-Level Hospital & SHCO Certification Standards, Clinical Audit Workshop and Continual Quality: Tools and Techniques Workshop.

The objective of this programme is to provide guidance to healthcare providers on implementation of NABH standards.

This programme is very useful to develop Internal Capability within the hospitals to work towards implementation of quality and patient safety standards, achieving accreditation and maintaining the same.

In all, 16 Programs were conducted during October 2018 to December 2018 wherein more than 640 healthcare professionals participated.

Program on Implementation on NABH Standard of Hospital Accreditation Program

Continual Quality Improvement: Tools and Techniques Workshop

Assessor Course for Pre Entry-Level

Program on Implementation on NABH Standard of Hospital Accreditation Program

Participation in 4th Edition of Advantage Healthcare India 2018

Participation in 4th Edition of Advantage Healthcare India 2018

NABH participated in the 4th Edition of Advantage Healthcare India 2018, an International Summit on Medical Value Travel which is a joint initiative of the Department of Commerce, Ministry of Commerce & Industry, Government of India, Federation of Indian Chambers of Commerce & Industry (FICCI) and Services Export Promotion Council (SEPC). The event is being supported by the Ministry of Health & Family Welfare, Ministry of AYUSH, Ministry of External Affairs and Ministry of Tourism, Government of India and NABH.

First Technical Committee Meeting of Yoga Certification:

First Technical Committee Meeting of Yoga Certification

Role of NABH in Ayushman Bharat Yojana or Pradhan Mantri Jan Arogya Yojana (PMJAY)

Ayushman Bharat Yojana or Pradhan Mantri Jan Arogya Yojana (PMJAY) is the largest and the most ambitious scheme launched by Honorable Prime Minister Mr. Narendra Modi on September 23, 2018. The main objective is to cover over 10 crore poor and vulnerable families (approximately 50 crore beneficiaries) providing coverage upto Rs 5 lakh per family per year for secondary and tertiary care hospitalization. This scheme will provide financial protection (Swasthya Suraksha) to poor, deprived rural families and identified occupational categories of urban workers' families (approx. 50 crore beneficiaries).

At least 6,000 private hospitals are likely to join the AB-NHPM, most of them will be accredited / certified by NABH.

NABH accreditation indicates that a hospital has best-in-class services and gives hospitals additional benefits as these hospitals will get more in the base rate in the scheme as compared to the non-accredited ones.

As per senior officials from Ministry of Health and Family Welfare (MoHFW) more and more NABH-accredited hospitals should join Ayushman Bharat because of the incentives. NABH-accredited hospitals will be paid 15% higher rate and entry-level NABH hospitals will be paid 10% higher rate for the same package than non-accredited ones.

National Accreditation Board for Education and Training

Formal Education Excellence Division

3-Day Awareness Workshops on Accreditation Standard for Quality School Governance

Growth of the economy of any country is largely dependent on the literacy level of people of that country and is directly proportional to level of education of that country. It is no different with India. In order to improve the education level in India, NABET is operating an scheme of Accreditation of School against Accreditation Standard for Quality School Governances (ASQG) being developed by it.

3-Day Awareness workshops on ASQG are being organized with objective to enable participants to understand the requirements of Accreditation Standard for Quality School Governance and enable schools to implement the standard so as to operate with increased effectiveness, consistency and efficiency.

Recently, these workshops were organized from 13th - 15th September, 2018 at Faculty of Education (K), BHU, Varanasi and 11th - 13th December, 2018 at DPS Navi Mumbai.

Participants of 3-Day Workshop at Varanasi

Participants at DPS Navi Mumbai

Group Presentation by Participants during Navi Mumbai Workshop

Presentation by Experts during Navi Mumbai Workshop

Lean Manufacturing Competitiveness Scheme

O/o DCMSME and NABET Jointly Organized Stakeholders' Consultation Meet on Industry 4.0 for MSME at NSIC, New Delhi

O/o DC (MSME) and NABET jointly conducted Stakeholders' Consultation Meet on Industry 4.0 for MSME on 10 December 2018 under Chairmanship of Mr Sudhir Garg, Joint Secretary & Additional Development Commissioner (ADC) , DC (MSME)/ CMD, NSIC at NSIC Bhawan, New Delhi

JS, MSME shared his vision on Industry 4.0 for MSME sector and how MSME sector could be benefitted from Implementation of Industry 4.0.

Brief presentation on Industry 4.0 was made by NABET – setting the context of Meeting; followed by industry perspective to implementation of Industry 4.0 by

    a.   M/s DALISOFT

    b.   M/s Siemens Industry Software, India

Apart from officers from DC, MSME and NSIC, the stakeholders' attending the meeting were : IIT, Delhi; CMTI, Bangaluru; QCI – ZED; FICCI; Automation India Association (AIA); Okhla Garments Textile Association (OGTC); SIEMENS; B&R Automation (an ABB Group); DALISOFT Technologies; Royal Datamatics; Tech Soft; Wazir Advisors.

Brief of deliberations made during the meeting was as follows:

1. It has been established that MSMEs need to quickly embrace appropriate and relevant 4.0 Technologies namely : Internet -of-Things (IoT), Cloud Computing, Big Data Analytics, Simulation, Artificial Intelligence (AI), Augmented Reality / Virtual Reality (AR/VR), Additive Manufacturing / 3D printing, Robotics etc. for ensuring *Data Driven decision making /Flexible manufacturing / Informed Design improvements* for staying competitive.

   One of the tasks of the stakeholders will be to recommend the priority pieces of Industry 4.0 to be adopted by MSMEs those will help them to transform to be globally competitive and attain excellence. Looking at the current situation of Indian MSMEs, Ministry of MSME needs to play the role of an enabler for ensuring quick successes at representative MSME establishments for subsequent replications by MSMEs en-masse across the country.

2. The Scheme on Implementation of Industry 4.0 in MSMEs is need of the hour. The Automobile & Garments could be the early adopters of Industry 4.0.

   Prime objective of Industry 4.0 beyond the holistic approach must ensure productivity and optimization of processes to manufacture smaller batch size (to be even for a single quantity) with reasonable returns. In addition,

the MSME will be able to build competency to 'improve' upon the existing product capabilities thereby becoming more impactful as the product supplier as well as build reputation.

3. Holistic methodology needs to be developed for complete integration of processes for successful implementation of Industry 4.0. (Typical MSMEs functions include – Order, Sales & Planning, Product Development, Material Management, Machine Management, Process Management, People Management).

4. Implementing of Smart Factory would include – Smart Machines, Smart Connectivity, Smart Products, Smart Skills, Smart Data Management, Smart Applications, Smart Analytics.

5. Smart Applications need to revolve around – Production Order Management, Product Improvement & Quality Management, Performance Management, Material Management, Quality Management, Genealogy, Operations Intelligence, Error Proofing, Energy Management, Maintenance Management, Environment & Safety, Workforce Management, Natural Resource Optimization.

6. Up to 60% of the production processes could be automated in production; based on the need and Returns on Investments (RoI). [As per McKinsey Study].

7. The schematic for I-4.0 implementation roadmap arrived is under:

Source : Ace Micromatic
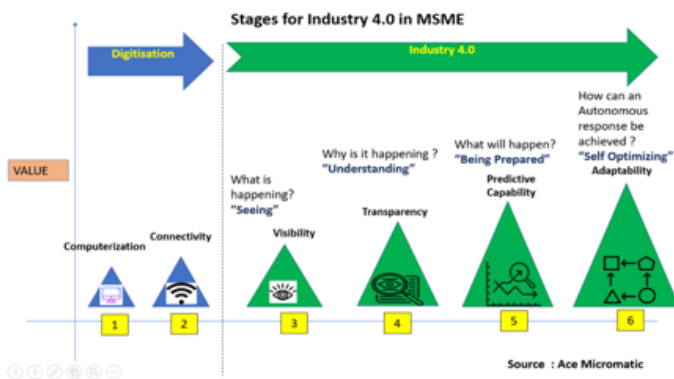
8. A step-by-step systematic approach needs to be followed; in the journey of I 4.0. Digital transformation should result in Speed, Flexibility, Quality & Efficiency ensuring safety, security & environment friendly.

9. One size doesn't fit all for implementation of Industry 4.0. (MSMEs vary in Level of Automation, Production Rate, Product Variant, Labour rate, Level of Complexity, Compliance & Regulation, Product Price).

70% Standardisation can be seen as the way to go forward and 30% customization as per need. The indicative modules are: Production Order Management, Product Development, Quality Management Performance Management, Material Management, Quality Management, Genealogy, Operations Intelligence, Error Proofing, Energy Management, Maintenance Management, Environment & Safety, Workforce Management, Natural Resource Optimization.

10. Continual Skilling and Reskilling of manpower is pertinent to successful Industry 4.0 implementation. Training programs needs to be developed suitably.

Master Trainers need to be created for spreading the awareness and technical know-how. Training modules to be developed at 3 levels for beginners, Intermediates and experts.

A brand neutral curriculum to be drawn along with IIT-AIA-FSM, New Delhi and CMTI, Bangaluru; Centres of Excellence (CoE) being established through 80% funding by Department of Heavy Industries (DHI) under Common Facility Centre (CFC) initiatives.

