THE QUALITY ENGINEER PRIMER

Tenth Edition - May 1, 2015

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CQE PRIMER CONTENTS

CQE Primer Question Contents

	Primer Section	Questions			
		%	Exam	Primer	CD
II.	Management & Leadership	11.2%	18	45	112
III.	Quality Systems	10%	16	40	100
IV.	Product, Process, & Service Design	14.4%	23	58	144
V.	Product & Process Control	8%	13	32	80
VI.	Testing & Measurement	7.6%	12	30	76
VII.	Continuous Improvement	16.9%	27	68	169
VIII.	Quantitative Methods	7.5%	12	30	75
IX.	Statistical Tools	7%	11	28	70
X.	Statistical Applications	8%	13	32	80
XI.	Risk Management	9.4%	15	37	94
	Total	100%	160	400	1000

Comparison B/T CQE Primer & ASQ BOK

Primer	II	III	IV	V	VI	VII	VIII	IX	X	XI
ASQ BOK	I A ➜ I	II A ➜ F	III A ➜ E	IV A ➜ F	IV A & B	V C ➜ F	VI A ➜ C	VI F & G	VI D,E,H	VII A ➜ C

I. CERTIFICATION OVERVIEW

CQE Exam (Continued)

Eligibility

CQE participants must register with ASQ headquarters. Eligibility entails a combination of eight years work experience and/or higher education. Three years of this requirement must be in a decision making position.

Cost

The national test fee is determined by ASQ and is detailed in the CQE brochure.

Location

Proctors are provided by ASQ sections in your area.

Duration

The test lasts 5 hours and will begin at an advised time (typically 8 A.M.).

I. CERTIFICATION OVERVIEW

ASQ CQE BOK (Continued)

C. Continuous Improvement Methodologies (Evaluate)

1. Total quality management (TQM)
2. Kaizen
3. Plan-do-check-act (PDCA)
4. Six sigma
5. Theory of constraints (TOC)

D. Lean tools (Evaluate)

1. 5S
2. Value-stream mapping
3. Kanban
4. Visual control
5. Waste (Muda)
6. Standardized work
7. Takt time
8. Single minute exchange of die (SMED)

I. CERTIFICATION OVERVIEW

Levels of Cognition

Remember
Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand
Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply
Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze
Break down information into its constituent parts and recognize their relationship to one another and how they are organized

Evaluate
Make judgments about the value of proposed ideas, solutions, etc., by comparing the proposal to specific criteria or standards.

Create
Put parts or elements together in such a way as to reveal a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further.

II. MANAGEMENT & LEADERSHIP I.A.1
QUALITY FOUNDATIONS

Management and Leadership

Management and Leadership is presented in the following topic areas:

- **Quality Foundations**
- **Continuous Improvement Foundations**
- **Quality Management Systems**
- **ASQ Code of Ethics**
- **Leadership Principles**
- **Facilitation Techniques**
- **Communication Skills**
- **Customer Relations**
- **Supplier Management**
- **Quality Improvement Barriers**

Dr. Kaoru Ishikawa (Continued)

There are 6 main characteristics that make CWQC different:

1. **More education and training in quality control**
2. **Quality circles are really only 20% of the activities for CWQC**
3. **Participation by all members of the company**
4. **Having QC audits**
5. **Using the seven tools and advanced statistical methods**
6. **Nationwide quality control promotion activities**

CWQC involves the participation of workers from top to bottom of the organization and from the start to the finish of the product life cycle. CWQC requires a management philosophy that has respect for humanity.

Kaoru Ishikawa was known for his lifelong efforts as the father of Japanese quality control efforts. The fishbone diagram is also called the Ishikawa diagram in his honor.

Lean Enterprise

Any truly lean system is highly dependent on the demands of its customers and the reliability of its suppliers. No implementation of lean manufacturing can reach its full potential without including the entire enterprise in its planning.

Lean Manufacturing

Lean techniques are, in their most basic form, the systematic identification and elimination of waste, the implementation of the concepts of continuous flow, and customer pull.

