QR VIEWS

A BIMONTHLY PUBLICATION OF NIQR TRIVANDRUM BRANCH

FOR PRIVATE CIRCULATION AMONG MEMBERS ONLY

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Contents

QUALITY IS NOT AN ACT, IT IS A HABIT.

-ARISTOTLE

Chairman's Message

Dear NIQR members,

Greetings to all

This time I would like to touch upon a topic of Quality and Trust. Any organization can build reputation and improve profitability only if it can build trust. Trust means firm belief in the reliability and ability of the organization in meeting customer expectations. Trust is earned in a very hard way and once it is lost, the loss is forever. In the recent times we have seen many organisations squandering the trust and reputation they had, in a very short time. It affects the reputation of the organization, its business opportunities, its credibility and many times the downfall of the organization itself. Some CEOs had to publicly apologize for loss of trust. Trust is built by organisational competence and integrity.

At this point of time I would like to emphasize the role of quality professionals in helping the organisations put in place competent systems to ensure that the activity of an organisation consistently delivers on its promises to customers and stakeholders.

This is achieved through:

1. Understanding the customer and stakeholder needs and expectations.
2. Helping the organisation align their values and culture to account for these needs.
3. Facilitating the management systems to consistently make the right decisions for customers, stakeholders and the organization
4. Helping organisations understand performance and identify the risks to trust and reputation
5. Helping organisations invest in the right improvements to improve performance and trust. Quality systems of assurance and improvement along with the culture of quality are the investment of any organization in trust and reputation. It is the responsibility of quality profession to enhance trust and reputation in the organization.

Request you all to ponder on this topic and contribute your might to the respective organisations. Even in personal life Trust is something which we cannot play with.

Wishing you all a very happy time ahead.

2. Report on Activities of the branch from January 2017 to August 2018

2.1 A technical lecture on **Engineering Standards** was delivered for the student chapter at Lourdes Matha College of Science and Technology on 17 February 2017 by Shri. KR Mohan Anantha narayanan, Head, Quality Division-External Mechanical, **Vikram Sarabhai Space Centre (VSSC)/ Indian Space Research Organization (ISRO)**.

2.2 One Day workshop on **Quality Management System-Requirements**

The workshop was conducted on 3 March 2017 at Hotel Apollo Dimora Trivandrum. The Workshop was inaugurated by **Shri. S.Somanath, Director, VSSC/ ISRO**. In his inaugural address, he mentioned about the importance of QMS in production environment and appreciated the efforts of NIQR in organizing the workshop. He also noted that the faculties are all well experienced and the workshop would add value to the participants.

Dr.B Valsa, Deputy Director, VSSC, Systems Reliability delivered the felicitation address and mentioned that VSSC has been successful in obtaining ISO 9001 2015 certificate and the exercise for which would be shared in the workshop.

Shri. C.A.Ignatious, Chairman of the branch released course CD containing the lectures and wished the function all success. **Shri.C.Athi Pagavan, Vice-chairman** of the branch delivered the welcome address.

Shri. KR Mohanan Anthanarayanan, Secretary of the branch briefed about the details of topics to be covered in the workshop and proposed the vote of thanks. About 120 delegates attended the programme and the delegates gave very good feedback. There were five lectures. Experience of implementing ISO 9001 2015 in VSSC was shared in the lecture by **Shri.S Saratchandran**, Group Director, Systems Reliability. **Shri.Sanub Fazil**, Tata Elxsi gave a lecture on the details of transition to ISO 9001:2015 in an industry. **Shri. KM Kalyanansundaram**, Quality advisor to Ananthapuri Hospitals talked about the "Risk Management and experiences in implementing QMS in hospitals with case studies". **Dr. S Aniyan**, AGM, Brahmos Aerospace, Thiruvananthapuram presented about AS 9100 implementation with a lot of interaction with participants. **Shri. KR Mohanan Anthanarayanan**, Head, Quality External Work Centre Mechanical, Systems Reliability, VSSC presented the overview of NADCAP requirements for special process with case studies.

2.3 One Day Workshop on NDT for Non-NDT professionals on 19 August 2017

Shri. **S Pandian, Director, IPRC, ISRO** inaugurating the workshop

The workshop was inaugurated by **Shri.S.Pandian, Director, ISRO Propulsion Complex (IPRC), Mahendragiri.** In his inaugural address he gave an outline of usefulness of NDT in aerospace systems and congratulated the team for organizing the programme.