11. A small batch size in production requirements is becoming the order of the day, data driven manufacturing needs to be established quickly for agile decision making by:
    i. Collection of Data
    ii. Analysing
    iii. Using digital tech to take actions

Decisions are required for action in both 'Design' and 'Manufacturing'; On-the-fly.

12. Objective of this exercise of implementing I-4.0 would be Speed (First time right), Flexibility (Mass customisation) and Quality (World Class).

13. The automation pyramid should be envisaged in levels defined :
    • Shop floor automation
    • Communications platform
    • Plant Management
    • ERP, PLM
    • Business Intelligence

14. The timelines drawn for implementation were as under:

1-3 Months	Connect, Digitize
3-6 Months	Fact or Data Intelligence
6-9 Months	Intelligent Factories & Networking

A total of 10 months would be required in order depending on level of automation being applied.

15. The Standards landscape for I4.0 implementation must ensure/strive for adoption of 'Open source technologies'

& protocols having access to 'Source Code' for keeping the cost solutions low; for envisaging complete interoperability of 'data / signals' between all machines /technologies.

16. In lines with current soft interventions available such as 'Software as a Service' (SaaS), efforts need to be made to push hardware vendors to offer 'Sensors as a Service' and 'Controls as a Service'; for encouraging MSMEs for adoption of I4.0 at lower risks of investments.

17. In the garments sector, a combination of 'Tech Providers' and 'Process Improvement Specialists' is felt. Under the challenges in the garment sector, improving lead times and flexible manufacturing practices for handling small orders, specific meaningful improvements and verifiable results is the key for improving bottom lines.

18. Digital Gap analysis is critical in identification of key parameters to be collected from factory, analysis required, software & hardware required. The parameters so selected will play a key driver in success of bottom-line improvements and ROI of automation. The methodology would be very effective for manufacturers which produce discrete products than continual products.

19. More demonstration centres need to be created for display and appreciation of technology. This will be good as a de-risking strategy for the vendor and the end beneficiary. NSIC could facilitate the setting up of more demonstration centres for early adoption in MSMEs across India.

20. Proof of Concept (PoC) and automation Return on Investment (RoI) are key drivers for adoption across sectors and locations. A pilot/ PoC across 20 MSMEs in Automobile & Garment Sector needs to be established through modular approach for replication. The result would lead to standardization of modules that could be replicated across various sectors. The modules are to be built around the following areas:
    a. Production
    b. Quality
    c. Safety
    d. Inventory
    e. Environment
    f. Energy
    g. Natural Resource
    h. Human Skills
    i. Performance
    j. Design (Alternate design evaluation)
    k. Manufacturing (Alternative Manufacturing strategies)

21. A Pilot needs to be conducted for devising programs

for training various stakeholders on Industry 4.0. (i.e. Consultants, System Integrators, Auditors, NMIUs, NSIC Officers etc.)

Recommendations

It was finally recommended that a Proof of Concept (PoC) be established in Phase-1 through Special Purpose Vehicle (SPV) models under Industry Associations along with tool rooms, Tech centres and NSIC; in lines with Common Facility Centre (CFC) model.

A full I4.0 scheme further needs to be developed on the above lines, across all sectors of MSMEs.

Accreditation Division

Accreditation of CAB for Operating Scheme based on ISO 21001: 2018 Educational Organization Management Systems for Educational Organizations – Requirements with Guidance for use

The newly launched ISO 21001:2018 standard provides a common management tool for organizations providing educational products and services capable of meeting learner and other customer requirements and needs.

It is a stand-alone management system standard, based on ISO 9001 (without being a sector application), and aligned with other ISO management system standards.

ISO 21001:2018 standard focuses on the specific interaction between an educational organization, the learner, customers and other relevant interested parties.

All requirements of ISO 21001:2018 standard are generic and intended to be applicable to all educational organizations that provide, share and facilitate the construction of knowledge to learners through teaching, training or research, regardless of type, size and product and service provided. The standard, therefore, applies to the management system of any organization which utilizes a curriculum to provide, share and transfer knowledge.

The ISO 21001:2018 standard ensures:

• Aligning of various elements of learning services, including advertising, information provided to learners, needs analysis, design, assessment and evaluation, for the purpose of improving the effectiveness, efficiency and transparency of learning services

- Enhancement of the credibility of learning services
- Establishing of a model for improving learning services that can be shared within an organization
- Providing an internationally recognized instrument that demonstrates the reliability and quality of learning services
- That there is a recognized means to enable organizations to demonstrate commitment to education management practices in the most effective manner

NABET has granted India's 1st accreditation for operating Certification as per ISO 21001:2018 standards (Educational Organization Management System) for the scope of 'school education'. NABET's accreditation scheme is as per ISO/IEC 17021-1:2015 standard.

With this, Quality Austria Central Asia Pvt. Ltd. has become India's first Conformity Assessment Body to offer NABET accredited Certification as per ISO 21001:2018 standard to schools in the country.

Assessors Harmonization Workshops

NABET held its Assessor Harmonization Meet in New Delhi from 13-14 December 2018 for assessors conducting accreditation assessments as per IS0/IEC 17024:2012 Standard (Conformity assessment -- General requirements for bodies operating certification of persons) and ISO/IEC 17021-1:2015 standard (Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements). NABET conducted the meet to harmonize the assessment process, to deliberate on specific issues and provide information about new standards /requirements to the assessors.

Environment Division

A meeting with State Level Environment Impact Assessment Authority (SEIAA) / State Level Expert Appraisal Committee (SEAC), Madhya Pradesh was held in Bhopal on 15 February 2019, wherein issues related to quality of EIA report being prepared by environmental consultants were discussed. Chairman and Members of SEIAA/SEAC, M.P. and CEO along with Asst. Director from QCI-NABET attended the meeting.

National Accreditation Board for Certification Bodies

NABCB

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NABCB secures International Equivalence for Energy Management Systems (EnMS) and Occupational Health and Safety Management Systems (OHSMS)

NABCB has secured international equivalence for its accreditation programme for Energy Management Systems (EnMS) Certification on 5th April, 2018 and Asia Pacific equivalence for Occupational Health and Safety Management Systems (OHSMS) on 19th Dec, 2018. It has signed the Multilateral Mutual Recognition Arrangement (MLA) of the International Accreditation Forum (IAF) for its accreditation programme based on international standards, ISO/IEC 17021-1 and ISO 50003. This signifies that the accreditation of Energy Management Systems Certification Bodies by NABCB is now accepted as internationally equivalent.

Also, NABCB has secured international equivalence for its accreditation programme for OHSMS Certification Bodies in Asia- Pacific region. It has signed the MLA of the Pacific Accreditation Cooperation (PAC) to this effect on 19th Dec 2018. The NABCB accreditation programme is based on international standards, ISO/IEC 17021-1 and ISO 45001, applicable for OHSMS. The recognition by PAC is based on demonstration by NABCB that it complies with international standard, ISO/IEC 17011, applicable to it and has competence in OHSMS to accredit Certification Bodies in this sector. NABCB is the third body in the Asia Pacific Region to become internationally equivalent, the other two being the accreditation bodies of Hong Kong and Mexico. MLA with PAC would facilitate signing MLA with IAF to secure full international equivalence. IAF signatory members signify that the accreditation of certification bodies by NABCB for OHSMS will be accepted as internationally equivalent.

With the above, NABCB hopes to facilitate export of Indian goods into the world market by attesting that these are certified as per international standards by the certifying bodies.

NABCB retains International Equivalence in Food Safety and Information Security Management System

NABCB has retained the international equivalence for Food Safety Management System (FSMS) and Information Security Management System (ISMS). Based on the peer revaluation of NABCB in Nov, 2017, NABCB's status as PAC Multilateral Recognition Agreement (MLA) signatory for FSMS and ISMS accreditation schemes has been reaffirmed - which means NABCB maintains the international equivalence for FSMS and ISMS.

NABCB hosts Sixth meeting of SAARC Expert Group on Accreditation (SEGA)

NABCB hosted the sixth meeting of SAARC Expert Group on Accreditation (SEGA) on 4-5 Dec 2018 and a 2-Day training on "Cooperation of Accreditation Bodies and Regulatory Bodies in SAARC Countries – Harmonised Approach to Advising Regulators" from 6-7 December, 2018 in Goa with the financial and technical assistance from PTB Germany.

The meeting was attended by distinguished guest Mr. Shyam Bang, Chairman, NABCB and delegates from the SAARC Member States (Bangladesh, Bhutan, India, Maldives, Nepal and Sri Lanka). Mr. Patrick Dolle, Project Coordinator, PTB; Mr. Chanchal Chand Sarkar, Director (Economic, Trade and Finance), SAARC Secretariat and Mr. Tashi Wangchuk, Deputy Director, SARSO, were also present there.

Mr. Anil Jauhri, CEO, NABCB, welcomed the guests and the delegates from the SAARC Member States. He highlighted the need of a permanent and sustainable structure of SEGA in SAARC.