Generally, five areas drive the lean producer: cost, quality, delivery, safety, and morale.

Strategic and Tactical Quality Goals

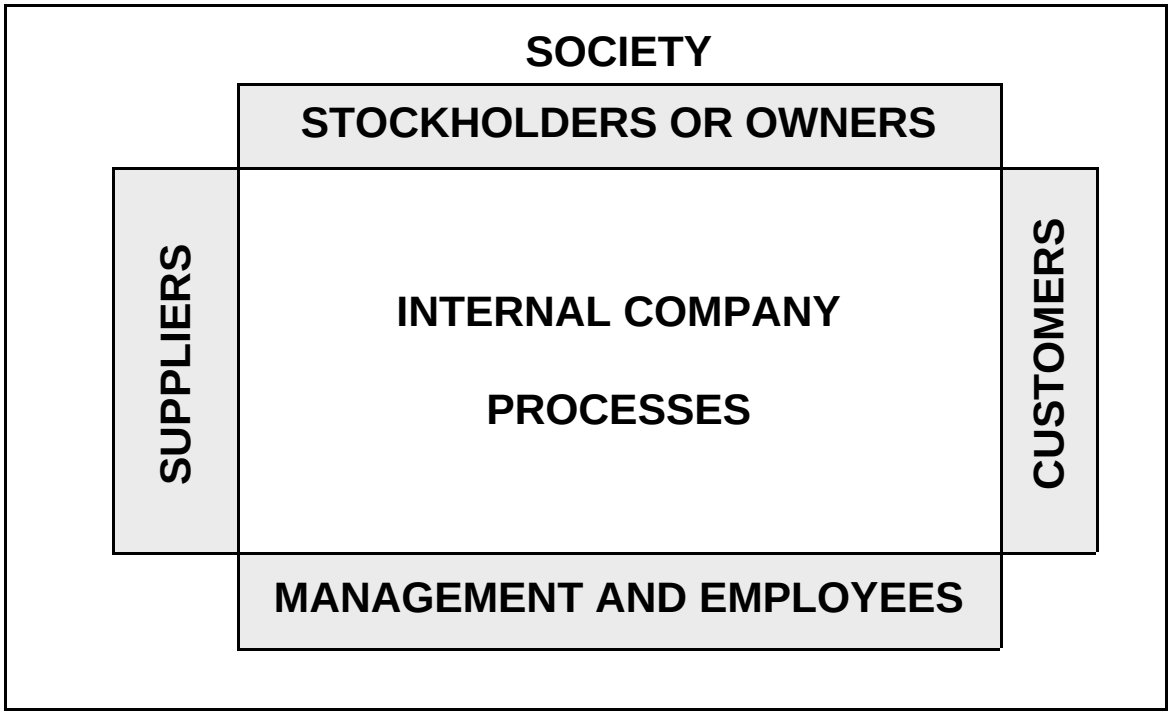
Strategic quality goals should be of such an important nature that they will fit into the strategic business plan. All departments will have quality goals or sub-goals that come from the strategic business plan (which they then need resources to attack).

For instance, the basic information could be divided into two groups:

- **Those of a strategic nature: items that cut across many departments and/or are issues that are applicable companywide.**
- **Secondly, tactical ones: the many detailed subgoals that are derived from strategic quality goals.**