The Course note CD was released by **Shri.G.Narayanan, Deputy Director, SRQA, Liquid Propulsion Systems Centre (LPSC), ISRO**. In his felicitation address he mentioned that the NIQR branch had conducted regular programme on Quality over the past several years. Shri. KR Mohanananthanarayanan Secretary of the branch briefed about the workshop and the details of topic to be covered. There were 63 delegates out of which 30 were students from student chapters of the branch There were four lectures viz;

- Approach to Non-Destructive Testing by **Shri.M Arumugam, GD, R&QA, LPSC**
- Fundamental NDT Methods by **Shri.S Adal Arasu, DGM NDT VSSC (retd.)**
- Setting up an NDT Laboratory by **Shri.Raju S, Head NDT Laboratory RFF VSSC**
- NDT certification and Standards by **Shri. K R Mohanananthanarayanan, NIQR**

Shri.Narayanan, DD, SR, LPSC, ISRO releasing the course note CD and participants.

2.4 Annual General body meeting

AGM of the branch was held on 20 September 2017 at Mascot Hotel,Trivandrum. AGM was preceded by an interesting and informative lecture on **"Biomimicry**: How nature Inspires Engineering Quality and Reliability" by **Dr.ArunSurendran, Principal and Strategic Director of the Trinity College of Engineering, Thiruvananthapuram**. About 63 members attended the AGM.

2.5 Quality Day 2017

Quality Day 2017 was organsied on 23 November 2017 at Hotel Pankaj, Thiruvananthapuram. The Student chapter members from Amal Jyothi College of Engineering gave a presentation on how smart cities can be developed titled **'Smart Future – A Quest for Utopia'**. The Presentation covered the various aspects on definition of smart city, barriers for smart city, how city can be marked smart, major international standards like ISO 37101, 37120, BIS PAS 181 etc., It was an excellent effort by the student chapter.

A lecture on **'Quality as I experienced'** by **Shri.L Muthu, Former Deputy Director, LPSC** gave the participants an insight into how quality is getting integrated in a complex system like launch vehicle technology



2.6 Conference on Quality Engineering for Zero Defects

A Two day conference on Quality Engineering for Zero Defects was held at **Lourdes Matha College of Science and Technology** on 16 & 17 February 2018 at the college premises. The conference was inaugurated by **Shri. C.A . Ignatious, Chiarman, NIQR Trivandrum Branch** in the presence of **Prof. P.M.Hormese, Director of the college**. **Shri. Frankin P.Joshua Professor of Mechanical Engineering** gave the welcome speech.

The following lectures were delivered during the conference.

- QA practices in ISRO by Shri.Ignatious C.A., DeputyDirector (Retd.), VSSC
- Fundamentals of Geometric Drawings and Tolerance by Shri.K Narasaiha, DGM Advanced Manufact uring Facility, MME/ VSSC
- Characterization of Material Quality by Dr. Ramesh Narayanan, Head, Material Characterization Division, VSSC
- Fundamentals of Quality in Engineering by Shri.C Athi Pagavan, Vice-chairman, NIQR Trivandrum branch
- Quality Improvement Methods in Learning by Shri. E. J. Francis, Group Director (Retd.), VSSC
- Quality Quiz was conducted by Shri.KR Mohanananthanarayanan, Secretary ,NIQR Trivandrum Branch.
- Around 140 students participated in the conference and it was well co-ordinated by Shri.Daniel C. Ribu, Professor of Mechanical Engineering

2.7 Visit by NIQR National Body

NIQR National president, Shri. P.K.Aggarwal, Vice President Dr.V.Swaminathan, Shri. S.Rajasekaran and National Secretary K.Sridharan Balaji visited Trivandrum on 20-05-2018. NIQR Trivandrum Branch executive committee members briefed the activities of the branch to the National Body members. The National body requested for maximum participation from Trivandrum branch for the National Convention going to be held on 10 & 11 August 2018 at Chennai.

2.8. New Members

During the period 3 life members joined the branch and 323 students enrolled at Amal Jyothi College of Engineering Kanchirapally Kottayam. Welcome to the new members Shri.NB Guru,VSSC, Shri. Prabhakaran Pillai, VSSC (retd), Shri. S.Mohan Raj, VSSC and student members.

Corrective Action Preventive Action (CAPA)

- P. Muthuganapathy

Introduction to CAPA

When illness strikes and we need medical attention, we put our trust in the medical products and care givers to provide relief. We expect the care we receive is without fault. Fortunately, failure is not experienced frequently in healthcare and medical devices. When failure does occur, we demand a rigorous process of investigation be initiated to identify why it occurred. Corrective Action Preventive Action (CAPA) is a process which investigates and solves problems, identifies causes, takes corrective action and prevents recurrence of the root causes. The ultimate purpose of CAPA is to assure the problem can never be experienced again. CAPA can be applied in many disciplines. A few of these disciplines are:

- Manufacturing
- Product Design
- Testing Verification and Validation
- Distribution, Shipping, Transport and Packaging
- Use-Applications

What is CAPA

Corrective Action Preventive Action (CAPA) is the result of a US FDA requirement, FDA 21 CFR 820.100. The CAPA requirement applies to manufacturers of medical devices and compels them to include CAPA in their Quality Management System (QMS).