Mr. Shyam Bang, in his opening remarks, highlighted the importance of increasing the share of global trade and improving the perception of quality of products

and services of South Asia in the global market. He requested the Members for continuously strengthening the accreditation process and enhancing the quality culture in the region.

Mr. Patrick Dolle, Project Coordinator, PTB, mentioned the support rendered by PTB to the Member States of SAARC in areas of Accreditation under the SAARC - PTB MoU for the last 15 years. He thanked the delegates for their participation.

Mr. Anil Jauhri, CEO, NABCB, host of the Sixth Meeting of SEGA, was elected as the Chairperson of the SEGA.

During the meeting, latest updates and developments of the Accreditation/ National Accreditation Focal Points (NAFP) activities in the SAARC Member States were reported. The discussions involved the country wise benefits accrued from the SAARC-PTB Project. A major recommendation was made that SEGA should become a permanent body in the form of SAA (SAARC Accreditation Association).

From International Arena

NABCB attends the APLAC 2-Day Experience Sharing Workshop in Inspection at Hanoi, Vietnam

The APLAC Training Committee held a 2-day Experience Sharing Workshop on Inspection on 5-6 Dec 2018 in Hanoi, Vietnam. The workshop was hosted by BoA, Vietnam. Ms. Rajalakshmi Subrahmanyam, Assessor, NABCB attended the workshop. The workshop was geared for officers of APLAC members who are responsible for and/or conduct assessments to ISO/IEC 17020.

ISO/IEC 17020:2012 (second edition), the standard for inspection bodies, was published in 2012. Since then there have been a number of issues relating to the implementation of this standard that have been raised and discussed at various inspection committee meetings.

The experience sharing workshop was attended by 9 participants and there were about 20 others who joined online. The sessions were lead by Mr. Julian Wilson from NATA Australia and Mr. Geoff Hallam, IANZ, New Zealand. The main objective of the workshop was to highlight the issues that accreditation bodies have experienced in interpretation and implementation of the standard, and to share their experiences in implementing the standard. The participants from member accreditation bodies shared their experiences and challenges with the implementation of the standard, with the goal of developing a common understanding of the standard and a consistent approach to assessment against the standard.

The issues raised by the Accreditation Bodies (ABs) prior to the workshop

formed the basis for the development of the topics considered for the 2-Day sessions. As several questions related to ISO 17011-2017 were raised by the ABs and with the release of ISO 17025 -2017, there were sessions devoted to ISO 17011 and ISO 17025-2017 as well. Considerable time was spent on independence of the IB and the Type A/B/C status. The core documents were specifically covered included ISO 17020-2012; ISO 17011-2017; ILAC G 27:06/2017; ILAC G 28:07/2018.

NABCB attends the Annual Meetings of IAF and ILAC in Singapore

NABCB delegation consisting of Mr Anil Jauhri, CEO, NABCB; Ms. Sashi Rekha, Director NABCB; Mr. V K Mediratta, Lead Assessor, NABCB and Ms. Shobha Hegde, Lead Assessor NABCB attended the joint meetings of IAF and ILAC at Singapore from 22nd Oct- 31st Oct 2018.

NABCB participates in Phase 1 of Strengthening Accreditation Networks in Asia-Pacific (SANAP 2) Project to Train the Trainers

Ms. Vani Bhambri Arora attended a 5-Day training programme on strengthening accreditation networks in Asia Pacific region held at Bangkok, Thailand. The objective of the programme was to provide training skills to the participants for creating pool of trainers in Asia Pacific Region on accreditation standards. The project strives to strengthen the regional accreditation network Asia Pacific Accreditation Cooperation (APAC) in its ability to support its members and aspiring members from developing and emerging economies in their sustainable economic development. The different aspects of training were discussed during these 5 days including presentation, designing power points, planning training etc.

It was well structured and provided a good experience and the participants could redesign their presentation and made them more effective. At the end of the training an evaluation was conducted and NABCB scored the highest marks in the evaluation.

Participation in training program makes Ms Vani Bhambri Arora a Trainer for different accreditation schemes in India.

NABCB participates in PAC Workshop on Process Certification: 15-17 November 2018 in Manila, Philippines

NABCB participated in an international workshop organized by Pacific Accreditation Cooperation (PAC) and hosted by the Philippines Accreditation Bureau (PAB) during 15-17 November 2018. This workshop was attended by 18 delegates from various countries in PAC region and Ms Vani Bhambari Arora attended the workshop from NABCB.

The purpose of the workshop was harmonising the accredited certification of processes in accordance with:

ISO/IEC 17065:2012, Conformity assessment -- Requirements for bodies certifying products, processes and services; and

ISO/IEC TR 17032, Conformity assessment -- Guidelines and examples of a certification scheme for processes, which is currently under development by ISO/CASCO WG52.

NABCB participates in a 3-Day workshop/training programme on Accredited ISO 13485, Medical Devices Quality Management System Certification

Mr. M.G. Sathyendra, Assessor, NABCB, participated in a 3-Day training programme/workshop on ISO 13485 organized by PAC and Standards Malaysia at Penang from October 30 to November 01. The programme was dedicated towards awareness about ISO 13485 including application of ISO/IEC 17021-1:2015 / IAF MD9.

NABCB participates in IHAF meetings in Singapore

NABCB participated in IHAF meetings in Singapore. Ms. Sashi Rekha, Director, NABCB, is Vice Chair of its MRA Committee. NABCB is founder member of IHAF.

NABCB participates in PAC organised ISO/IEC 17024 training

Mr. Anupam Gupta, NABCB Assessor attended the 3-Day training held from 17-19 Oct at Sydney, Australia. The training was hosted by Joint Accreditation System of Australia and New Zealand (JAS-ANZ) on

behalf of Pacific Accreditation Cooperation (PAC). The purpose of the training was to facilitate understanding of ISO/IEC 17024 and how its requirements can be consistently assessed by PAC Member Accreditation Bodies and implemented by person certification bodies. The faculty of the training was Dr. Cynthia D. Woodley, Vice President of Professional Testing and lead psychometrician has been the program manager for various personnel certification programs for over 20 years.

From the National Arena

NABCB actively participates in MSME Support and outreach Programme

The Government of India launched a special programme to support Micro, Small and Medium Enterprises (MSME) and reach out to them through credit plus services in 80 districts on 2nd November, 2018. As part of this programme, a campaign was launched to support MSMEs to have awareness and access to Quality Certification Services. The programme was organised at HUDA Convention Centre, Sector 12 Faridabad on 2nd November 2018 and inaugurated by *Mr. Vipul Goel, Cabinet Minister in the state of Haryana & in-charge of Ministry of Industries & Commerce, Ministry of Environment,*

Skill Development & Industrial Training Minister, Haryana. Ms. Poonam Gupta, NABCB, addressed MSMEs on the importance of Quality and Certifications and how it will help in the growth of their business. An update on NABCB activities, its processes and benefits were briefed to participants from MSMEs.

The other participants also included participants from Small Industries Development Bank of India (SIDBI), Government eMarketplace (GeM), Engineering Export Promotion Council (EEPC), Central Goods and Services Tax (CGST), Excise and Taxation.

NABCB nominated as a member of National Medical Devices Promotion Council

Government of India has set up National Medical Devices Promotion Council with Department of Industrial Policy and Promotion (DIPP) under Ministry of Commerce on 7 Dec 2018 with an aim to boost the medical device sector. The formal announcement was made on the occasion of 4th WHO Global Forum on Medical Devices in Vishakhapatnam by Mr. Suresh Prabhu, Union Minister of Commerce and Industry and Civil Aviation.

Mr. Anil Jauhri, CEO, NABCB, has been nominated as a member on this Council. It gives us an opportunity to contribute to this sector which is largely under-regulated. The Council would act as a facilitating, promotional & developmental body for the Indian Medical Devices Industry.

NABCB takes initiative for development of certification scheme for private security agencies

QCI and the Central Association of Private Security Industry (CAPSI), the prominent organization for security professionals,

have signed an MoU to operate a voluntary certification and rating programme for Private Security Agencies. This process of standardization will help the Agencies enhance their credibility and consequently their business.

While QCI and CAPSI shall be the Joint Scheme Owners, the governing structure of the scheme shall be under a multi stakeholder Steering Committee and the scheme will be operated on a non-profit but self-sustaining basis.

The Scheme will be based on criteria for certification specifying the requirements for a quality management system for the management, staffing and operation of a Private Security Agency providing uniformed security guarding services on a static site and/or mobile and patrol basis, at different capability levels.

These capability levels can be used for rating and a basis of voluntary certification and demonstrating the ability of the Private Security Agency to consistently provide security services that meet customer and applicable statutory and regulatory requirements. The ratings and certification would enable a Private Security Agency to provide assurance to the stakeholders of capability at subscribed level and also provide a stepped approach to improvements.