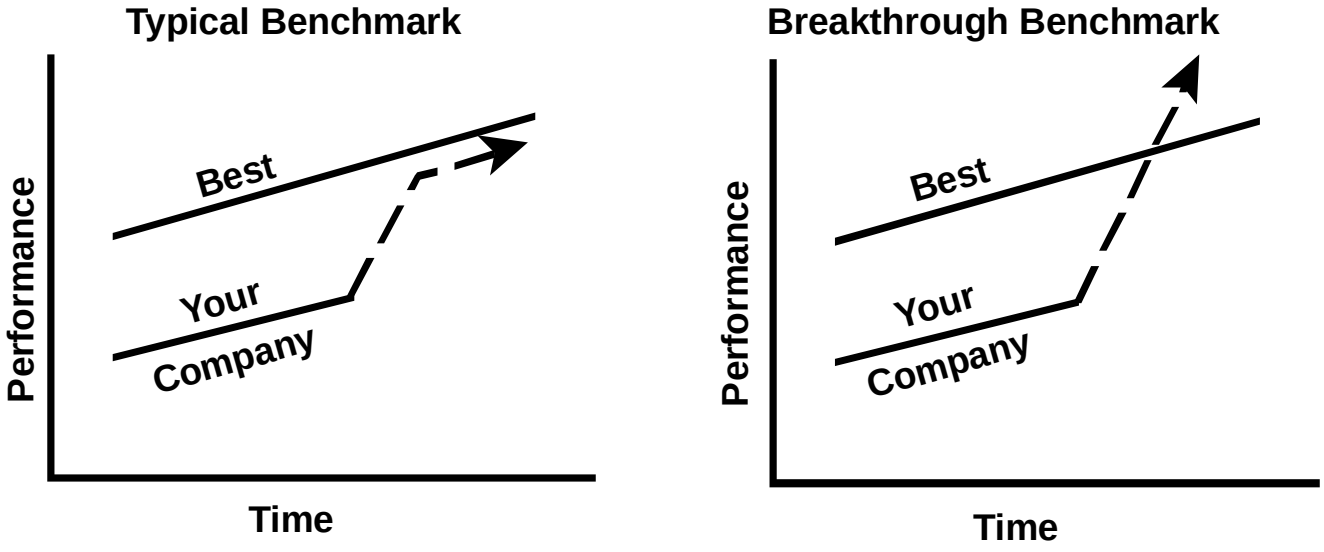
Stakeholder Identification

Businesses have many stakeholders including stockholders, customers, suppliers, management, employees (and their families), the community, and society. Each stakeholder has unique relationships with the business. some typical business – stakeholder relationships are shown below:



Benchmarking (Continued)

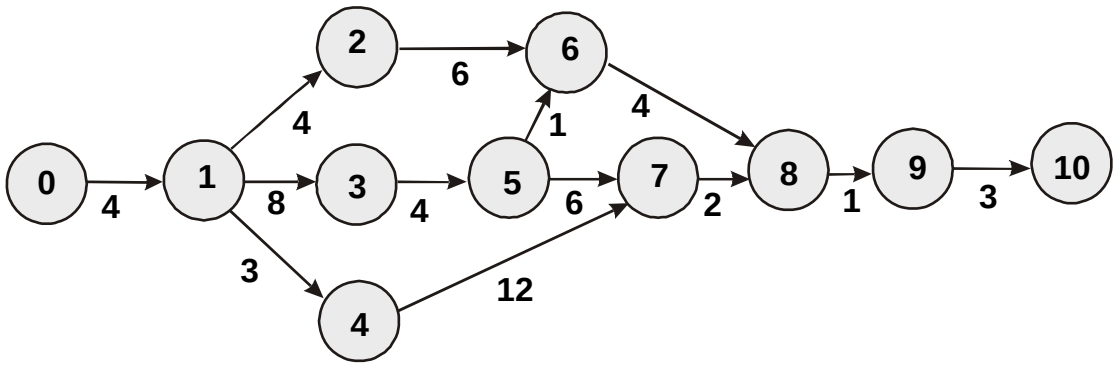
Shown below is a comparison between a typical and a breakthrough benchmark approach.



