Enhancing Audit Program Using Dr. Deming’s 14 points

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Dr. Deming, the Father of Quality

• W. Edward Deming is famous for the insightful views, ideas and commentary on improving business and customer satisfaction using statistical techniques and quality control tools.
• New York Times referred to him as “High Prophet of Quality”. Deming advised Japan on how to rebuild its shattered industries after World War II. Japanese companies created a Deming Prize for companies that made striking advances in quality.
• He exhorted managers to "drive out fear," so that workers would not feel intimidated to make improvements in the workplace.
Dr. Deming’s Philosophy

• Specifications may not tell the whole story. Important characteristics may not be covered in specs or sometimes they are too tight to produce and in fact it is not necessary to have such tight specs.

• Using the Process Control Technique and distribution of the characteristic will allow you to predict the future. You could reduce/eliminate the inspections if your distribution is good.

• When the supplier gives you a better price not knowing his quality, he may be chiseling you on quality or may go out of business trying to meet price that he quoted and leave you stranded.
Dr. Deming’s Philosophy

- Do it right the first time: it is necessary to start with good materials and not to create defectives anywhere. You cannot afford any other policy.
- Require statistical evidence of process control along with incoming critical parts.
- Choose/educate suppliers and purchasing managers who could use SQC tools. There is no other way for you or your supplier to know and achieve best economy and productivity.
Naren with Dr. Deming at Pitney Bowes in 1981
What Is Quality?

A wide array of definitions of quality are available.

• Philip R. Crosby, a quality expert asserts that quality is “conformance to requirements.”
• J. M. Juran, defines quality as “fitness for use.”
• Armand V. Feigenbaum, a quality pioneer, states that quality is “what the customer says it is.”
• The International Organization for Standardization (ISO) define: “Quality is the total features and characteristics of a product or service that provide its ability to satisfy stated or implied needs.”
### Products

- The customer owns an object.
- The goal of producing products is to reduce variability and make products uniform.
- A product can be placed in inventory; a sample can be sent in advance for the customer to review.
- If improperly produced, the product can be pulled off the line or recalled.

### Services

- The customer owns a memory. The experience cannot be sold or passed on to a third party.
- The goal of service is uniqueness; each customer and each contract are “special”.
- A service happens in a moment. It cannot be stockpiled.
- If a service is improperly performed, apologies and reparations are the only means of recourse.
What is a Quality Audit?

• Is the process of systematic examination of a quality system carried out by an internal or external quality auditor or an audit team.

• It is an important part of organization's quality management system.

• is a key element in the ISO quality system standard ISO 9001, FDA GMP, GLP, GCP and various quality and regulatory requirements.
What is a Quality Audit  Cont’d

• Objective assessment, performed at defined intervals and at sufficient frequency, of a company’s quality system to operate against a given criteria.
  – Systematic
  – Independent
  – Documented

• Provide factual, unfiltered information to manage the quality system.

• A tool for use by management.

• Regulatory requirement (FDA, ISO, etc.).

• Help minimize risk.

• “Close the loop” for other elements of the quality system.
What is a Quality Audit

Cont’d

• Audits are not a quick look.
• Audits are *preventive*.
• Audits are planned, organized, and coordinated.
• Audits are carried out for the benefit of customers and the company, not the auditor.
• A single audit will not find all noncompliant issues or potential problems.
ASQ Quality Auditing History

• In 1975 ASQC established a Quality Auditing Technical Committee (QATC) to explore quality auditing as a potentially major segment of the society's technical program.

• In 1986 the committee issued Generic Guidelines for Auditing of Quality Systems and developed an authoritative set of audit definitions.

• In 1987, 28 members of the QATC took a pilot exam. Based on the success of these pilots, the Society formally adopted the Certified Quality Auditor Program. Now there are 21,000 Certified Quality Auditors (CQA).

• Quality Audit division has more than 8500 members.
Can you avoid Regulatory Audit?

Dear IRS,

I am writing to you to cancel my subscription.

Please remove my name from your mailing list.
Surprise Visit from Regulator

"We're going to parachute in and do a surprise audit, but I want to keep the whole thing low key."
OUR ANNUAL ISO 9000 AUDIT IS NEXT WEEK.

WE CAN PASS THE AUDIT IF WE PUT ALL OF OUR NON-CONFORMING DOCUMENTS IN THE TRUNKS OF OUR CARS.

DOESN'T THAT DEFEAT THE PURPOSE OF A VOLUNTARY AUDIT? AND THEN TORCH THE CARS.
"It's safe to come out - the auditors have gone."
Interviews as part of the Audit Process

• Auditors rely heavily on personal interviews with managers and employees to obtain information. It is the primary means of verifying what is observed in the workplace or summarized in policy and procedure manuals.

• Audit interviews are often organized around lists of written questions designed to identify control weaknesses, operating inefficiencies, lack of compliance, or other matters.
WE WANT TO
MAKE SURE YOU'RE
FIT FOR PURPOSE
Is your Audit Process Encouraging?

