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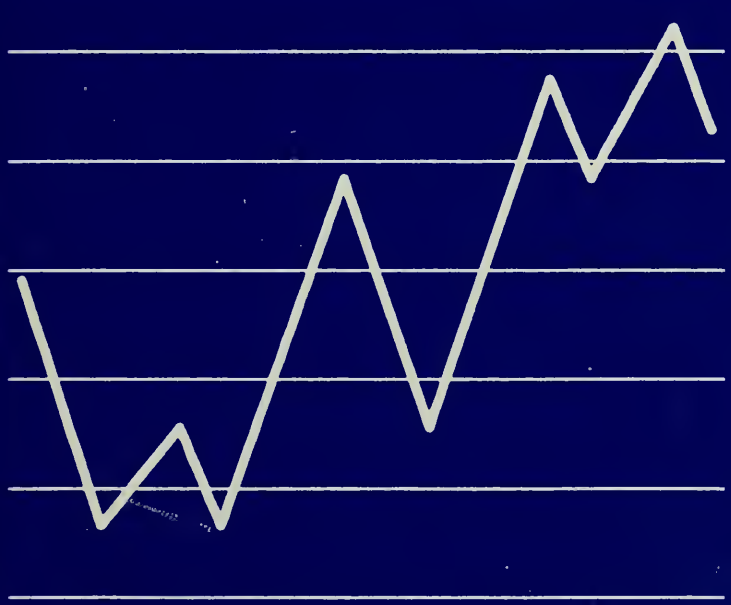
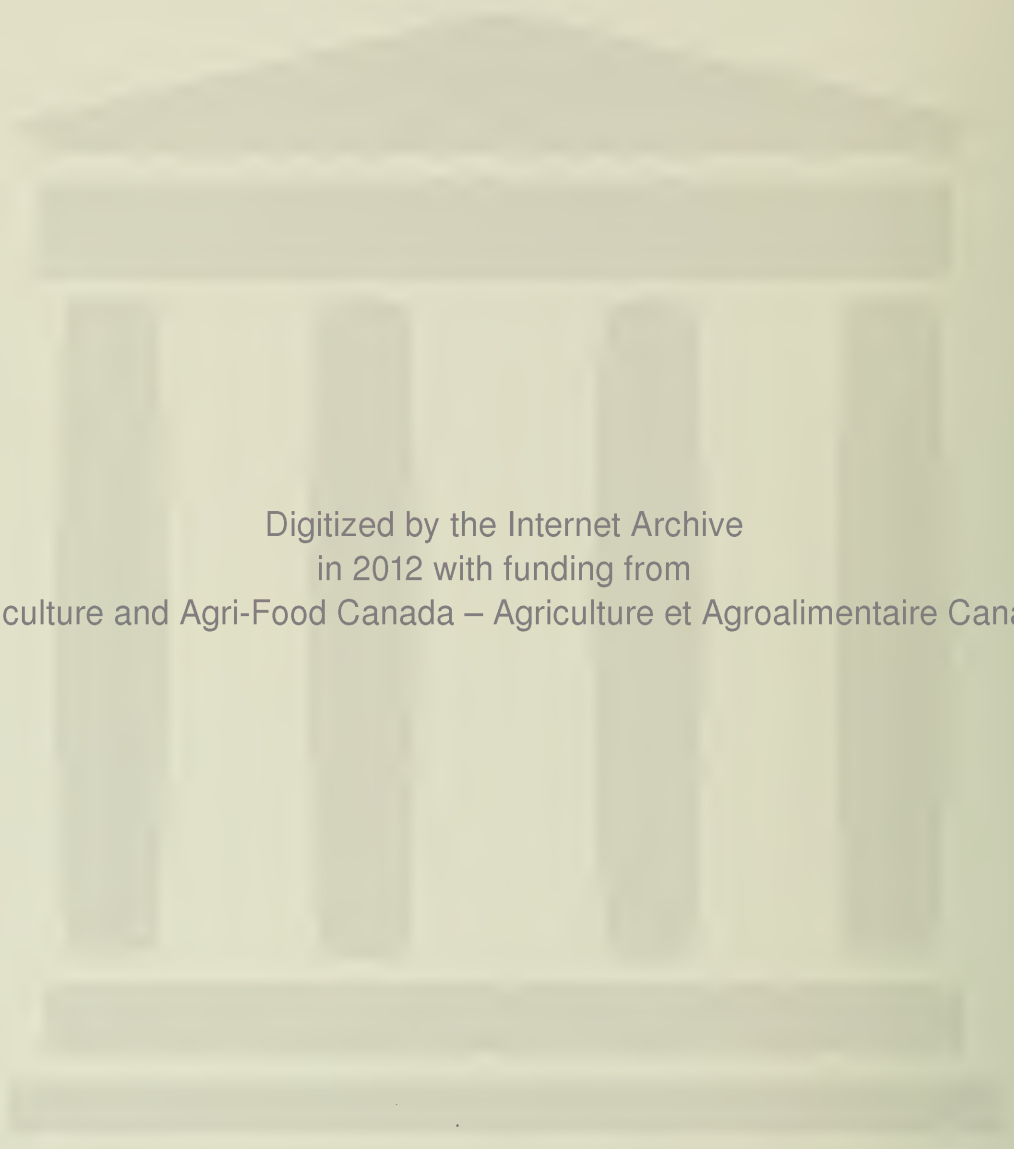
STATISTICAL METHODS FOR FOOD QUALITY MANAGEMENT





STATISTICAL METHODS FOR FOOD QUALITY MANAGEMENT

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CONTENTS

PREFACE

"The search for excellence continues ....."

One of the most fundamental concerns in the management of the agri-food sector pertains to the quality and safety aspects of food and agricultural products. This concern is shared equally and collectively by the producer, the consumer, and the regulatory authority, and they all endeavour to seek methods of ensuring production of high quality food products.

The achievement of excellence in food production requires the establishment of an effective total quality management system that systematically lays down optimally precise procedures. Additionally, effective decision-making within the framework of any quality management system, whatever its nature, type or magnitude, also requires an analytical ability for scientific analysis and interpretation of information generated by the system. This book is intended to provide some guidelines for establishing quality assurance procedures as well as basic statistical tools for the analysis and interpretation of data. The concepts and techniques are presented in the simplest manner and are expected to be of value to anyone engaged in the management of quality and safety of food products.

The author wishes to thank Donna McGovern for extensive assistance in the preparation of the book, to Roger Trudel for providing excellent professional comments and to Elise Benoit for helping us in the design work. I would also like to express my profound gratitude to my wife Shashi and my two daughters Pamela and Anu for their patience and endurance.

Ottawa, Canada

Subhash C. Puri

To my in-laws: Ram Parkash and Bimla Sahney

CHAPTER 1

TOTAL QUALITY MANAGEMENT

1.1 Introduction

Food is fundamental to human survival. Its quality, therefore, is of paramount importance to all of us. We must all endeavour to ensure that our agri-food products are wholesome, nutritious, safe and risk-free. This goal can be achieved by setting high quality-safety standards and instituting effective total quality management systems to ensure their conformance.

There are generally three principal parties involved in the agri-food business: the producer, the consumer, and the regulatory agency. The consumer specifies the quality/safety requirements, the producer undertakes to meet them, and the regulatory authority confirms that the stipulated requirements have been met. Each party has an important role to play, but it is through their collective determination, commitment and cooperation that excellence in food quality can be achieved.

The basic issues relating to food quality and safety, critical to all three parties, include the following:

- Fitness for consumption
- Wholesomeness, nutrition, and safety
- Conformance to specifications, tolerances, standards and regulations set for quantity, quality, and contents
- Proper use and declaration of pesticides, insecticides, herbicides, fertilizers, residues, additives, preservatives and other chemicals

The responsibility for producing high quality food products must be shared equally by the three parties. For example, the producer has the following threefold responsibility:

- to achieve and sustain the actual quality of the product in a manner that will continually satisfy the consumer's expected needs,
- to provide evidence/confidence to its own management that the intended quality is being achieved,
- to provide evidence/confidence to the regulatory authority and to the purchaser that the intended quality is being achieved in the delivered product. When contractually required, this provision of evidence/confidence may involve agreed demonstration of compliance.

The regulatory agency has a dual role to play: assisting producers in the production of high quality products and safeguarding consumers through enforcement verification. They should, therefore, assist the producers to develop and establish an internal total quality management system and establish their own quality assurance protocol to which the producer is expected to conform.

The consumer, while only being a recipient of the product, must attempt to provide effective feedback and communication to the producer as well as the regulatory agency regarding the quality, quantity, price, safety and risk aspects of food products.

An effective total quality management system helps to apportion responsibility and direct it to the true sources. It provides a systematic mechanism for continuous quality diagnosis and improvement. Some of the major benefits that accrue from a properly implemented TQM program are: consistency and uniformity in the application of procedures; reduction in final product inspection; verification and audit; increased quality and credibility; reduction in costs associated with appraisal, detection, prevention, internal failures, external failures, waste, nonconformity, and inspection; continuous improvement in product quality and safety; etc.

1.2 Definitions and Terminology

Total Quality Management (TQM) refers to the totality of functions necessary for the overall management of food quality and safety. As a corporate strategy for continuous quality improvement, it provides a structured, disciplined approach for identifying and solving problems as well as an adaptable framework for institutionalizing the ensuing improvements. Total quality systems are referenced through several different names: TQM (Total Quality Management), TQC (Total Quality Control), CWQC (Company-wide Quality Control, used by the Japanese), etc. A TQM system has basically three components:

- Quality Management (Q.M.): management functions
- Quality Control (Q.C.): operational techniques and activities
- Quality Assurance (Q.A.): planned actions to provide confidence

Following is a list of definitions of some quality-related terms, as developed in the International Standard, ISO 8402: "Quality – Vocabulary".

Quality: The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

Note: Quality is also defined as "fitness for use", "fitness for purpose", "conformance to the requirements", or "customer satisfaction". The Japanese Standards Association defines it as "the loss imparted to society from the time a product is shipped". Quality is a state rather than a specific characteristic of an entity. As a sum total of all the characteristics of a product, it should be all-encompassing.

Quality Management:	That aspect of the overall management function that determines and implements the quality policy.
Quality Assurance:	All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.
Quality Control:	The operational techniques and activities that are used to fulfill requirements for quality.
Quality System:	The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

1.3 Developing a TQM Program

The major responsibility in producing a product right the first time rests with the producer. He can achieve better quality by introducing effective controls through a TQM program. An internal TQM program properly implemented and actively operating at the producer's facility can reduce the need for extensive internal final product inspection or external verification and audit by a regulatory agency. A total quality management system is a vehicle for continuous quality improvement.

The guidelines for developing a TQM program can only be given in terms of generic elements. These elements then help in preparing a unique TQM program for any particular enterprise commensurate with its specific requirements. For instance, a TQM program for a manufacturing facility must incorporate the following components:

- **Quality Management System:** includes all quality management aspects such as management responsibility, management systems, control systems, cost systems, evaluation systems, improvement systems, market analysis, policy, resource allocation, etc.
- **Quality Control:** comprises all critical control points and the operational and technical aspects of controlling quality during production.
- **Procurement Quality Assurance:** quality assurance procedures to ensure supply of high quality input.
- **Internal Quality Assurance:** in-house assessment procedures to assure that the final product is of high quality.
- **External Quality Assurance:** contractual quality assurance protocol to assure the regulatory authority and the purchaser, or ultimately the consumer, that the delivered product is of high quality.

A basic sequence of steps in the development of a TQM program includes the following:

- Identify the situation/product/entity for which a TQM program needs to be established.

- Identify the goals and objectives.
- Prepare an exhaustive list of all the activities associated with the situation.
- Categorize the activities into management, systems, control, procedural, analytical, evaluation, verification, audit, action, feedback, improvement, etc.
- For each category, list all the requisite action items for that category.
- For each action item within a category, outline the detailed instructions required to effect the action.
- The completed document will serve as a TQM protocol.

1.4 TQM Program Elements

A generic master list of program elements from a producer's perspective, which is generally all-encompassing, follows. The list is generic in nature so that it can be conveniently modified and utilized to devise a TQM program for any specific entity. It is based on the guidelines developed in: (i) National Standard of Canada, CAN3-Z299: Quality Assurance Program – Canadian Standards Association, and (ii) International Standard, ISO/9004: Quality Management and Quality System Elements – Guidelines.

Elements of a TQM Program – Master List

- **Management responsibilities:** policy, objectives, planning, management system, organizational structure and responsibilities
- **Structure of the quality system:** quality responsibility and authority, organizational structure, resources and personnel, operational procedures
- **Documentation of the quality system:** quality policies and procedures, quality manual, quality plans, quality records
- **Auditing of the quality system:** audit plan, conducting the audit, reporting of audit findings and follow-up
- **Review and evaluation of the quality management system**
- **Quality related cost considerations:** selecting appropriate elements; collection and analysis of cost data; cost categories: detection, appraisal, prevention, internal failure, external failure; cost reporting to management
- **Quality in marketing:** market analysis, product brief, customer feedback information
- **Quality in specification and design:** design planning and objectives, product testing and measurement, design qualification and validation, design review, design baseline and production review, market readiness review, design change control, design requalification

- **Quality in procurement:** requirements for specifications and purchase orders, selection of qualified suppliers, agreement on quality assurance, agreement on verification methods, provision for settlement of quality disputes, receiving inspection planning and control, receiving quality records
- **Quality in production:** planning for controlled production; process capability; supplies, utilities and environments
- **Control of production:** material control and traceability, equipment control and maintenance, special processes, documentation, process change control, control of verification status, control of nonconforming materials
- **Product verification:** incoming materials and equipment, in-process inspection, completed product verification
- **Control of measuring and test equipment:** measurement controls, elements of control, supplier measurement controls, corrective action, outside testing
- **Nonconformity:** identification, segregation, review, disposition, documentation, prevention of recurrence
- **Corrective action:** assignment of responsibility, evaluation of importance/priority, investigation of possible problems, analysis of problem, preventive measures, process control, disposition of nonconforming items, permanent changes
- **Handling and post-production functions:** handling, storage, identification, packaging and delivery; post-sales service; market reporting and product supervision
- **Quality documentation:** specifications, inspection instructions, test procedures, work instructions, quality manual, operational procedures, quality assurance procedures, etc.
- **Quality records:** inspection reports, test data, qualification reports, validation reports, audit reports, material review reports, calibration data, quality cost reports, etc.
- **Personnel:** training, qualifications, appraisal, motivation
- **Product safety and liability:** suitable safety standards; declaration of quality, quantity and content; risk warning to user; product traceability for safety assurance
- **Use of statistical methods:** market analysis, process control, conformance/compliance level, process average, data analysis, safety evaluation and risk analysis, statistical sampling procedures, quality control charts, design methodology, performance appraisal, setting/changing of tolerances, etc.

1.5 TQM Program for a Regulatory Agency

A TQM program for a food and agriculture regulatory agency can be likewise developed by selecting appropriate elements from the above master list. A generic list of such elements could include the following:

- Management responsibilities
- Structure of the quality system
- Documentation of the quality system
- Monitoring/inspection/verification plans
- Description of tolerances, specifications and regulatory requirements
- Quality documentation and records
- Action on nonconformance
- Corrective action
- Use of statistical methods for information analysis

Furthermore, for each of these main elements, a sequential list of sub-elements is prepared, for each of which a set of detailed instructions is also provided. Some of the essential operational considerations to be incorporated into the sub-elements include the following:

- To determine the comparative risk level associated with each commodity.
- For each risk level or category, to identify a suitable frequency of inspection level.
- For each risk level, production volume and quality status, to determine a frequency of product inspection.
- For each inspection visit, to specify the sample size for inspection commensurate with the acceptable quality level and established compliance rate.
- For each sampling inspection activity, to ensure lot homogeneity and the randomness/representativeness of sampling procedures.

1.6 Example: Quality Assurance Program for Analytical Laboratories

From the general guidelines and program elements outlined in Section 1.4, it is relatively easy to develop a quality assurance protocol for any entity. Consider as one such application the establishment of a quality assurance program for an analytical laboratory. As a first step, the following action plan should be considered:

- Establish a profile of total quality assurance requirements.

- Evaluate the existing laboratory practices with respect to these requirements.
- Outline the precise procedures that would describe how the quality assurance requirements are to be applied to the laboratory.
- Indoctrinate and train the laboratory personnel in the new or modified practices and procedures.
- Establish a management system of periodic assessment to ensure that the program is actually effective.

The next step is to develop a list of quality assurance program elements that would encompass all of the activities of a laboratory's operation. Following the guidelines of Section 1.4, the essential elements would include the following:

- Quality Assurance Plan
- Policy Statements
- Objectives
- Quality Planning
- Quality Costs
- Record Keeping and Document Control
- Chain of Custody Procedures
- Quality Training
- Procurement and Control
- Reagents and Reference Standards
- Instrument Calibration
- Preventive Maintenance
- Sampling - Sample Identification and Control
- Data and Methods Validation
- Laboratory Analysis and Control
- Interlaboratory and Intralaboratory Testing
- Statistical Quality Control Procedures
- Corrective Action Mechanism
- Safety Procedures
- Laboratory Design
- Performance and Systems Audits
- Reports to Management

Another essential feature of the quality assurance protocol is the establishment of a quality assurance manual. This manual clearly identifies the specific meth-

ods and operating procedures that the laboratory uses to satisfy its own needs and achieve its quality objectives. A quality assurance manual is a set of documents intended to give confidence in the laboratory's work. The manual identifies the policy, organization, objectives, functional activities and specific quality assurance activities designed to achieve the quality goals set out for the operation of the laboratory.

A typical format for a laboratory quality assurance manual would appear as follows:

- Title page, with provisions for approved signatures
- Table of contents
- Laboratory organization and responsibilities
- Organizational structure
- Quality assurance plan and objectives
- Quality assurance system
- Corrective action
- Forms
- Quality assessment procedures
- Quality assurance reports to management
- Distribution list

1.7 Continuous Quality Improvement

Quality is not a tactical but a strategic issue. Quality is everyone's business and cannot be manufactured. It is infused and embedded into a product through systematic means. In brief, quality is a long-term focus, not a short-term function. Therefore, to realize quality goals, it is imperative to first establish an effective TQM system and then develop a quality improvement monitoring program. Some of the essential components and elements that a quality improvement program should encompass are as follows:

The Program:

- Complete and active management commitment, support, and participation
- Highly visible, action-oriented, exhibiting seriousness of intentions, full participation of everyone concerned
- Total worker immersion and awareness
- Worker respect and recognition
- Customer-oriented quality control
- Long-term strategic focus

The System:

- Quality improvement teams
- Project-by-project quality control
- Management orientation and training

The Methodologies:

- Use of statistical tools for management decision-making: frequency distribution, histogram, cause-effect diagram, Pareto analysis, economic cost analysis, etc.
- Formal, structured, disciplined approach: task analysis, problem analysis, root cause identification, corrective-preventive action procedure, etc.
- Statistical process control

A typical check-list of questions, commensurate with the program elements described above, should be formulated on the following lines:

- Were the goals and objectives clearly disseminated and understood by everyone concerned?
- Were the assigned roles and responsibilities appropriate, clearly defined, well understood and accepted?
- Were the allocated resources (human, financial, technological) suitable and optimal?
- Are there any deviations from the expected results?
- Who is to be held accountable for the deviations?
- What type of action is required to achieve the expected results and move towards further improvement?
- Can a system be instituted to automatically check the periodic status of the program?

As a measure of program performance, the following procedure is recommended:

- Assign a project team; clarify the problem; establish theories and dominant causes; develop corrective action.
- Implement and communicate action plan.
- Select an issue; identify the characteristics to be measured; collect pertinent data.
- Analyze data through appropriate statistical methods.
- Test results; measure progress; confirm removal of dominant causes as planned.
- Standardize; establish/revise procedures; review other problems.

1.8 Productivity Measurement and Improvement

Productivity and quality are inseparable concepts. We must measure productivity as our ability to provide high-value products and services that meet customer requirements at a minimum cost. The priorities are safety, quality, and cost.

Productivity can be defined as the quality, timeliness, and cost-effectiveness with which an organization achieves its mission. It is a measure of how well resources are brought together and utilized in accomplishing a set of results.

Productivity and production are not the same thing. Greater production does not necessarily mean greater productivity. Whereas productivity is concerned with the effective utilization of resources, production is concerned with the process and/or the methodologies of producing goods and services. A productive plant is one that has a large production volume relative to the amount of material, energy, labour, capital and other resources consumed.

Productivity is a combination of effectiveness and efficiency and is expressed as an index:

$$\text{Productivity Index} = \frac{\text{Resource Output}}{\text{Resource Input}} = \frac{\text{Effectiveness}}{\text{Efficiency}}$$

Effectiveness relates to how well an objective is reached and is concerned only with the achievement of desired results without serious regard for the costs involved. Efficiency refers to how well the available resources are utilized in achieving the stated results and is concerned with the total cost of all the inputs involved.

A more elaborate index of productivity advocated by Craig and Harris (1973) is given as follows:

$$P_t = O_t / (L_t + C_t + R_t + Q_t)$$

where

P_t = productivity measurement for period t

O_t = total output of good units produced in period t (measured in deflated or base-year dollars)

L_t, C_t, R_t, Q_t = base-year dollar value of all labour, capital, raw material, and miscellaneous goods and services consumed in period t, respectively

To improve productivity, the productivity index must be monitored and analyzed. This analysis is carried out with the help of control chart methods described in Chapter 5.

1.9 Diagnostic Methods: Cause–Effect Diagrams

A process is a set of conditions or a system of causes which work together to produce a given result or an effect. Most generally, the causes relate to the six M's: Material, Machine, Man, Method, Money, and Management. An effective way of studying the relationship between causes and an effect is through the use of **cause-effect (C-E) diagrams** developed by Japanese Professor Kaoru Ishikawa in 1950. This diagram is also known by other names, such as **brain storming diagram** or **fishbone diagram.** A basic C-E diagram is shown in Figure 1.1. The diagram serves as a diagnostic tool to recognize the problem or effect, identify all the causes, evaluate operational procedures, identify solutions to correct the problem, and help in process quality improvement.

Construction of C-E Diagram

- Identify the quality characteristics or effects for which causes are to be found.
- Draw a horizontal line with an arrow at the right end and a box in front of it indicating the effect or problem.
- Write the main factors or causes, i.e., the six M's: Material, Man, Method, Machine, Money, Management, joining each of these by a slanted arrow directed to the horizontal arrow.
- Add twigs with directed arrows to identify sub-causes to the main cause. Proceed similarly in adding sub-sub-causes.
- Ensure that all possible causes of priorities are taken into account.
- The completed graph or chart is a C-E diagram.

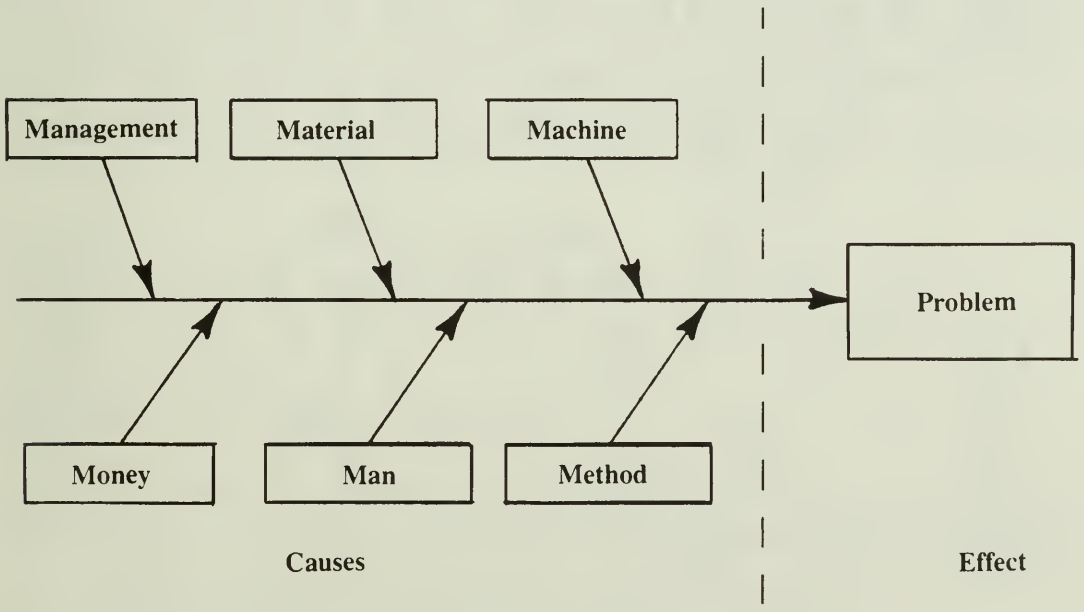

Figure 1.1 Cause-Effect Diagram Identifying Major Causes

As an example, a complete schematic of a C-E diagram is presented in Figure 1.2 for a problem associated with 'cap torque defects' on the processing line of a food processing plant. Once the defect had been identified, a comprehensive search was conducted for all possible causes which were diagnosed with the help of the C-E diagram. It was then quite easy to identify and prioritize the causes, allowing prompt and effective management decision-making for corrective/preventive action.