CAPA is split between two distinct but related functions.

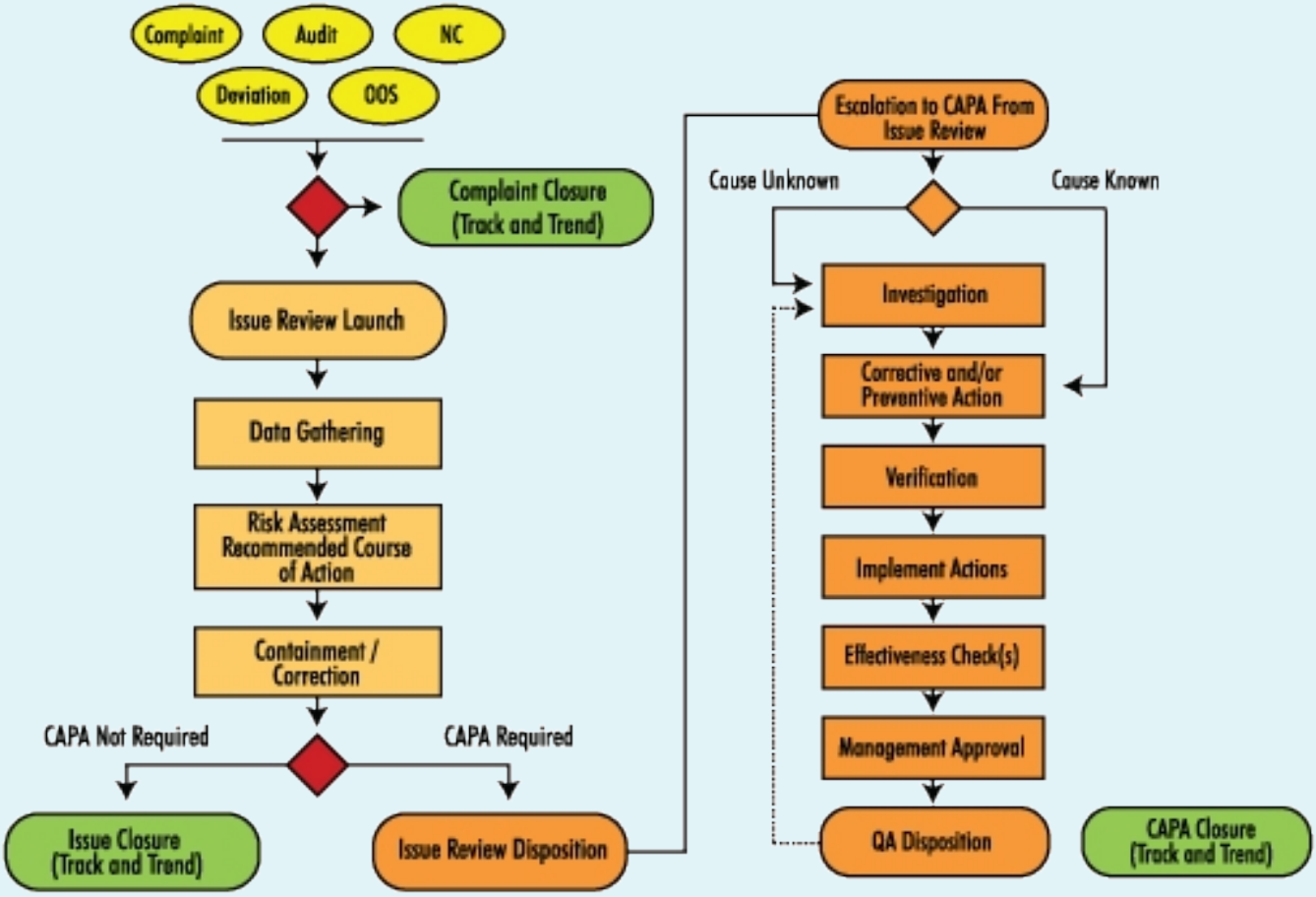
1. Corrective Action (CA) is an extension of Root Cause Analysis (RCA). The first goal of CA is to find the root cause, base event or error that preceded the problem. The second goal is to take action directed at the root cause or error.

2. Preventive Action (PA) is similar to Lessons Learned / Read Across. PA resembles the replication activity of Design for Six Sigma (DFSS). Another example of PA in industry is Yokaten, a Japanese term used by Toyota, describing a sharing across the organization. The primary goal of PA is to inform an organization and prevent the problem from returning in other facilities lines or products.

Why Implement CAPA

Identifying the root cause of failure is a key tenet of any effective QMS. When a problem occurs, it is often just a symptom of the real issue. Symptoms can be treated but finding out why the symptom is experienced is the true purpose for implementing CAPA. Failure to implement an effective Corrective Action Preventive Action process is a violation of FDA regulations defining Good Manufacturing Practice (GMP).