“Don’t you think this internal audit’s gone too far?”
Deming's 14 Points for Management

1. Create constancy of purpose toward improvement of product and service.
2. Adopt the new philosophy. Management to lead.
3. Cease dependency on inspection to achieve quality.
4. End the practice of awarding business on the basis of price tag alone.
5. Improve constantly and forever the system of production and service.
6. Institute training on the job.
7. Institute leadership.
Deming's 14 Points for Management

8. Drive out fear.
10. Eliminate numerical goals and slogans.
11. Eliminate work standards & MBOs.
12. Remove barriers that rob hourly employees and people in management and in engineering of their right to pride of workmanship.
13. Institute a vigorous program of education and self-improvement.
14. Put everybody in the company to work to accomplish the transformation.
Quality Progress – Japan vs. USA

![Graph showing the trend of quality progress in Japan and USA over the years](graph.png)
“PDCA” in Audit Program

- Authority for the audit program
  - Establishing the audit program
    - objectives & extent
    - responsibilities
    - resources
    - procedures
  - Implementing the audit program
    - scheduling
    - evaluating auditors
    - selecting audit team
    - directing audit activities
    - maintaining records
  - Monitoring and reviewing the audit program
    - monitor and reviewing
    - identifying needs for corrective and preventive actions
    - Identifying opportunities for improvement
  - Competence and evaluation of auditors
  - Audit activities

PLAN
DO
CHECK
ACT
Our customer is the Lead Auditor
Who are the Customers

Three types of customers:
1. Internal customers.
2. Stockholders.
3. External customers.
   - Permitting customers.
   - End users.
Customers Satisfaction

“So, as you can see, customer satisfaction is up considerably since phasing out the complaint forms.”
Customer Expectations Define Quality
Key Benefits of Customer focus

• Increased customer value.
• Increased customer satisfaction.
• Improved customer loyalty.
• Enhanced repeat business.
• Enhanced reputation of the organization.
• Expanded customer base.
• Increased revenue and market share.
Are Leaders Listening?

A good leader listens to his underlings.

Fine. I'm overworked and underpaid. I hate my co-workers, I don't have the resources to do my job, and we have no clear strategy.

No wonder leaders listen. It's a lot easier than fixing all of that stuff.
Leadership

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives.

• Improved communication between levels and functions of the organization. Better coordination of the organization’s processes.

• Effectiveness and efficiency greatly improved.

• Development and improvement of the capability of the organization and its people to deliver desired results.
Engaging with employees

Before I make my decision, I’d like to ask for your opinions.

It’s supposed to make you feel “engaged.”

And you actually plan to listen to us? I’m hoping it will look that way on the outside.
Auditor Skills

The most important attribute of an auditor is:

• Inter-personal skills. Listening.
• Ability to get auditee relaxed so that he/she can freely engage in communications with auditor.
• Encourage auditee and leverage his/her knowledge in initiating recommended improvements.

In fact, the auditing literature rarely address the skills require to ask questions effectively.
Employee Engagement

WE NEED MORE OF WHAT THE MANAGEMENT EXPERTS CALL “EMPLOYEE ENGAGEMENT.”

I DON’T KNOW THE DETAILS, BUT IT HAS SOMETHING TO DO WITH YOU IDIOTS WORKING HARDER FOR THE SAME PAY.

IS ANYTHING DIFFERENT ON YOUR END?

I THINK I’M Supposed TO BE HAPPIER.
Auditee engagement during Audit

• Positive motivation from auditor and organization management significantly influence auditee behavior during the audit. Motivated employees will fully engage during the audit.

• An 'engaged employee' is someone who sees their job as worthwhile or interesting and is therefore more likely to be fully involved in and enthusiastic about the things they do.

• Engaged auditee puts an extra effort beyond commitment and job satisfaction during an audit interview and offer recommendations for improvement.

• Auditee engagement is also about the way an auditor listens to, builds trust and relationships with auditee.
Examples of getting employees engaged

• Evaluating customer complaints and establishing quality improvement and an Audit program.
• Setting up a new business unit.
• Financial crises with budget deficit.
• Fierce competition for service contracts and talent.
• Company running at a loss.
• Business transformation.
• Not operating to full potential with negative affect on service levels.
Summary on communications

• Auditor should discover auditee true needs and concerns.
• Many auditors regard questions merely as a vehicle for obtaining info. When in fact, questions represent the driving force that determines the content, tone, and direction of most audit.
• Questions can engender cooperation, build trust, resolve conflicts, and demonstrate respect and support for the auditee organization.
• In organizations characterized by internal competition and secrecy, questions can be used as negotiating tools to obtain information.
• Questions can also be used to help auditee persuade themselves of the Value of the auditor’s suggestions.
Conclusion

Enhancing Audit Program Using Deming 14 Points
Auditing is more than a Checklist
Maintain Independence when Auditing

THINK OF ME AS YOUR PERSONAL TRAINER

INDEPENDENT AUDIT LIMITED

INTERNAL AUDIT
Get every one involve in Audit Program
Efficient Audit Program

An efficient system is the result of an integration of employees engagement

- In strategic planning.
- In reviewing complaints.
- In establishing process metrics.
- In developing training.
- In improving customer satisfaction.
Dr. Deming Books

• The Essential Leadership Principles from the Father Of Quality 2013
• The New Economics 1993
• “Out Of The Crisis” 1986
• White Paper “The System Of Profound Knowledge” The W. Edward Deming Institute