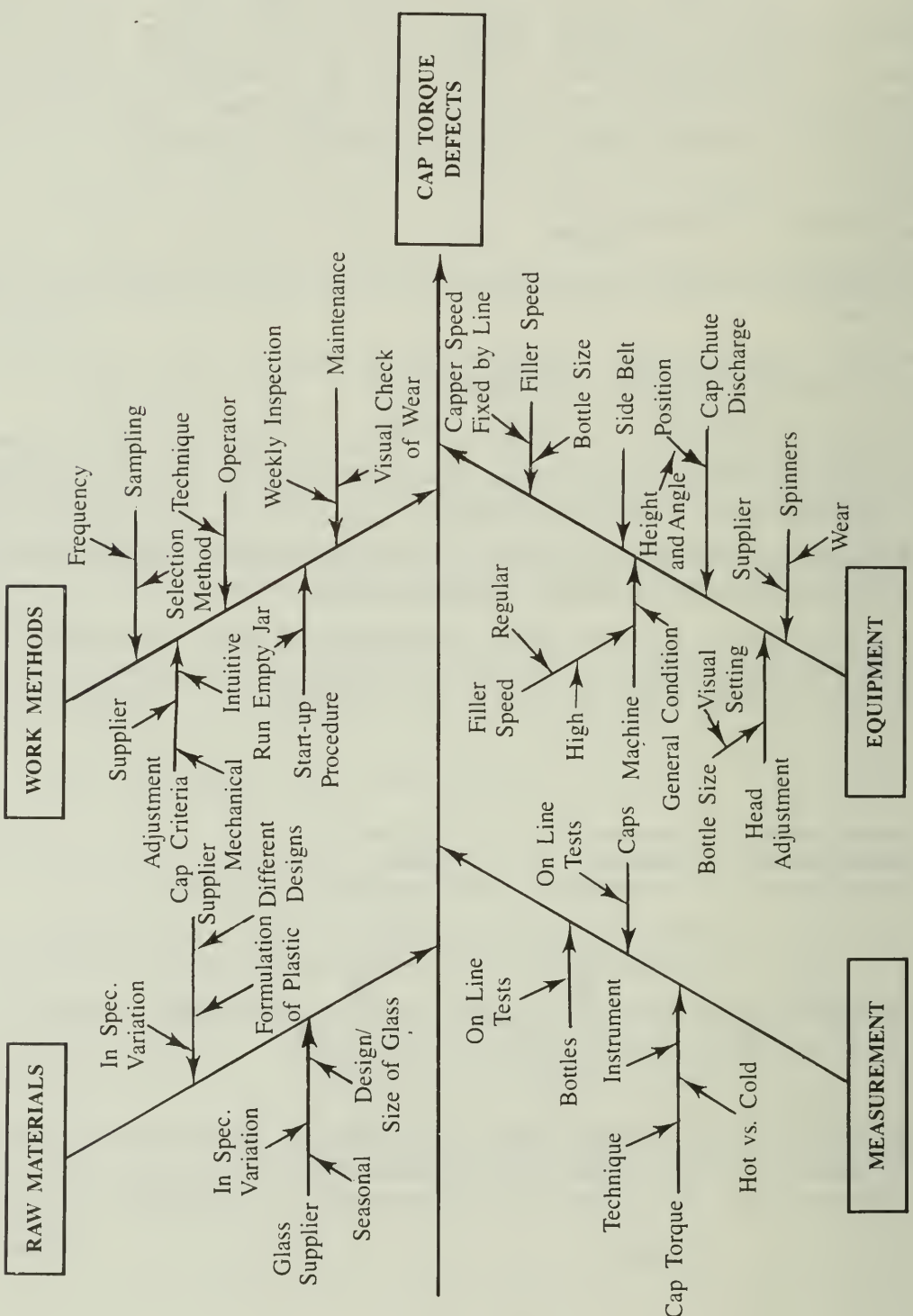

Figure 1.2 Cause-Effect Diagram: Cap Torque Defects

1.10 Diagnostic Methods: Pareto Analysis

Pareto analysis is another useful diagnostic technique, supplementing the method of cause-effect diagrams, which helps in prioritizing and analyzing causes of nonconformity. The principal idea behind this technique rests on the premise that all events or causes are not uniformly distributed as far as their effects are concerned. They are maldistributed in the sense that relatively few of the causes are responsible for most of the effects. The Pareto principle calls it the 80-20 phenomenon, implying that often about 80% of the nonconformities result from only 20% of the causes.

The original concept of the Pareto distribution was developed by Vilfredo Pareto, a nineteenth-century Italian sociologist-economist, with regard to the maldistribution of wealth and income. He suggested that 80% of the wealth in a country is normally controlled by 20% of the people. This idea was extended to quality control applications by Juran in 1964. Juran suggested sorting out the causes of nonconformity into two categories, the **'vital few'** and the **'trivial many'**, and then prioritizing data so as to take corrective action on the **vital few** causes which contribute to the major losses due to nonconformity.

Construction of Pareto Diagram

- List all the essential process elements of interest.
- Decide on the mode of data classification, i.e., defect type, part number, shift, operation, etc.
- Select an appropriate time period and collect all pertinent data.
- For each category, record the total frequency of occurrence.
- Order the elements according to this measure, not their classification.
- Plot a frequency bar graph, beginning on the left with the category of highest frequency and moving to the right with categories of successively lower frequency. An effective diagram has five to six categories.
- On the same diagram, plot the line graph for the cumulative frequency of each category.
- Add a title and legend to the graph.
- Take corrective action on the 'vital few'.

Example 1.1 Pareto Analysis

Consider a processing operation producing the product 'Mayonnaise' in a food processing plant. The year-end analysis of the cost figures revealed heavy losses due to quality failures. Table 1.1 lists the various cost categories in rank order and the corresponding Pareto diagram is shown in Figure 1.3.

TABLE 1.1: Losses Due to Quality Failures

Rank	Category	Cost ($)	Percent Cost
1	Line Downtime	30,000	39.6
2	Container and Closure Waste	18,000	23.7
3	Spillage	15,000	19.7
4	Batch Adjustment	5,000	6.5
5	Damage due to Material Handling	4,000	5.3
6	Reblend	3,000	3.9
7	Customer Complaint Adjustments	1,000	1.3
	Total	76,000	100.0

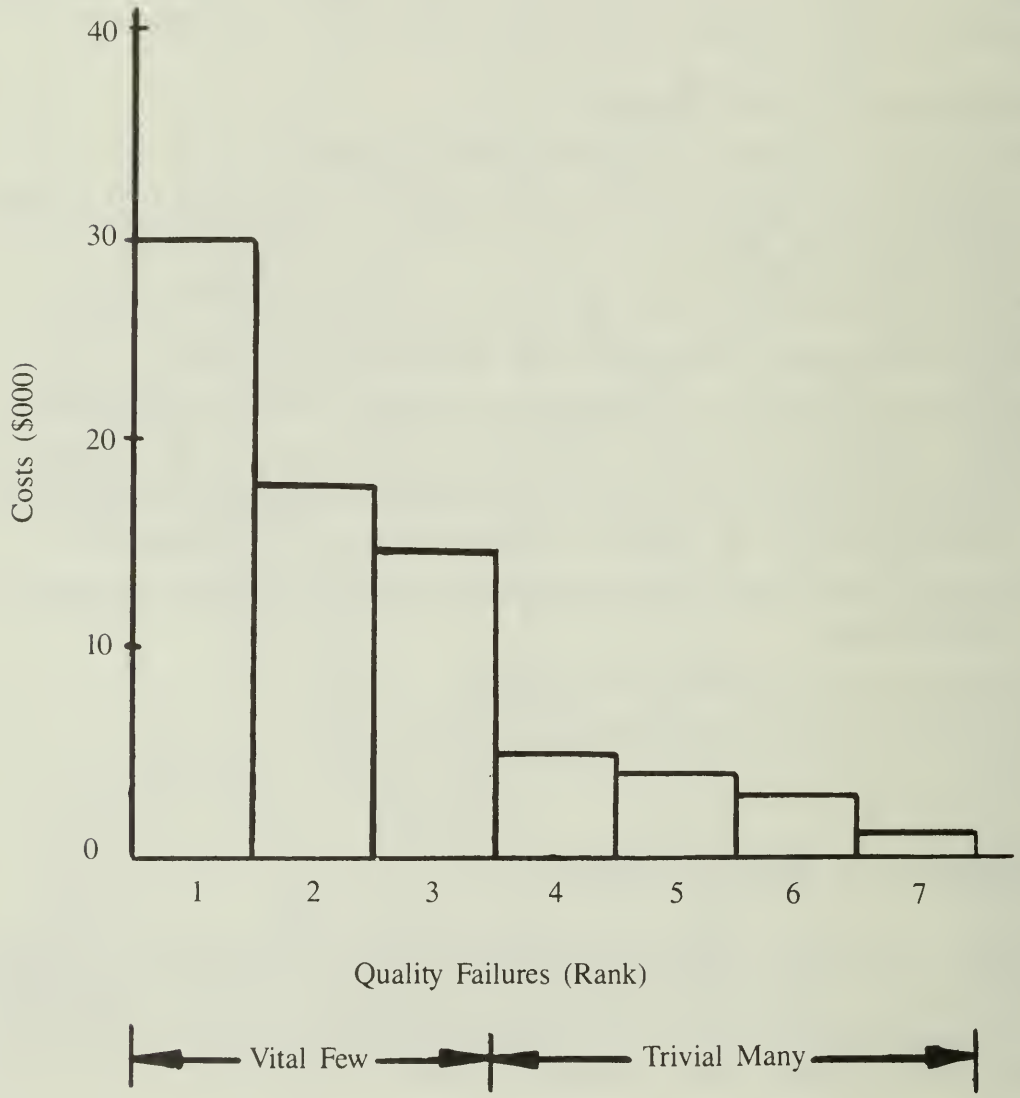

Figure 1.3 Pareto Diagram for Data in Table 1.1

As can be seen from this analysis, the major cause of losses seems to be the average line downtime. This category can be further analysed by identifying and prioritizing the causes as given in Table 1.2 and the corresponding Pareto diagram in Figure 1.4.

TABLE 1.2: Average Downtime (minutes per shift) on Packing Line (3-week period)

Rank	Category	Downtime (mins.)	Percent Downtime	Cumulative % Downtime
1	Case Packer Problem	58	30.1	30.1
2	Labeler Problem	47	24.4	54.5
3	No Glass	39	20.2	74.7
4	No Product	12	6.2	80.9
5	No Caps	10	5.2	86.1
6	Capper Problem	9	4.7	90.8
7	Broken Glass	8	4.1	94.9
8	Glue Pot Empty	6	3.1	98.0
9	Glue Condition	3	1.5	99.5
10	Case Taping	1	0.5	100.0
	Total	193	100.0	

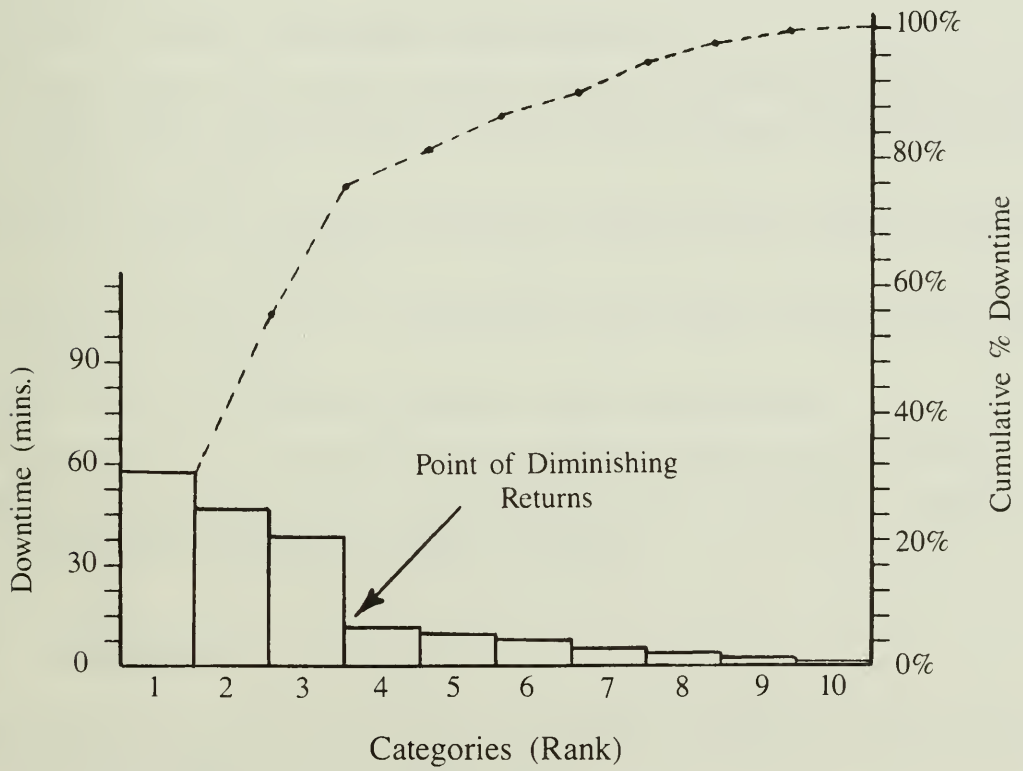

Figure 1.4 Pareto Diagram for Data in Table 1.2

From the above analysis, it is now easy for management to make a decision on which aspect of failure should be tackled first. Since it is not cost-effective to try to prevent all defects, Pareto analysis helps in effectively prioritizing our strategy for corrective action. The real challenge for quality management, however, still lies in preventing defects from ever occurring in the first place.

CHAPTER 2

BASIC STATISTICAL METHODS

2.1 Introduction

Every scientific investigation yields information and numerical data. Repeatedly scanning through individual records of raw, unorganized data is generally tedious. There is a need for brevity in the description and summary of results for effective management decision-making. This is accomplished through statistical methods which provide scientific tools for organizing, summarizing, analyzing, and interpreting the results.

From a statistical viewpoint, each value in a group of measurements (sample) is considered as only one realization of a hypothetical, infinite population of similar measurements. Although, in general, all members of this sample refer to measurements of the same property on the same population or lot, they are not expected to be identical. The differences among them are attributable to chance factors as well as a multitude of other assignable factors associated with the measuring process. The fundamental aim of statistics, therefore, is to identify these causes of variation, evaluate their significance, and ultimately provide means to make inferences from a sample to a population.

Some of the questions most frequently asked during a study, survey or experiment include:

- how to design a statistically valid experiment
- what sample size to take so that it will be cost-effective, feasible, statistically valid, and sufficient to provide reliable estimates with an effective decision criterion
- how to ensure a sample's homogeneity, randomness and representativeness of the lot or population
- how to estimate population parameters from sample statistics with a high degree of confidence
- how to study differences between several sample results
- how to carry out regression and correlation analysis for forecasting
- how to establish control procedures to achieve consistency, uniformity, repeatability and reproducibility of results

2.2 Definitions

Population or Lot: the total group of units under consideration, the group to which the results are to be generalized.

Sample: a portion of the population. A sample should be representative of the population and be chosen in a random fashion. A **simple random sample** is one that has been selected by a random process such that each unit in the population has an equal and independent chance of being included in the sample.

Kinds of Data:

- **Discrete:** where the variable can assume only specific values (usually integers) and involves counting, e.g., number of cows on a farm, count of items not meeting a grade, etc. When characteristics such as these are dichotomous (i.e., defective-nondefective), they are called **attributes**.
- **Continuous:** data resulting from a measurement or other numerical estimation procedure; these characteristics yield **variables**, e.g., temperature readings, pH values, crop yield, etc.

2.3 Organization of Data

Statistical data from a scientific study usually consists of a large number of observations. To obtain meaningful information, this unorganized set of values must be concisely summarized, described, and presented. The common visual technique for presenting such data is the **histogram** or **bar graph**. For discrete data, these graphs are generally not difficult to construct. Continuous data such as weight, temperature, pressure, length, and percentage dry matter are not already grouped into natural categories and, consequently, must first be arranged into some convenient grouping. This is done through a **frequency table**, whereby the range of the data is divided into a reasonable number of categories and each observation is assigned to exactly one of these categories. The number of categories is arbitrary but a good rule of thumb is to let $k = \sqrt{n}$, where k is the number of categories and n the number of observations. If R is the range of the data (range = largest observation minus smallest observation), then the width of each category is approximately R/k. For simplicity, we will only consider situations in which all categories have the same width.

Example 2.1 Organization of Data

Table 2.1 gives the moisture content (%) of skim milk powder obtained through the laboratory analysis of 50 independent samples.

TABLE 2.1: Percent Moisture in Skim Milk Powder

3.4	2.9	4.6	3.9	3.5	2.8	3.4	4.0	3.1	3.7
3.5	3.1	2.5	4.4	3.7	3.2	3.8	3.2	3.7	3.2
3.6	3.0	3.3	4.0	3.4	3.0	4.3	3.8	3.8	3.6
3.4	2.7	3.5	3.6	3.6	3.3	3.7	3.5	4.1	3.1
3.7	3.2	3.9	4.2	3.5	2.9	3.9	3.6	3.4	3.3

The number of categories should be approximately $\sqrt{50}$, or k = 7. The range of the data is R = 4.6 − 2.5 = 2.1. The consecutive categories, each of width R/k = 2.1/7 = 0.3, are then 2.5 − 2.8, 2.8 − 3.1, ..., 4.3 − 4.6. As a convention, any observation falling on the border of two categories will be put in the higher one of the two. The frequency table may be presented as in Table 2.2.

TABLE 2.2: Frequency Table for Percent Moisture in Skim Milk Powder

Class Boundaries	Class Midpoint (X)	Class Frequency (f)	Cumulative Frequency
2.5 − 2.8	2.65	2	2
2.8 − 3.1	2.95	5	7
3.1 − 3.4	3.25	10	17
3.4 − 3.7	3.55	15	32
3.7 − 4.0	3.85	11	43
4.0 − 4.3	4.15	4	47
4.3 − 4.6	4.45	3	50

Once the data have been arranged into a frequency table, they may be presented in a histogram (see Figure 2.1) by plotting the class frequency (on the vertical axis) against its boundaries (on the horizontal axis). One assumes that all the observations in any category now adopt the class midpoint as their value.

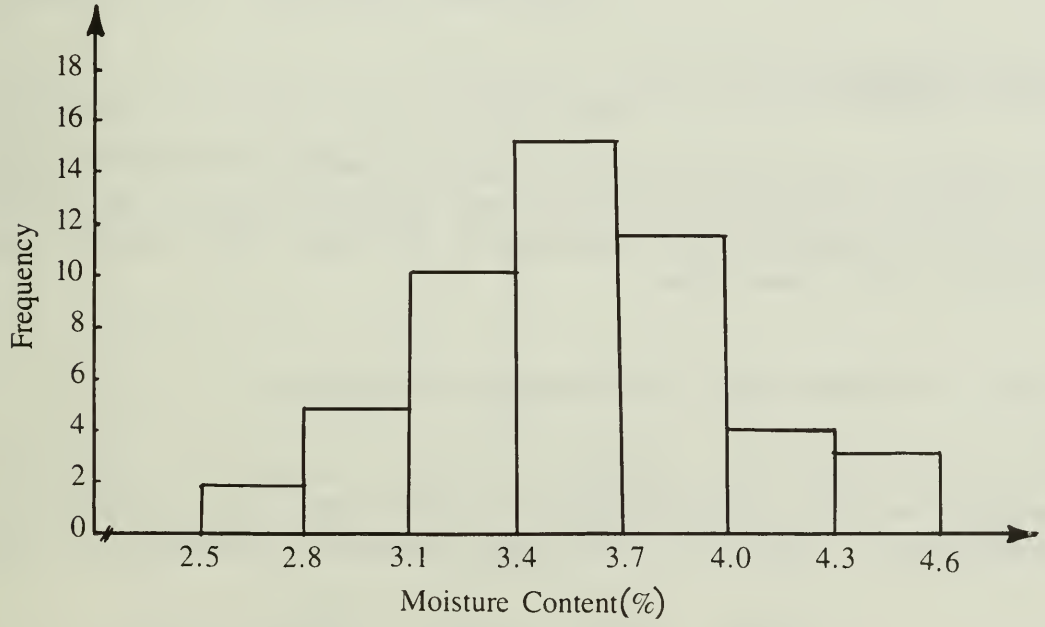

Figure 2.1 Histogram for Data in Table 2.2

2.4 Statistical Measures

Whether data is raw and ungrouped or summarized and grouped in a frequency table, large sets of data can be uninformative. Data needs to be characterized, especially for comparison purposes and decision-making. Typical statistical summaries include measures of location (or center) and measures of dispersion (or spread from the center).

2.4.1 Mean

The mean provides the most commonly used statistical measure of location. For a sample of observations $X_1, X_2, \ldots, X_n$, the **sample arithmetic mean** (or **sample mean** or, simply, the **mean**) is denoted by $\bar{X}$ where

$$\bar{X} = \frac{X_1 + X_2 + \ldots + X_n}{n} = \frac{\sum_{i=1}^{n} X_i}{n} .$$

The corresponding population mean is denoted by the Greek letter μ (mu).

For grouped data, where the class midpoints $X_1, X_2, \ldots, X_k$ occur with respective frequencies $f_1, f_2, \ldots, f_k$, the mean is defined as

$$\bar{X} = \frac{X_1 f_1 + X_2 f_2 + \ldots + X_k f_k}{f_1 + f_2 + \ldots + f_k} = \frac{\sum_{i=1}^{k} X_i f_i}{\sum_{i=1}^{k} f_i} .$$

2.4.2 Range

The range for a set of observations is the positive difference between the largest and smallest observations. For a frequency table, the range is the positive difference between the upper boundary of the highest class and the lower boundary of the lowest class.

2.4.3 Variance and the Standard Deviation

The extent of variability in a data set is effectively estimated by calculating the statistical measure of dispersion known as the variance. For a sample of n observations $X_1, X_2, \ldots, X_n$, the **sample variance** is denoted by s^2 where

$$s^2 = \frac{\sum_{i=1}^{n} (X_i - \bar{X})^2}{n - 1} = \frac{\Sigma X_i^2 - \frac{(\Sigma X_i)^2}{n}}{n - 1} .$$

The corresponding **population variance** is denoted by σ^2 (sigma squared), where the denominator $n - 1$ is replaced by the population size.

The square root of the variance is called the **standard deviation** and is denoted appropriately by s or σ. In the case of a grouped frequency distribution, where a set of class midpoints $X_1, X_2, \ldots, X_k$ have the respective frequencies $f_1, f_2, \ldots, f_k$, the variance is given by

$$s^2 = \frac{\sum_{i=1}^{k} (X_i - \bar{X})^2 f_i}{\sum_{i=1}^{k} f_i - 1} = \frac{\Sigma X_i^2 f_i - \frac{(\Sigma X_i f_i)^2}{\Sigma f_i}}{\Sigma f_i - 1} .$$

2.4.4 Coefficient of Variation

It is frequently difficult to make a comparison between two or more sets of data expressed in different units of measurement. This is accomplished by a measure known as the coefficient of variation, given by

$$\text{C.V.} = \frac{\text{Standard Deviation}}{\text{Mean}} = \frac{s}{\bar{X}} \times 100\% .$$

The C.V., expressed as a percentage, provides a comparison of the average variability to the mean in a data set and is unit free. A small percentage indicates a rather homogeneous group of observations.

Example 2.2 Statistical Measures

Using the data in Table 2.1, find the mean, range, variance, standard deviation, and coefficient of variation for moisture content (%) in skim milk powder for the 50 observations given. For the raw data,

$$\text{Mean} = \bar{X} = \frac{3.4 + 3.5 + \ldots + 3.3}{50} = \frac{175.5}{50} = 3.51$$

$$\text{Range} = 4.6 - 2.5 = 2.1$$

$$\Sigma X_i = 175.5, \ \Sigma X_i^2 = 625.37$$

$$\text{Variance} = s^2 = \frac{625.37 - \frac{(175.5)^2}{50}}{50 - 1} = 0.1911$$

$$\text{Standard Deviation} = s = \sqrt{0.1911} = 0.4372$$

$$\text{Coefficient of Variation} = \text{C.V.} = \frac{s}{\bar{X}} \times 100\%$$

$$= \frac{0.4372}{3.51} \times 100\% = 12.46\%$$

For the grouped data (see Table 2.2),

$$\text{Mean} = \bar{X} = \frac{(2 \times 2.65) + (5 \times 2.95) + \ldots + (3 \times 4.45)}{2 + 5 + \ldots + 3}$$

$$= \frac{178.1}{50} = 3.56$$

$$\text{Range} = 4.6 - 2.5 = 2.1$$

$$\Sigma X_i f_i = 178.1, \quad \Sigma X_i^2 f_i = 643.565$$

$$\text{Variance} = s^2 = \frac{643.565 - \frac{(178.1)^2}{50}}{50 - 1} = 0.1872$$

$$\text{Standard Deviation} = s = \sqrt{0.1872} = 0.4327$$

$$\text{Coefficient of Variation} = \text{C.V.} = \frac{s}{\bar{X}} \times 100\%$$

$$= \frac{0.4327}{3.56} \times 100\% = 12.15\%$$

2.5 Probability

There are two approaches to defining probability: the **classical** and the **relative frequency**. According to the classical approach, if a procedure gives rise to n equally likely outcomes, of which r have attribute A, then the probability of A is r/n. This definition is somewhat restrictive since to calculate any probability we need to know the value of n and be sure that each outcome is equally likely. Since most food and agricultural problems do not satisfy these requirements, a more pragmatic definition of probability, called the frequency concept of probability, is used. We shall interpret probability as a relative frequency in a large number of trials, i.e., when we talk of the probability of an event A, we mean the relative frequency of A in a large number of similar trials. If an event of interest, A, occurs a times in b trials and if the ratio a/b approaches a limit, r/n, as b becomes arbitrarily large, then r/n is called the probability of A and we write $P(A) = r/n$.

One sees, from either definition of probability, that $P(A) \geq 0$, $P(A) \leq 1$, and, if $\bar{A}$ represents the complement of A, then $P(\bar{A}) = 1 - P(A)$. Note that, if an event A

is impossible, then $r = 0$ and $P(A) = 0$. If an event A is certain (i.e., it occurs at every trial), then $r = n$ and $P(A) = 1$.

If, for example, a sample of 200 oranges is inspected from a large consignment and 10 are found to be diseased, then the proportion of diseased oranges (or the relative frequency of diseased oranges) in the consignment is estimated as 10/200. Thus, the probability that an orange is diseased, written as P (an orange being diseased), is 0.05.

2.6 Permutations and Combinations

For a set of n items, any arrangement of r of them in a definite order is called a **permutation**. The number of different permutations is denoted by ${}^nP_r$ and calculated by the following formula:

$$ {}^nP_r = \frac{n!}{(n - r)!}, $$

where $n! = n(n - 1)(n - 2)\ldots1$, $(n - r)! = (n - r)(n - r - 1)\ldots1$, and $0!$ is taken to be 1. For example, $3! = 3 \cdot 2 \cdot 1 = 6$.

For a set of n items, any subset of r of them (chosen without regard to their order of selection) is called a **combination**. The number of different such combinations is denoted by $\binom{n}{r}$ and calculated by the following formula:

$$ \binom{n}{r} = \frac{n!}{r!\,(n - r)!} $$

If we consider n repeated trials, each with two possible outcomes (e.g., defective and nondefective), then the total possible number of different arrangements or sequences that can be obtained, each having x defectives and $n - x$ non-defectives, is $\binom{n}{x}$.

2.7 Statistical Distributions

Any set of data, whether discrete or continuous, exhibits a distributional pattern. The analysis of a data set becomes easier if it belongs to a distribution whose properties are known. The three main probability distributions that deal with counting or discrete data are the **binomial, Poisson and hypergeometric**. For measured or continuous data, probabilities are generally calculated by using the **normal distribution**.

2.7.1 Binomial Distribution

If p is the probability that any item is defective, then the probability that in a

random sample of n items there will be x defectives is given by the binomial distribution whose formula is as follows:

$$P\ (x \text{ defectives among } n \text{ items}) = \binom{n}{x} p^x (1-p)^{n-x} ,$$

for $x = 0, 1, 2, \ldots, n$.

Example 2.3 Binomial Distribution

A labelling process is known to produce 20% defective items. What is the probability of finding two defectives in a sample of four items?

Here, $n = 4$, $x = 2$, $p = 0.2$.

$$P\ (2 \text{ defectives}) = \binom{4}{2} (0.2)^2 (0.8)^2$$
$$= 0.1536 .$$

2.7.2 Poisson Distribution

In the case of a rare, random event, where n is large and p is small, probabilities are calculated by using the Poisson distribution as follows:

$$P\ (x \text{ defectives among } n \text{ items}) = \frac{e^{-\lambda} \lambda^x}{x!} ,$$

where $\lambda = np$ and $e = 2.718$. The approximation of binomial probabilities, using the Poisson distribution, is generally adequate if n is larger than 20 and p is smaller than 0.05. If n is larger than 100, then p may be as large as 0.1.