NABCB conducts a 2-Day Assessors Conclave

NABCB held the 2-Day, second Assessors Conclave for the year, in Ranthambore from Nov 30-1 Dec 2018. The 2-Day conclave was organized to discuss and apprise the participants about the various new developments. Day 1 of the conclave focussed on discussions related to certification bodies and various topics were discussed like issues in reporting, writing, issues relating to assessment of certification bodies, changes in ISO 22000:2018 requirements, Risk- based

assessment principles and soft skills. A demonstration to assessors was also provided on the newly developed accreditation software to be used. Second day of the Conclave focussed on the discussions related to inspection bodies which focussed on the update related to recently released documents in Oil and Gas sector and revision related to BCB_201.

NABCB delivers talks during Specialized training programme on Standards, Regulations and WTO SPS and TBT Measures organised by Centre for WTO Studies, IIFT

The Centre for WTO Studies, IIFT conducted a Specialized training programme on Standards, Regulations and WTO SPS and TBT Measures from 26 November to 5 December 2018 under the Indian Technical and Economic Cooperation (ITEC) Programme of the Ministry of External Affairs. This training

was attended by participants from different countries like Algeria, Bhutan, Cambodia, Cuba, Ecuador, Ethiopia, Ghana, Iraq, Kenya, Madagascar, Mongolia, Nigeria, Sri Lanka, Tunisia, Uzbekistan, Vietnam, Zambia, Zimbabwe.

Mr. Anil Jauhri, CEO, NABCB, and Dr Aparna Dhawan, Joint Director, NABCB delivered talks on Challenges of Standards and Conformity Assessment and Accreditation and Conformity Assessment structure during specialised training programme respectively. The presentations were well received by participants.

NABCB outreach to Industry and Consumers

NABCB, in collaboration with Association of Regulatory Affairs Professionals (ARAP), holds its first Indian Regulatory and Quality Summit on Credible Certifications

NABCB, in association with ARAP, organized a one-of-its-kind comprehensive Indian Regulatory & Quality Summit on Credible Certification in New Delhi on 15 Oct, 2018. The Summit was attended by representatives of Central Drugs Standards Control organisation (CDSCO), NABCB, AiMED, FSSAI, NHRSC, ARAP, Notified Bodies, Pharmaceuticals and Medical Devises Industries.

Eminent Government and Industry luminaries like Dr. V.G. Somani, JDC (I), CDSCO; Dr K. Bangaraurjan, JDC (I), CDSCO; Mr. Shyam Bang, Chairman, NABCB; Mr Anil Jauhari CEO- NABCB; Mr. A

K Nasa, Head of Office/Licensing Authority - Drug Control Department- Delhi; Mr. B R Sikri, President, FOPE and Mr. Rajiv Nath from AiMED, shared their valuable insights on the Accreditation of Notified bodies under Medical Device Rule, 2017 and credible certification as per standards issued by NABCB and other various aspects.

Mr. Shyam Bang, the Guest of Honor, addressed the gathering and stressed on the need to develop an adequate regulatory and quality mechanism in healthcare industry. Mr. Anil Jauhri delivered a special address and stressed on the need to regulate by category rather than product. It was emphasized that regulators should rely on third-party assessments. NABCB officers Mr M Jena, Dr Aparna Dhawan and Ms. Vani provided insights to participants about credible certification and importance of accreditation.

Consumer Awareness Programmes

NABCB conducted a Consumer Awareness Programme on Quality in Products and Services in collaboration with the Consumer Coordination Council (CCC) at Kanpur on 25 Oct 2018. The programme was attended by 50 consumer related organizations. Dr. Aparna Dhawan, Joint Director, NABCB briefed the participants about the significance of Voluntary Standards and Technical Regulations, Role

of Accreditation and Product and Systems Certification. Mr. Vishnu Srivastava, Deputy Advisor, QCI explained about the complaint handling process and the measures to be taken into consideration while lodging consumer complaints. NABCB plans to conduct more such programmes across the country jointly with the Consumer Coordination Council.

NABCB participates in Wockhardt Group Hospital's 6th Annual Conference "DOING IT THE RIGHT WAY".

Wockhardt Group Hospital's organized the 6th Annual Conference "DOING IT THE RIGHT WAY" on 7th & 8th December 2018 in Mumbai. The conference was attended by several industry experts who spoke on various topics on Infection Control, Safe Medication Management and Use, Data - How to collect, collate, analyse and use data for improvement, IT as a facilitator for processes and much more. Mr. Anil Jauhri, CEO, NABCB, addressed the gathering and spoke about the risks of unauthentic certifications. The presentation was well received.

NABCB conducts 2-Day Assessors Conclave

NABCB held the 2-Day second Assessors Conclave for the year in Ranthambore from Nov 30-1 Dec 2018. The 2-Day Assessors Conclave was organized to discuss and apprise the participants about the various new developments.

Day 1 of the Conclave focussed on discussions related to certification bodies and various topics were discussed like issues in reporting, writing, issues relating to assessment of certification bodies, changes in ISO 22000:2018 requirements, risk-based assessment principles and soft skills. A demonstration to assessors were also provided on the newly developed accreditation software to be used. Second day of the Conclave focussed on the discussions related to inspection bodies which focussed on the update related to recently released documents in Oil and Gas sector and revision related to BCB_201.

NABCB delivers talks during Specialized training programme on Standards, Regulations and WTO SPS and TBT Measures organised by Centre for WTO Studies, IIFT

The Centre for WTO Studies, IIFT conducted a Specialized training programme on Standards, Regulations and WTO SPS and TBT Measures from 26 November to 5 December 2018 under the Indian Technical and Economic Cooperation (ITEC) Programme of the Ministry of External Affairs. This training was attended by participants from different countries like Algeria, Bhutan, Cambodia, Cuba, Ecuador, Ethiopia, Ghana, Iraq, Kenya, Madagascar, Mongolia, Nigeria, Sri Lanka, Tunisia, Uzbekistan, Vietnam, Zambia, Zimbabwe.

Mr. Anil Jauhri, CEO NABCB, and Dr Aparna Dhawan, Joint Director, NABCB, delivered talks on Challenges of Standards and Conformity Assessment and Accreditation and Conformity Assessment structure during specialised training programme respectively. The presentations were well received by participants.

Why employers should insist on certified manpower

- Assurance of competence
- Regular recertification helps maintain and update professional knowledge
- Certified person is an assurance of professional conduct
- Reduced cost of training
- Reduced timelines for hiring processes
- Reduced downtime of equipment used by Certified Professionals
- Reduced intangible & linked costs such as Insurance, potential loss due to compromised reputation etc.

National Board for Quality Promotion

Board Updates

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Workshops/ Seminars conducted under National Quality Campaign

Workshop on ISO 22000:2018 (Food Safety Management System)

A Workshop on ISO 22000:2018 (Food Safety Management System) was conducted at- National Productivity Council, New Delhi on 26th October 2019.

The objective of the workshop was to provide participants an understanding of what is new in ISO 22000:2018 along with its interpretations. The course was for the organizations to understand the changes from previous version of ISO 22000:2005.

ISO 22000:2018 encompasses the latest trends and food safety requirements aligned with a timely response to the rising global challenges facing the Food Industry. It addresses the growing needs to ensure the established trust in current food security systems and its sustainability. In addition to this, it projects a new understanding of the concept of risk & mitigation and its difference at operational as well as strategic level of a management system.

Workshop on Demystifying Smart Manufacturing

A Workshop on Demystifying Smart Manufacturing was conducted at IIT Delhi, New Delhi on 29th October 2019. Agenda of the workshop was to facilitate, introduce and enlighten the industry with an evolved genre of quality-focused smart manufacturing. QCI, supported by IITD-AIA Foundation for Smart Manufacturing, organized the awareness workshop with hands-on exposure in the FSM Cyber Physical Laboratory.

To strengthen the 'Make in India' eco-system with adoption of smart technologies, the Automation Industry Association and IIT Delhi have created a Special Purpose Vehicle called the Foundation for Smart Manufacturing (FSM) to take the emerging wave of Smart Technologies and adapt it with relevance to the needs of grassroot manufacturing in MSME and talent incubators in Educational and Vocational Institutes.

Workshop on 'Digital Forensic: Challenges and Future'

A Workshop on 'Digital Forensic: Challenges and Future' was conducted at India Habitat Centre, New Delhi on 6th December 2019. Agenda of the workshop Digital Technology has entered deep into the daily groves of mankind and made humans completely dependent on it. The current state of digital forensic investigation is continuously challenged by the rapid technological changes, the increase in the use of digital devices (both the heterogeneity and the count), and the sheer volume of data that these devices could contain. QCI, supported by Ministry of Electronics and Information Technology, Govt. of India, conducted a workshop with the objective to train the people, who can appreciate the upcoming challenges due to rapidly changing technology, its legal aspects and also to embrace the state-of-the-art solutions to upgrade themselves.

NBQP Consultant and Auditor Scheme

NBQP has rolled out schemes for Registration of Auditors & Consultants for various ISO Standards based on the revised versions of all the standards such as Quality Management System (ISO 9001:2015), Environment Management System (ISO 14001:2015), Food Safety Management System (ISO 22001:2018), Information Security Management System (ISO 27001:2013), Occupational Health & Safety Management System (ISO 45001:2018), Energy Management System (ISO 50001:2018) and Environment, Health & Safety (EHS). Apart from this, NBQP has started registering individuals as Hospital & Healthcare Consultants based on NABH Standard as well. The criteria for these schemes have been revised and uploaded on NBQP website for people to get themselves registered with NBQP. The objective of these schemes is to register individuals who are well versed with the standards and can be utilized by any organization/firm/Govt body as the need may be from our Register of Auditors & Consultants. This helps individuals too to have a recognition from QCI/NBQP as a QCI/NBQP registered Auditor or Consultant.