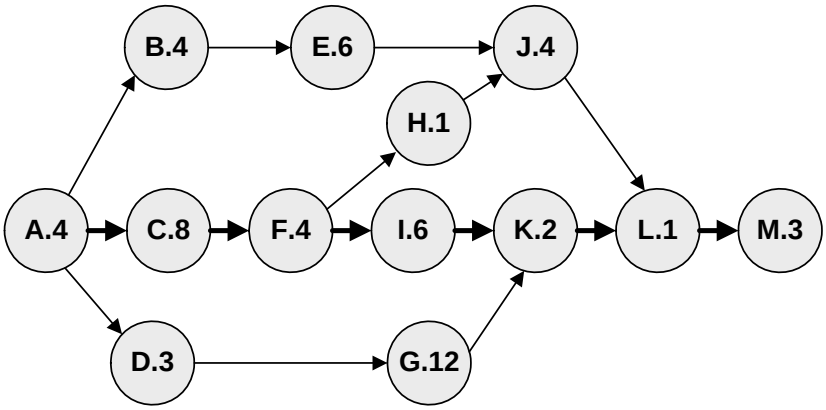
It should be noted that organizations often choose benchmarking partners who are not best-in-class, because they have identified the wrong partner or simply picked someone who is handy.

PERT (Continued)

An example of a PERT chart for a company seeking ISO 9001 certification is shown in the Primer. Circles represent the start and end of each task. The numbers within the circles identify the events. The arrows represent tasks and the numbers along the arrows are the task durations in weeks.