Example 2.4 Poisson Distribution

Reconsider the above example of the labelling process. Suppose that the proportion of defectives is 5% and every hour a sample of forty items is taken. What is the probability of finding in a sample one defective item?

Here, n is large (40), p is small (0.05), and $\lambda = np = 2$. Using the Poisson distribution,

$$P\ (1 \text{ defective}) = \frac{e^{-2} \times 2^1}{1!} = 0.2707 .$$

2.7.3 Hypergeometric Distribution

To calculate probabilities involving samples from small populations, one uses the hypergeometric distribution. If the population contains N units of which X

are defective and a sample of n units is randomly selected, the probability of finding x defective units in the sample is given by:

$$P\ (x \text{ defectives}) = \frac{\binom{X}{x}\binom{N-X}{n-x}}{\binom{N}{n}} \quad ,$$

for $x = 0, 1, 2, \ldots, n$.

Example 2.5 Hypergeometric Distribution

If a population consists of twenty items, of which two are defective, and a sample of five items is selected for examination, what is the probability of the sample containing one defective item?

Here, $X = 2$, $x = 1$, $N = 20$ and $n = 5$.

$$P\ (1 \text{ defective}) = \frac{\binom{2}{1}\binom{18}{4}}{\binom{20}{5}} = 0.3947 \quad .$$

2.7.4 Normal Distribution

The most important distribution dealing with continuous or measured data is the normal distribution, whose formula is:

$$P\ (X) = \frac{1}{\sigma\sqrt{2\pi}}\, e^{-1/2\{(X-\mu)/\sigma\}^2} \text{, for all values of X,}$$

where μ and σ are the population mean and standard deviation. Figure 2.2 shows the graph of a normal distribution. The probability that a variable X, which has a normal distribution with mean μ and standard deviation σ, lies between two values a and b is the area under the distribution curve between a and b.

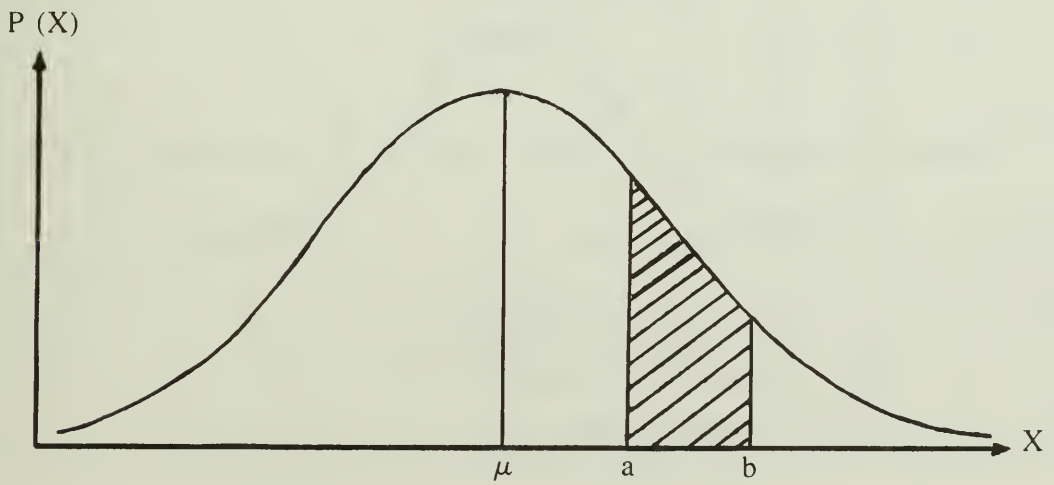

Figure 2.2 A Typical Normal Distribution

Some important features of the normal curve include the following:

1. Once μ and σ are specified, the normal curve is completely determined.
2. The curve is symmetrical about a vertical axis through the mean. The observations tend to cluster about the mean.
3. The total area under the curve is equal to 1.
4. Although the curve extends indefinitely in both directions, for all practical purposes, there is negligible area beyond 3σ on either side of the mean. Empirically, the following is known (see Figure 2.3):

   68.26% of the area is encompassed between $\mu \pm 1\sigma$,

   95.44% of the area is encompassed between $\mu \pm 2\sigma$,

   99.73% of the area is encompassed between $\mu \pm 3\sigma$.

The normal curve, being fully dependent on μ and σ, changes shape and location with different values of μ and σ, thereby generating an infinite family of distributions. It would be a hopeless task to set up individual tables of normal probabilities or areas for every conceivable combination of values for μ and σ. Fortunately, it is not necessary to do so. We transform the normally distributed random variable X with mean μ and standard deviation σ to a new random variable, called Z, where

$$Z = \frac{X - \mu}{\sigma}$$

which has a **standard normal distribution** with $\mu = 0$ and $\sigma = 1$. The curve of the standard normal distribution is centered at zero and has the bulk of its area between -3 and 3. The probability that Z lies between any two numbers a and b (assuming that $a < b$) may be evaluated from Appendix Table 1.

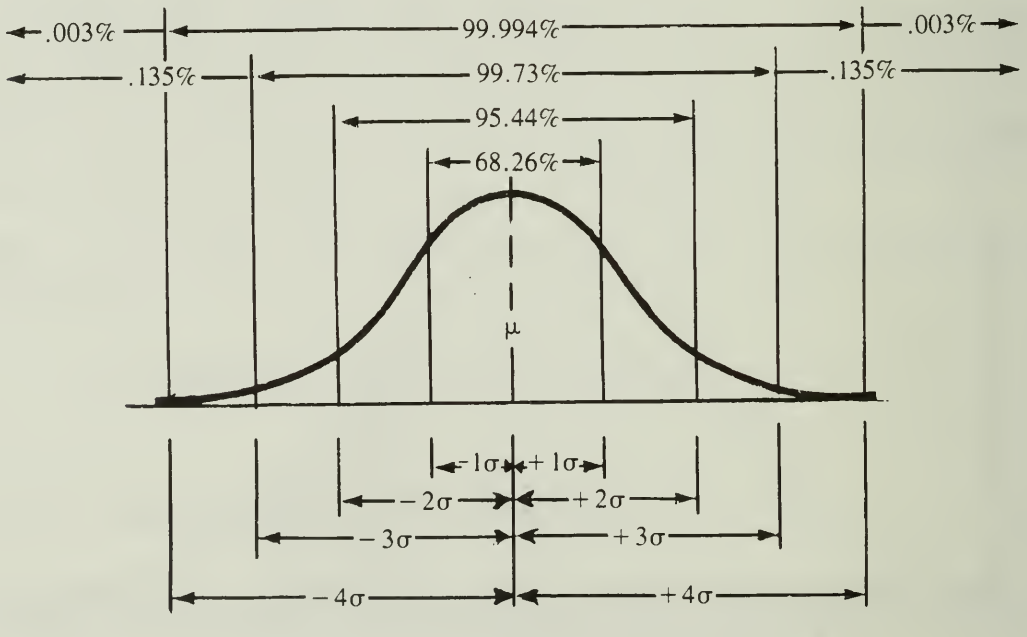

Figure 2.3 Percentages of the Normal Distribution

Example 2.6 Normal Distribution

Assuming that the moisture content of skim milk powder has a normal distribution with mean $\mu = 3.51(\%)$ and standard deviation $\sigma = 4372\ (\%)$, what is the probability that the moisture content of a randomly chosen sample of skim milk powder will be between 2.9 and 3.8(%)?

$$\text{When } X = 2.9,\ Z = \frac{2.9 - \mu}{\sigma} = \frac{2.9 - 3.51}{0.4372} = -1.40\ .$$

$$\text{When } X = 3.8,\ Z = \frac{3.8 - \mu}{\sigma} = \frac{3.8 - 3.51}{0.4372} = 0.66\ .$$

The probability that the moisture content (X) is between 2.9 and 3.8 is then the same as the probability or area under the standard normal curve (Z) between -1.40 and 0.66, i.e., $P(-1.40 < Z < 0.66)$ as depicted in Figure 2.4. Thus, from Appendix Table 1, we have:

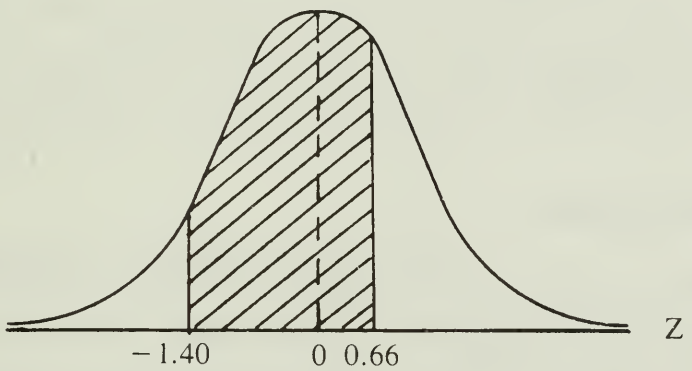

Figure 2.4 Standard Normal Distribution for Example 2.6

$$\begin{aligned} P(-1.40 < Z < 0.66) &= P(-1.40 < Z < 0) + P(0 < Z < 0.66) \\ &= P(0 < Z < 1.40) + P(0 < Z < 0.66) \\ &= 0.4192 + 0.2454 \\ &= 0.6646\ . \end{aligned}$$

2.8 Distribution of Sample Mean and Sample Variance

If a population has N elements in it, then the total possible number of distinct samples of size n that can be selected from it is $\binom{N}{n}$. For each of these samples exists a mean $\overline{X}$ and these $\overline{X}$'s have a distribution of their own. If the original population has a normal distribution, then the variable $\overline{X}$ itself also has a normal distribution. If the original population is not normal, then a very important theorem in mathematical statistics, called the **central limit theorem**, tells us that the distribution of $\overline{X}$ is approximately normal and that the approximation

improves as n gets larger. If μ and σ are the mean and standard deviation of the original population, then the mean and standard deviation of the sampling distribution of $\bar{X}$, denoted as $\mu_{\bar{X}}$ and $\sigma_{\bar{X}}$ respectively, are given as

$$\mu_{\bar{X}} = \mu \text{ and } \sigma_{\bar{X}} = \sigma \sqrt{\frac{N - n}{n(N - 1)}} .$$

For large populations (N large), $\sigma_{\bar{X}}$ is approximately equal to $\sigma/\sqrt{n}$ and is known as the **standard error** of the mean. Note that the standard deviation refers to the average variation of the observations for individual units whereas the standard error refers to the random variation of an estimate in a whole experiment. If a variable follows any normal distribution, it may be reduced to the standard normal distribution by subtracting the mean from it and dividing by its standard deviation. Since the distribution of $\bar{X}$ is normal with mean μ and standard deviation $\sigma/\sqrt{n}$, one can standardize it by subtracting μ from it and dividing by $\sigma/\sqrt{n}$, giving

$$Z = \frac{\bar{X} - \mu}{\sigma/\sqrt{n}} .$$

2.9 t-Distribution

A basic difficulty arises in that σ is generally unknown and has to be estimated by the sample standard deviation s. However, upon subtracting μ and dividing by $s/\sqrt{n}$, the variable $\dfrac{\bar{X} - \mu}{s/\sqrt{n}}$ no longer has the standard normal distribution but follows a **t-distribution**. The t-distribution is symmetric, bell-shaped, and centered at zero, just like the standard normal distribution. However, there is not a single t-distribution but a family of them, each member of the family being distinguished by its number of **degrees of freedom (d.f.), f,** defined as $f = n - 1$.

Whereas, in the standard normal distribution, 95% of the area lies between ± 1.96 (from Appendix Table 1), for every t-distribution, there is a number, which we denote as $t_{.025}$, such that 95% of the area under the t curve lies between $-t_{.025}$ and $+t_{.025}$. The actual value of $t_{.025}$ changes for varying degrees of freedom and these are given in Appendix Table 2, along with other values of t. For example, let us find the two numbers from the t-distribution between which 95% of the area is centrally contained when $n = 15$.

For $n = 15$, $f = 14$ and, therefore, $t_{.025} = 2.1448$ from Appendix Table 2. Thus, 95% of the area under the t-distribution for 14 degrees of freedom lies between -2.1448 and 2.1448. Notice that, as n increases, the values of $t_{.025}$ and $-t_{.025}$ draw closer together. For a very large n, $t_{.025} = 1.96$, the comparable value obtained from the standard normal distribution. For all practical

purposes, the t-distribution becomes equivalent to the standard normal distribution when $n > 30$.

2.10 Chi-Square Distribution

Just as there is a mean $\overline{X}$ for each of the $\binom{N}{n}$ samples of size n that can be selected from a population of N elements, each sample also possesses a standard deviation s and a variance s^2. As $\overline{X}$ has a normal (or approximately normal) distribution, so does s^2 have a distribution. Specifically, we usually consider the quantity $(n-1)s^2/\sigma^2$, which follows what is known as a **chi-square** (χ^2) distribution.

Probabilities may be calculated for $(n-1)s^2/\sigma^2$ (and hence for s^2) by finding appropriate areas under the χ^2 curve, whose values are given in Appendix Table 3. Like the t-distribution, the χ^2-distribution is a family of distributions, each distinguished by its number of degrees of freedom $f = n - 1$. If we wish to find the two values for the χ^2-distribution which have 95% of the area centrally contained between them, we denote the smaller value as $\chi^2_{.975}$ and the larger value as $\chi^2_{.025}$ and then obtain these corresponding values from Appendix Table 3. For example, if $n = 10$, the $\chi^2_{.975}$ and $\chi^2_{.025}$ values for $f = n - 1 = 9$ degrees of freedom are respectively given as 2.700 and 19.023 from Appendix Table 3.

2.11 Estimation: Confidence Intervals

The sample mean $\overline{X}$ and sample variance s^2, calculated from sample observations to estimate the corresponding population parameters μ and σ^2, are known as **point estimators** of the population mean and variance. However, the sample statistics are most likely to differ in value from the respective population parameters. Consequently, it is, therefore, generally desirable to establish an interval within which the population parameters may be expected to lie with a certain degree of confidence. This procedure, known as **interval estimation**, provides a **confidence interval** which aims at bracketing the true value of a population parameter by taking into account the uncertainty associated with the sample estimates. The **level of confidence** is denoted by $1 - \alpha$, where the Greek letter α (alpha) is known as the **level of significance**. For example, when $\alpha = 0.05$, the computed confidence interval will have a confidence level of 0.95 or 95%.

1. **Confidence Interval for the Mean μ of a Normal Distribution**

   (i) **Variance, σ^2, known**

   The general $100(1-\alpha)\%$ confidence interval for μ is given by

$$\left(\overline{X} - Z_{\alpha/2}\frac{\sigma}{\sqrt{n}} \;,\; \overline{X} + Z_{\alpha/2}\frac{\sigma}{\sqrt{n}}\right).$$

More specifically, a 95% confidence interval for μ is given by

$$\left(\bar{X} - 1.96 \frac{\sigma}{\sqrt{n}} , \bar{X} + 1.96 \frac{\sigma}{\sqrt{n}}\right) .$$

Here $1 - \alpha = 0.95$ and $Z_{\alpha/2} = Z_{.025} = 1.96$ from Appendix Table 1, i.e., the value such that 95% of the area under the standard normal curve lies between $-Z_{.025}$ and $+Z_{.025}$. One is 95% confident that this interval contains μ.

(ii) **Variance, σ^2, unknown**

When the variance σ^2 is unknown and is estimated by the sample variance s^2, the $100(1 - \alpha)\%$ confidence interval for μ is given by

$$\left(\bar{X} - t_{\alpha/2} \frac{s}{\sqrt{n}} , \bar{X} + t_{\alpha/2} \frac{s}{\sqrt{n}}\right) ,$$

where $t_{\alpha/2}$ is the t-value read from Appendix Table 2 for $(n - 1)$ degrees of freedom. For example, for a 95% confidence interval, the t-values are read vertically under $t_{.025}$ for $(n - 1)$ degrees of freedom.

2. Confidence Interval for the Variance σ^2 of a Normal Distribution

To calculate a 95% confidence interval for σ^2, one computes s^2, the sample variance based on a random sample of size n, and reads the values of $\chi^2_{.975}$ and $\chi^2_{.025}$ from Appendix Table 3 for $(n - 1)$ degrees of freedom. Thus, a 95% confidence interval for σ^2 is given as

$$\left(\frac{(n - 1)\, s^2}{\chi^2_{.025}} , \frac{(n - 1)\, s^2}{\chi^2_{.975}} \right) .$$

More generally, the $100\ (1 - \alpha)\%$ confidence interval for σ^2 is given by

$$\left(\frac{(n - 1)\, s^2}{\chi^2_{\alpha/2}} , \frac{(n - 1)\, s^2}{\chi^2_{1-\alpha/2}} \right) ,$$

where $\chi^2_{\alpha/2}$ and $\chi^2_{1-\alpha/2}$ are the χ^2-values read from Appendix Table 3 for $(n - 1)$ degrees of freedom.

It follows that a 95% confidence interval for σ, the standard deviation of a normal distribution, is expressed as

$$\left(\sqrt{\frac{(n - 1)\, s^2}{\chi^2_{.025}}} , \sqrt{\frac{(n - 1)\, s^2}{\chi^2_{.975}}} \right) .$$

3. Confidence Interval for a Proportion

If a discrete random variable has a binomial distribution, one may be concerned with estimating the population proportion of defectives, p. Suppose that a random sample of size n is drawn and X of the units are found defective. Then X/n measures the proportion of defectives in the sample. If n is large and p is not too close to 0 or 1, the central limit theorem allows the use of the normal approximation to the binomial, giving that

$$\frac{X/n - p}{\sqrt{\frac{p(1-p)}{n}}}$$

approximately has a standard normal distribution. The 95% confidence interval for p then becomes

$$\left(\frac{X}{n} - 1.96\sqrt{\frac{p\,(1-p)}{n}} \;,\; \frac{X}{n} + 1.96\sqrt{\frac{p\,(1-p)}{n}} \right) .$$

Unfortunately, this interval depends on p, which, of course, is unknown. However, if we replace p by its point estimate X/n, we obtain the following approximate 95% confidence interval for p:

$$\left[\frac{X}{n} - 1.96\sqrt{\frac{\frac{X}{n}\left(1 - \frac{X}{n}\right)}{n}} \;,\; \frac{X}{n} + 1.96\sqrt{\frac{\frac{X}{n}\left(1 - \frac{X}{n}\right)}{n}} \right].$$

Example 2.7 Confidence Intervals for the Mean and Variance

Calculate 95% confidence intervals for μ, σ^2, and σ for the data given in Section 2.3 on percent moisture in skim milk powder and the ensuing calculations performed in Example 2.2.

Here, $\bar{X} = 3.51$, $s^2 = 0.1911$, $s = 0.4372$, and $n = 50$.

The 95% confidence interval for μ is evaluated as

$$\left(3.51 - \frac{(2.01)\ (0.4372)}{\sqrt{50}} \;,\; 3.51 + \frac{(2.01)\ (0.4372)}{\sqrt{50}} \right)$$

or (3.39 , 3.63), where the value of $t_{.025}$ is approximately equal to 2.01, for 49 degrees of freedom, from Appendix Table 2. We are highly confident, i.e., 95% confident, that the true mean skim milk percent moisture content lies between 3.39 and 3.63(%).

For the 95% confidence intervals for σ^2 and σ, we first read the required χ^2-values for 49 degrees of freedom from Appendix Table 3 as

$$\chi^2_{.025} = 70.222 \text{ and } \chi^2_{.975} = 31.555.$$

Thus, a 95% confidence interval for σ^2 is obtained as

$$\left(\frac{(50 - 1)\,(0.1911)}{70.222} \;,\; \frac{(50 - 1)\,(0.1911)}{31.555} \right)$$

or (0.1333 , 0.2967).

The 95% confidence interval for σ is, therefore

$$(\sqrt{0.1333} \;,\; \sqrt{0.2967}) = (0.3651 \;,\; 0.5447).$$

Example 2.8 Confidence Interval for a Proportion

From a large lot of apples, a random sample of 100 is inspected, yielding 15 bad apples. Calculate a 95% confidence interval for p, the true proportion of bad apples in the entire lot.

Here, $n = 100$, $X = 15$, $\frac{X}{n} = 0.15$ and $\sqrt{\frac{\frac{X}{n}\left(1 - \frac{X}{n}\right)}{n}} = 0.0357.$

An approximate 95% confidence interval for p is then computed as

$$(0.15 - 1.96 \times 0.0357 \;,\; 0.15 + 1.96 \times 0.0357) = (0.08 \;,\; 0.22).$$

Hence, we are 95% confident that the actual proportion of bad apples in the lot is between 8% and 22%.

2.12 Hypothesis Testing

Whereas statistical estimation uses sample observations to form point or interval estimates of unknown parameters, hypothesis testing is used to test the validity of certain assumptions made on these parameters.

Null and Alternative Hypotheses

The main hypothesis that we test is called the **null hypothesis** and is denoted by H_0. Any other complementary hypotheses are called **alternative hypotheses** and are denoted by H_A. For example, in controlling the fill weight of canned peaches on a production line, we might hypothesize that the mean fill weight is greater than 32 ounces. Thus, we have H_0: $\mu = 32$ and H_A: $\mu > 32$. If two production lines are involved in this process, we might hypothesize that the

mean fill weight is the same for both lines. In this case, we have H_0: $\mu_1 = \mu_2$ and H_A: $\mu_1 \neq \mu_2$ where μ_1 and μ_2 refer to the true fill weight of canned peaches produced on lines 1 and 2 respectively.

Type I and Type II Errors

In hypothesis testing, two types of errors can occur. A **type I error** is made upon rejecting H_0 when in fact it is true. The probability of committing a type I error is called the **level of significance** of the test and is denoted by α (alpha). A **type II error** is made upon accepting H_0 when in fact it is false. The probability of a type II error is denoted by the Greek letter β (beta) and $1 - \beta$ is known as the **power** of the test. Since it is generally difficult to predict the probability of committing a type II error, we develop our testing procedures to accommodate and control the type I error.

A decision to accept or reject the null hypothesis is made by establishing **acceptance** and **critical (rejection) regions** based on a **confidence level** of $1 - \alpha$. The **critical values** act as boundaries to separate the acceptance region from the critical region. For example, for $\alpha = 0.05$, critical values for the standard normal distribution are $-Z_{\alpha/2} = -1.96$ and $Z_{\alpha/2} = 1.96$ from Appendix Table 1. If upon computation the test statistic Z falls in the critical region, defined by values less than -1.96 or greater than 1.96, the null hypothesis is rejected at the 5% level of significance. The null hypothesis is accepted if Z falls in the acceptance region bounded by -1.96 and 1.96 (see Figure 2.5).

One and Two-Tailed Tests

The critical regions for a distribution can vary between tests conducted at the same significance level, depending on the statement of the alternative hypothesis. A test procedure for any statistical hypothesis where the alternative is one-sided, such as

$$H_0: \mu = 4,\ H_A: \mu > 4 \quad \text{or} \quad H_0: \mu = 4,\ H_A: \mu < 4\ ,$$

is called a **one-sided** or **one-tailed test**. The critical region for the alternative hypothesis H_A: $\mu > 4$ lies entirely in the right tail of the distribution, while the critical region for the alternative hypothesis H_A: $\mu < 4$ lies entirely in the left tail. In such cases when a symmetrical distribution is being used, if $\alpha = 0.05$ or 5%, we require the acceptance region to comprise the area under the curve on one side of the mean along with 45% from the mean on the other side (see Figure 2.5).

A test method for any statistical hypothesis where the alternative is two-sided, such as

$$H_0: \mu = 4,\ H_A: \mu \neq 4\ ,$$

is called a **two-sided** or **two-tailed test**. The alternative hypothesis states that either $\mu < 4$ or $\mu > 4$. Consequently, an equal area in both tails of the distribution constitute the critical region. Here, for a symmetrical distribution, if $\alpha = 0.05$ or 5%, we want half of the acceptance region, namely an area of 47.5%, on either side of the mean (see Figure 2.5).

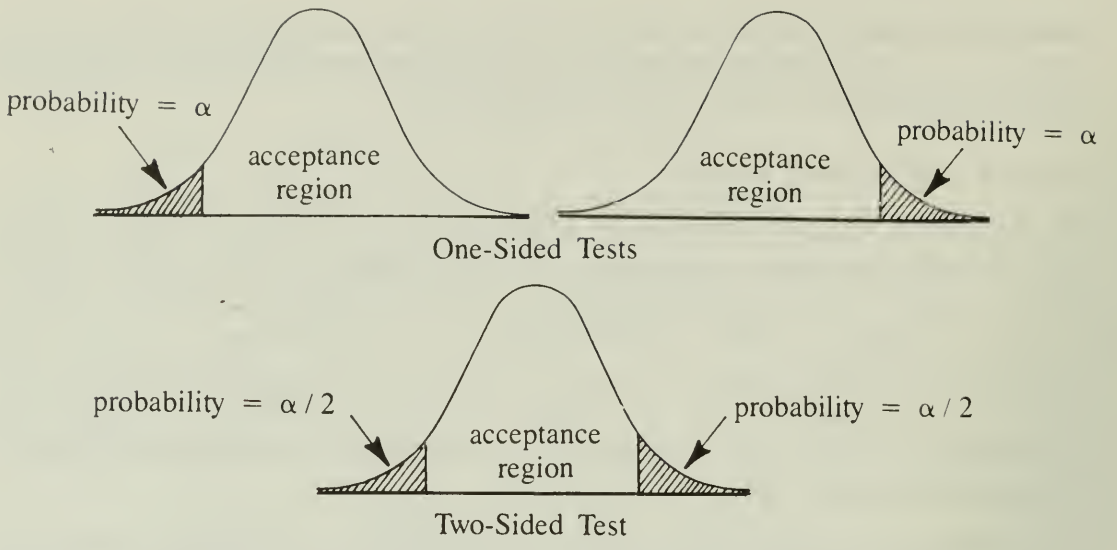

Figure 2.5 Acceptance and Critical Regions for One and Two-Sided Tests for Normal Distribution

2.12.1 Tests of Significance

1. **Testing a Mean Value μ_0, σ^2 Known: Z-test**

Null Hypothesis $H_0: \mu = \mu_0$

Test Statistic $Z = \dfrac{\overline{X} - \mu_0}{\sigma/\sqrt{n}}$

Alternative Hypothesis	**Reject H_0 at the 0.05 Level of Significance if**
$\mu \neq \mu_0$	$Z > 1.96$ or $Z < -1.96$
$\mu > \mu_0$	$Z > 1.645$
$\mu < \mu_0$	$Z < -1.645$

2. **Testing a Mean Value μ_0, σ^2 Unknown: t-test**

Null Hypothesis $H_0: \mu = \mu_0$

Test Statistic $t = \dfrac{\overline{X} - \mu_0}{s/\sqrt{n}}$, with $f = (n - 1)$ d.f.