Learning Mission on Manufacturing Excellence

NBQP participated in the Learning Mission on Manufacturing Excellence organised by FICCI on 29 – 30 November 2018. The visit comprised of brief presentation highlighting the best practices followed by visit to Honda Cars India Ltd., Honda Motorcycle & Scooter India Pvt. Ltd. and Maruti Suzuki India Ltd. and interaction with officials from the organization. It provided an opportunity to learn and understand the best manufacturing and quality practices in sync with idea to promote learning through sharing.

Industry and businesses worldwide are striving to formulate strategies, sharpen operations, bring down costs, improve quality and differentiate products to increase their worth in the market. This is an era of continuous improvement in thoughts & processes, which is the only way to move towards competitiveness. The competitive pressures on the Manufacturing Industry, in terms of productivity, quality, delivery and safety call for a strategic and holistic approach that the industry needs to adopt to make their operations "World Class". With the Manufacturing Sector gaining business maturity, it is important to explore new and innovative horizons for sustaining the growth in the industry to deliberate and unleash full potential of the Manufacturing Industry as well as to promote best practices among the manufacturing sector.

Quality Month

The month of November is celebrated as 'Quality Month' worldwide. The purpose of Quality Month is to promote awareness of quality around the world to encourage individuals' and organizations' growth and prosperity and to recognize the importance of an overall quality focus and incorporate proven principles into daily life. The objective is mainly to emphasise on learning and sharing of knowledge in quality, innovation and best practices as well as for facilitating development of a quality and innovation culture.

Every year, QCI invites individuals and organisations to be a part of the quality culture. This year the theme was 'Swachh Environment -- The Essence of Quality'. The environment in which we live provides natural services for humans which are essential to our health, quality of life and survival. The human interaction with natural systems is depleting life-sustaining resources. For the environment to support life, good health, and human productivity it demands a closer examination of how the environment we build and inhabit is organized and managed. Man cannot live and survive amidst waste. Quality of the environment is a key factor in people's well-being because the quality of life is strongly affected by the health of the physical environment.

This year saw the participation of individuals and organisations in large numbers in the various competitions conducted by QCI. These competitions included Poster Making, Kaizen Implementation, Slogan Writing, Quiz Competition, Essay/ Quality Success Story and Photography and Celebration of Quality Month at the Organisation.

Quality Month Winners 2018

LIST OF QUALITY MONTH WINNERS

Quality Poster Competition	
S. No.	**Name of the Winners**	**Institution / Company / Organization**
1	Namrata Madhav Misal	Maharashtra State Board
2	Dr. Mohini Saxena	Healthy City Trauma Center & Super Specialty Hospital, Gomti Nagar
3	Akshay Khondhalkar	Ecoman Enviro Solutions Pvt. Ltd.
4	Monika Singh	District Male Hospital Moradabad (U.P.)
5	Asfar	AJ Institute of Hospital Management

6	Jovita Dsouza	AJ institute of Hospital Management
7	Shweta Bandivadekar	Envirocare Labs Pvt. Ltd.
8	Shrusti Pardeshi	Envirocare Labs Pvt. Ltd.
9	Shraddha Desai	Envirocare Labs Pvt. Ltd.
10	Atul Bhushan	CARE Hospitals ,Nagpur
11	Paresh Kumar Bhatt	IDMC Limited
12	Suparna Roy	Chacha Nehru Bal Chikitsalaya
13	Nilam Kumari	Chacha Nehru Bal Chikitsalaya
14	Anuja Chandrakant Nagare	Ashwamedh Engineers & Consultants
15	Anita Shivaji Pansare	Ashwamedh Engineers & Consultants
16	Poonam Hiralal Sathe	Greaves Cotton Limited, Aurangabad
17	Mehak Yadav	Desai College

Quality Slogan Competition

S. No.	Name of the Winners	Institution / Company / Organization
1	Mekha Nair	Sakra World Hospital
2	Krishna Nirmalya Sen	L&T Construction, MMH SBG
3	Rajubhai Shah	Escon Tech
4	Dr. Swati Rai	A J Hospital & Research Centre
5	Binod Kumar Satpathy	BHEL
6	P. Selva Sundar Rajan	Aadithiyaa Training and Consultant
7	Tarun Kumar Kar	Ircon International Limited
8	Suneeta	AJIHM
9	Surender	S-VYASA

Quality Quiz Competition

S. No.	Name of the Winners	Institution / Company / Organization
1	Sourav Maiti	Institute of Neurosciences
2	Neha Rawat	All India Institute of Medical Sciences
3	Ekta	AIIMS Rishikesh
4	Avneet Kaur	AIIMS Rishikesh
5	Harsha	AIIMS
6	Muthu Kumar	Sanofi
7	Nidhish Zacharias	BSTRH and MIMER Medical College and Hospital
8	MGS Saravanaraj	A 2 Z Infra

Kaizen Implementation Competition		
S. No.	Name of the Winners	Institution / Company / Organization
1	Hardik Patel	Welspun Corp Ltd.
2	Anant Prakash Jain	Welspun Corp Ltd. Pipes Division
3	Kalpesh Patel	Welspun Corp Ltd. Pipes Division
4	Nilesh Kumar Patel	Welspun Corp Ltd. Pipes Division
5	Jani Basha Shaik	Bharat Heavy Electricals Limited, Hyderabad
6	Anoop K Menon	Nitta Gelatin India Limited
7	Dr Bijoy Johnson	Baby Memorial Hospital
8	Santosh Shatpalkar	Axalta Coating System Savli
9	Arkray Healthcare Pvt. Ltd.	Arkray Healthcare Pvt. Ltd.

Quality Essay Writing Competition		
S. No.	Name of the Winners	Institution / Company / Organization
1	Col Prosenjit Ganguli	Indian Army
2	Chaitali S Hajare	Envirocare Labs Pvt.Ltd.
3	Prajakta H Dolas	Envirocare Labs Pvt. Ltd.
4	Jayant Shinde	KSPL
5	Simit N Pandya	IDMC Ltd.

Quality Photography Competition		
S. No.	Name of the Winners	Institution / Company / Organization
1	Stephy Mathew	Rainbow Children's Hospital
2	Suchithra Bhat	NITTA GELATIN INDIA LIMITED
3	Dr. Monica Madvariya	Rainbow Children's Hospitals BG road

Celebration at the Organization Competition		
S. No.	Name of the Winners	Institution / Company / Organization
1	Dr. Renuka Vidyashankar	Kauvery Hospital, Chennai
2	Mishra Anup	Capitol Hospital, Jalandhar
3	Vaibhav Shinde	Nashik Engineering Cluster
4	Sayali Chintaman Kadbhane	Nashik Engineering Cluster
5	Sayali Kadbhane	Nashik Engineering Cluster
6	Lakshmi S	Natural Remedies Private Limited
7	Dr Nivedita Dasgupta	Fortis Hospital Kidney Institute

8	Dr. Anal Panchal	Adwait Multispecialty Hospital
9	Dr. Mohini Saxena	Healthy City Trauma Center & Super Specialty Hospital
10	Kannan Raghavan	Independant
11	Rajneesh Chaudhari	District Male Hospital Moradabad (U.P.)
12	Dr Ramya Raveendranathan	Rainbow Children's Hospital
13	E Shrinivas Rao	MGM Eye Institute, Raipur
14	Dr Harsh Sharma	UP Health System Strengthening Project
15	SR ALLY	ST. JOSEPHS HOSPITAL
16	Ashwini K M	Nethradhama Super Speciality Eye Hospital
17	Suchithra Bhat	NITTA GELATIN INDIA LIMITED
18	Nupur Singh	District Women Hospital Meerut
19	Dr. Sanjeevani Gogawale	Aadishakti Foundation
20	Ankur Raj	Max speciality films, Nawanshahar
21	Rakesh Dayal	Nitesh Udyog
22	M K Somanathan	Ashok Leyland
23	Gracy Mathai	Baby Memorial Hospital
24	Kalyan Patil	Greaves Cotton Limited
25	Amit Kumar	Max Bupa Health Insurance Company Limited
27	Vijay Parashar	Johnson Matthey Chemicals India Pvt. Ltd.
28	Dr Anubha Agarwal	AIIMS, Rishikesh
29	Rainbow Children Hospitals- Dr Monica Madvariya	Rainbow Children's Hospitals
30	Ulka Sunil Belan	Ashwamedh Engineers & Consultants,Nashik
31	N.V.Subrahmanyam	Indocool Composites Private Limited
32	Dr. Shiv Prakash Singh	Legion Laboratories Pvt. Ltd.
33	Vishal Mittal	AES Laboratories Pvt. Ltd.
34	Santosh Shatpalkar	Axalta Coating System Savli
42	IDMC Limited	IDMC LIMITED
44	Prabha	Wockhardt Hospitals
46	Shyam Kothawade	EPCOS India Private Limited

Arobinda Mookherjee

Parth Ganatra Ashvinbhai

Low-Cost Solution to
Condition Vibration Monitoring CNC Machines

Monitoring of prevailing machine conditions is a challenge and an expensive process. The skill level which is involved in analysis is also quite high. The authors have made an attempt to obtain a low cost solution (Less than one thousand Rupees) and fairly reliable data for Machine condition analysis for predictive Maintenance.