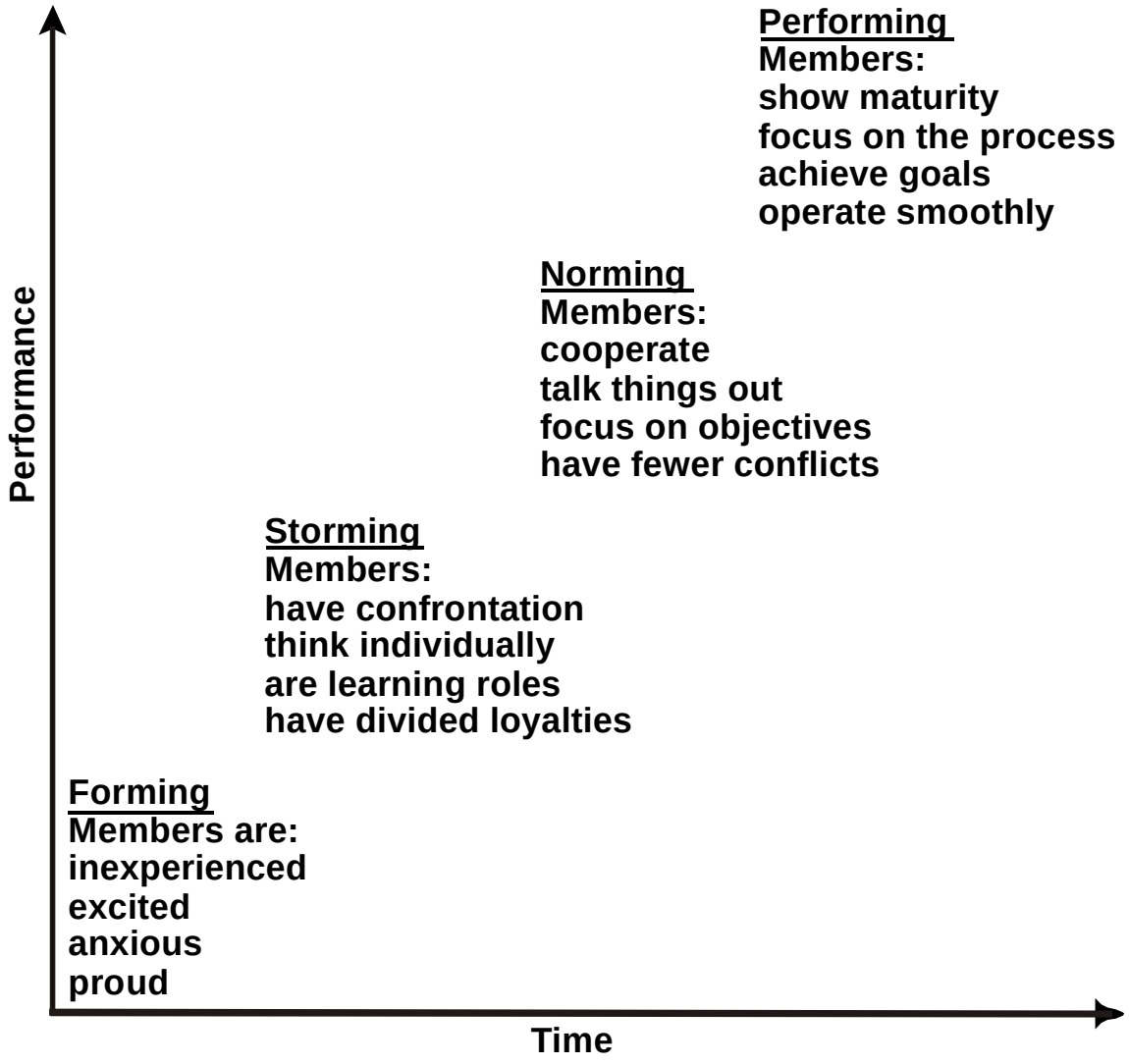
CPM Example



The critical path is indicated by the thicker arrows, along path A-C-F-I-K-L-M.

TASK	ACTIVITY	DURATION weeks		COST $		COST/ WEEK
0	ISO 9001 Certification	normal	crash	normal	crash	CRASH
A	Planning	4	3	2000	3000	1000
B	Select Registrar	4	3	1000	1200	200
C	Write Procedures	8	6	12000	15000	1500
D	Contact Consultant	3	1	500	700	100
E	Schedule Audit	6	5	200	1000	800
F	Write Quality Manual	4	3	800	1200	400
G	Consultant Advising	12	9	9600	14400	1600
H	Send Manual to Auditor	1	1	100	100	-
I	Perform Training	6	4	9000	12000	1500
J	Auditor Review Manual	4	3	1000	1250	250
K	Internal Audits	2	1	600	750	150
L	ISO Audit	1	1	10000	10000	-
M	Corrective Action	3	2	1600	2000	400
10	Certification	Milestone				

Team Stages (Continued)



Adjourning

At the end of some projects the team disbands. This step is called adjourning to rhyme with the four other team stages. Adjourning is also a very common practice for project teams, and ad hoc teams.

Multivoting (Continued)

5. Members may make their initial choices silently and then the votes are tallied. This is usually done by a show of hands as each item is announced.

6. To reduce the list, eliminate those items with the fewest votes. Group size will affect the results. Items receiving 0-4 votes might be eliminated altogether.

It should be noted that most problem solving teams can only work on two or three items at a time. The items receiving the largest number of votes are usually worked on or implemented first. The original list should be saved for future reference and/or action.

Blueprint Information (Continued)

(9) Tolerance block. Nothing can be to the exact size specified on a drawing. Normal machining and manufacturing processes allow for slight deviations. Many times, the amount of allowed deviation is critical to proper operation.

(10) Finish block. This space gives information on how the part is to be finished. That is, will it be buffed, plated, painted, anodized, etc.

(11) Parts list. This space is usually positioned right above the title block. Individual component parts, their part numbers and the quantity required for each unit are listed.

(12) Revision block. The revision block is a separate block positioned in the upper right-hand corner of the drawing. It notes any changes made to the drawing after its final approval.

Virtual Condition (Continued)

Examples of violations of dimensional virtual condition are:

Size:	**Oversize shaft, undersized hole**
Form:	**Tapered keyway, crooked shaft, bent pin**
Position:	**The feature is out of location**

Material Conditions

The ANSI terms for maximum material condition and least material condition are Ⓜ and Ⓛ respectively. The definitions are:

MMCⓂ **The condition of a dimension where the most material allowed (by the tolerance) is still there (the maximum weight).**

LMCⓁ **The condition of a dimension where the most material to be removed (by the tolerance) has been (the least weight).**

Verification and Validation (Continued)

The following definitions are important verification and validation activities.