Alternative Hypothesis	**Reject H_0 at the 0.05 Level of Significance if**
$\mu \neq \mu_0$	$t > t_{.025}$ or $t < -t_{.025}$
$\mu > \mu_0$	$t > t_{.05}$
$\mu < \mu_0$	$t < -t_{.05}$

3. **Testing Differences between Two Means: Variances Unknown**

Null Hypothesis $H_0: \mu_1 = \mu_2$ or $H_0: \mu_1 - \mu_2 = 0$

Test Statistic

$$t = \frac{\bar{X}_1 - \bar{X}_2}{s_p \sqrt{\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}},$$

with $f = (n_1 + n_2 - 2)$ d.f.

where $s_p^2 = \frac{(n_1 - 1)\, s_1^2 + (n_2 - 1)\, s_2^2}{n_1 + n_2 - 2}$.

Alternative Hypothesis	**Reject H_0 at the 0.05 Level of Significance if**
$\mu_1 \neq \mu_2$	$t > t_{.025}$ or $t < -t_{.025}$
$\mu_1 > \mu_2$	$t > t_{.05}$
$\mu_1 < \mu_2$	$t < -t_{.05}$

4. **Testing a Proportion Value p_0**

Null Hypothesis $H_0: p = p_0$

Test Statistic

$$Z = \frac{\frac{X}{n} - p_0}{\sqrt{\frac{p_0(1 - p_0)}{n}}}$$

where X is the number of occurrences for the attribute of interest in the n trials.

Alternative Hypothesis	**Reject H_0 at the 0.05 Level of Significance if**
$p \neq p_0$	$Z > 1.96$ or $Z < -1.96$
$p > p_0$	$Z > 1.645$
$p < p_0$	$Z < -1.645$

Example 2.9 Testing a Mean Value

It is hypothesized that the mean weight of chicken eggs produced by hens fed a particular diet is higher than 55 grams. To test this assumption, a random sample of 25 eggs is taken and each egg is weighed, yielding $\bar{X} = 56.0$ g and

s = 6.0 g. Using a one-sided test at a significance level of 5%, test the hypothesis H_0: $\mu = 55$ against H_A: $\mu > 55$.

The appropriate test statistic is given as

$$t = \frac{\bar{X} - \mu_0}{s/\sqrt{n}} = \frac{56.0 - 55}{6.0/\sqrt{25}} = 0.83 .$$

From Appendix Table 2, the value of $t_{.05}$ for $f = n - 1 = 24$ degrees of freedom is given as 1.71. Since the calculated t-value is less than the tabulated t-value, we cannot reject the null hypothesis at the 5% significance level. Therefore, we have no significant evidence to conclude that this specific diet produces a mean egg weight greater than 55 grams.

Example 2.10 Testing the Difference Between Two Means

To compare the mean effect of two different treatments on corn yield, 25 plots of corn are given treatment 1 and 20 other similar plots receive treatment 2. The corresponding sample means and variances for the number of bushels of corn harvested per plot are obtained as follows:

$$\bar{X}_1 = 83, \bar{X}_2 = 64, s_1^2 = 7.3, s_2^2 = 9.8 .$$

At the .05 level of significance, test the hypothesis H_0: $\mu_1 = \mu_2$ against H_A: $\mu_1 \neq \mu_2$. Here, the proper test statistic is given by

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{s_p^2 \left(\frac{1}{n_1} + \frac{1}{n_2}\right)}} = \frac{83 - 64}{\sqrt{8.4 \left(\frac{1}{25} + \frac{1}{20}\right)}} = 21.9$$

$$\text{where } s_p^2 = \frac{(25 - 1)(7.3) + (20 - 1)(9.8)}{25 + 20 - 2} = 8.4 .$$

The tabulated $t_{.025}$ value for $f = n_1 + n_2 - 2 = 43$ degrees of freedom is approximately 2.02 from Appendix Table 2. Since the calculated t-value of 21.9 is greater than the tabulated t-value of 2.02, we reject the null hypothesis and conclude that, at the 5% level of significance, the two treatments exhibit a statistically significant difference in mean corn yield.

Example 2.11 Testing a Proportion Value

Using the random sample of 100 apples inspected in Example 2.8, investigate the hypothesis, at the 5% level of significance, that the proportion of bad apples in the corresponding lot is at most 12%.

Here, we need to test the hypothesis H_0: $p = 0.12$ against H_A: $p > 0.12$. The applicable test statistic is calculated as

$$Z = \frac{\frac{X}{n} - p_0}{\sqrt{\frac{p_0 (1 - p_0)}{n}}} = \frac{0.15 - 0.12}{\sqrt{\frac{0.12 \times 0.88}{100}}} = 0.923 .$$

Since this calculated Z-value of 0.923 is less than 1.645, we find no evidence from the data to reject the null hypothesis and hence accept at the 5% significance level that at most 12% of the apples contained in the lot are bad.

Furthermore, upon referring to Example 2.8, we note that $p_0 = 0.12$ or 12% falls within the 95% confidence interval evaluated for p, which confirms our above results.

2.13 Linear Regression and Correlation

2.13.1 Linear Regression

Correlation analysis measures the degree or strength of association between two quantitative variables while regression analysis further identifies the nature of that relationship for prediction purposes. Predicting the behavior of two variables, exhibiting a linear relationship, is achieved through a straight line regression equation $Y = A + BX$, where Y is the unknown dependent variable and X is the known independent variable. The constant A, called the **Y-intercept**, is the Y-value at which the line intersects the Y-axis. The constant B, called the **regression coefficient**, is the **slope** of the line and represents the change in Y caused by a unit change in the value of X.

For any given sample of n observations Y_i corresponding to n selected values X_i, the predicted value of Y for any fixed value of X, denoted by $\hat{Y}$ (read Y-hat), is obtained from the **best-fitting line** to this data, derived by the **method of least squares** which yields the **(estimated) regression equation** as

$$\hat{Y} = a + bX$$

$$\text{where } b = \frac{\Sigma XY - \frac{(\Sigma X)(\Sigma Y)}{n}}{\Sigma X^2 - \frac{(\Sigma X)^2}{n}} \quad \text{and } a = \frac{\Sigma Y}{n} - b\left(\frac{\Sigma X}{n}\right).$$

Thus, for any specified value of X, say $X = X_0$, the corresponding predicted value of Y is given as $\hat{Y} = a + bX_0$. For an interval estimate of Y, a 95% **prediction interval** can be computed as

$$\hat{Y} \pm t_{.025}\,(s_{\hat{y}}) \quad ,$$

where $t_{.025}$ is the tabulated t-value for $(n - 2)$ degrees of freedom in Appendix Table 2 and $s_{\hat{y}}$ is the standard error (S.E.) of an individual predicted value for Y, with

$$s_{\hat{y}}^2 = s_{y.x}^2 \left(1 + \frac{1}{n} + \frac{(X_0 - \bar{X})^2}{\Sigma X^2 - \frac{(\Sigma X)^2}{n}} \right) ,$$

where $s_{y.x}$ is the standard error of estimate for a linear regression of Y on X and

$$s_{y.x}^2 = \frac{\Sigma(Y - \hat{Y})^2}{n - 2} = \frac{\Sigma Y^2 - a(\Sigma Y) - b(\Sigma XY)}{n - 2} .$$

The 95% prediction interval for Y can, therefore, also be written as

$$\hat{Y} \pm t_{.025} \sqrt{s_{y.x}^2 \left(1 + \frac{1}{n} + \frac{(X_0 - \bar{X})^2}{\Sigma X^2 - \frac{(\Sigma X)^2}{n}} \right)} .$$

2.13.2 Correlation

The linear association between two variables is measured by a correlation coefficient that is calculated, for a sample of n observations, as

$$r = \frac{\Sigma XY - \frac{(\Sigma X)\,(\Sigma Y)}{n}}{\sqrt{\left(\Sigma X^2 - \frac{(\Sigma X)^2}{n} \right) \left(\Sigma Y^2 - \frac{(\Sigma Y)^2}{n} \right)}} .$$

The value of r may fall anywhere within the range -1 to $+1$. Negative values of r indicate that an inverse relationship exists between X and Y whereas positive values of r are obtained when there is a direct relationship between X and Y. If $r = 0$, no linear relationship exists between the two variables.

It is also meaningful to know the degree or strength of the linear relationship between X and Y, based on the magnitude of the correlation coefficient. This is done by calculating r^2, called the **coefficient of determination**, which measures the proportion of the total variation in Y which is due to the linear association between X and Y.

To test the significance of r, the population correlation coefficient, denoted by ρ (rho), is set equal to zero, i.e., H_0: $\rho = 0$. The test statistic is then evaluated as

$$t = \frac{r}{\sqrt{\frac{1 - r^2}{n - 2}}}$$

which has a t-distribution with $(n - 2)$ degrees of freedom. The decision to accept or reject H_0 is made as before by comparing the calculated and the tabulated t-values at a given level of significance.

Example 2.12 Regression and Correlation Analysis

In a study on the effect of the percentage of growth hormone in the feed (X) upon the weight at 20 weeks of turkeys in kg (Y), a random sample of birds was obtained and the results recorded as shown in Table 2.3. Perform a regression and correlation analysis of this data.

TABLE 2.3: Regression Data for Turkey Study

Hormone Percentage (X)	4	6	8	10	12	14	16	18	20
Weight (kg.) (Y)	4.1	4.9	4.6	5.3	5.8	5.6	6.4	6.4	6.7

Here, $n = 9$, $\Sigma X = 108$, $\Sigma Y = 49.8$, $\overline{X} = 12$, $\overline{Y} = 5.53$, $\Sigma X^2 = 1536$, $\Sigma Y^2 = 281.88$, $\Sigma XY = 635.2$.

$$\text{Hence, } b = \frac{635.2 - \frac{(108)\ (49.8)}{9}}{1536 - \frac{(108)^2}{9}} = 0.157 \text{ and}$$

$$a = \frac{49.8}{9} - \frac{(0.157)\ (108)}{9} = 3.649$$

Thus, the regression equation is expressed as

$$\hat{Y} = 3.649 + 0.157X$$

To draw the estimated regression line, find $\hat{Y}$ for two selected values of X (say, 2 and 20). When $X = 2$, $\hat{Y} = 3.963$. When $X = 20$, $\hat{Y} = 6.789$. Join these two points with a straight edge to obtain the desired line (see Figure 2.6).

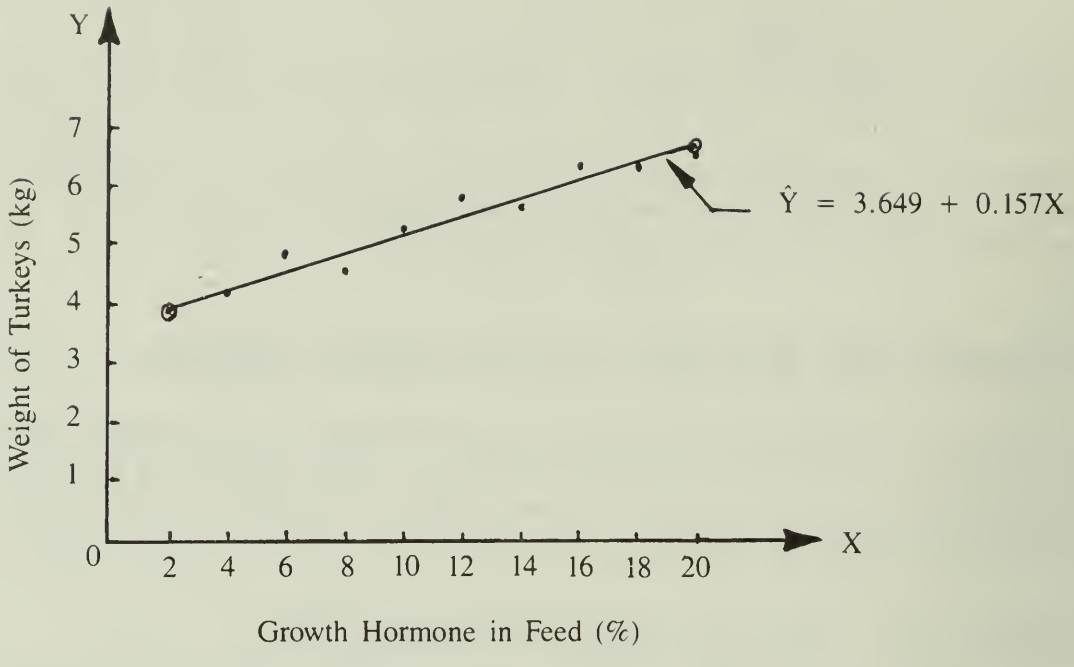

Figure 2.6 Regression Line for Data in Table 2.3

Let us construct a 95% prediction interval for Y when X = 15(%). When $X = X_0 = 15$, $\hat{Y} = 6.004$,

$$s_{y.x}^2 = \frac{281.88 - (3.649)(49.8) - (0.157)(635.2)}{9 - 2} = 0.0619, \text{ and}$$

$$s_{\hat{y}}^2 = 0.0619 \left(1 + \frac{1}{9} + \frac{(15 - 12)^2}{1536 - \frac{(108)^2}{9}} \right) = 0.0711 .$$

Thus, a 95% prediction interval for Y, when $X = X_0 = 15$, is given by $6.004 \pm 2.3646 \sqrt{0.0711}$ or (5.373 , 6.635) kg, where 2.3646 is the tabulated $t_{.025}$ value from Appendix Table 2 for $f = n - 2 = 7$ degrees of freedom.

The correlation coefficient is given as

$$r = \frac{635.2 - \frac{(108)(49.8)}{9}}{\sqrt{\left(1536 - \frac{(108)^2}{9}\right)\left(281.88 - \frac{(49.8)^2}{9}\right)}} = 0.9654 .$$

To test the significance of this correlation coefficient, i.e., H_0: $\rho = 0$ against H_A: $\rho > 0$, the pertinent test statistic is calculated as

$$t = \frac{r}{\sqrt{\frac{1 - r^2}{n - 2}}} = \frac{0.9654}{\sqrt{\frac{1 - (0.9654)^2}{9 - 2}}} = 9.795 .$$

From Appendix Table 2, the $t_{.05}$ value for $n - 2 = 9 - 2 = 7$ degrees of freedom is 1.8946. Since the calculated t-value of 9.795 is much greater than the tabulated t-value of 1.8946, we reject H_0 and conclude at the 5% level of significance that a highly significant positive correlation exists between the hormone percentage and the weight.

We, therefore, conclude from the above analysis that a direct relationship exists between X and Y, i.e., an increase in the percentage growth hormone given in the feed produces an increase in weight in 20-week old turkeys. The same conclusion can be drawn from the coefficient of determination $r^2 = (0.9654)^2 = 0.9320$, which reveals that 93.2% of the variation in the weight of 20-week old turkeys is explained by the linear association existing between the weight and the percentage of growth hormone present in the feed.

CHAPTER 3

SAMPLING METHODS

3.1 Introduction

In any investigation, whether it be a laboratory experiment, sampling inspection of food products, or a survey, the purpose is to estimate or compare lot or population characteristics or to make decisions about lot acceptance/rejection. Ideally, of course, we would like to be able to make use of the entire population to study the characteristics of interest. However, for most enquiries, complete enumeration of the population or 100% inspection is either impossible, impractical, time-consuming, or uneconomical, creating fatigue and boredom for the inspection personnel. Consequently, generalizations and inferences about populations are derived by observing the behavior and properties of a relatively small number of the population units, called a sample.

The purpose of sampling theory is to make sampling more efficient, i.e., to develop methods of sample selection and of estimation that provide optimum information at the lowest possible cost. The ensuing estimates are expected to be sufficiently accurate and precise. Accuracy refers to the closeness of a measured value to its true value and is measured by the positive difference between the expected and the true value. The precision of an estimate is measured by the amount of variability among repeated measurements and is expressed by σ^2. Thus, an estimate will be accurate and unbiased if the true value and the expected value are identical and will be precise if σ^2 is small.

3.2 Types of Sampling Enquiries

The nature and purpose of an enquiry determines the type of sampling process to be used. Generally, there are four types of enquiries:

- **Sampling priority:** for a multitude of products involving divergent risks or critical characteristics, to establish a priority of sampling inspection for an optimal allocation of resources.
- **Sampling frequency:** determining the level of inspection needed for each product or activity.
- **Sample size:** determining the amount of product to be selected for inspection for each activity or lot.
- **Sample selection method:** determining the most feasible statistical method for selecting the designated sample size.

3.2.1 Sampling Priority

Sampling priority is a function of several factors, such as:

- the relative importance of products in the domestic, import, and export markets
- the product characteristics and their impact
- the production schedule, volume, and quality/compliance history of a product
- the inspection costs
- the physical location of a product
- the availability of inspection resources
- the impact on trade
- the consumer needs and expectations

Sampling priority can be established either by developing a multivariate model which takes into consideration the essential factors or by utilizing management techniques to optimally allocate the available financial and human resources.

3.2.2 Sampling Frequency

Like sampling priority, the determination of sampling frequency also depends on many factors, including:

- the production volume, frequency and schedule
- the quality/compliance history of the product
- the quality management system of the organization
- the distance an inspector has to travel to carry out an inspection
- the physical layout of the product and facility
- the required inspection resources and costs
- the regulatory requirements and consumer needs

Generally, one can start with a normal frequency of inspection, commensurate with the available resources, and then switch to either a tightened or a reduced mode depending on whether the product quality deteriorates or improves.

Sometimes, a probabilistic approach, such as the following, can effectively be used to establish sampling frequency:

$$\text{Sampling frequency} = f = \log p_2 / \log p_1$$

where

p_1 = the probability of failing to detect the presence of 'trouble' with the first sample selected after 'trouble' has entered the process,

p_2 = the probability of failing to detect the presence of such 'trouble' for f consecutive samples.

For example, if $p_1 = 0.83$ and $p_2 = 0.05$, the value of f equals 16. This means that, even though the probability of failing to detect the presence of 'trouble' in the first sample is as high as 0.83, the probability that the presence of this 'trouble' will remain undetected while 16 consecutive samples are selected is not more than 0.05.

3.2.3 Sample Size

Sample size determination is the most frequently asked question in an investigation. Sample sizes are basically required for two purposes: to estimate lot or population parameters and to make a decision on lot acceptance. The latter, known as acceptance sampling, is discussed in Chapter 4.

A basic difficulty in solving most types of "sample size" problems is that often we don't know what we want and we lack certain information necessary for calculations. To solve the problem of determining sample size, three questions must first be answered:

1. What variation is expected in the experiment?
2. What difference between the estimated and true values or what difference between the treatments is expected?
3. What accuracy of estimation is desired?

Many short-cut methods have been used for determining sample size such as extracting the square root of the number of units in a lot or taking a fixed percentage of the units, say 10%, from a lot. While these techniques are easy to use, they are not based upon a statistical consideration of the experiment. A basic formula for determining sample size for estimation purposes, assuming normality, will be discussed in Section 3.3.

3.2.4 Sample Selection Method

Once the sample size has been designated, the next question is how to select a random and representative sample. Basically, one can either use a judgement or haphazard method or choose from the available probabilistic sample selection methods discussed in Section 3.4.

3.3 Sample Size Determination: A Formula

When the characteristic under measurement is approximately normally distributed, a simple formula for determining sample size is given as follows:

$$n = \frac{N}{1 + \frac{e^2 (N - 1)}{Z^2 (p) (1 - p)}}$$

where

n = sample size

N = lot size

Z = standard normal value for desired confidence level (e.g., Z = 1.96 for 95% confidence)

e = error that the investigator is willing to tolerate between the estimated and the true value

p = estimated proportion of defectives.

Note that the value of e is arbitrarily chosen by the investigator; the smaller the e selected, the larger the sample size will be. The value of p is obtained from the overall process average.

A corresponding formula, when the value of the standard deviation σ is available, is given as

$$n = \frac{N}{1 + \frac{e^2 (N - 1)}{Z^2 \sigma^2}} .$$

In cases where N is very large or the sampling fraction $\frac{n}{N}$ is close to one, the above formulas reduce to

$$n = \frac{Z^2 (p) (1 - p)}{e^2} = \frac{Z^2 \sigma^2}{e^2} .$$

An appreciation of the joint effect of the parameters e and p in the formula for sample size determination can be realized from Table 3.1. The table gives the respective value of n for selected values of N, p, and e at a 95% confidence level, i.e., when Z = 1.96.

TABLE 3.1: Effect of Parameters on Sample Size
$(1 - \alpha = 0.95)$

e	.01			.10		
N \ p	.01	.10	.20	.01	.10	.20
500	217	437	463	4	33	55
1,000	276	776	861	4	34	58
2,000	320	1268	1510	4	35	60
5,000	354	2045	2758	4	35	61
10,000	367	2570	3807	4	35	62
50,000	378	3234	5474	4	35	62

Example 3.1 Sample Size Determination

If 4% of a manufactured product is found defective on a long-term average, what minimum sample size is required from a lot of 400 units of this product so that there will be 95% confidence that the error in the mean estimate will not exceed 3%?

We have $p = 0.04$, $1 - p = 0.96$, $N = 400$, $e = 0.03$, and $Z = 1.96$. Then,

$$n = \frac{N}{1 + \frac{e^2 (N - 1)}{Z^2 (p) (1 - p)}} = \frac{400}{1 + \frac{(0.03)^2 (399)}{(1.96)^2 (0.04) (0.96)}} = 116.47$$

Therefore, under the conditions specified, a sample size of at least 117 items is required from a lot containing 400 units of product.

3.4 Sample Selection Methods

Once the sample size has been determined, its physical selection from the lot can be done either by non-random sample selection methods or by probability sampling procedures. Some of the non-probability sampling methods are: judgement sampling, haphazard sampling, convenience sampling, grab sampling, chunk sampling, quota sampling, etc.

Although there may arise situations where only non-probability sampling methods are feasible, attempts should be made to ensure the randomness and representativeness of a sample. Some of the probability sampling methods include: simple random sampling, systematic sampling, stratified sampling, cluster sampling, etc.

3.4.1 Simple Random Sampling

A simple random sample is selected from a lot or population through a random process where all the elements in the lot have an equal and independent chance of being included in the sample. Simple random samples can be drawn by using tables of random numbers. Numerous random number tables are available, one of which is provided in Appendix Table 4 and has been abstracted from the Rand Corporation's "A Million Random Digits with 100,000 Normal Deviates" (Free Press of Glenco, New York, 1955). To explain the use of random numbers, the first 150 random numbers in Appendix Table 4 are reproduced in Table 3.2. For larger populations and the repeated use of random numbers, consult the more extensive Rand Corporation table.

Drawing a Simple Random Sample

Suppose a simple random sample of eight boxes is to be drawn from a lot of 90 boxes. The boxes in the lot are numerically labelled from 1 to 90.

TABLE 3.2: Random Numbers

93108	77033	68325	10160	38667	62441
87023	94372	06164	30700	28271	08589
83279	48838	60935	70541	53814	95588
05832	80235	21841	35545	11148	34775
17308	88034	97765	35959	52843	44895

Reading two-digit numbers from the top of the first column of Table 3.2 identifies the following boxes to be drawn for this sample:

93 10 87 70 33 68 32 51

Note that the layout of numbers in groups of five within the table is simply for reading convenience. The number 93 is ignored since no corresponding box can be found in the lot. Proceeding along the first row, we then select the next random number to replace 93, namely 01. Similarly, if a number were to be repeated, the next random number would be selected to take its place. Thus, the final eight boxes chosen to make up the required sample are numbered:

10 87 70 33 68 32 51 1

3.4.2 Stratified Random Sampling

A stratified random sample is one obtained by separating the population units into some non-overlapping groups, called strata, and then selecting a simple random sample from each stratum. There are three main reasons why stratified random sampling often results in increased information for a given cost:

1. The data is more homogeneous within each stratum than in the population as a whole.
2. The cost of conducting the actual sampling tends to be lower for stratified random sampling than for simple random sampling because of administrative convenience.
3. When stratified sampling is used, separate estimates of the population parameters can be obtained for each stratum without additional sampling.

Reduced variability within each stratum produces stratified sampling estimators which have smaller variances than do the corresponding simple random sampling estimators for the same sample size.

For example, if in a shell egg packing station the boxes of eggs are placed on pallets according to their grade size, the population is naturally divided into strata (i.e., small, medium, large and extra large) and the sampling inspection may be carried out by using stratified random sampling.

3.4.3 Systematic Sampling

A sample obtained by randomly selecting one item from the first k population units and every kth unit thereafter is called a one-in-k systematic random sample. Consider N population units numbered serially from 1 to N from which a sample of size n is to be drawn. We find an integer k, called the sampling interval, evaluated as the integer closest to N/n, i.e., $k \simeq \frac{N}{n}$, and then randomly select a number c between 1 and k inclusively. The required systematic random sample then comprises the units numbered

$$c,\ c + k,\ c + 2k,\ \ldots,\ c + (n - 1)k\ .$$

Systematic sampling provides a useful alternative to simple random sampling in the sense that it is easier to perform, less subject to error, and provides greater information per unit cost.

For example, a farmer producing maple syrup can use a one-in-ten systematic sample to determine the quality of sap contained in his maple trees, where the total number of trees on his farm, N, is unknown and he therefore cannot conduct a simple random sample.

3.4.4 Cluster Sampling

A cluster sample is a simple random sample in which each sampling unit is a collection, or cluster, of elements. The population is divided into clusters, designed to be as similar as possible to one another. The heterogeneity in the population is reflected within each cluster.

Cluster random sampling is less costly than simple or stratified random sampling if the cost of obtaining a frame listing all the population units is very high

or if the cost of obtaining observations increases as the distance separating the units increases.

The first task in cluster sampling is to specify approximate clusters. Elements within a cluster are often physically close together and hence tend to have similar characteristics. Thus, the amount of information pertinent to a population parameter may not be substantially increased as new measurements are taken within a cluster. In general, the number of elements within a cluster will be small relative to the population size and the number of clusters in the sample will be reasonably large.

To illustrate, suppose a Turkey Marketing Board wishes to estimate the annual volume of turkey purchased per household in a widespread thinly populated county. Travel costs from household to household are substantial. Therefore, the 15,000 households in the county are listed in 600 like geographical clusters of 25 households each and a simple random sample of 30 clusters is selected.

3.5 Bulk Sampling

Bulk sampling refers to the sampling of material which is available in bulk form. Bulk material may be gaseous, liquid or solid. The material may be homogeneous (non-segregated), like acid in a container, or it may be segregated as is generally the case with bulk material occurring in nature, like solids and liquids shipped in large tanks, rail cars, and ships or kept in stockpiles. The material may occur in piles with no uniquely identifiable subdivisions that can be used as sampling units. It may also come packaged, bagged or subdivided into unique sampling units practicable for a routine sampling operation. Furthermore, the material may be in a **static condition** or a **dynamic situation**.

Static situations include bulk piles at a manufacturer's warehouse or dock, bulk loads in transit in barges, rail cars and road wagons, bulk heaps or silos at farms and stores, etc. From pure sampling theory, it is impossible to obtain a representative sample from a static heap because one of the basic rules of sampling cannot be obeyed, i.e., every particle must have an equal chance of selection. Unless the entire heap can be passed through the sampling device or it can be coned or sectioned completely, this requirement cannot be satisfied. Particles in the very center or on the bottom layer may have no chance at all of being selected. In addition, the problems of segregation in static heaps are well-known; segregation may affect the distribution of such characteristics as chemical composition, physical properties, etc. Segregation may occur because of size variation between the particles or density variation between the constituents of a mix.