Vibration is most widely used for detecting any abnormal behaviour and only also to diagnose problems to give a prognosis i.e. Residual life analysis. The prognosis is much more difficult and often relies on the continued monitoring of the fault to determine a suitable time when the equipment can be taken out of service or relies on known experience with similar problems. A fault that begins as a single defect, such as a spall on a raceway, is normally dominated by impulsive events at the raceway pass frequency, resulting in a narrow band frequency spectrum. As the damage increases, there is

likely to be an increase in the characteristic defect frequencies and sidebands, followed by a drop in these amplitudes and an increase in the broadband noise with considerable vibration at shaft rotational frequency.

Where machine speeds are very low, the bearings generate low energy signals, which may also be difficult to detect. Furthermore, bearings located within a gearbox can be difficult to monitor because of the high energy at the gear meshing frequencies, which can mask the bearing defect frequencies.

Overall Vibration Level

This is the simplest way of measuring vibration and usually involves measuring the RMS (Root Mean Square) vibration of the bearing housing or some other point on the machine with the transducer located as close to the bearing as possible. The vibration is measured over a wide frequency range, such as 10-1000Hz or 10-10000Hz.

Caution : It is also easily influenced by other sources of vibration, such as unbalance, misalignment, looseness, electromagnetic vibration etc. In some situations, the Crest Factor (Peak-to-RMS ratio) of the vibration is capable of giving an earlier warning of bearing defects.

As a local fault develops, this produces short bursts of high energy, which increase the peak level of the vibration signal but have little influence on the overall RMS level. As the fault progresses, more peaks will be generated until finally the Crest Factor decreases but the RMS vibration increases. The main disadvantage of this method is that, in the early stages of a bearing defect, the vibration is normally low compared with other sources of vibration present and is therefore easily influenced, so any changes in bearing condition are difficult to detect.

Building a Vibration Collection System

The Arduino Uno is a microcontroller with 14 digital inputs and six analog inputs with 10-bit resolution. It can be purchased for as little as $6 on eBay, programmed in C, and can be interfaced to a computer through USB, and the software is free. There exists a lot of inexpensive sensors the Arduino can interface to such as the LM35 for temperature sensor, the TSL2561 luminosity sensor, and the ADXL-335 triple-axis accelerometer, all under Rs. 500 As an example of this, an ADXL335 accelerometer, which outputs 10 mV/oC is monitored with an Arduino UNO, shown in Fig.

Arduino IDE

Arduino 1.8.5 was used to program the ADXL-335 to measure the analog data and convert the acceleration in terms of g (gravitational acceleration). The program was modified later to include the collection of data into the excel sheet.

ADXL335 triple axis accelerometer

The accelerometer is connected to the Arduino Uno using Jumper cables.

Interfacing with Excel

PLX-DAQ was used to collect the live data into an excel sheet, which can be used later for analysis. The Arduino code was modified accordingly to take input with a delay of 500ms.

MATLAB

MATLAB was used for the Fast Fourier Transform of the collected vibration data

Frequency Spectrum & FFT (Fast Fourier Transform)

Frequency analysis plays an important part in the discovery and analysis of machine faults. In the time domain, the individual contributions such as unbalance, bearings, gears etc to the overall machine vibration are difficult to recognize. In the frequency domain, they become much easier to identify and can therefore be much more easily related to individual sources of vibration.

As already discussed, a fault developing in a bearing will show up as increasing vibration at frequencies related to the bearing characteristic frequencies, making detection possible at a much earlier stage than with overall vibration. The Fast Fourier Transform algorithm converts the time domain waveform to the frequency domain. The frequency domain form helps distinguish the bearings and their individual vibrating amplitude.

Regularly collecting data of the machines can help identify the faulty part of the machine through their vibration amplitudes by analysis of specific machine part detoriation.
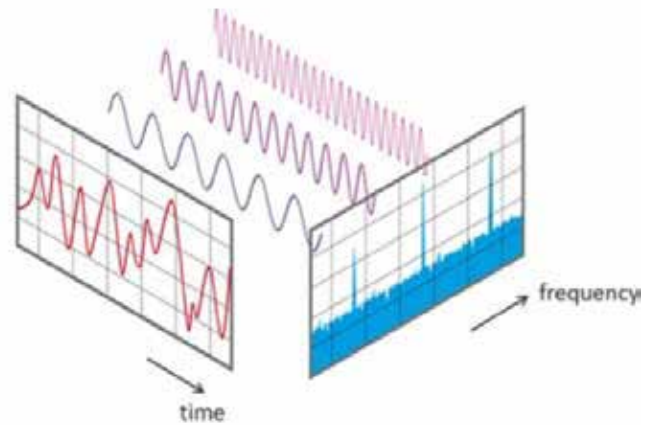
Vibration Data collected on CNC Horizontal Boring Machine at a predefined condition

Process Vibration Alarms

Sensors are designed to withstand the harsh industrial environments and provide critical measurements year after year. Cables and connectors are constructed of the most rugged materials available, and provide the critical link from the sensor to data collection. Designed for all types of environments, the proper cable and connector combination will eliminate any concerns for data transfer. Mounting hardware is available for a broad range of applications. Measurements are accomplished quickly with portable magnet mounts or quick disconnects. Permanent sensor installation can be accomplished with epoxy, stud mounting, or an array of special mounts designed for permanent applications.

A recent development in the predictive maintenance and reliability market is to leverage the investment already made in process control systems (PLC, DCS, & SCADA). This allows the operations, maintenance, and process control teams to monitor and alarm vibration levels on critical machines.

Using a standard 4-20 mA output, the loop power vibration transmitters and sensors provide a current output proportional to the overall value of the machine vibration. This is not a dynamic analog signal, and it cannot be used to analyze the machine fault, but it can be used to alarm the machine and indicate when vibration levels are too high.

When high vibrations are measured by the process control system, action can be initiated to determine the cause.

International standards for Vibration analysis

VIBRATION SEVERITY PER ISO 10816					
Machine		**Class I** small machines	**Class II** medium machines	**Class III** large rigid foundation	**Class IV** large soft foundation
in/s	mm/s				
0.01	0.28	good			
0.02	0.45				
0.03	0.71				
0.04	1.12				
0.07	1.80		satisfactory		
0.11	2.80				
0.18	4.50				
0.28	7.10	unsatisfactory			
0.44	11.2				
0.70	18.0				
0.71	28.0	unacceptable			
1.10	45.0				

(Vibration Velocity VMS)

The severity of machine vibration is standardized by the International Standards Organization (ISO) in the ISO 10816 publication. The standard describes acceptable vibration levels for four different classes of machines. This data, as laid out in the chart below, proves useful as a reference point when analyzing vibration measurements.

The measurement and analysis of dynamic vibration involves accelerometers to measure the vibration, and a data collector or dynamic signal analyzer to collect the data. The analog voltage output of the accelerometer is measured by the data collector and presented as a Time Waveform and FFT (Fast Fourier Transform) for frequency identification.

There are several faults in rotating machinery that can be identified by measuring and analyzing the vibration generated by the machine.

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Techniques of Making Smart Factory
For Competitive Manufacturing

About Smart Factory

Concept of Smart Factory (SF) is a new dimension in modern manufacturing system and evolution of the fourth-generation industrial revolution i.e. Industry 4.0, which digitally connects all production facilities through processes, operations, manpower and outputs. It is a factory which is well controlled, lagging Information, least wastage and zero defects, optimum utilization of resources, on-time delivery with competitive price.

Purpose of SF with Trend

Basic purpose of SF is to transform the traditional factory to smart factory with Smart Manufacturing (SM). World-wide manufacturing industries in both developed and developing countries are facing several challenges as per their circumstances like selection of technology, processes, costs of manufacturing, mass production, labour scarcity, sustainability in production performance. These challenges are outcomes of numerous factors such as an aging workforce in developed countries, changes in the landscape of global manufacturing and slow adaption of smart manufacturing by IT interventions.

Recently, German and US governments have started establishing separate initiatives to accelerate the use of the Industrial Internet of Things (IoT) Technologies and Smart Analytics Technologies in manufacturing industries, consequently to improve the overall performance, quality and controllability of manufacturing process. SM is the integration of all recent IoT, technological advances in computer networks, data integration and analytics to bring transparency in factories.