CAPA Management System



Once implemented, the CAPA system must exhibit ten objectives to meet the intent of the FDA 21 CFR 820.100 requirement. The 10 objectives of CAPA implementation are:

1. Verification of a CAPA system procedure(s) that addresses the requirements of the quality system regulation. It must be defined and documented.
2. Evidence that appropriate sources of product and quality problems have been identified.
3. Tracking of Trends (which are unfavorable) are identified.
4. Data sources for Corrective and Preventive Action are of appropriate quality and content.
5. Verify that appropriate Statistical Process Control (SPC) methods are used to detect recurring quality problems.
6. Verify the RCA work performed is aligned to the level of Risk the problem has been identified with.
7. Actions address the root cause and preventive opportunities.
8. CAPA process actions are effective and verified or validated prior to implementation.
9. Corrective and preventive actions for product and quality problems are implemented and documented.
10. Nonconforming product, quality problems and corrective / preventive actions have been properly shared and included in management review.

How to Implement CAPA

There are many ways to apply the two functions of CAPA. The Quality-One Corrective Action Preventive Action approach is as follows:

Corrective Action

When a symptom is observed or communicated, a systematic set of activities are initiated. The activities are intended to describe the problem in sufficient detail so that the team can identify a root cause path. Once a root cause path is selected, a permanent corrective action is identified, verified, implemented and validated. The Quality-One nine-steps for Corrective Action are detailed below:

1. Symptom is observed or communicated. The symptom must be quantified through the application of five questions, or 5Q, and confirmed as a true symptom, worthy of defining further.
2. Problem Statement is created by using the 5 Why approach, driving as deep into the problem as data will permit.
3. Affinity or Ishikawa (fishbone) diagram is used to identify possible causes of the Problem Statement.
4. Problem Description is written based on further investigation of the What, Where, When and How Big data collected.
5. Possible causes on the Affinity or Ishikawa (fishbone) diagram can then be reduced by using data from the Problem Description.
6. Theories are developed on remaining possible causes.
7. Root cause is verified by turning it on or off at will.
8. Permanent Corrective Actions are determined for root cause and inspection process (which also failed to stop the cause from escaping).
9. Implementation and Validation of the Corrective Action.

Preventive Action

Often the root cause of a root cause is the system or lack of policies, practices or procedures which supported the creation of the physical root cause. Preventive Action (PA) occurs after the physical root cause has been identified and permanent corrective action has been validated. PA recognizes the value of the information and actions taken during the CA function. This information is shared within the organization. Quality-One suggests the following steps for Preventive Action:

1. Capture the Problem Statement as an Object-Defect for searchable databases.
2. Link root causes to the Problem Statement with the Permanent Corrective Action.
3. Identify other systems, facilities and processes which could benefit from the knowledge captured.
4. Assure Systems Documents are updated, including but not limited to:

- **Failure Mode and Effects Analysis (FMEA)**
- **Control Plan Methodology**
- **Work Instructions**

5. Archive information for future retrieval including supporting information.
   Publish and close-out team experience.

"Mere allocation of huge sums of money for quality will not bring quality"

— Edwards Deming

16th NIQR Global Quality Convention

16th NIQR National Convention on "Digital Quality for Disruptive Future" was held on 10 & 11 August 2018 at Chennai Trade Centre, Chennai. The convention was inaugurated by Ma Foi K.Pandiarajan, Minister for Tamil Official Language & Tamil Culture and in his inaugural address he has emphasized the need of NIQR to become the self regulatory statutory body.

The two days convention was well organised and attended by delegates from industries, institutions and R&D organizations. Eminent personalities from various industries and organizations shared their experiences through case studies. The topics covered are :

- **Transforming Indian Business – Leadership Challenges & Opportunities**
- **Future mobility**
- **Smart Manufacturing**
- **Disruptive Transformation-MSME's perspective**
- **Feeling the Transformation and**
- **Digital Quality (Panel Discussion)**

The NIQR awards were given in the valedictory function.

NIQR Awards

NIQR- ASHOK LEYLAND AWARD FOR OUTSTANDING ORGANISATION

NIQR- LUCAS-TVS AWARD FOR OUTSTANDING SERVICE ORGANISATION

NIQR-T V N KIDAO AWARD FOR OUTSTANDING EDUCATIONAL INSTITUTION

NIQR-ACCURATE AWARD FOR OUTSTANDING QUALITY MAN

NIQR- SCHWING STETTER AWARD FOR OUTSTANDING SMALL SCALE INDUSTRY

NIQR- BEST STUDENT AWARD

NIQR Students chapter, Students from ACE College of Engineering attended the QUIZ programme.

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