Dynamic situations include filling a bulk storage area at a factory, loading a bulk transport carrier; emptying a bulk cargo at the point of delivery, etc. In these situations, conveyor belts may be accessible to allow sampling either by mechanical or alternate means or there may exist a free-fall position which will enable samples to be drawn from the whole falling stream. Dynamic situations are easier to handle and will normally accommodate available sampling plans.

The objectives of bulk sampling may include one or more of the following:

- characterization of material with respect to amount, content, value, grade, homogeneity, etc.
- estimation of the mean value of the characteristics involved as well as their variability
- lot-by-lot acceptance
- control during processing
- conformance to specifications and tolerances
- establishing uniform procedures for sampling of materials.

3.5.1 Selecting Samples of Segregated Material

Usually, bulk material is sampled by taking increments of the material, blending these increments into a simple composite sample and then, if necessary, reducing this gross sample to a size suitable for laboratory testing. For bulk material involving containers in batches with a known segregation pattern, a nested sampling plan is often appropriate. Such a plan calls for randomly selecting containers within these sampled batches, and finally choosing random samples or increments from these sampled containers. Where the material is known to be stratified, the plan may elect to take random samples or increments from each stratum or from a number of randomly selected strata.

For example, in double-stage sampling, where the bulk population consists of N primary units, each of which is composed of M possible increments, the sampling plan calls for randomly selecting n primary units followed by a random sampling of m increments from each of these. Upon compositing, this gross sample is then reduced to a size suitable for laboratory testing.

Although very little statistical thinking has gone into the preparation of standard procedures for the sampling of bulk material, some situations are well documented. One such case is the sampling of fertilizer. The Official Methods of Analysis of the Association of Official Agricultural Chemists gives the following directions for taking the original increments of fertilizer and forming the composite sample:

> Use slotted single or double tube, or slotted tube and rod, with solid cone tip at one end. Take sample as follows: lay bag horizontally and remove core diagonally from end to end. From lots of 10 bags or more, take core from each of 10 bags. When necessary to sample lots of fewer than 10 bags, make sure that at least one core is taken from each bag present. For bulk fertilizers, draw at least 10 cores from different regions. Bulk shipments may be sampled at time of loading or unloading by passing container through entire stream of material as it drops from transfer belt or chute. For small packages (10 pounds or less), take one entire package as a sample. Reduce composite to quantity required, preferably by riffling, or by mixing thoroughly on clean oilcloth or paper and quartering. Place sample in airtight container.

To prepare the sample for laboratory analysis, the directions read as follows:

> Reduce gross sample to quantity sufficient for analysis or grind not less than 0.5 lb. of reduced sample without previous sieving. For fertilizer materials and moist fertilizer mixes, grind to pass sieve with 1 mm circular openings, or No. 29 std. sieve; for dry mixes that tend to segregate, grind to pass No. 40 std. sieve. Grind as rapidly as possible to avoid loss or gain of moisture during operation. Mix thoroughly and store in tightly stoppered bottles.

3.6 General Layout for Sampling Method

The sampling process has to be designed and planned judiciously. A well-planned standard layout of sampling procedures ensures the inclusion of all requisite elements and uniformity in their application. A suggested general format for sampling procedures for agricultural and food products, based on the international standard ISO/7002, is outlined below. Modifications to this layout can be made, commensurate with the particular needs of a sampling situation.

A generic list of elements required/recommended for the layout of a standard sampling method includes the following:

- Objective(s)
- Principle of the method of sampling: essential steps of the method to be used, nature of the product to be sampled, purpose of sampling, appropriate sampling plan
- Administrative arrangements: sampling personnel, representation of parties concerned, health, safety, and security precautions, signing of the sampling report
- Identification and general inspection of the lot prior to sampling: identification of the lot before sampling, conditions and features of the lot and its surroundings, segregation of the lot into homogeneous units, method of marking units in the lot for random sample selection, methods of lot acceptance/rejection
- Sampling equipment and ambient conditions
- Sample containers and special packing: cleanliness, quality, suitability, robustness
- Sampling procedures: sample size, incremental sampling method, preparation of bulk sample, composite sample and reduced sample, selection of sample of prepackaged products
- Packing, sealing and marking of samples and sample containers
- Precautions during storage and transportation of samples

- Sampling report: administrative details, details of the units packed or the enclosures containing the lot, material sampled, sampling method, preparation and sealing of samples
- Annexes as necessary: model reports, cautionary notes, references to statutory regulations

CHAPTER 4

ACCEPTANCE SAMPLING

4.1 Introduction

Acceptance sampling refers to the process of accepting or rejecting a lot by inspecting a sample selected in accordance with a predetermined sampling plan. A **sampling plan** specifies the number of units to be sampled, the acceptance/rejection criteria, and the associated probabilities and risks of acceptance. The purpose of acceptance sampling is not to estimate lot quality but to sentence lots. Acceptance sampling plans do not provide any direct form of quality control; they are basically audit tools to ensure that the output of a process conforms to the requirements.

Sampling plans are based on several quality characteristics and the choice of a particular type of plan depends largely on the nature of the product and the purpose of inspection. Selecting an adequate and suitable sampling plan, while being very important, is not always an easy task because the selection is dependent on a number of different factors such as the ease of administration, the protection afforded, the amount of inspection required, the cost of inspection, and the power of a plan to discriminate between a good and a bad lot.

4.2 Classification of Sampling Plans

There are a number of different ways to classify acceptance sampling plans. One major classification is by attributes and variables. **Variables**, of course, are quality characteristics that are measured on a continuous numerical scale. **Attributes** are quality characteristics that are expressed on a dichotomous basis such as "go, no-go" and "defective, nondefective". The next classification of sampling plans is with respect to quality indices and risks. Some important quality indices are defined as follows:

- **Acceptable Quality Level (AQL)**
  It is a quality level which for the purpose of sampling inspection is the limit of a satisfactory process average. The **process average** is the process level averaged over a defined time period or quantity of production. The AQL is associated with the **α (alpha) risk**, also known as the **"producer's risk"**, which is the probability of making a type I error, i.e., the risk of rejecting a good lot.
- **Limiting Quality (LQ)**
  It is a quality level which for the purpose of sampling inspection is the limit of an unsatisfactory process average. It is also known as **"Lot Toler-**

ance Percent Defective (LTPD)". The LQ is associated with the **β (beta) risk**, also known as the **"consumer's risk"**, which is the probability of making a type II error, i.e., the risk of accepting a bad lot.

- **Average Outgoing Quality (AOQ)**
  It is the expected average quality level of outgoing product for a given value of incoming product quality and is computed over all accepted lots plus all non-accepted lots after the latter have been inspected 100% and the nonconforming items replaced by good items. The **"Average Outgoing Quality Limit (AOQL)"** is defined as the maximum AOQ over all possible values of incoming product quality, for a given acceptance sampling plan and lot disposal specification.

4.3 Characterization of a Sampling Plan

Every acceptance sampling plan is characterized by the following elements: sample size (n), acceptance number (Ac) and rejection number (Re), and probability of acceptance (P_a). The **sample size** is the number of items selected for inspection. The **acceptance number** is the largest number of defective items (or defects) in the sample that will permit the lot to be accepted. The **rejection number** is the least number of defective items (or defects) in the sample that will lead to the rejection of the lot. The **probability of acceptance** of a sampling plan is the percentage of samples out of a long series of samples that will cause the product to be accepted. A complete plotting of the probability of acceptance for all possible levels of percent defective is known as an **operating characteristic (OC) curve**. The OC curve of a sampling plan quantifies the risks and makes it possible to state them numerically and describe the quantity of product that can be expected to be accepted if the quality standard is met and the quantity rejected if the standard is not met.

In practice, a 95% acceptance probability is used with a given AQL and a 10% acceptance probability is used with a given LQ. Consequently, a lot which is of AQL quality is accepted with a probability of $1 - \alpha = 0.95$ and a lot of LQ quality is accepted with a probability of $\beta = 0.10$. Figure 4.1 shows an OC curve for these specific values of the probability of acceptance (P_a), corresponding to an AQL of 2% and an LQ of 8%, for fixed sample size $n = 100$ and acceptance number $Ac = 4$. As can be seen from the figure, under these circumstances, a 2% defective product will be accepted 95% of the time and, if the product yields an 8% defective rate, it will only be accepted 10% of the time.

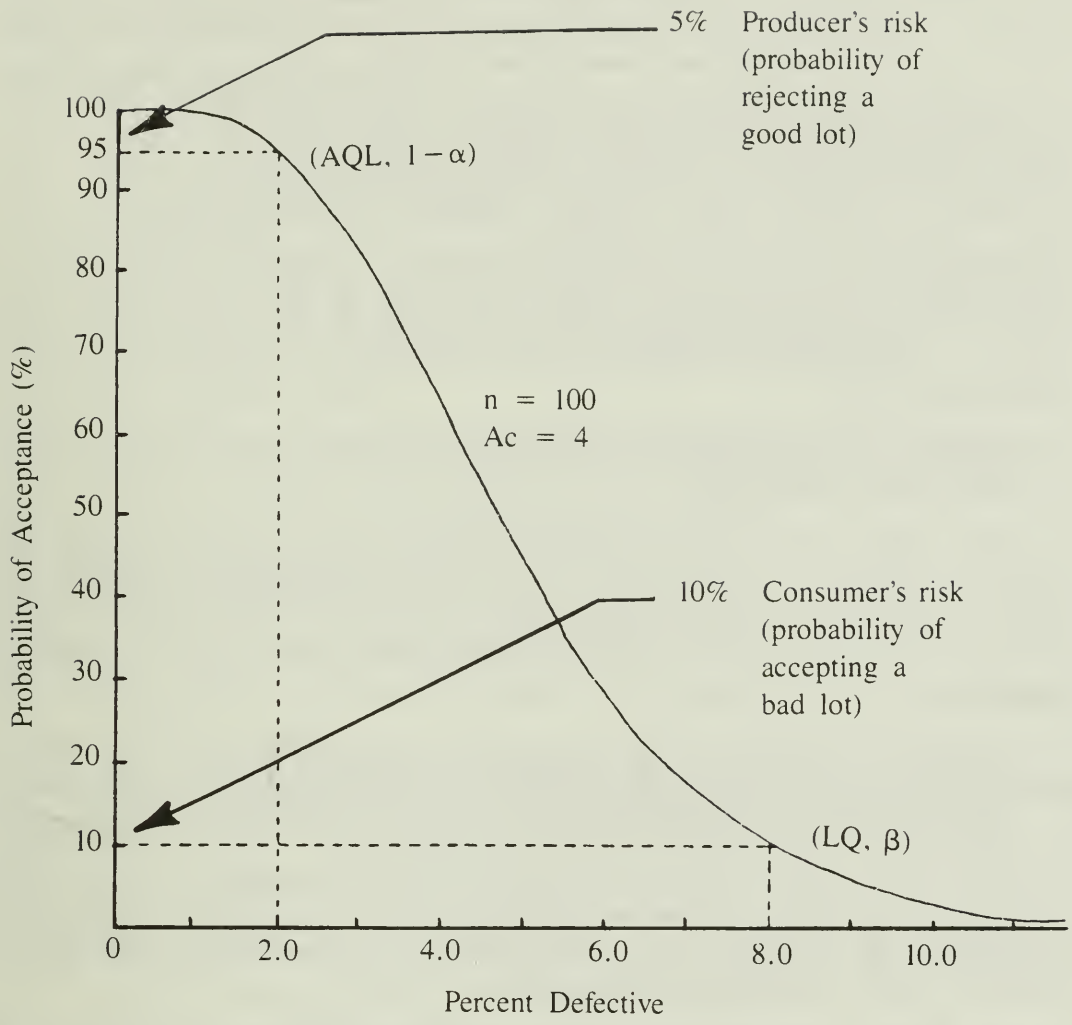

Figure 4.1 OC Curve for Single Sampling Plan

4.4 Choosing a Sampling Plan

Many factors influence the choice of an appropriate sampling plan for a particular situation. Some basic considerations are: (i) purpose of inspection, (ii) nature of product, (iii) type of testing methods used, and (iv) nature of the lots to be sampled. The purpose of the inspection may be to make an accept/reject decision, to measure average quality or to determine product variability/uniformity. The sample size may be influenced by factors associated with the material, such as its homogeneity, unit size, consistency in meeting prior specifications, and cost. The test procedure itself may influence the sampling procedure; for example, the test may consider critical rather than minor defects, it may be destructive rather than nondestructive, or it may require considerable resource investment. The size of the lot may affect the type of distribution used to set up a sampling plan while its composition and the extent to which the individual units in the lot follow a random distribution may influence the nature of the sampling plan used.

Once the presampling considerations have been taken into account, the next decision is with regard to the choice between attributes and variables sampling. In most practical applications, acceptance sampling is done on an attributes basis. Observations obtained from an attribute are usually simpler, less costly and less time-consuming than those from a variable. However, variables data provide more information about the quality characteristics of the product and may, therefore, require smaller samples. Variables sampling also gives information regarding the degree of nonconformance and can identify specific areas in which quality improvement is required. In choosing between variables and attributes sampling in situations where either could be used, various trade-offs should be considered with respect to cost of inspection, sample size, ease of administration, etc.

The sampling plans are generally indexed by one or more of the quality indices, viz., AQL, LQ, and AOQ.

The AQL plans are basically producer-oriented plans. They are used by the regulatory authority or the buyer to ensure that the producer is meeting the quality and safety requirements agreed upon. A product of AQL quality or better guarantees a high probability of lot acceptance during the process of sampling inspection.

The LQ plans, on the other hand, are consumer-oriented plans. They are used to ensure that the probability of acceptance of a lot of quality LQ or less is very low. These plans are generally meant to be used for isolated lot inspection.

The AOQ plans apply only to programs that submit rejected lots for 100% inspection. These plans are designed so as to minimize the process average and the average total inspection for a given AOQL. Unless rectifying inspection is used, the AOQL concept is meaningless.

One can devise a sampling plan based jointly on both the AQL and the LQ, if needed. Alternatively, a plan can be based on only the AQL but the expected LQ can be easily identified, or vice-versa. A requisite plan can be derived either by using basic mathematical formulas or it can be selected from one of the ready-made statistical sampling tables, documents or standards. For the sake of simplicity, we shall limit our discussion to the selection of acceptance sampling plans using one of the international standards. Since the most common inspection situation for food commodities pertains to lot-by-lot inspection of product presented by the producer to the regulatory body, we shall describe, in Section 4.6, the method of selecting an attributes sampling plan indexed by AQL using the international standard ISO/2859-1.

4.5 Ready-Made Sampling Plan Systems

For the benefit of more ambitious readers, we present, in this section, a list of important documents relating to acceptance sampling. Most of these documents are in the form of international standards developed by ISO (International

Organization for Standardization). For further reference, the reader should consult the bibliography.

- **Plans Indexed by AQL:**
  - — ISO/2859-1: Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by AQL for lot-by-lot inspection. This document is identical to MIL-STD-105D of the United States Defence Department.
  - — ISO/3951: Sampling procedures and charts for inspection by variables for percent nonconforming. This document is identical to MIL-STD-414 of the United States Defence Department.
- **Plans Indexed by LQ:**
  - — ISO/2859-2: Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by LQ for isolated lot inspection.
  - — Dodge and Romig sampling inspection tables.
- **Plans Indexed by AOQ:**
  - — Dodge and Romig sampling inspection tables.
- **Other Types of Sampling Plan Systems:**
  - — ISO/8550: Guide for selection of an acceptance sampling system scheme or plan.
  - — ISO/2859-0: Sampling procedures for inspection by attributes — Part 0: Introduction to the ISO/2859 attribute sampling system.
  - — ISO/2859-3: Sampling procedures for inspection by attributes — Part 3: Skip lot sampling plan.
  - — ISO/8422: Sequential sampling plans for inspection by attributes.
  - — ISO/8423: Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation).
  - — Continuous sampling plans.
  - — Chain lot sampling plans.
  - — ISO/3534: Statistics vocabulary and symbols
    - — Part 1: Probability and general statistical terms
    - — Part 2: Statistical quality control
    - — Part 3: Design of experiments

4.6 AQL Attributes Sampling Plans: ISO/2859-1

The acceptance sampling standard **ISO/2859-1** has been developed by the International Organization for Standardization, Technical Committee TC69, and is based on the United States Department of Defence document **MIL-STD-105D: Sampling Procedures and Tables for Inspection by Attributes**.

The ISO/2859-1 provides sampling inspection plans by attributes based on AQL and are designed to be applied to lots emerging from long production runs of many units of product. Information is also provided to allow for easy extraction of the protection afforded by these plans in terms of LQ and AOQL.

The basic aim of the standard is the maintenance of the outgoing quality level at a given "acceptable quality level" or better. It is designed such that, if the production runs consistently at precisely the AQL, then a large majority of its lots can be expected to pass inspection. Thus, the AQL is the minimum quality performance at which the producer may safely run his operation; he is, therefore, advised to operate at a quality level at least as good as the AQL.

Three types of sampling plans are provided in this standard: **single, double** and **multiple**. The choice of which type to use depends on many factors such as quality history, quality requirements, inspection level, lot size, type of sampling, AQL, and other economic considerations.

Single Sampling:

In a single sampling plan, a single sample of n items is selected at random from the lot. The decision concerning the acceptability of the lot is made on the basis of the results obtained from this sample. If the number of defective units found in the sample is less than or equal to the acceptance number Ac, the lot is accepted. If the number of defectives is equal to or greater than the rejection number Re, the lot is rejected.

Double Sampling:

In a double sampling plan, a first sample of n_1 units is selected at random from the lot and inspected. If the number of defectives is less than or equal to the first acceptance number Ac_1, the lot is accepted. If the number of defectives is equal to or greater than the first rejection number Re_1, the lot is rejected. If no decision can be made from the first sample because the number of defectives is greater than Ac_1 but less than Re_1, a second sample of n_2 units is selected at random from the lot and inspected. If the cumulative number of defectives from the first and second sample is less than or equal to the second acceptance number Ac_2, the lot is accepted. And, if the cumulative number of defectives is equal to or greater than the second number Re_2, the lot is rejected.

The average number of items inspected under double sampling is generally less than that inspected under single sampling. Despite this smaller sampling rate, double sampling is less frequently used than single sampling since it demands more record keeping. Some inspectors improperly interpret double sampling as giving the product a second chance. Generally, double sampling is used in situations where the lot quality is known to be either very good or very bad.

Multiple Sampling:

The procedure in multiple sampling is similar to that for double sampling with the exception that the number of successive samples required to reach a decision to accept or reject the lot may be more than two. The number of steps required to reach a firm decision depends on the cumulative number of defectives found in the samples taken progressively. There is an acceptance/rejection criterion at each step, namely, accept the lot at any step where the cumulative number of defectives is equal to or less than the acceptance number and reject it

whenever the cumulative number of defectives equals or exceeds the rejection number. If the cumulative number of defectives is between the accept/reject figures, another sample is drawn. All multiple sampling is terminated after a specified number of steps by arranging the acceptance and rejection figures to be consecutive at the last step, thus forcing a decision to accept or reject the lot. However, the size of the cumulative sample at the last step is larger than the equivalent in single and double sampling plans.

Inspection Levels:

Seven inspection levels, S-1, S-2, S-3, S-4, I, II, and III, are provided in the standard for varying degrees of discrimination and each level provides different sample sizes for a given lot size. In the order given above, sample size (and, therefore, discrimination) increases from a minimum at special level S-1 to a maximum at general level III. Levels S-1 to S-4 are considered special levels, which are limited in application to situations where it is imperative that only small sample sizes be used, such as in the case of destructive testing of expensive units of product. General inspection level II is considered the normal level and is to be used at the commencement of any inspection activity unless otherwise specified.

The standard also provides three levels of inspection in terms of the severity of inspection: **normal**, **tightened**, and **reduced**. Normal inspection is used at the start. Then, if the quality is shown to be poor, the inspector is directed to be more severe in his inspection and use the tightened level. If the quality is shown to be consistently high, reduced inspection is indicated. Guidelines for establishing switching rules between the normal, tightened, and reduced levels of inspection are further provided.

Sample Size:

A letter code system is used for determining sample size. This is given in Table 1 of ISO/2859-1 and as Table 5A of the Appendix. The letter assigned to a given sample is dependent on the inspection level and the lot size. In Table 5A, varying blocks of lot sizes are listed vertically against the inspection levels listed horizontally so that any specific lot may fall within one of these blocks to provide the corresponding letter designating sample size.

AQL:

The AQL serves as a border-line value, chosen to demarcate what will and will not be considered acceptable as a process average, and as such is an indicator of the quality required in production. A realistic AQL must be chosen to compromise the capability of the producer, the expectation of the consumer, and the available process average. In ISO/2859-1, several AQL values are given, progressing from a minimum of 0.010 to a maximum of 1000. AQLs from 0.010 to 10 inclusively may be expressed either in percent nonconforming (percent defective) or in nonconformities (defects) per 100 units. AQLs greater than 10 are expressed in defects per 100 units only. The sampling tables provide what are known as "preferred AQLs". For ease of administration, it is advisable to use

preferred AQL values as much as possible. However, if a specified AQL is not a preferred AQL, the tables are not applicable and a sampling plan must be specially derived for that particular AQL.

4.6.1 Layout of Sampling Plans in ISO/2859-1

The generic layout for the sampling plans contained in ISO/2859-1 is as follows:

- **Table 1** contains: ranges of lot sizes; inspection levels (special levels: S-1, S-2, S-3, S-4 and general levels: I, II, III); sample size code letters.
- **Tables 2-A,B,C; 3-A,B,C; 4-A,B,C** provide: preferred AQLs; sample sizes for selected code letters; acceptance/rejection numbers; the type/nature of inspection as follows:

Nature / Type	Normal	Tightened	Reduced
Single	2-A	2-B	2-C
Double	3-A	3-B	3-C
Multiple	4-A	4-B	4-C

- **Tables 5-A,B** provide: AOQL values for normal and tightened inspection. These tables assist in identifying what limit of average outgoing quality to expect when using a specified AQL plan.
- **Tables 6-A,B and 7-A,B** provide: LQ values for normal, single inspection plans. These tables assist in identifying, for a specified AQL plan, the limit of an unsatisfactory process average for which there is a low probability of acceptance. LQ values are always greater than the AQL, and in some cases considerably greater, but the difference between the LQ and the AQL values decreases as the sample size increases.
- **Tables 8 and 9** provide: limit numbers for reduced inspection and average sample size curves for double and multiple sampling respectively.
- **Tables 10-A to 10-S** give: for each sample size code letter, the OC curves and the exact probabilities of acceptance.

A reproduction of a few sample pages from the standard are given in the Appendix to help explain the working of the document. Thus, Tables 1, 2-A and 3-A of the standard are referenced as Appendix Tables 5A, 5B and 5C, respectively.

4.6.2 Procedure for Selecting a Sampling Plan from ISO/2859-1

A step-by-step procedure for using ISO/2859-1 is as follows:

1. Decide on the size of the lot (N) which is to be sampled and inspected. This need not be a production lot size.
2. Decide upon an inspection level. In general, level II is recommended at the commencement of inspection activities.
3. Using the information from steps 1 and 2, enter Table 1 of ISO/2859-1 (Appendix Table 5A) to find the corresponding sample size code letter, A, B, ..., or R, the latter calling for the largest sample sizes.
4. Decide upon single, double, or multiple sampling.
5. Decide whether to start with normal (almost always), tightened, or reduced sampling.
6. Decide upon the basis of inspection, viz., defectives or defects.
7. Decide upon the desired AQL from the preferred AQLs available in the document, if at all possible. AQL values of 10.0% or less may be expressed either in percent defective or in defects per 100 units; those over 10.0% are expressed in defects per 100 units only.
8. For the nature and the type of sampling, the AQL and the sample size code letter determined in steps 5, 4, 7, and 3 respectively, enter the relevant table in the document. The acceptance/rejection numbers are commonly given in the body of the table against the sample size (n) listed to the left.
9. Following the above, we may reach a dot or an arrow. A dot denotes the use of the single sampling plan, corresponding to the desired AQL and code letter, instead of double or multiple sampling plans. If an arrow is encountered, follow it to the first entry containing acceptance/rejection numbers and use the sample size to the left of this entry, not the one associated with the original code letter.

Example 4.1 Selecting a Sampling Plan Using ISO/2859-1

Consider a situation of lot-by-lot inspection of skim milk powder where we have lot sizes of 250 bags and will use inspection level II, for normal sampling, with an AQL of 0.40% defective for the characteristic in question.

For a lot size of 250, the appropriate sample size code letter is G, from Appendix Table 5A.

If a normal single sampling plan is desired, we use Appendix Table 5B. In this table, in the column 0.40 and the row G, we read Ac = 0, Re = 1, and the sample size n = 32. Thus, the plan calls for taking a random sample of 32 bags from the 250 in the lot, inspecting each one for the characteristic of interest and,

finding d defective bags: (i) accepting the lot if $d = 0$, and (ii) rejecting the lot if $d \geq 1$.

On the other hand, if a normal double sampling plan is desired for the same conditions, then we use Appendix Table 5C and find that the two cumulative sample sizes are $n_1 = n_2 = 20$ and that a dot (•) appears as the entry under the column 0.40. The dot (•) indicates two alternatives: either (i) to use the corresponding single sampling plan or (ii) to use the double sampling plan below, where available, in Appendix Table 5C. Following the latter course of action, we obtain $Ac_1 = 0$, $Re_1 = 2$, $Ac_2 = 1$, and $Re_2 = 2$. To the left of these entries, we now find $n_1 = n_2 = 80$. Note, very particularly, that we do not use the sample sizes $n_1 = n_2 = 20$, which normally apply to code letter G. Thus, our plan is to take a random sample of 80 bags from the 250 in the lot, inspect each one, and, finding d_1 defective bags: (i) accept the lot if $d_1 = 0$, (ii) reject the lot if $d_1 \geq 2$, or (iii) take another sample from the lot if $d_1 = 1$. If the latter option is required, suppose that this second sample of 80 from the 170 remaining bags in the lot yields d_2 defective bags. Then, (i) accept the lot if $d_1 + d_2 = 1$ and (ii) reject it if $d_1 + d_2 \geq 2$.

Note: If a reduced double sampling plan would have been used instead, one would have come across a gap between the acceptance and rejection numbers, specifically, $Ac_2 = 0$ and $Re_2 = 2$. Now, if a two-sample inspection revealed $d_1 + d_2 = 1$, it appears that no decision could have been reached. This circumstance is covered in Section 11.1.4 of the standard where it says that, if such an event occurs, one is to accept this lot (because the previous quality had been excellent relative to the AQL) but be alerted to the possibility that the quality has now slipped from its previous level of excellence. Therefore, one is to abandon reduced sampling with its rather lenient OC curve and return to normal sampling under the same conditions.

4.7 Other Acceptance Sampling Procedures

Although we are not going to give any detailed description of other acceptance sampling procedures, a brief idea of the principles behind some of the more important of these procedures is presented here. The reader should consult the bibliography for a more elaborate explanation and usage of these methods.