Contents of Smart Factory

SM is envisaged as a fully automated plant which includes various techniques, processes and outcomes

Quality – Zero Defect	Innovative	Cost Effective and Best Customer Services
Production Speed – Highest Productivity	Competent Manpower	Best Suited Working Environment
Technology- Digitally Managed	Smart Manufacturing System	Total Integrated System
Flexibility and Quick Reaction	Digitally Monitored and Managed	

Techniques and Technology of Smart Factory

SM is a new approach in multi-scale manufacturing with Additive Manufacturing Techniques, which uses the most recent IoT, consisting of smart sensors, computing & predictive analytics and resilient control technologies. Technologies in SF must be integrated together to acquire, transfer, interpret, and analyse the information, and to control the manufacturing process as intended. A Cyber-Physical Systems (CPS) is an integral part of SM. It is in preliminary stage in India and other developing counties and exploring more in-depth research & studies for their practical usage and establishing it in various manufacturing sectors.

Strategy requires for selection of technology and techniques, steps of implementation for making SF in various scales industries like Small, Medium and Large and types like manufacturing, processing, pharmacy etc. for a country.

Key elements of SF would be intelligent machines with latest technology, facility fleets, network with advanced sensors, controls and software applications.

Improved Process with Reengineering: Always improves the processes, equipped with advance analytics; physics-based analytics, predictive algorithms, automation with deep domain expertise, competent people at work - higher service quality, Augmented Reality in Maintenance and Industry 4.0 Management System are techniques of SF.

Glimpse of Smart Factory

With technology and techniques, a SF requires the Quality 4.0 as per the Industry 4.0, Manpower 4.0 and 4.0 Business Strategy to Implement these Techniques

Frontiers Of Smart Factory
- Auto, Semi-Auto Technology
- Balance of Process & Techniques
- Manage BIG Data
- Smart Manufacturing
- Smart People
- Smart Quality, Zero Defect
- Lean Plant
- Low Cost of Manufacturing

Smart Factory Glimpse Industry 4.0 and Quality 4.0
- Planning and Strategy in Smart Factory
- Individual Strategy
- Product Specific Strategy
- Quality and Control Process
- 4.0 Business Strategy
- Best Quality in Cheaper Price

Imperatives of On-Line Quality and Productivity in Smart Factory, Making Digital Thread

Using the Digital Thread the entire manufacturing and production processes could be seen as an integrated whole. The digital part of the manufacturing process can be sub-divided into the layers. These are:

Delivery Layer

It comprises devices that provide delivery of digital information to the humans.

Operations Layer

It comprises the virtual factory that has the entire physical plant layout represented digitally. The process of material flow between stations in the physical factory is equated to the process of information flow between the virtual stations. Every machine in the physical factory is represented by a "digital twin" (a 2D or 3D model of the physical machine with the capability to digitally analyze its structure, performance, inputs, process, outputs, etc.) in the virtual factory.

Devices Layer

It comprises all of the lower level control software (programmable logic controllers) that collects raw data from equipment, sensors, etc.

Application Layer

It comprises higher-level software that performs a certain function across multiple machines and production lines, such as production scheduling, traceability etc.
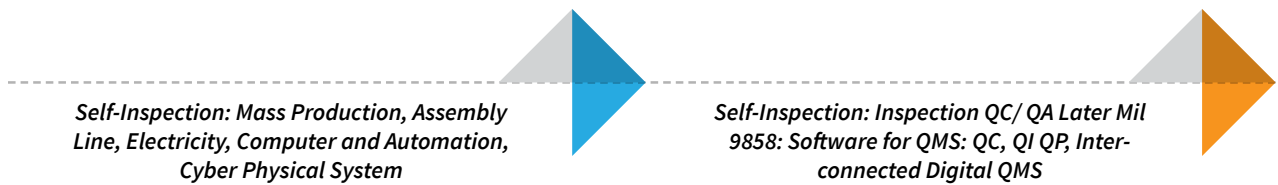
Systems Layer

The layer that manages hardware and provides a platform for application software. Application Software needs the system software for its execution (Courtesy - APO, Japan).

About Quality 4.0

In SF both Process and Quality require a deep-to-deeper look into sub-process & outsourced processes, reengineering with process competency and techniques like FTR, OTIF, LPA (Layered Process Audits) etc. Quality 4.0 will be a major transformation of Quality tools like 7QC, FEMA, Six Sigma, Lean Manufacturing, Plant Specific Online Quality & Reporting, Operations and Process Monitoring, Monitoring the Range of Products – Inhouse & Outsourced. There will be a transformation in various levels of skill requirements, in systems and standardisations, process & quality-oriented Maintenance i.e Hinshitsu Mentenansu/ Hinshitsu Hozen etc., in SF.

Self-Inspection: Mass Production, Assembly Line, Electricity, Computer and Automation, Cyber Physical System

Self-Inspection: Inspection QC/ QA Later Mil 9858: Software for QMS: QC, QI QP, Inter-connected Digital QMS

About Manpower 4.0

Digitization needs specific skills for working digitally on data analysis, for efficient & fast audits, developing manpower suppliers' skills for supporting SF. Help from quality professionals on SF will be inevitable for identification of digitally skilled manpower and preparation of skills matrixes in SFs.

Making Smart Factory

Sector-wise Existing Study Data of a Country and Region

Every country be prepared with sector-wise study on the scope of the Industry 4.0 and making SF to be followed by the industry for various extents of digitization in global and country perspective with various sources of digital solution, technology, manufacturing specific requirements to make manufacturing sector competent.

SM Implementation within a Plant

Phase – I: Study based - existing critical & constraint areas of productions, market & customer based CTB, CTC, CTQ, design the possible areas of improvement in technology and digitization, phase-wise planning from short to long-term.
Phase – II: Strategic planning on steps of implementation on levels of digitization on cost benefit analysis, team and action plan.

Phase – III: Phase-wise investment with planning of continuous improvement and after implementation businesses.

Digitization in total quality, reengineering, digitized data & records, manage the big data on total business, planned improvements in eliminations of wastages - PDCA cycle & value engineering, customer-driven individual roles will be final stages of SF.

Benefits of Smart Factory

There are immense benefits of SF -- from creating safe environment to product & service quality, reduced times, total supply chain, total services to customers for business and optimum utilization of all resources. System Efficiency and Effectiveness are goals of SF.

Conclusion

SF has not so far progressed in India, except some global OEMs. Now it is at awareness and understanding stages. Cost of automated technologies in SM with comparison of labour cost, non-availability of digitised manufacturing techniques, problem of initial investment, market risk, lack of awareness of the entrepreneurs, absence of sector-wise govt. study etc. are the factors for slow progress of SF for smart manufacturing.

Dr. J. S. I. Rajkumar

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Biocompatibility Testing
of Medical Device

Wide range of medical devices are available for diverse clinical disciplines, mainly due to recent discoveries in biotechnology, tissue engineering, biomaterials, cell and molecular biology, polymer science, nanotechnology and other related fields. Medical devices may contain different components made up of different materials with their own physical and chemical characteristics. Intended use of a medical device may lead to release of non-bioactive compounds that may lead to harmful effects in the living tissues.
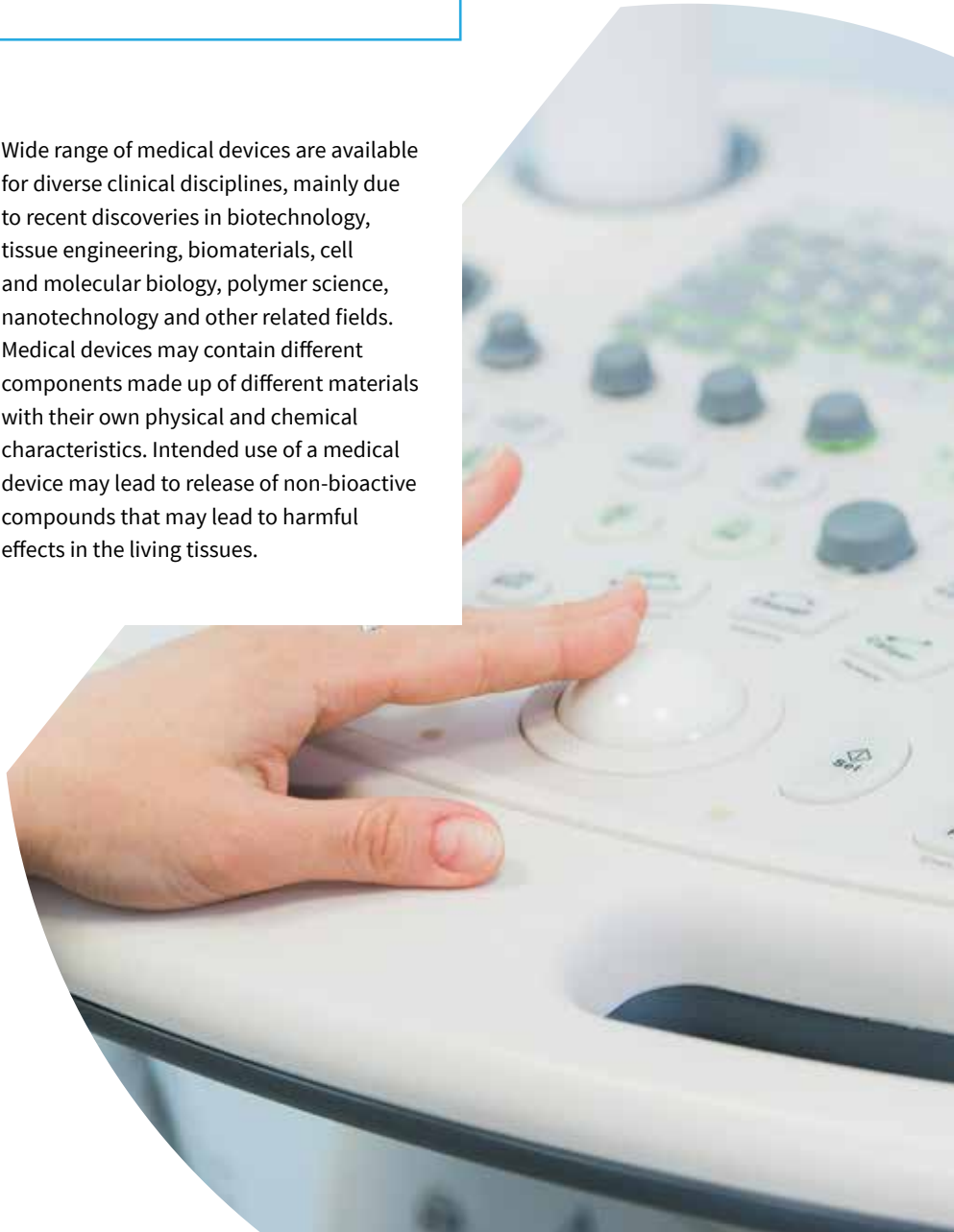
The physical and chemical properties of the medical device may interact indirectly with a medical device functionally and may malfunction a device and put the patient into significant risk for patients and remains a critical issue in longevity and functionality of specific devices. It is hence important to assess and optimize the biocompatibility of medical devices. Biocompatibility, defined as a vital test procedure to determine the potential toxicity *(in vitro and in vivo)* emerging as reactions by both local and systemic from bodily contact with a medical device. The critical nature of medical devices has caused them to come under stringent regulations. The safety considerations of medical device shall be in deliberation with contamination, breakdown or decomposition, migration of device materials to other parts of the body, through degradation over a life cycle of a medical device.