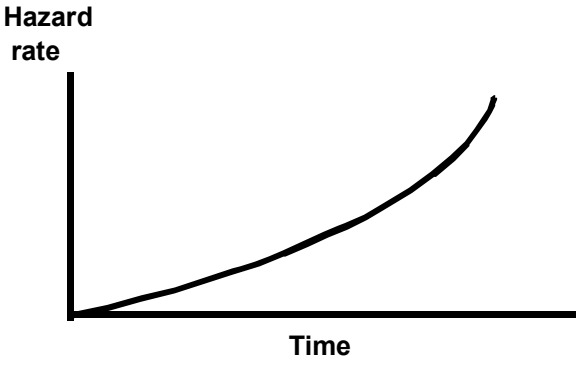
Installation qualification (IQ)	**Establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendations of the supplier of the equipment are suitably considered.**
Performance qualification (PQ)	**Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.**
Operational qualification (OQ)	**Establishing by objective evidence process control limits and action levels which result in product that meets all predetermined requirements.**

Preventive Maintenance

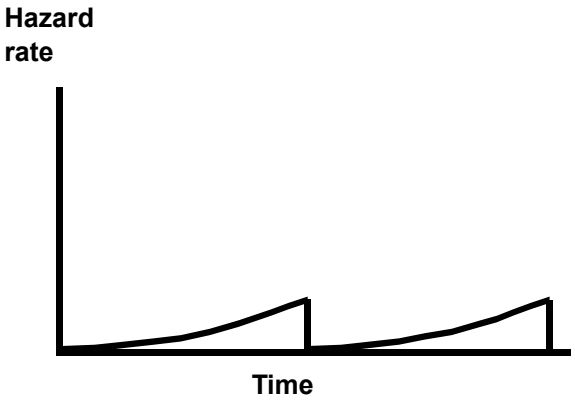
In general, most pieces of equipment, machinery, or systems are under some sort of preventive maintenance program. When an item or system experiences a breakdown or failure, the item is normally repaired. Individual parts may be replaced in the system, but the bigger system is maintained.

In the operation of a plant, equipment and systems fail unexpectedly. The repair of these types of failures is considered corrective maintenance items. Corrective maintenance cannot be planned, but can be determined by reliability. The mean time to repair (MTTR) is applicable for such items. If an item cannot be repaired upon failure, it is characterized by a mean time to failure (MTTF).

Preventive Maintenance (Continued)



Increasing hazard rate. Scheduled replacement of a part will reduce the probability of failures.

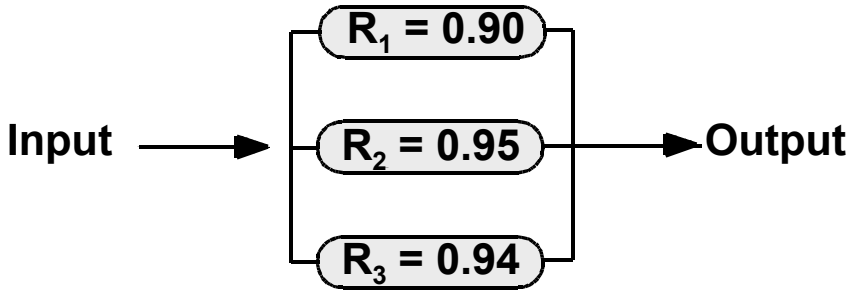


Increasing hazard rate with near failure free life. Scheduled maintenance will ensure near failure free probability.

Parallel System Reliability

In a parallel system, the reliability of the system is calculated by subtracting the product of the unreliabilities from 1.

Example: Determine the parallel system reliability.



Formula:

$$U_1 = 1 - R_1 = 0.10$$
$$U_2 = 1 - R_2 = 0.05$$
$$U_3 = 1 - R_3 = 0.06$$

$$R_{parallel} = 1 - (U_1 \times U_2 \times U_3)$$
$$= 1 - (0.10 \times 0.05 \times 0.06)$$
$$= 1 - (0.0003)$$

Answer: $R_{parallel} = 0.9997$

FMECA Process Steps (Continued)

15. **RPN. The risk priority number is the product of the indices from the previous three columns.**

$$RPN = P \cdot S \cdot D$$

16. **The actions then are based upon what items either have the highest RPN and/or where the major safety issues are.**

17. **There is a column for actions to be taken to reduce the risk, a column for who is responsible and finally a column for the revised RPN, once corrective action is implemented.**

In summary, the FMECA provides a disciplined approach for the engineering team to evaluate designs to ensure that all the possible failure modes have been taken into consideration.