4.7.1 Continuous Sampling Plans

Continuous sampling plans are used for a production process where no separate "lots" exist. They are generally used on conveyors but are applicable to any continuously running operation where we do not wish to accumulate the product into lots for purposes of inspection.

To give a general picture of continuous sampling, suppose we have a continuous flow of product which is 3.0% defective. We begin to inspect this product,

classifying each unit in order as defective or nondefective. If 0 represents a nondefective unit and X a defective one, the record of inspection results may resemble the following pattern:

00X 00000X 000X 00000000000X

00000000X 000000000000000X 0000

The number of nondefective units between two consecutive defectives, referred to as "defective spacing (s)", generally follows a probabilistically predictable pattern. If a product is worse than 3.0% defective, the defective units will occur more frequently and the spacing s will tend to become shorter. If the product is less than 3.0% defective, the defective units will occur less often and the spacing s will tend to become longer. Since products of different quality produce different patterns of s, it is possible to set up an "acceptance criterion" in terms of s which will reject more product of a "bad" level of quality and accept more of a "good" quality level, where good and bad may be defined as desired and varied for different applications.

The basic continuous sampling plan, called CSP-1, operates by specifying a "clearing interval (i)" which is a fixed parameter for a given continuous sampling plan, denoting the number of consecutive units to be inspected and found clear of defects before the process qualifies for regular random sampling.

Initially, consecutive units are 100% inspected until the clearing interval (i) qualification is met. Thereupon, only a fraction (f) of the units are inspected, selecting individual units one at a time from the flow of product, in such a manner as to assure an unbiased sample of fraction f. A simple operation schematic of CSP-1 is shown in Figure 4.2.

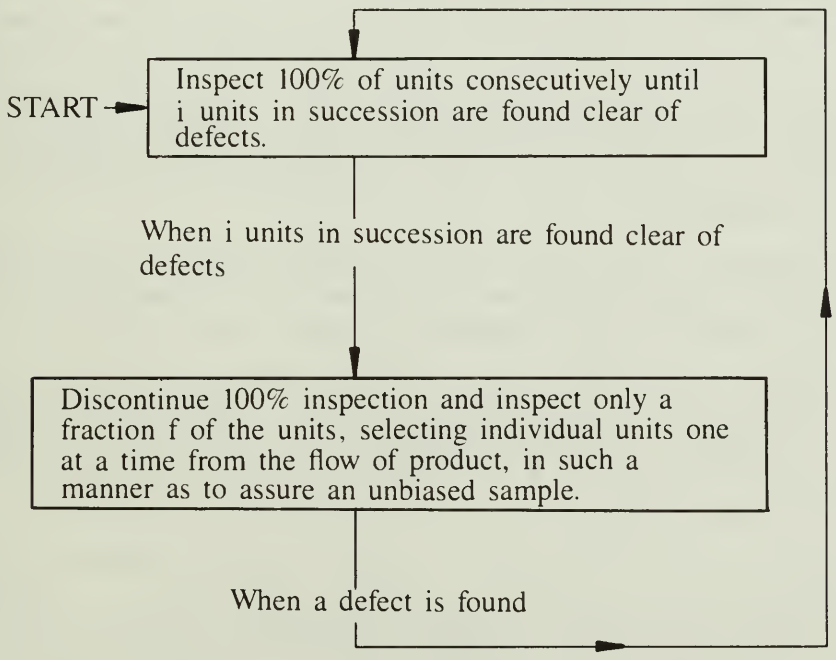

Figure 4.2 Operation Schematic for Continuous Sampling Plan: CSP-1

When a unit is found to be defective during the regular sampling period, immediate reversion to 100% inspection is again required until the qualification for regular sampling is met by again satisfying the clearing interval, i. Continuous sampling is generally of the AOQL type, involving periods of 100% inspection and periods of regular random sampling. The AOQL achieved is determined by the selected values of i and f. For further details regarding continuous sampling procedures, the reader should consult Stephens (1979).

4.7.2 Skip-Lot Sampling Plans: ISO/2859-3

Skip-lot sampling is an acceptance sampling procedure in which some lots in a series are accepted without inspection (other than possible spot checks) when the sampling results for a specified number of immediately preceding lots meet the stated criteria. It is a procedure for reducing the inspection effort on products submitted by those suppliers who have demonstrated their ability to control, in an effective manner, all facets of product quality and consistently produce superior quality material.

These plans are intended only for a continuous series of lots or batches and should not be used for isolated lots. The lots to be inspected are chosen randomly in accordance with a stated frequency, called the "skip-lot frequency". A skip-lot frequency of 1 lot in 2, for example, means that the long-run average proportion of inspected lots is fifty percent. For a method of determining the skip-lot frequency and the sample size, the reader should refer to the international standard ISO/2859-3.

4.7.3 Sequential Sampling Plans by Attributes: ISO/8422

Under a sequential sampling plan by attributes, units are selected at random and subjected to inspection, one by one, and a cumulative count is kept of the number of nonconforming units (or of the number of nonconformities). Following the individual inspection of each unit, this cumulative count is used to assess whether or not there is sufficient information to sentence the lot at that stage of the inspection.

If, at a certain stage, the cumulative count is such that the risk of accepting a lot of unsatisfactory quality (the consumer's risk) is sufficiently low, the lot is considered acceptable and the sampling of that lot is terminated.

If, on the other hand, the cumulative count is such that the risk of non-acceptance for a lot of satisfactory quality (the producer's risk) is sufficiently low, the lot shall be considered non-acceptable and the sampling of that lot is terminated.

If the cumulative count does not allow either of the above decisions to be taken, then an additional unit of product is inspected. The process is continued until sufficient sample information has been accumulated to warrant a final decision for the lot. For further details, consult ISO/8422: Sequential Sampling Plans for Inspection by Attributes.

CHAPTER 5

STATISTICAL PROCESS CONTROL

5.1 Introduction

The traditional approach to manufacturing is to depend on production to make the product and on quality control to inspect the final product and screen out items not meeting specifications. This strategy of detection is often wasteful and uneconomical because it involves after-the-event inspection when the unacceptable production has already occurred. Instead, it is much more effective to institute a strategy of prevention to avoid waste by not producing unusable output in the first place. This can be accomplished by gathering process information and analyzing it so that action can be taken on the process itself. This is accomplished through **Statistical Process Control (SPC)** methods.

The object of statistical process control is to serve in establishing and maintaining a process at an acceptable and stable level so as to ensure the conformity of products and services to specified requirements. The major statistical tool used to achieve this is the **control chart,** which is a graphical method of presenting and comparing information, based on a sequence of samples representing the current state of a process against limits established after consideration of the inherent process variability. The control chart method helps first to evaluate whether or not a process has attained, or continues in, a state of statistical control at the proper specified level and then to obtain and maintain control and a high degree of uniformity in important product or service characteristics by keeping a continuous record of the quality of the product while production is in progress.

The control chart as a graphical means of applying the principles of statistical significance to the control of the production process was first proposed by Dr. Walter Shewhart in 1924. Control chart theory recognizes two kinds of variability. The first kind is random variability due to **"chance causes"** or **"common causes".** The elimination or correction of common causes requires a management decision to allocate resources to improve the process and system. The second kind of variability represents a real change in the process. Such a change can be attributed to some identifiable causes that are not an inherent part of the process and which can, at least theoretically, be eliminated. These identifiable causes are referred to as **"assignable causes"** or **"special causes"** of variation. They may be attributable to the lack of uniformity in material, workmanship or procedures, a broken tool, or to the irregular performance of manufacturing or testing equipment.

Control charts aid in the detection of unnatural patterns of variation in data resulting from repetitive processes and provide criteria for detecting a lack of statistical control. A process is in **statistical control** when the variability results only from random or common causes. Once this acceptable level of variation is

determined, any deviation from that level is assumed to be the result of assignable causes which should be identified and eliminated or reduced.

5.2 Types of Control Charts

The most important types of control charts commonly used for process control studies are the following:

- **Shewhart System of Charts**
  - — Charts for Variables: Mean ($\overline{X}$) Chart, Range (R) or Standard Deviation (s) Chart
  - — Charts for Attributes: Fraction Defective (p) Chart, Number Defective (np) Chart, Number of Defects (c) Chart, Number of Defects per Unit (u) Chart
  - — Charts for Individuals (X), and Moving Ranges (R)
  - — Median (Me) Chart and Range (R) Chart
- **Cumulative Sum (or Cusum) Charts**
- **Acceptance Control Charts**

We shall limit our discussion to the Shewhart $\overline{X}$ and R charts for variables, the p chart for attributes and the Cusum charts.

5.3 Shewhart System of Charts

A Shewhart control chart requires data obtained by sampling the process at regular intervals. The intervals may be defined in terms of time (e.g., hourly) or quantity (e.g., every lot) and determine the **subgroups** or samples selected from the process. From each subgroup, one or more subgroup characteristics are computed such as the subgroup average, $\overline{X}$, and the subgroup range, R, or standard deviation, s. The chart consists of the values of a given subgroup characteristic plotted against the subgroup numbers, a **central line (CL)** located at a reference value, and two statistically determined control limits, one on either side of the central line, which are called the **upper control limit (UCL)** and the **lower control limit (LCL)** (see Figure 5.1).

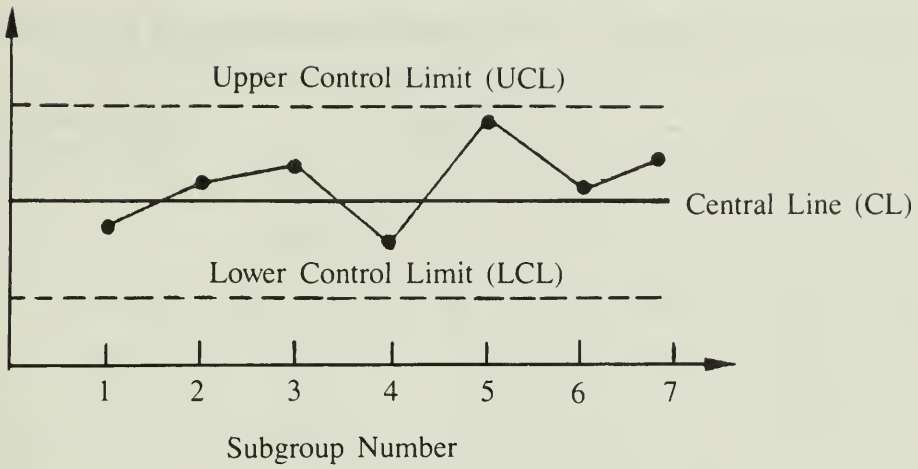

Figure 5.1 Outline of a Control Chart

Limits on the control charts were proposed and established by Shewhart at 3σ distance on each side of the central line, where σ is the population within-subgroup standard deviation estimated from sample ranges or standard deviations. The 3σ limits indicate that approximately 99.7% of the subgroup values will be included within these control limits, provided the process is in statistical control. Interpreted another way, there is approximately a 0.3% chance, or an average of three times in a thousand, that a value will spuriously fall outside of the limits when the process is properly centered and in control. The possibility that a violation of these limits is really a chance event rather than a signal of real process change is considered so small that, when a point plots outside of the limits, action should be taken. Since action is required at this point, the 3σ control limits are sometimes called **action limits**. Frequently, 2σ limits (called **warning limits**) are also drawn to warn of an impending out-of-control situation when a value plots outside of these limits.

When a plotted value falls outside of either control limit or a series of values reflects unusual patterns, the state of statistical control can no longer be accepted. When this occurs, an investigation is initiated to locate the assignable cause(s) and the process may be stopped or adjusted. Once the assignable cause is determined and eliminated, the process is ready to continue. After a control chart has exhibited a state of control over a reasonable number of subgroup values, permanent control chart parameters can be established.

5.4 Shewhart Control Charts: Formulas and Factors

Table 5.1 provides the necessary formulas for plotting the control chart lines for control charts by variables, attributes, and individual values.

TABLE 5.1: Control Limit Formulas for Shewhart Control Charts

Type	Central Line (CL)	Upper Control Limit (UCL)	Lower Control Limit (LCL)
Variables Control Charts			
$\bar{X}$	$\bar{\bar{X}}$	$\bar{\bar{X}} + A_2\bar{R}$ or $\bar{\bar{X}} + A_3\bar{s}$	$\bar{\bar{X}} - A_2\bar{R}$ or $\bar{\bar{X}} - A_3\bar{s}$
R	$\bar{R}$	$D_4\bar{R}$	$D_3\bar{R}$
s	$\bar{s}$	$B_4\bar{s}$	$B_3\bar{s}$
Attributes Control Charts			
p	$\bar{p}$	$\bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$	$\bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$
np	$n\bar{p}$	$n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$	$n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$
c	$\bar{c}$	$\bar{c} + 3\sqrt{\bar{c}}$	$\bar{c} - 3\sqrt{\bar{c}}$
u	$\bar{u}$	$\bar{u} + 3\sqrt{\frac{\bar{u}}{n}}$	$\bar{u} - 3\sqrt{\frac{\bar{u}}{n}}$
Control Charts for Individuals			
X	$\bar{X}$	$\bar{X} + E_2\bar{R}$	$\bar{X} - E_2\bar{R}$

Note: 1. The values of the factors A_2, A_3, D_3, D_4, B_3 and B_4 are given below in Table 5.2 for various values of the subgroup size n.

2. The symbols $\bar{\bar{X}}$, $\bar{R}$, and $\bar{s}$ represent the average of the subgroup averages, ranges, and standard deviations respectively.

3. In the case of charts for individuals, where only one observation per subgroup is available, a measure of variability is obtained from the moving range of two observations. A moving range is the absolute difference between successive pairs of measurements in a series, i.e., the positive difference between the first and second measurement, then that between the second and third measurement, and so on. From these moving ranges, the average moving range, $\bar{R}$, is calculated and used in the construction of control charts for individuals. The value of the factor E_2 is obtained as $3/d_2$, where values of d_2 are given in Table 5.2 for the subgroup size n. For instance, if a moving range of two observations is considered, then n = 2 and, therefore, $E_2 = 3/1.128 = 2.66$.

TABLE 5.2: Factors for Shewhart Variables Control Charts

Number of Observations in a Subgroup (n)	A_2	A_3	D_3	D_4	B_3	B_4	d_2
2	1.880	2.659	—	3.267	—	3.267	1.128
3	1.023	1.954	—	2.574	—	2.568	1.693
4	0.729	1.628	—	2.282	—	2.266	2.059
5	0.577	1.427	—	2.114	—	2.089	2.326
6	0.483	1.287	—	2.004	0.030	1.970	2.534
7	0.419	1.182	0.076	1.924	0.118	1.882	2.704
8	0.373	1.099	0.136	1.864	0.185	1.815	2.847
9	0.337	1.032	0.184	1.816	0.239	1.761	2.970
10	0.308	0.975	0.223	1.777	0.284	1.716	3.078
11	0.285	0.927	0.256	1.744	0.321	1.679	3.173
12	0.266	0.886	0.283	1.717	0.354	1.646	3.258
13	0.249	0.850	0.307	1.693	0.382	1.618	3.336
14	0.235	0.817	0.328	1.672	0.406	1.594	3.407
15	0.223	0.789	0.347	1.653	0.428	1.572	3.472

5.5 Construction of Shewhart Control Charts

The steps involved in the construction of the $\overline{X}$ chart and the R chart are described here as an example. The same basic procedure is followed for all the other types of control charts.

1. Obtain data, subgroup by subgroup, by taking 20 to 25 subgroups (k), each of size 4 or 5 (n), and measuring the characteristic of interest. The classification of observations into subgroups should be done carefully so that the variation within a subgroup may be considered to be due to chance causes only and the variation between subgroups may be attributed to assignable causes which the control chart is intended to detect.
2. For each subgroup, calculate the average, $\overline{X}$, and the range, R.
3. Compute the grand average of all the observation values, $\overline{\overline{X}}$, i.e., the average of all the subgroup averages, and the average of all the subgroup ranges, $\overline{R}$.
4. On a suitable form or graph paper, lay out an $\overline{X}$ and an R chart. The vertical scale on the left is used for $\overline{X}$ or for R, as applicable, and the horizontal scale identifies the subgroup number. Plot against the appropriate subgroup numbers the computed values for $\overline{X}$ on the chart for averages and the values for R on the chart for ranges. On these respective charts, draw solid horizontal lines to represent $\overline{\overline{X}}$ and $\overline{R}$, thus situating the central lines.

5. Place the control limits on these charts. On the $\overline{X}$ chart, draw two horizontal dotted lines at $\overline{\overline{X}} \pm A_2\overline{R}$ and, on the R chart, draw a horizontal dotted line at $D_3\overline{R}$ and another at $D_4\overline{R}$, where A_2, D_3 and D_4 depend on n, the number of observations in a subgroup, and are given in Table 5.2. The LCL on the R chart is not needed whenever n is less than 7 since the ensuing value of D_3 is considered to be zero.

6. Plot the R chart first by joining consecutive points with straight lines. Check for data points outside the control limits, signaling an out-of-control situation, and for unusual patterns or trends. For each indication of an assignable cause in the range data, conduct an analysis of the operation of the process to determine the cause; correct that condition and plan to prevent its recurrence.

7. Exclude all subgroups affected by an identified assignable cause; then, recalculate and plot the new average range, $\overline{R}$, with its revised control limits. Verify that all the range points now confirm statistical control when compared to the new limits, repeating the identification/correction/ recalculation sequence if necessary.

8. Any subgroup dropped from the R chart because of identified assignable causes should also be excluded from the $\overline{X}$ chart. The revised $\overline{R}$ and $\overline{\overline{X}}$ should be used to recalculate the trial control limits for averages, $\overline{\overline{X}} \pm A_2\overline{R}$.

9. When the ranges are in statistical control, the process spread, i.e., the within-subgroup variation, is considered to be stable. The averages can then be analyzed to see if the process location is changing over time.

10. Now plot the $\overline{X}$ chart and check for data points outside the control limits, signaling an out-of-control condition, and for unusual patterns or trends. Like the R chart, analyze any out-of-control condition and take corrective and preventive action. Exclude any subgroup exhibiting out-of-control points for which assignable causes have been found; recalculate and plot the new process average, $\overline{\overline{X}}$, with its revised control limits and confirm statistical control, repeating the identification/correction/recalculation sequence if necessary.

11. When the range and average values are consistently contained within the trial control limits, extend these limits to cover future periods. These limits would then be used for an ongoing control of the process, with the responsible individuals (operator and/or supervisor) responding to signs of out-of-control conditions appearing on either the $\overline{X}$ or R chart with prompt action.

5.6 Process Control and Process Capability

A process is deemed to be stable if the points plotted from the subgroup data fall within the control limits. An out-of-control condition is specified by any of the following criteria:

- a point outside of the control limits
- a run of 7 consecutive points, all on the same side of the central line
- a run of 7 consecutive points, steadily moving up or steadily going down
- any other obviously nonrandom pattern such as cycles, a gradual change in level, grouping or bunching, interaction, a systematic pattern, trends, etc.

Once a process has been brought under statistical control, the next step is to study its capability to meet the specifications. **Process capability** represents the performance of the process itself and its assessment begins after all the control issues in both the $\bar{X}$ and R charts have been resolved, that is, the special causes have been identified, analyzed, corrected and prevented from recurring.

Process capability is generally measured in terms of a **process capability index, PCI (or C_p)**, as follows:

$$\text{PCI} = \frac{\text{Tolerance Specified}}{\text{Process Capability}} = \frac{\text{UTL} - \text{LTL}}{6\sigma}$$

where

UTL is the upper tolerance limit,

LTL is the lower tolerance limit, and

σ is estimated from the within-subgroup variability given by $\frac{\bar{R}}{d_2}$.

It should be noted that process capability for p and np control charts is expressed as the average proportion conforming to the specifications. Thus, for p and np control charts, capability $= 1 - \bar{p}$. For c and u control charts, process capability cannot be expressed in the same manner. Here, $\bar{c}$ and $\bar{u}$ are used, respectively, as the measures of process performance.

Example 5.1 $\bar{X}$ Chart and R Chart

In Table 5.3, measurements for the humidity level in skim milk powder samples are given. Four independent measurements are taken for every half hour of production for a total of 10 hours, giving $k = 20$ subgroup samples all of size $n = 4$. The subgroup averages and ranges are also included in Table 5.3. The upper and lower tolerance limits are specified as 0.219% and 0.125%, respectively. The objective is to evaluate the process performance and to statistically control the process with respect to its location and spread so that the process will meet the specifications.

TABLE 5.3: Production Data on % Humidity in Skim Milk Powder

Subgroup Number	% Humidity				Mean ($\bar{X}$)	Range (R)
	X_1	X_2	X_3	X_4		
1	0.1898	0.1729	0.2067	0.1898	0.1898	0.0338
2	0.2012	0.1913	0.1878	0.1921	0.1931	0.0134
3	0.2217	0.2192	0.2078	0.1980	0.2117	0.0237
4	0.1832	0.1812	0.1963	0.1800	0.1852	0.0163
5	0.1692	0.2263	0.2086	0.2091	0.2033	0.0571
6	0.1621	0.1832	0.1914	0.1783	0.1788	0.0293
7	0.2001	0.1927	0.2169	0.2082	0.2045	0.0242
8	0.2401	0.1825	0.1910	0.2264	0.2100	0.0576
9	0.1996	0.1980	0.2076	0.2023	0.2019	0.0096
10	0.1793	0.1715	0.1829	0.1961	0.1822	0.0246
11	0.2166	0.1748	0.1960	0.1923	0.1949	0.0418
12	0.1924	0.1984	0.2377	0.2003	0.2072	0.0453
13	0.1768	0.1986	0.2241	0.2022	0.2004	0.0473
14	0.1923	0.1876	0.1903	0.1986	0.1922	0.0110
15	0.1924	0.1996	0.2120	0.2160	0.2050	0.0236
16	0.1720	0.1940	0.2116	0.2320	0.2024	0.0600
17	0.1824	0.1790	0.1876	0.1821	0.1828	0.0086
18	0.1812	0.1585	0.1699	0.1680	0.1694	0.0227
19	0.1700	0.1567	0.1694	0.1702	0.1666	0.0135
20	0.1698	0.1664	0.1700	0.1600	0.1666	0.0100

Here,

$$\bar{\bar{X}} = \frac{\Sigma \bar{X}}{k} = \frac{3.8480}{20} = 0.1924 ,$$

$$\bar{R} = \frac{\Sigma R}{k} = \frac{0.5734}{20} = 0.0287 .$$

The first step is to plot an R chart and evaluate its state of control.

R Chart:

Central line $= \bar{R} = 0.0287$

UCL $= D_4\bar{R} = 2.282 \times 0.0287 = 0.0655$

LCL $= D_3\bar{R} = 0 \times 0.0287 = -$

Note: When n is less than 7, the LCL is not shown.

The values of the multiplying factors D_3 and D_4 are taken from Table 5.2 for n = 4. Since the R values in Table 5.3 are all within the R chart control limits, the R chart indicates a state of statistical control with respect to the spread. The $\overline{R}$ value can now be used to calculate the $\overline{X}$ chart control limits.

$\overline{X}$ Chart:

$$\text{Central line} = \overline{\overline{X}} = 0.1924$$

$$\text{UCL} = \overline{\overline{X}} + A_2\overline{R} = 0.1924 + (0.729 \times 0.0287) = 0.2133$$

$$\text{LCL} = \overline{\overline{X}} - A_2\overline{R} = 0.1924 - (0.729 \times 0.0287) = 0.1715$$

The value of the factor A_2 is obtained from Table 5.2 for n = 4. The control charts for $\overline{X}$ and R are graphed in Figure 5.2. An examination of the $\overline{X}$ chart reveals that the last three points are signaling an out-of-control condition. They indicate that some assignable causes of variation are operating in the process. If the control limits had been calculated from some previous data, action would have been called for at subgroup 18.

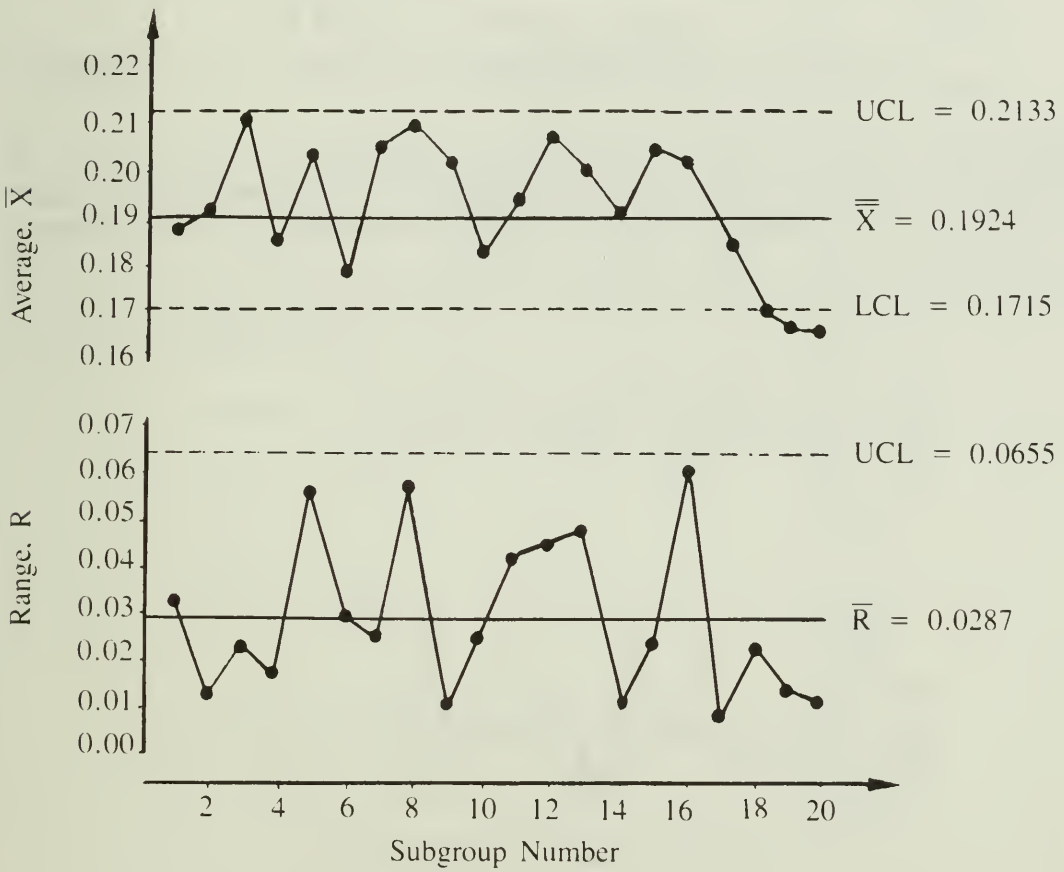

Figure 5.2 Average and Range Charts for Data in Table 5.3

At this point, suitable remedial action is taken to eliminate the assignable causes and prevent their recurrence. The charting procedure is continued by establishing revised control limits by discarding the out-of-control points, i.e., the values for subgroups 18, 19 and 20. The new values for $\overline{\overline{X}}$, $\overline{R}$ and the control chart lines are recalculated as follows:

$$\text{Revised } \overline{\overline{X}} = \frac{\Sigma \overline{X}}{k} = \frac{3.3454}{17} = 0.1968$$

$$\text{Revised } \overline{R} = \frac{\Sigma R}{k} = \frac{0.5272}{17} = 0.0310$$

Revised $\overline{X}$ Chart:

$$\text{Central line} = \overline{\overline{X}} = 0.1968$$

$$\text{UCL} = \overline{\overline{X}} + A_2\overline{R} = 0.1968 + (0.729 \times 0.031) = 0.2194$$

$$\text{LCL} = \overline{\overline{X}} - A_2\overline{R} = 0.1968 - (0.729 \times 0.031) = 0.1742$$

Revised R Chart:

$$\text{Central line} = \overline{R} = 0.0310$$

$$\text{UCL} = D_4\overline{R} = 2.282 \times 0.0310 = 0.0707$$

$$\text{LCL} = D_3\overline{R} = 0 \times 0.0310 = -$$

Note: When n is less than 7, the LCL is not shown.