According to the International Organization for Standardization (ISO) and national standards, medical devices are required to evaluate their biocompatibility within the scope of risk management, when they have contact with the body, irrespective of their properties viz., mechanical, physical and chemical. ISO has many standards that are internationally accepted and many countries have their additional set of requirements to verify the standards of the manufactures. The intention of biocompatibility testing is to establish preliminary levels of toxicity and provide information for any possible adverse effects or allergic reactions. The tasks for evaluating the biocompatibility of medical devices are very complex and require profession experience.

Medical Devices and Biocompatibility

Medical devices are made up of different types of materials and are classified based upon their application viz., synthetic polymer, biodegradable, tissue-derived, bio-derived macromolecules, passive surface coatings, bioactive and tissue-adhesive, metals, ceramics and glassy carbons, composites, and Nano materials. Synthetic polymers such as sutures, vascular grafts, heart-valve stents, high-volume tubing, connectors, hydrogel coatings, angioplasty catheters and bags are commonly used. Polymers are categorized as poly (amides), poly (vinyl chloride) (PVC), poly (ethylene terephthalate) textiles, polymethylmethacrylate (PMMA), poly (tetrafluoroethylene) (PTFE), poly (ethylene oxide), Poly (ether urea urethanes). These are stable, biocompatible and cost effective. Having ability for absorption and biodegradability wherein by-products are considered as nontoxic and eliminated by body metabolic pathways, these biodegradable biomaterials are of high interest in biomedical devices like bioresorbable sutures and drug-eluting stents. Widely used biodegradable materials are homopolymers or copolymers of alpha-hydroxy acids, such as lactic and/or glycolic acids, polyanhydrides and polyorthoesters.

Metal and metallic alloys include austenitic stainless steels, cobalt-chrome-molybdenum, tantalum and titanium. Intended use is permanent implants for orthopedic and dental applications, guide wires for angioplasty and angiography catheters, endovascular stents, fracture plates, nails, screws, and joint replacement, heart-valve and artificial-heart structural components pacemaker cases, fracture plates, nails and screws, and joint-replacement packaging for electrical stimulators. Metal and metallic alloys have low corrosion rate, low density, and high strength, are fatigue resistance, stiffness, and are biocompatible lacking cytotoxic effects. These materials require anticoagulation and antiplatelet therapy.

Ceramics like dense, high- purity alumina, dense hydroxylapatite are used extensively in dental and ball and socket of total-hip, maintenance of the alveolar ridge. Granules of hydroxylapatite are widely used to fill bony, periodontal, and alveolar ridge defects. Carbons like glassy and pyrolytic carbon have been widely used as dental implants, heart-valve components and particularly as leaflets in mechanical valves, highly resistant to degradation and wear and tear. Composite structures have high strength and low density such as coextruded tubes with wires, carbon-fiber composites, radio-opaque fillers such as barium sulfate. Nanomaterials such as TAXUS drug eluting stent are well suited to enhance the biocompatibility and mechanical properties of medical devices such as drug delivery, molecular diagnostics, and imaging, implants, as membranes. There are many unknowns about the potential safety effects of nanomaterials, particularly nanoparticulates.

Overall biocompatibility assessment of a medical device requires physical and chemical characterization of materials used in a medical device, which is a complex and time-consuming procedures and may result in rejection of a medical device that may be a minimal risk to the patients.

Biocompatibility Guidelines

The ISO is an international, non-governmental body that develops worldwide proprietary industrial and commercial standards. ISO also develops documents and many standards with a general title 'Biological evaluation of medical devices' (ISO 10993), which is a set of harmonized standards for the evaluation of biocompatibility of medical devices before clinical trials. The standards that is approved by the European Union standards body European Committee for Standardization (CEN) automatically become the standards applicable in Europe (EN ISO).

ISO Standard 10993 is the best guideline to start any biocompatibility requirement such as Biological Evaluation of Medical Devices. Part 1 of the standard is the Guidance on Selection of Tests; Part 2 covers animal welfare requirements, and Parts 3 through 19 guidelines for specific test procedures or other testing-related issues. FDA has significantly implemented the ISO guideline, though in some areas FDA's testing requirements go beyond those of ISO. The specific ISO test trials vary slightly from the USP procedures historically used for FDA submissions.

The ISO procedures tend to be more stringent, so companies planning to register their product in both Europe and the U.S. should follow ISO test methods. FDA requirements are to be verified so additional testing may be needed. Japanese procedures for sample preparation and testing are slightly different from either USP or ISO tests. Test methods for dental materials are covered by ISO 7405, Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry (1997). ISO 14155 (2003) and A Guidance on a Risk-Management Process, issued as ISO 20993 (2006), and multiple standards cover manufacturing of medical devices are standards for clinical testing.

The ISO rules, generally, refer to the compendial strategies described in the U.S. Pharmacopeia (USP) and found in the standards and guidelines of American Society for Testing and Materials (ASTM) F-748.United States Pharmacopeia (USP) is an independent, non-governmental organization that promotes the public health by establishing testing standards that ensure the quality of medicines and other health devices. There are several stages in overall process of determining

the biocompatibility of any medical device. The biological evaluation process is initiated by collecting data on the materials comprising the device, then executing in *vitro* screening and ultimately conducting confirmatory in *vivo* tests on the finished device. It is essential to make sure that the finished device does not produce any harmful effects on human use.

Studies related to evaluation of medical device are designed to assess the safety of a medical product in nonclinical models, including biocompatibility studies for medical devices and are conducted according to Good Laboratory Practice (GLP) principles and procedures of OECD. Medical device manufacturers are required to have their biocompatibility studies done per GLP to utilize the data in any type of regulatory submission. GLP procedures are similar across geographical boundaries. All testings are performed on the final version of the product.

Biocompatibility Testing

A device consists of several materials, so it may come combined; devices with different components and should be extracted separately because there is a possibility of dilution of different components. Use of animal studies to justify omission of specific biocompatibility tests and efficacy study of the final finished device performed in a relevant animal model can be designed to include assessments that may be used to justify omission of some biocompatibility tests. Interaction between the medical devices, biomaterials or extracts with in *vivo* environment (cellular and

molecular aspects) is emphasized with preclinical biocompatibility testing that has not been sufficiently investigated. Cellular and tissue responses are more accurate and informative than typical scoring methodology for biocompatibility of medical implants and devices. Medical devices may undergo biocompatibility tests of cytotoxicity, sensitization, hemocompatibility, pyrogenicity, implantation, genotoxicity, carcinogenicity, reproductive and developmental toxicity, biodegradation, immunotoxicity, and a series of tests prior to intended use in clinical environment.

No biocompatibility testing is required if the device has demonstrable history of clinical use. It is obvious that not all tests identified in a category are necessary, since the test methods used are sensitive, precise and accurate. The results should be reproducible (interlaboratory) as well as repeatable (intralaboratory). The Biocompatibility assessment of biomaterials and medical devices is dependent on the end-use application of the device. New and innovative biomaterials and medical devices will require new test procedures for evaluation.

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