Point Estimate for Population Variance

The sample variance, s^2, is the best point estimate of the population variance, σ^2.

The sample standard deviation, s, is the best point estimate of the population standard deviation, σ.

$$s^2 = \frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1} \qquad \sigma^2 = \frac{\sum_{i=1}^{n}(x_i - \mu)^2}{N}$$

$$s = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}} \qquad \sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \mu)^2}{N}}$$

Hypothesis Testing (Continued)

The steps of hypothesis testing are:

- **State the null and alternative hypothesis**
- **Specify the level of significance, α**
- **Determine the critical values separating the reject and nonrejection areas**
- **Determine the sampling distribution and test statistic**
- **Determine if the test statistic is in the reject or nonrejection area**
- **Conclude if the null hypothesis is rejected or failed to be rejected**
- **State the statistical decision in terms of the original problem**

Hypothesis Tests for Means (Continued)

Student's t Test

The student's t distribution is used for making inferences about a population mean when the population variance σ^2 is unknown and the sample size n is small. A sample size of 30 is normally the crossover point between the t and Z tests. The test statistic formula is:

$$t = \frac{\bar{X} - \mu_0}{\left(\frac{s_X}{\sqrt{n}}\right)}$$

$\bar{X}$ = The sample mean
μ_0 = The target value or population mean
s_x = The sample standard deviation
n = The number of test samples

The null and alternative hypotheses are the same as were given for the Z test. The degrees of freedom is determined by the number of samples, n, and is simply:

$$d.f. = n - 1$$

XII. APPENDIX

Table IX - Control Chart Factors

	CHART FOR AVERAGES		CHART FOR STANDARD DEVIATIONS			CHART FOR RANGES		
Sample Observations	Control limit Factors		Center Line Factors	Control Limit Factors		Center Line Factors	Control Limit Factors	
n	A_2	A_3	C_4	B_3	B_4	d_2	D_3	D_4
2	1.880	2.659	0.7979	0	3.267	1.128	0	3.267
3	1.023	1.954	0.8862	0	2.568	1.693	0	2.574
4	0.729	1.628	0.9213	0	2.266	2.059	0	2.282
5	0.577	1.427	0.9400	0	2.089	2.326	0	2.114
6	0.483	1.287	0.9515	0.030	1.970	2.534	0	2.004
7	0.419	1.182	0.9594	0.118	1.882	2.704	0.076	1.924
8	0.373	1.099	0.9650	0.185	1.815	2.847	0.136	1.864
9	0.337	1.032	0.9693	0.239	1.761	2.970	0.184	1.816
10	0.308	0.975	0.9727	0.284	1.716	3.078	0.223	1.777
15	0.223	0.789	0.9823	0.428	1.572	3.472	0.347	1.653
20	0.180	0.680	0.9869	0.510	1.490	3.735	0.415	1.585
25	0.153	0.606	0.9896	0.565	1.435	3.931	0.459	1.541

$\bar{X}$ - R Charts

$$CL_{\bar{x}} = \bar{\bar{X}} \pm A_2\bar{R}$$

$$UCL_R = D_4\bar{R}$$

$$LCL_R = D_3\bar{R}$$

Approximate capability

$$\hat{\sigma} = \frac{\bar{R}}{d_2}$$

$\bar{X}$ - S Charts

$$CL_{\bar{x}} = \bar{\bar{X}} \pm A_3\bar{S}$$

$$UCL_S = B_4\bar{S}$$

$$LCL_S = B_3\bar{S}$$

Approximate capability

$$\hat{\sigma} = \frac{\bar{S}}{c_4}$$

XII. APPENDIX
INDEX

Index

The *CQE Primer* contains the following:

- **Author/Name Index**
- **Subject Index**
- **Letter answers for questions given in the Primer**