The revised control charts are plotted in Figure 5.3 and indicate that the process shows a state of statistical control with respect to both location and spread.

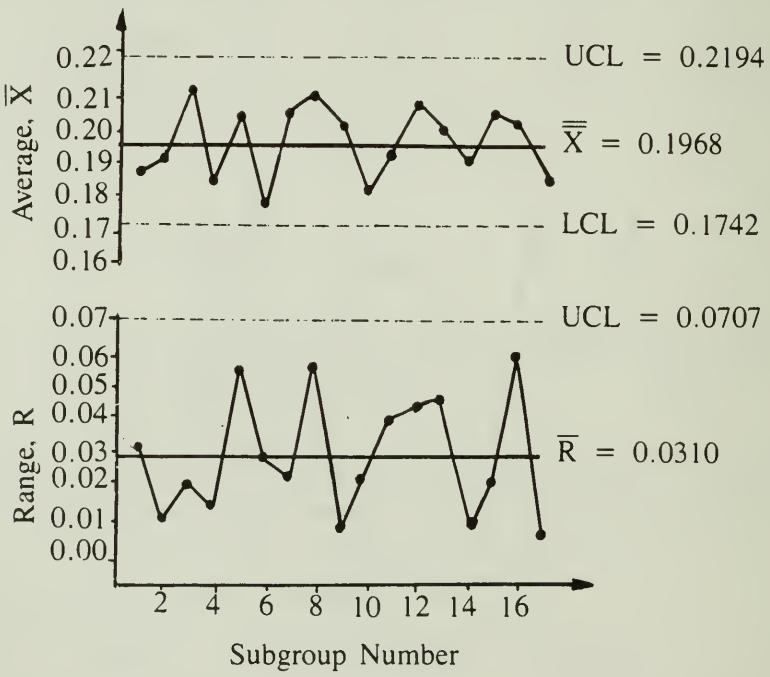

Figure 5.3 Revised $\overline{X}$ and R Charts for Data in Table 5.3

With the process exhibiting a state of statistical control under the revised control limits, the process capability index can now be evaluated as follows:

$$PCI = \frac{\text{Tolerance Specified}}{\text{Process Capability}} = \frac{UTL - LTL}{6\sigma}$$

where σ is estimated as $\bar{R}/d_2 = \frac{0.031}{2.059} = 0.0151$.

Thus,

$$PCI = \frac{0.219 - 0.125}{6 \times 0.0151} = \frac{0.094}{0.0906} = 1.04 .$$

The value of the quantity d_2 is obtained from Table 5.2 for $n = 4$. Since PCI is greater than 1, the process can be considered capable. However, on close examination, it can be seen that the process is not centered properly with respect to the specifications and, consequently, about 11.8% of the individual measurements fall above the upper specification limit. Therefore, before permanent control chart parameters are established, attempts should be made to center the process properly while maintaining a state of statistical control.

Example 5.2 Fraction Nonconforming (p) Chart

In a food processing company, it was decided to install a fraction nonconforming p chart to control the performance of the machine labelling the canned food products. Data was collected and analyzed for a period of 26 working days. From each day's production, a random sample of cans was collected at the end of the day and each one examined for nonconformance in labelling. The results are shown in Table 5.4.

TABLE 5.4: Process Control for Labelling Machine

Subgroup Number	Number of Cans Inspected	Number Noncon-forming	Fraction Noncon-forming	UCL	LCL
1	158	11	0.070	0.117	0.003
2	140	11	0.079	0.120	
3	140	8	0.057	0.120	
4	155	6	0.039	0.117	0.003
5	160	4	0.025	0.116	0.004
6	144	7	0.049	0.119	0.001
7	139	10	0.072	0.120	
8	151	11	0.073	0.118	0.002
9	163	9	0.055	0.116	0.004
10	148	5	0.034	0.119	0.001
11	150	2	0.013	0.118	0.002
12	153	7	0.046	0.118	0.002
13	149	7	0.047	0.118	0.002
14	145	8	0.055	0.119	0.001
15	160	6	0.038	0.116	0.004
16	165	15	0.091	0.115	0.005
17	136	18	0.132	0.121	
18	153	10	0.065	0.118	0.002
19	150	9	0.060	0.118	0.002
20	148	5	0.034	0.119	0.001
21	135	0	0.000	0.121	
22	165	12	0.073	0.115	0.005
23	143	10	0.070	0.120	0.000
24	138	8	0.058	0.121	
25	144	14	0.097	0.119	0.001
26	161	20	0.124	0.116	0.004
Total	3893	233			

The values of the fraction nonconforming, p, calculated for each subgroup, is also given in Table 5.4. The average fraction nonconforming for the month is calculated as follows:

$$\bar{p} = \frac{\text{Total number nonconforming}}{\text{Total number inspected}} = \frac{233}{3893} = 0.060 .$$

Since the subgroup sizes are different, the UCL and LCL values are calculated for each subgroup separately from

$$\bar{p} \pm 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$

where n is the size of the subgroup. These values are also included in Table 5.4.

It can be seen that plotting the UCL and LCL values for each subgroup is a time-consuming task. However, it can be observed from Table 5.4 that the fraction nonconforming for subgroups 17 and 26 are falling outside their corresponding upper control limits. These two subgroups are eliminated from the data as they are shown to be subject to variations other than those affecting the other subgroups. To include them in the computations would result in an overestimated process average and control limits which would not reflect the true random variations in the process. The causes of these high values should be sought so that corrective action may be taken to prevent future occurrences. A revised average fraction nonconforming is then calculated from the remaining 24 subgroup values as

$$\bar{p} = \frac{195}{3596} = 0.054 \ .$$

Calculating the revised UCL and LCL values for each subgroup, by using the revised $\bar{p}$ value, would reveal that all the fractions nonconforming are within their corresponding UCL values. Hence, this revised value of $\bar{p}$ is taken as the standard fraction nonconforming for the purpose of constructing control charts so that the central line is situated at $\bar{p} = 0.054$.

As remarked above, the plotting of upper control limits for each subgroup of varying size is a time-consuming and tedious process. However, since the subgroup sizes do not vary widely from the average subgroup size, which is evaluated as approximately 150, the revised p chart can be plotted with an upper control limit based on the average subgroup size of n = 150. Thus, the revised p chart lines are calculated as follows:

Revised p Chart:

Central line $= \bar{p} = 0.054$

$$\text{UCL} = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} = 0.054 + 3 \times \sqrt{\frac{0.054 \times 0.946}{150}}$$

$$= 0.109$$

$$\text{LCL} = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} = 0.054 - 3 \times \sqrt{\frac{0.054 \times 0.946}{150}}$$

$$= -$$

Note: Since negative values for p are not possible, the lower control limit is not shown.

The revised p chart is plotted in Figure 5.4 and illustrates that the process is exhibiting a state of statistical control.

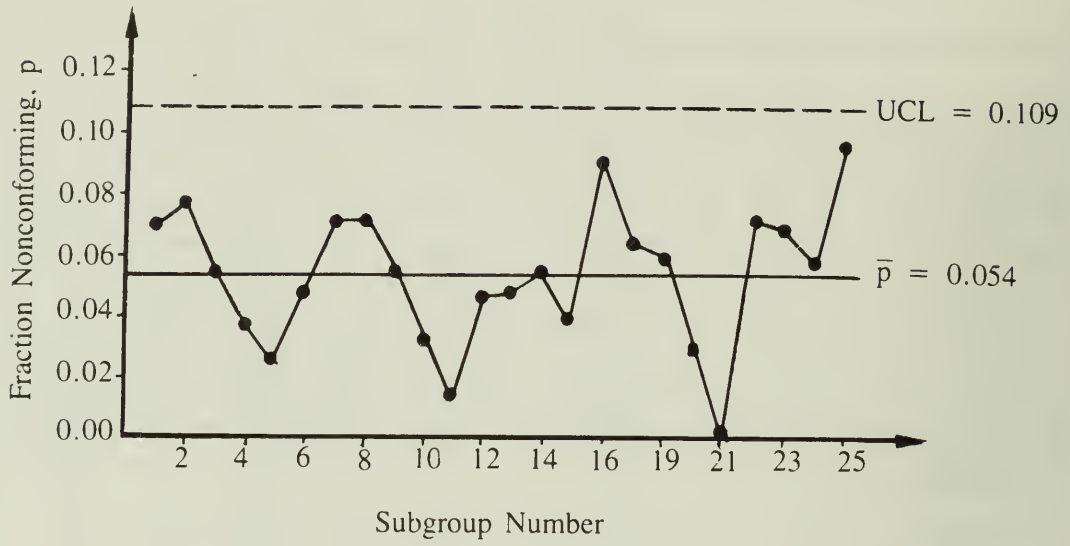

Figure 5.4 Revised p Chart for Data in Table 5.4

5.7 Cumulative Sum Control Charts

The cumulative sum charts, more commonly known as **Cusum charts**, were developed by Page in 1961 as an alternative to Shewhart control charts to exercise tighter process control through faster detection and correction of small process deviations from control. The Shewhart control chart uses only the information about the process contained in the last plotted point and ignores any information contributed by the entire sequence of points, except by way of tests for runs or the use of warning limits. The Cusum chart directly incorporates information about the whole sequence of sample values by plotting the cumulative sum of the deviations of the sample values from a preselected target value.

Both the Shewhart chart and Cusum chart have their own merits and demerits. Whereas the Shewhart chart is more effective in detecting larger short-term changes in the process level, the Cusum chart is more effective in detecting sustained changes within the region 0.5σ to 2σ. The Cusum chart possesses greater sensitivity in visually detecting small process shifts and noting the time at which the change(s) occurred. However, it is slow in detecting large process shifts and the diagnosis of patterns is difficult because the sequence of points are not independent and uncorrelated. A cautious analyst would make use of both types of charts, Cusum charts for quickly detecting small process changes and Shewhart charts for analyzing past data to detect lack of control and to bring a process under statistical control.

5.7.1 Procedure for Cusum Charts

The Cusum chart is a graphic plot of the running summation of the process deviations from a control or target value. Its underlying mathematical concept and decision rules are highly involved but its construction is simple.

1. Identify the control or target value, T. The target value is the accepted or expected value of the variable under examination.
2. Calculate the deviations of T from each observed subgroup average, i.e., $\bar{X}_i - T$, where $\bar{X}_i$ is the average of the ith subgroup measurements for $i = 1, 2, \ldots, k$.
3. Calculate and plot the cumulative sum of these deviations,

$$S_k = \sum_{i=1}^{k} (\bar{X}_i - T) ,$$

against the total number of subgroups recorded, k, on suitable graph paper. A convenient scaling convention is to regard the horizontal distance between consecutive plotted Cusum (S_k) values on the X-axis as one unit and have the same distance on the vertical scale or Y-axis to be approximately 2σ units, where σ is estimated as the average of the within-subgroup standard deviations, similar to that for Shewhart charts.

5.7.2 Decision Rules for Cusum Charts

If a statistical tool is to have wide practical usage by non-statisticians, then a reasonable degree of simplicity and standardization becomes extremely valuable. The Shewhart control charts with 2σ and 3σ limits possess these virtues and, consequently, owes much of its wide acceptance to them. The exact decision rules for Cusum charts, on the other hand, are very involved mathematically. These rules require the construction of a **V-mask** based on the approximate solutions of a random walk with absorbing barriers on the edge of the V. The V-mask is superimposed on the Cusum chart and defines a decision interval. The process is then considered to be performing satisfactorily as long as all the previously plotted points are visible and not obscured by the mask.

Instead of going through the mathematical derivation of V-masks here, we shall limit our discussion to some simple decision rules useful in studying the state of control of a process from a Cusum chart.

As a general rule, it should be noted that the Cusum graph is essentially horizontal when the process is in control at the target value T. If the mean shifts upward to some value $T_1 > T$, then an upward or positive drift will develop in the cumulative sum. If the mean shifts downward to some value $T_2 < T$, a downward or negative drift will develop. Therefore, if a trend develops in the plotted points either upward or downward, this serves as an indication of a shift in the process mean and a search should be initiated for some assignable cause(s).

Two simple methods are described below to determine when a turning point on the Cusum chart is significant.

Method 1:

Draw a straight line by eye to the points on the cumulative sum chart, extending the direction that this graph would have taken in the absence of the apparent upward change, i.e., estimate the average value of the points before the suspected point of change (see Figure 5.5). At this point, mark a point A at a distance of 5σ above the value of the cumulative sum, where σ is the standard deviation of the short-term variability of the series and is estimated as given above. This identifies the **decision interval**. Then, at a point ten intervals further along the chart, mark a point B at a height of 10σ above the position that the graph would have reached if there had been no apparent change. Draw the decision line AB. If the plotted points fall above the line AB, a change is declared at the suspected point. Unless the graph crosses this decision line before the next suspected point of change, no significant change at point A is indicated. At any further indication of a change in slope, a new decision line is similarly drawn and this suspected change is again assessed by reference to the new decision line.

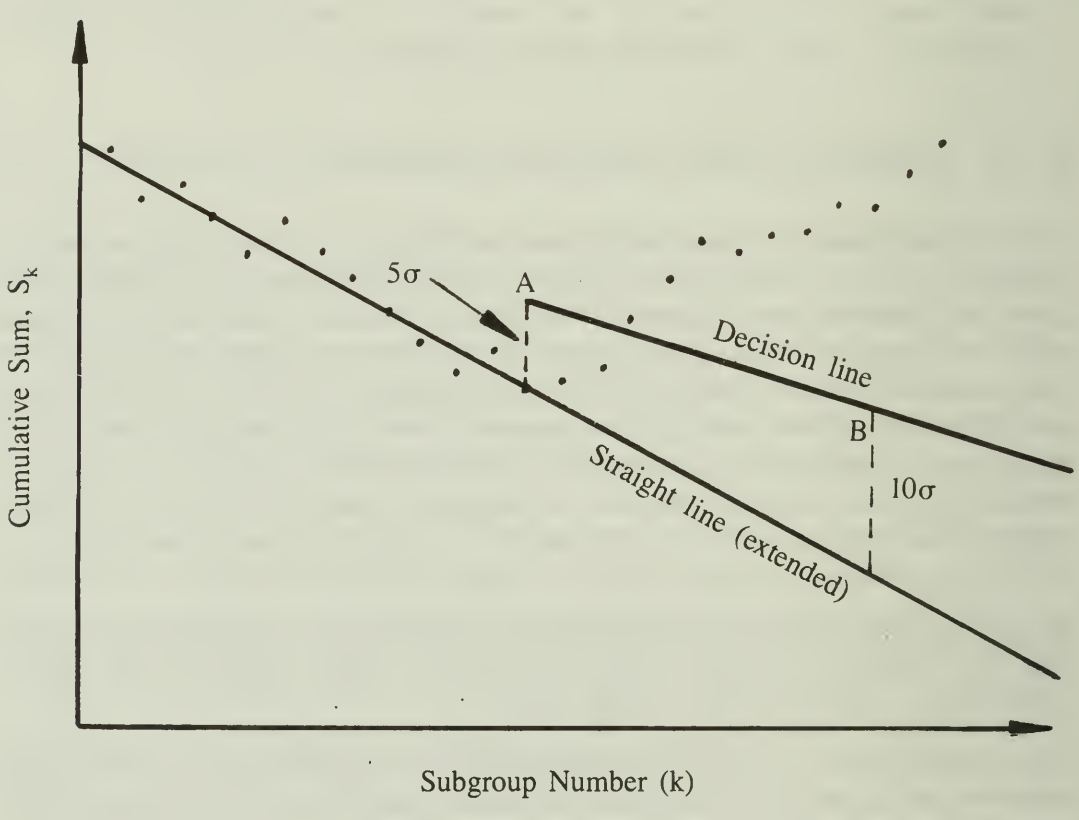

Figure 5.5 Decision Interval: Method 1

Method 2:

This method is an extension of Method 1 and requires the development of a truncated V-mask. The V-mask may be cut out from cardboard or paper or a transparent material, which may be more useful. The construction of the mask is detailed in Figure 5.6. This mask is used by placing the datum A over any point on the chart; this will often be the most recently plotted point or the last point in some segment of particular interest. The AF-axis is laid parallel to the subgroup number axis of the chart, both axes possessing subgroup intervals of equal length. If the Cusum values wander beyond the sloping axes BD or CE, called the **decision lines**, a significant departure from the target value is signaled. However, if the entire Cusum path remains inside these arms, no significant shift is indicated.

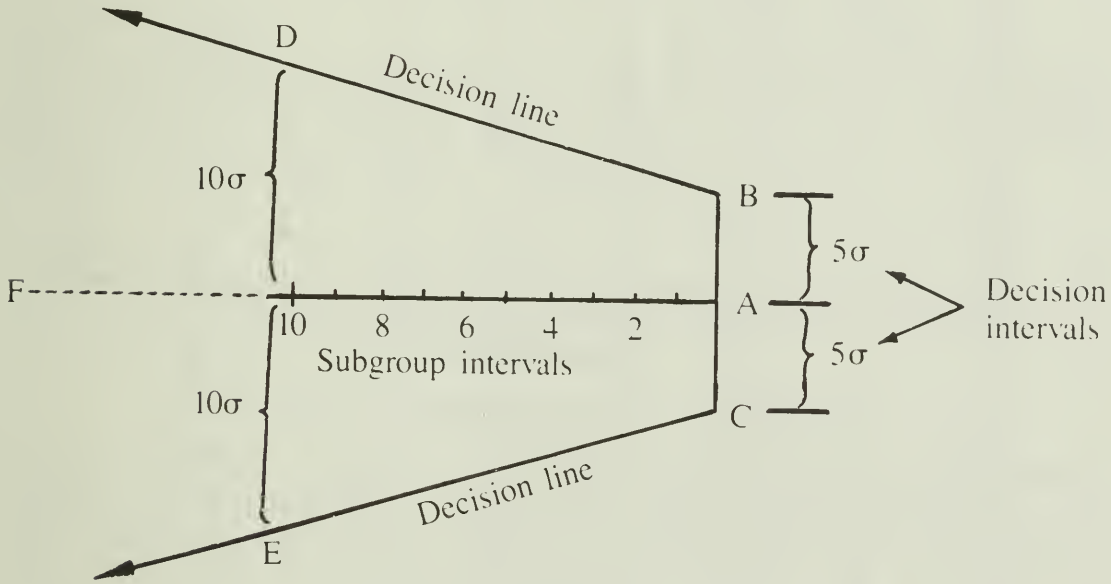

Figure 5.6 Decision Rule with Truncated Mask: Method 2

Example 5.3 Cusum Chart with Truncated V-mask

Table 5.5 gives 33 subgroup average values for a food production process, observed over a particular time sequence. A target value of T = 15 was deemed appropriate.

TABLE 5.5: Data for Cusum Analysis

Subgroup Number (k)	$\overline{X}$	$\overline{X} - T$	$S_k = \Sigma(\overline{X} - T)$
1	12	−3	−3
2	17	+2	−1
3	14	−1	−2
4	14	−1	−3
5	17	+2	−1
6	16	+1	0
7	14	−1	−1
8	11	−4	−5
9	13	−2	−7
10	14	−1	−8
11	15	0	−8
12	11	−4	−12
13	14	−1	−13
14	16	+1	−12
15	13	−2	−14
16	14	−1	−15
17	11	−4	−19
18	12	−3	−22
19	13	−2	−24
20	16	+1	−23
21	12	−3	−26
22	18	+3	−23
23	18	+3	−20
24	17	+2	−18
25	20	+5	−13
26	15	0	−13
27	14	−1	−14
28	18	+3	−11
29	20	+5	−6
30	16	+1	−5
31	18	+3	−2
32	14	−1	−3
33	16	+1	−2

The Cusum chart is plotted in Figure 5.7. For comparative analysis, a conventional Shewhart chart is also plotted in Figure 5.8.

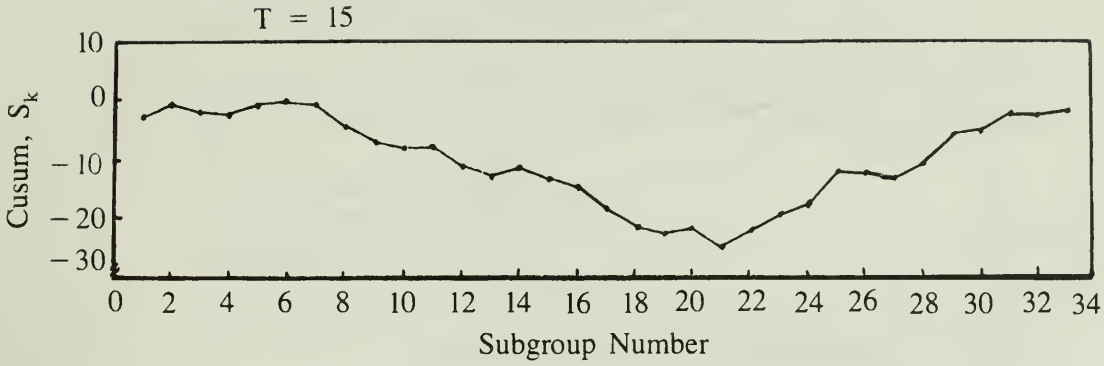

Figure 5.7 Cusum Chart for Data in Table 5.5

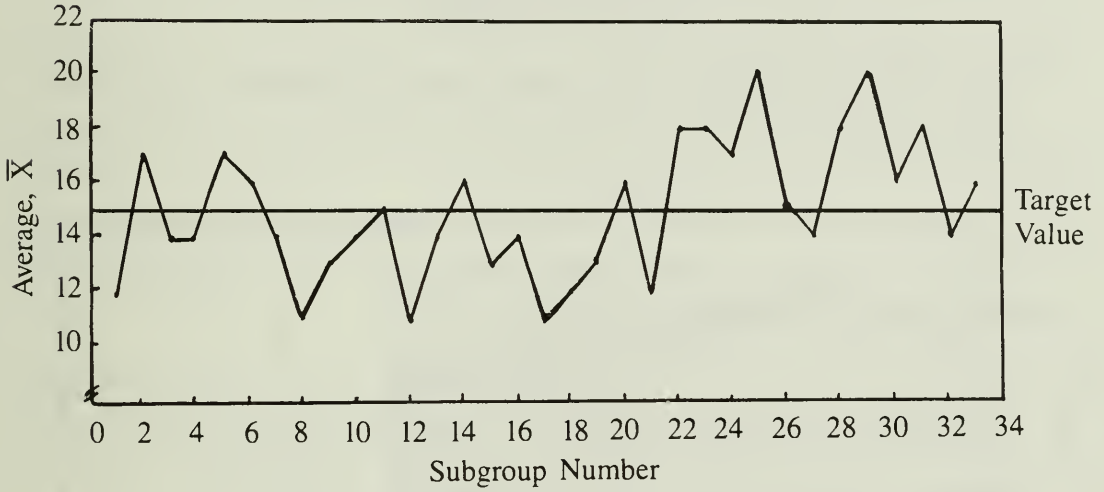

Figure 5.8 Conventional Chart for Data in Table 5.5

As can be seen from Figure 5.7, the chart clearly divides into three distinct segments. From subgroup 1 to 7, the Cusum path is roughly horizontal about zero, suggesting that these observations come from a population whose mean is close to the target value. From subgroup 8 to 21, the path is recognizably moving downward and the observations, therefore, appear to have been sampled from a population whose mean is below 15. Finally, from subgroup 22 to 33, the path is shifting upward, indicating that the observations belong to a population whose mean is greater than 15.

The conventional Shewhart chart, on the other hand, only indicates that the last dozen values are clustered around a different mean level than the first 20 or so. Plotting in the Cusum mode, therefore, provides a much clearer picture of the trends actually present in the data.

Figures 5.9 and 5.10 show a truncated V-mask applied at two different points on the Cusum chart. The value of σ is assumed to be 2.0. With the mask applied at subgroup 16, the Cusum path remains well within the sloping arms and so the segment from subgroup 8 to 16 does not significantly differ from the target value of T = 15. However, when the mask is applied at subgroup 18, the Cusum path is seen to touch the upper decision line, indicating that, by the time the eighteenth subgroup average value is obtained, sufficient evidence has been accumulated to signal a significant downward shift from the target value.

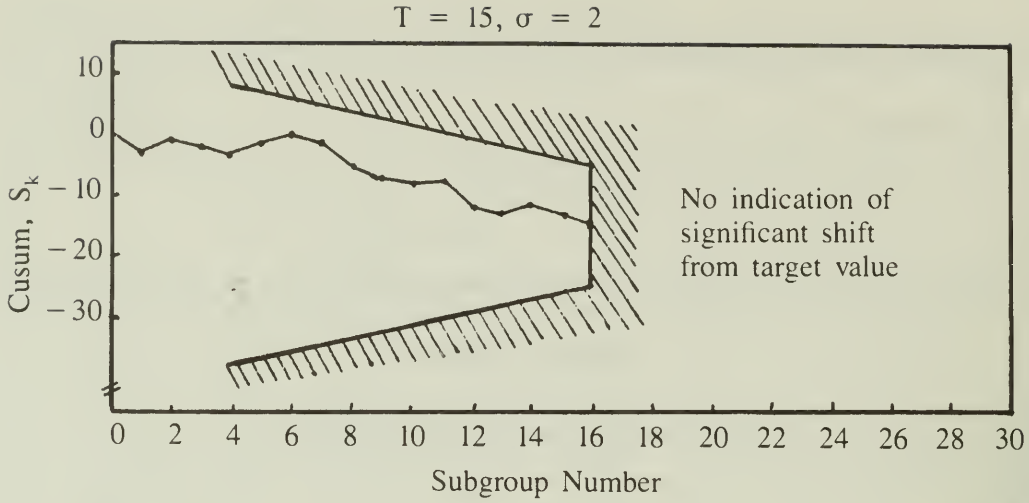

Figure 5.9 Truncated V-Mask Applied to Cusum Chart (Figure 5.7) at Subgroup 16

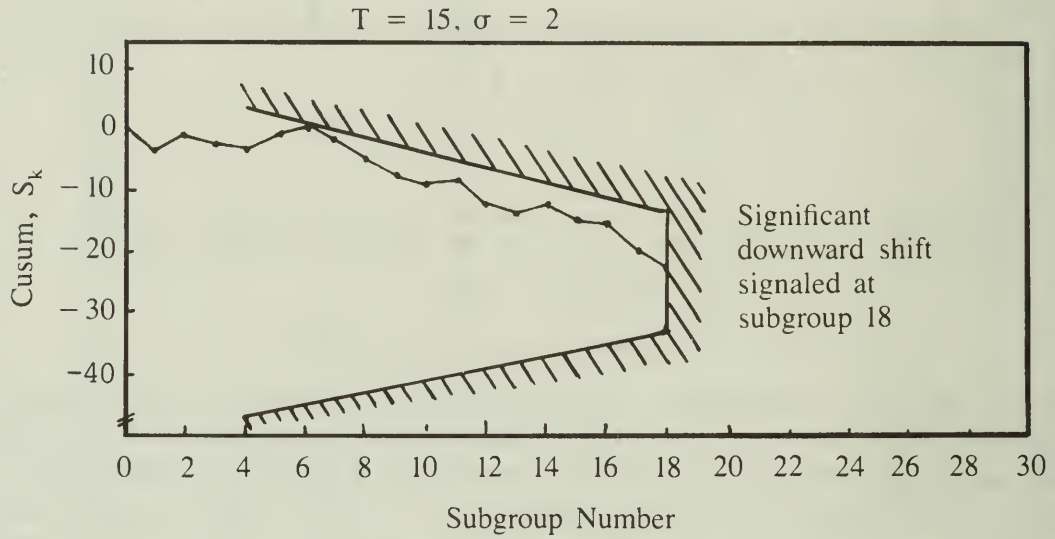

Figure 5.10 Truncated V-Mask Applied to Cusum Chart (Figure 5.7) at Subgroup 18

At this point, corrective action is taken to identify and eliminate the assignable causes of variability and the process is reset as needed. Further data plotting and Cusum analysis is then performed until the process exhibits a state of statistical control.

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   - ISO/8402 : Quality Vocabulary
   - ISO/9004 : Quality Management and Quality System Elements — Guidelines
   - ISO/3951 : Sampling Procedures and Charts for Inspection by Variables for Percent Nonconforming
   - ISO/3534 : Statistics Vocabulary and Symbols
     - — Part 1 : Probability and General Statistical Terms
     - — Part 2 : Statistical Quality Control
     - — Part 3 : Design of Experiments
   - ISO/2859 : Sampling Inspection Procedures for Inspection by Attributes
     - — Part 0 : Introduction to the ISO/2859 Attributes Sampling System
     - — Part 1 : Sampling Plans Indexed by Acceptance Quality Level (AQL) for Lot-by-Lot Inspection
     - — Part 2 : Sampling Plans Indexed by Limiting Quality (LQ) for Isolated Lot Inspection
     - — Part 3 : Skip Lot Sampling Plan
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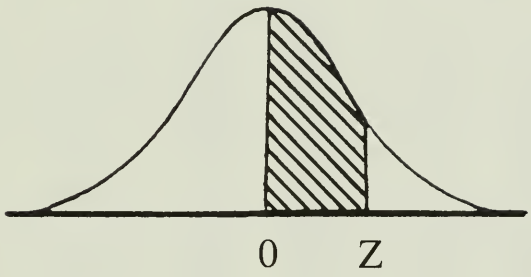
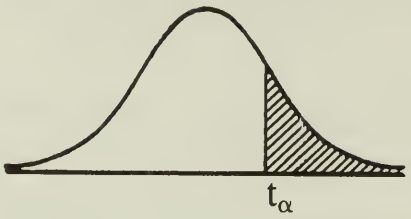
APPENDIX

TABLE 1. Normal Curve Areas



Z	.00	.01	.02	.03	.04	.05	.06	.07	.08	.09
0.0	.0000	.0040	.0080	.0120	.0160	.0199	.0239	.0279	.0319	.0359
0.1	.0398	.0438	.0478	.0517	.0557	.0596	.0636	.0675	.0714	.0753
0.2	.0793	.0832	.0871	.0910	.0948	.0987	.1026	.1064	.1103	.1141
0.3	.1179	.1217	.1255	.1293	.1331	.1368	.1406	.1443	.1480	.1517
0.4	.1554	.1591	.1628	.1664	.1700	.1736	.1772	.1808	.1844	.1879
0.5	.1915	.1950	.1985	.2019	.2054	.2088	.2123	.2157	.2190	.2224
0.6	.2257	.2291	.2324	.2357	.2389	.2422	.2454	.2486	.2517	.2549
0.7	.2580	.2611	.2642	.2673	.2704	.2734	.2764	.2794	.2823	.2852
0.8	.2881	.2910	.2939	.2967	.2995	.3023	.3051	.3078	.3106	.3133
0.9	.3159	.3186	.3212	.3238	.3264	.3289	.3315	.3340	.3365	.3389
1.0	.3413	.3438	.3461	.3485	.3508	.3531	.3554	.3577	.3599	.3621
1.1	.3643	.3665	.3686	.3708	.3729	.3749	.3770	.3790	.3810	.3830
1.2	.3849	.3869	.3883	.3907	.3925	.3944	.3962	.3980	.3997	.4015
1.3	.4032	.4049	.4066	.4082	.4099	.4115	.4131	.4147	.4162	.4177
1.4	.4192	.4207	.4222	.4236	.4251	.4265	.4279	.4292	.4306	.4319
1.5	.4332	.4345	.4357	.4370	.4382	.4394	.4406	.4418	.4429	.4441
1.6	.4452	.4463	.4474	.4484	.4495	.4505	.4515	.4525	.4535	.4545
1.7	.4554	.4564	.4573	.4582	.4591	.4599	.4608	.4616	.4625	.4633
1.8	.4641	.4649	.4656	.4664	.4671	.4678	.4686	.4693	.4699	.4706
1.9	.4713	.4719	.4726	.4732	.4738	.4744	.4750	.4756	.4761	.4767
2.0	.4772	.4778	.4783	.4788	.4793	.4798	.4803	.4808	.4812	.4817
2.1	.4821	.4826	.4830	.4834	.4838	.4842	.4846	.4850	.4854	.4857
2.2	.4861	.4864	.4868	.4871	.4875	.4878	.4881	.4884	.4887	.4890
2.3	.4893	.4896	.4898	.4901	.4904	.4906	.4909	.4911	.4913	.4916
2.4	.4918	.4920	.4922	.4925	.4927	.4929	.4931	.4932	.4934	.4936
2.5	.4938	.4940	.4941	.4943	.4945	.4946	.4948	.4949	.4951	.4952
2.6	.4953	.4955	.4956	.4957	.4959	.4960	.4961	.4962	.4963	.4964
2.7	.4965	.4966	.4967	.4968	.4969	.4970	.4971	.4972	.4973	.4974
2.8	.4974	.4975	.4976	.4977	.4977	.4978	.4979	.4979	.4980	.4981
2.9	.4981	.4982	.4982	.4983	.4984	.4984	.4985	.4985	.4986	.4986
3.0	.4987	.4987	.4987	.4988	.4988	.4989	.4989	.4989	.4990	.4990
3.1	.4990	.4991	.4991	.4991	.4992	.4992	.4992	.4992	.4993	.4992
3.2	.4993	.4993	.4994	.4994	.4994	.4994	.4994	.4995	.4995	.4995
3.3	.4995	.4995	.4995	.4996	.4996	.4996	.4996	.4996	.4996	.4997
3.4	.4997	.4997	.4997	.4997	.4997	.4997	.4997	.4997	.4997	.4998

TABLE 2. Percentage Points of the t-Distribution



d.f.	$t_{.40}$	$t_{.30}$	$t_{.20}$	$t_{.10}$	$t_{.05}$	$t_{.025}$	$t_{.01}$	$t_{.005}$	$t_{.0005}$
1	0.3250	0.7270	1.376	3.078	6.3138	12.706	31.821	63.657	636.619
2	.2885	.6172	1.061	1.886	2.9200	4.3027	6.965	9.9248	31.598
3	.2766	.5840	.978	1.638	2.3534	3.1825	4.541	5.8409	12.924
4	.2707	.5692	.941	1.533	2.1318	2.7764	3.747	4.6041	8.610
5	.2672	.5598	.920	1.476	2.0150	2.5706	3.365	4.0321	6.869
6	.2648	.5536	.906	1.440	1.9432	2.4469	3.143	3.7074	5.959
7	.2632	.5493	.896	1.415	1.8946	2.3646	2.998	3.4995	5.408
8	.2619	.5461	.889	1.397	1.8595	2.3060	2.896	3.3554	5.041
9	.2610	.5436	.883	1.383	1.8331	2.2622	2.821	3.2498	4.781
10	.2602	.5416	.879	1.372	1.8125	2.2281	2.764	3.1693	4.587
11	.2596	.5400	.876	1.363	1.7939	2.2010	2.718	3.1058	4.437
12	.2590	.5387	.873	1.356	1.7823	2.1788	2.681	3.0545	4.318
13	.2586	.5375	.870	1.350	1.7709	2.1604	2.650	3.0123	4.221
14	.2582	.5366	.868	1.345	1.7613	2.1448	2.624	2.9768	4.140
15	.2579	.5358	.866	1.341	1.7530	2.1315	2.602	2.9467	4.073
16	.2576	.5351	.865	1.337	1.7459	2.1199	2.583	2.9208	4.015
17	.2574	.5344	.863	1.333	1.7396	2.1098	2.567	2.8982	3.965
18	.2571	.5338	.862	1.330	1.7341	2.1009	2.552	2.8784	3.922
19	.2569	.5333	.861	1.328	1.7291	2.0930	2.539	2.8609	3.883
20	.2567	.5329	.860	1.325	1.7247	2.0860	2.528	2.8453	3.850
21	.2566	.5325	.859	1.323	1.7207	2.0796	2.518	2.8314	3.819
22	.2564	.5321	.858	1.321	1.7171	2.0739	2.508	2.8188	3.792
23	.2563	.5318	.858	1.319	1.7139	2.0687	2.500	2.9073	3.767
24	.2562	.5315	.857	1.318	1.7109	2.0639	2.492	2.7969	3.745
25	.2561	.5312	.856	1.316	1.7081	2.0595	2.485	2.7874	3.725
26	.2560	.5309	.856	1.315	1.7056	2.0555	2.479	2.7787	3.707
27	.2559	.5307	.855	1.314	1.7033	2.0518	2.473	2.7707	3.690
28	.2558	.5304	.855	1.313	1.7011	2.0484	2.467	2.7633	3.674
29	.2557	.5302	.854	1.311	1.6991	2.0452	2.462	2.7564	3.659
30	.2556	.5300	.854	1.310	1.6973	2.0423	2.457	2.7500	3.616
35	.2553	.5292	.8521	1.3062	1.6896	2.0301	2.438	2.7239	3.5919
40	.2550	.5286	.8507	1.3031	1.6839	2.0211	2.423	2.7045	3.5511
45	.2549	.5281	.8497	1.3007	1.6794	2.0141	2.412	2.6896	3.5207
50	.2547	.5278	.8489	1.2987	1.6759	2.0086	2.403	2.6778	3.4965
60	.2545	.5272	.8477	1.2959	1.6707	2.0003	2.390	2.6603	3.4606
70	.2543	.5268	.8468	1.2938	1.6669	1.9945	2.381	2.6480	3.4355
80	.2542	.5265	.8462	1.2922	1.6641	1.9901	2.374	2.6388	3.4169
90	.2541	.5263	.8457	1.2910	1.6620	1.9867	2.368	2.6316	3.4022
100	.2540	.5261	.8452	1.2901	1.6602	1.9840	2.364	2.6260	3.3909
120	.2539	.5258	.8446	1.2887	1.6577	1.9799	2.358	2.6175	3.3736
140	.2538	.5256	.8442	1.2876	1.6558	1.9771	2.353	2.6114	3.3615
160	.2538	.5255	.8439	1.2869	1.6545	1.9749	2.350	2.6070	3.3527
180	.2537	.5253	.8436	1.2863	1.6534	1.9733	2.347	2.6035	3.3456
200	.2537	.5252	.8434	1.2858	1.6525	1.9719	2.345	2.6006	3.3400
∞	.2533	.5244	.8416	1.2816	1.6449	1.9600	2.326	2.5758	3.2905

SOURCE: Reproduced from *Documenta Geigy Scientific Tables*, 7th edition, by permission of CIBA-GEIGY Limited, Basle, Switzerland.

TABLE 3. Percentage Points of the χ^2-Distribution

d.f.	$\chi^2_{.995}$	$\chi^2_{.975}$	$\chi^2_{.9}$	$\chi^2_{.5}$	$\chi^2_{.1}$	$\chi^2_{.05}$	$\chi^2_{.025}$	$\chi^2_{.01}$	$\chi^2_{.005}$	$\chi^2_{.001}$	d.f.
1	0.000	0.000	0.016	0.455	2.706	3.841	5.024	6.635	7.879	10.828	1
2	0.010	0.051	0.211	1.386	4.605	5.991	7.378	9.210	10.597	13.816	2
3	0.072	0.216	0.584	2.366	6.251	7.815	9.348	11.345	12.838	16.266	3
4	0.207	0.484	1.064	3.357	7.779	9.488	11.143	13.277	14.860	18.467	4
5	0.412	0.831	1.610	4.351	9.236	11.070	12.832	15.086	16.750	20.515	5
6	0.676	1.237	2.204	5.348	10.645	12.592	14.449	16.812	18.548	22.458	6
7	0.989	1.690	2.833	6.346	12.017	14.067	16.013	18.475	20.278	24.322	7
8	1.344	2.180	3.490	7.344	13.362	15.507	17.535	20.090	21.955	26.124	8
9	1.735	2.700	4.168	8.343	14.684	16.919	19.023	21.666	23.589	27.877	9
10	2.156	3.247	4.865	9.342	15.987	18.307	20.483	23.209	25.188	29.588	10
11	2.603	3.816	5.578	10.341	17.275	19.675	21.920	24.725	26.757	31.264	11
12	3.074	4.404	6.304	11.340	18.549	21.026	23.337	26.217	28.300	32.910	12
13	3.565	5.009	7.042	12.340	19.812	22.362	24.736	27.688	29.819	34.528	13
14	4.075	5.629	7.790	13.339	21.064	23.685	26.119	29.141	31.319	36.123	14
15	4.601	6.262	8.547	14.339	22.307	24.996	27.488	30.578	32.801	37.697	15
16	5.142	6.908	9.312	15.338	23.542	26.296	28.845	32.000	34.267	39.252	16
17	5.697	7.564	10.085	16.338	24.769	27.587	30.191	33.409	35.718	40.790	17
18	6.265	8.231	10.865	17.338	25.989	28.869	31.526	34.805	37.156	42.312	18
19	6.844	8.907	11.651	18.338	27.204	30.144	32.852	36.191	38.582	43.820	19
20	7.434	9.591	12.443	19.337	28.412	31.410	34.170	37.566	39.997	45.315	20
21	8.034	10.283	13.240	20.337	29.615	32.670	35.479	38.932	41.401	46.797	21
22	8.643	10.982	14.042	21.337	30.813	33.924	36.781	40.289	42.796	48.268	22
23	9.260	11.688	14.848	22.337	32.007	35.172	38.076	41.638	44.181	49.728	23
24	9.886	12.401	15.659	23.337	33.196	36.415	39.364	42.980	45.558	51.179	24
25	10.520	13.120	16.473	24.337	34.382	37.652	40.646	44.314	46.928	52.620	25
26	11.160	13.844	17.292	25.336	35.563	38.885	41.923	45.642	48.290	54.052	26
27	11.808	14.573	18.114	26.336	36.741	40.113	43.194	46.963	49.645	55.476	27
28	12.461	15.308	18.939	27.336	37.916	41.337	44.461	48.278	50.993	56.892	28
29	13.121	16.047	19.768	28.336	39.088	42.557	45.722	49.588	52.336	58.301	29
30	13.787	16.791	20.599	29.336	40.256	43.773	46.979	50.892	53.672	59.703	30
31	14.458	17.539	21.434	30.336	41.422	44.985	48.232	52.191	55.003	61.098	31
32	15.134	18.291	22.271	31.336	42.585	46.194	49.480	53.486	56.329	62.487	32
33	15.815	19.047	23.110	32.336	43.745	47.400	50.725	54.776	57.649	63.870	33
34	16.501	19.806	23.952	33.336	44.903	48.602	51.966	56.061	58.964	65.247	34
35	17.192	20.569	24.797	34.336	46.059	49.802	53.203	57.342	60.275	66.619	35
36	17.887	21.336	25.643	35.336	47.212	50.998	54.437	58.619	61.582	67.985	36
37	18.586	22.106	26.492	36.335	48.363	52.192	55.668	59.892	62.884	69.346	37
38	19.289	22.878	27.343	37.335	49.513	53.384	56.896	61.162	64.182	70.703	38
39	19.996	23.654	28.196	38.335	50.660	54.572	58.120	62.428	65.476	72.055	39
40	20.707	24.433	29.051	39.335	51.805	55.758	59.342	63.691	66.766	73.402	40
41	21.421	25.215	29.907	40.335	52.949	56.942	60.561	64.950	68.053	74.745	41
42	22.138	25.999	30.765	41.335	54.090	58.124	61.777	66.206	69.336	76.084	42
43	22.859	26.785	31.625	42.335	55.230	59.304	62.990	67.459	70.616	77.419	43
44	23.584	27.575	32.487	43.335	56.369	60.481	64.202	68.710	71.893	78.750	44
45	24.311	28.366	33.350	44.335	57.505	61.656	65.410	69.957	73.166	80.077	45
46	25.042	29.160	34.215	45.335	58.641	62.830	66.617	71.201	74.437	81.400	46
47	25.775	29.956	35.081	46.335	59.774	64.001	67.821	72.443	75.704	82.720	47
48	26.511	30.755	35.949	47.335	60.907	65.171	69.023	73.683	76.969	84.037	48
49	27.249	31.555	36.818	48.335	62.038	66.339	70.222	74.919	78.231	85.351	49
50	27.991	32.357	37.689	49.335	63.167	67.505	71.420	76.154	79.490	86.661	50

SOURCE: Abridged with permission from *Biometrika Tables for Statisticians*, Vol. 1. Edited by E.S. Pearson and H.O. Hartley, Cambridge University Press (1966).

TABLE 4. Random Numbers

93108	77033	68325	10160	38667	62441	87023	94372	06164	30700
28271	08589	83279	48838	60935	70541	53814	95588	05832	80235
21841	35545	11148	34775	17308	88034	97765	35959	52843	44895
22025	79554	19698	25255	50283	94037	57463	92925	12042	91414
09210	20779	02994	02258	86978	85092	54052	18354	20914	28460
90552	71129	03621	20517	16908	06668	29916	51537	93658	29525
01130	06995	20258	10351	99248	51660	38861	49668	74742	47181
22604	56719	21784	68788	38358	59827	19270	99287	81193	43366
06690	01800	34272	65497	94891	14537	91358	21587	95765	72605
59809	69982	71809	64984	48709	43991	24987	69246	86400	29559
56475	02726	58511	95405	70293	84971	06676	44075	32338	31980
02730	34870	83209	03138	07715	31557	55242	61308	26507	06186
74482	33990	13509	92588	10462	76546	46097	01825	20153	36271
19793	22487	94238	81054	95488	23617	15539	94335	73822	93481
19020	27856	60526	24144	98021	60564	46373	86928	52135	74919
69565	60635	65709	77887	42766	86698	14004	94577	27936	47220
69274	23208	61035	84263	15034	28717	76146	22021	23779	98562
83658	14204	09445	41081	49630	34215	89806	40930	97194	21747
78612	51102	66826	40430	54072	62164	68977	95583	11765	81072
14980	74158	78216	38985	60838	82836	42777	85321	90463	11813
63172	28010	29405	91554	75195	51183	65805	87525	35952	83204
71167	37984	52737	06869	38122	95322	41356	19391	96787	64410
78530	56410	19195	34434	83712	50397	80920	15464	81350	18673
98324	03774	07573	67864	06497	20758	83454	22756	83959	96347
55793	30055	08373	32652	02654	75980	02095	87545	88815	80086
05674	34471	61967	91266	38814	44728	32455	17057	08339	93997
15643	22245	07592	22078	73628	60902	41561	54608	41023	98345
66750	19609	70358	03622	64898	82220	69304	46235	97332	64539
42320	74314	50222	82339	51564	42885	50482	98501	02245	88990
73752	73818	15470	04914	24936	65514	56633	72030	30856	85183
97546	02188	46373	21486	28221	08155	23486	66134	88799	49496
32569	52162	38444	42004	78011	16909	94194	79732	47114	23919
36048	93973	82596	28739	86985	58144	65007	08786	14826	04896
40455	36702	38965	56042	80023	28169	04174	65533	52718	55255
33597	47071	55618	51796	71027	46690	08002	45066	02870	60012
22828	96380	35883	15910	17211	42358	14056	55438	98148	35384
00631	95925	19324	31497	88118	06283	84596	72091	53987	01477
75722	36478	07634	63114	27164	15467	03983	09141	60562	65725
80577	01771	61510	17099	28731	41426	18853	41523	14914	76661
10524	20900	65463	83680	05005	11611	64426	59065	06758	02892
93815	69446	75253	51915	97839	75427	90685	60352	96288	34248
81867	97119	93446	20862	46591	97677	42704	13718	44975	67145
64649	07689	16711	12169	15238	74106	60655	56289	74166	78561
55768	09210	52439	33355	57884	36791	00853	49969	74814	09270
38080	49460	48137	61589	42742	92035	21766	19435	92579	27683
22360	16332	05343	34613	24013	98831	17157	44089	07366	66196
40521	09057	00239	51284	71556	22605	41293	54854	39736	05113
19292	69862	59951	49644	53486	28244	20714	56030	39292	45166
79504	40078	06838	05509	68581	39400	85615	52314	83202	40313
64138	27983	84048	42631	58658	62243	82572	45211	37060	15017

SOURCE: Abstracted with permission from *A Million Random Digits with 100,000 Normal Deviates*, The Rand Corporation, Santa Maria, Calif.

TABLE 5A. ISO/2859-1: Sample Size Code Letters

Lot or batch size	Special inspection levels				General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1 200	C	C	E	F	G	J	K
1 201 to 3 200	C	D	E	G	H	K	L
3 201 to 10 000	C	D	F	G	J	L	M
10 001 to 35 000	C	D	F	H	K	M	N
35 001 to 150 000	D	E	G	J	L	N	P
150 001 to 500 000	D	E	G	J	M	P	Q
500 001 and over	D	E	H	K	N	Q	R

SOURCE: Reproduced with permission from *ISO/2859-1*, International Organization for Standardization (ISO), Central Secretariat, Geneva.

TABLE 5B. ISO/2859-1: Single Sampling Plans for Normal Inspection

Sample size code letter	Sample size	Acceptable quality levels (normal inspection)																										
		0.010	0.015	0.025	0.040	0.065	0.10	0.15	0.25	0.40	0.65	1.0	1.5	2.5	4.0	6.5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	1 2	⇩	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	40 45	⇧		
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧			
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧		
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧		
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
L	200	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
M	315	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
N	500	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
P	800	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
Q	1 250	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧		
R	2 000	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧

⇩ = Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, carry out 100 % inspection.

⇧ = Use first sampling plan above arrow.

Ac = Acceptance number

Re = Rejection number

TABLE 5C. ISO/2859-1: Double Sampling Plans for Normal Inspection

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptable quality levels (normal inspection)																														
				0.010		0.015		0.025		0.040		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5		10		15	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A				⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		●				⇩	
B	First	2	2																									●		⇧		⇩		0	2
	Second	2	4																															1	2
C	First	3	3																													0	2	0	3
	Second	3	6																							●		⇧		⇩		1	2	3	4
D	First	5	5																																
	Second	5	10																					●		⇧		⇩		0	2	0	3	1	4
E	First	8	8																																
	Second	8	16																					●		⇧		⇩		0	2	0	3	1	4
F	First	13	13																																
	Second	13	26																							⇧		⇩		0	2	0	3	1	4
G	First	20	20																																
	Second	20	40																							⇧		⇩		0	2	0	3	1	4
H	First	32	32																																
	Second	32	64																							⇧		⇩		0	2	0	3	1	4
J	First	50	50																																
	Second	50	100																							⇧		⇩		0	2	0	3	1	4
K	First	80	80																																
	Second	80	160																							⇧		⇩		0	2	0	3	1	4
L	First	125	125																																
	Second	125	250																							⇧		⇩		0	2	0	3	1	4
M	First	200	200																																
	Second	200	400																							⇧		⇩		0	2	0	3	1	4
N	First	315	315																																
	Second	315	630																							⇧		⇩		0	2	0	3	1	4
P	First	500	500																																
	Second	500	1 000																							⇧		⇩		0	2	0	3	1	4
Q	First	800	800																																
	Second	800	1 600																							⇧		⇩		0	2	0	3	1	4
R	First	1 250	1 250																																
	Second	1 250	2 500	⇧		⇧		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇩		⇧		⇧		⇧		⇧		⇧	

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptable quality levels (normal inspection)																																					
				25		40		65		100		150		250		400		650		1 000																					
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re																					
A				●		●		●		●		●		●		●		●		●																					
B	First	2	2	0	3	1	4	2	5	3	7	5	9	7	11	11	16	17	22	25	31																				
	Second	2	4	3	4	4	5	6	7	8	9	12	13	18	19	26	27	37	38	56	57																				
C	First	3	3	1	4	2	5	3	7	5	9	7	11	11	16	17	22	25	31																						
	Second	3	6	4	5	6	7	8	9	12	13	18	19	26	27	37	38	56	57																						
D	First	5	5	2	5	3	7	5	9	7	11	11	16	17	22	25	31																								
	Second	5	10	6	7	8	9	12	13	18	19	26	27	37	38	56	57																								
E	First	8	8	3	7	5	9	7	11	11	16	17	22	25	31																										
	Second	8	16	8	9	12	13	18	19	26	27	37	38	56	57																										
F	First	13	13	5	9	7	11	11	16																																
	Second	13	26	12	13	18	19	26	27																																
G	First	20	20	7	11	11	16																																		
	Second	20	40	18	19	26	27																																		
H	First	32	32	11	16																																				
	Second	32	64	26	27																																				
J	First	50	50																																						
	Second	50	100																																						
K	First	80	80																																						
	Second	80	160																																						
L	First	125	125																																						
	Second	125	250																																						
M	First	200	200																																						
	Second	200	400																																						
N	First	315	315																																						
	Second	315	630																																						
P	First	500	500																																						
	Second	500	1 000																																						
Q	First	800	800																																						
	Second	800	1 600																																						
R	First	1 250	1 250																																						
	Second	1 250	2 500	⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧																					

⇩ = Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, carry out 100 % inspection.

⇧ = Use first sampling plan above arrow.

Ac = Acceptance number

Re = Rejection number

● = Use corresponding single sampling plan (or alternatively, use double sampling plan below, where available).

Date Due

DEC 2 8 2011			

Canada