U.S. ATOMIC ENERGY COMMISSION

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REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

REGULATORY GUIDE 6.6

ACCEPTANCE SAMPLING PROCEDURES FOR EXEMPTED AND GENERALLY LICENSED ITEMS CONTAINING BYPRODUCT MATERIAL

A. INTRODUCTION

Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material," of Title 10 of the Code of Federal Regulations requires certain minimum quality assurance practices for exempted and generally licensed items containing byproduct material, including the use of acceptance sampling. Section 32.110, "Acceptance Sampling Procedures Under Certain Specific Licenses," specifies acceptance sampling procedures for use under certain specific licenses.

This guide describes certain information needed by the Regulatory staff in its review of applications for licenses and provides guidance concerning alternative sampling plans that are acceptable to the Regulatory staff.

B. DISCUSSION

The purpose of the acceptance sampling procedures specified in §32.110 is to limit the risk that inspection lots of devices of excessively poor conformance to specifications will reach the public. Of the various criteria for selecting plans for acceptance sampling by attributes, lot tolerance percent defective (LTPD) is the most appropriate for this purpose.

The following definitions* are relevant to this guide:

1. **Lot Tolerance Percent Defective** is defined by the American Society for Quality Control as ". . . expressed in percent defective, the poorest quality in an individual lot that should be accepted."

2. **Consumer's Risk** (or β), the risk of accepting a lot of quality equal to the LTPD, is defined by the American Society for Quality Control as "Risk, Consumer's–(β)–For a given sampling plan, the probability of accepting a lot, when the sampling plan is applied to a submitted lot or process of a given relatively poor quality, whichever is applicable."

3. **Acceptance Number** means the largest number of defectives (or defects) in the sample or samples under consideration that will permit the acceptance of the inspection lot.

4. **Acceptance Sampling** means sampling inspection in which decisions are made to accept or reject product; also, the science that deals with procedures by which decisions to accept or reject are based on the results of the inspection of samples.

Note 1: The alternative to acceptance is termed "rejection" for purpose of the definition, although in practice the alternative may take some form other than outright rejection.

Note 2: In lot-by-lot sampling, acceptance and rejection relate to individual lots. In continuous sampling, acceptance and rejection relate to individual units, or to blocks of consecutive units, depending on the stated procedure.

5. **Defect** means an instance of a failure to meet a requirement imposed on a unit with respect to a single quality characteristic.

*ASQC STANDARD A2-1962, "Definitions and Symbols for Acceptance Sampling by Attributes," American Society for Quality Control. Copies may be obtained from the American Society for Quality Control, 161 W. Wisconsin Avenue, Milwaukee, Wisconsin 53203. This document is the source for standard definitions used in this guide.

6. A **Defective** means a defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

7. **Inspection** means the process of measuring, examining, testing, gaging, or otherwise comparing the unit with the applicable requirements.

8. **Operating Characteristic Curve for an Acceptance Sampling Plan** (OC Curve) means a curve that shows for an acceptance sampling plan the relation between the probability of acceptance and the submitted lot or process quality, whichever is applicable. Expressed another way: A curve that shows for an acceptance sampling plan the percentage of lots that may be expected to be accepted for all possible submitted lot or process qualities, whichever is applicable.

9. **Sample** means, in acceptance sampling, one or more units of product (or a quantity of material) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.

10. **Sampling, Single** means sampling inspection in which the decision to accept or to reject a lot is based on the inspection of a single sample.

11. **Sampling, Double** means sampling inspection in which the inspection of the first sample leads to a decision to accept a lot, to reject it, or to take a second sample; the inspection of a second sample, when required, leads to a decision to accept or to reject the lot.

12. **Sampling at Random**, as commonly used in acceptance sampling theory, means the process of selecting sample units in such a manner that all units under consideration have the same probability of being selected.

Note: Actually, equal probabilities are not necessary for random sampling—what is necessary is that the probability of selection be ascertainable. However, the stated properties of published sampling tables are based on the assumption of random sampling with equal probabilities. An acceptable method of random selection with equal probabilities is the use of a table of random numbers in a standard manner.

The sampling tables of §32.110(b) were adapted from the Dodge and Romig sampling inspection tables* which are the most commonly used tables indexed directly for LTPD (among other criteria). The consumer's risk, β, for the Dodge and Romig tables is set at 0.10, and also is set at 0.10 for the sampling plans given in §32.110(b). The tables of §32.110(b) are based on the simplest attribute sampling procedure that will give the required protection against acceptance of a lot of poor quality, in terms of LTPD, with a consumer's risk of 0.10.

There is no intention of optimizing efficiency of total inspection effort. To do this would require taking into account the process average quality level. A licensee may improve efficiency by selecting from the full set of Dodge and Romig sampling inspection tables a plan for the designated LTPD and for his process average. Double sampling available in the Dodge and Romig tables is more efficient than single sampling and gives essentially the same protection.

Typical operating characteristic curves for the sampling tables of §32.110(b) are given in Figures 1 through 8, identified by sample size n and acceptance number c. Each curve was computed for the largest lot size of the interval to which the sample applies, using the hypergeometric distribution. For any given LTPD, operating characteristic curves for sample sizes other than those plotted, computed on the same basis, would generally fall between the two typical curves shown.

Values of LTPD for which tables are given should be chosen when designating the LTPD for characteristics for which sampling risks are allowable.

It should be remembered that LTPD represents the poorest quality which should rarely be accepted. The manufacturing goal should be a process whose actual process average quality level is substantially better than the LTPD.

C. REGULATORY POSITION

The acceptance sampling procedures set out in §32.110 represent the minimum procedures to adequately ensure conformance to requirements.

Although the tables of §32.110(b) are based on attributes, variables measurements converted to attributes information would be a generally acceptable method for complying with the procedures.

It is not the intent, however, to preclude a licensee from taking advantage of the more efficient methods which may be applicable to his processes, provided they afford at least equivalent quality assurance. Under §§32.15(b), 32.55(c), and 32.62(d), an application for a license or for amendment of a license may include a description of procedures proposed as alternatives to the procedures prescribed in §§32.15(a)(2), 32.55(b), and 32.62(c). A variables sampling plan, or properly documented process control data, for example, might be applicable and more efficient. The licensee would be expected to show that the operating characteristic curve or confidence interval estimate for his procedure meets the required LTPD at the consumer's risk of 0.10.

*H. F. Dodge and H. G. Romig, "Sampling Inspection Tables," 2nd ed., John Wiley & Sons, Inc., New York, 1959.

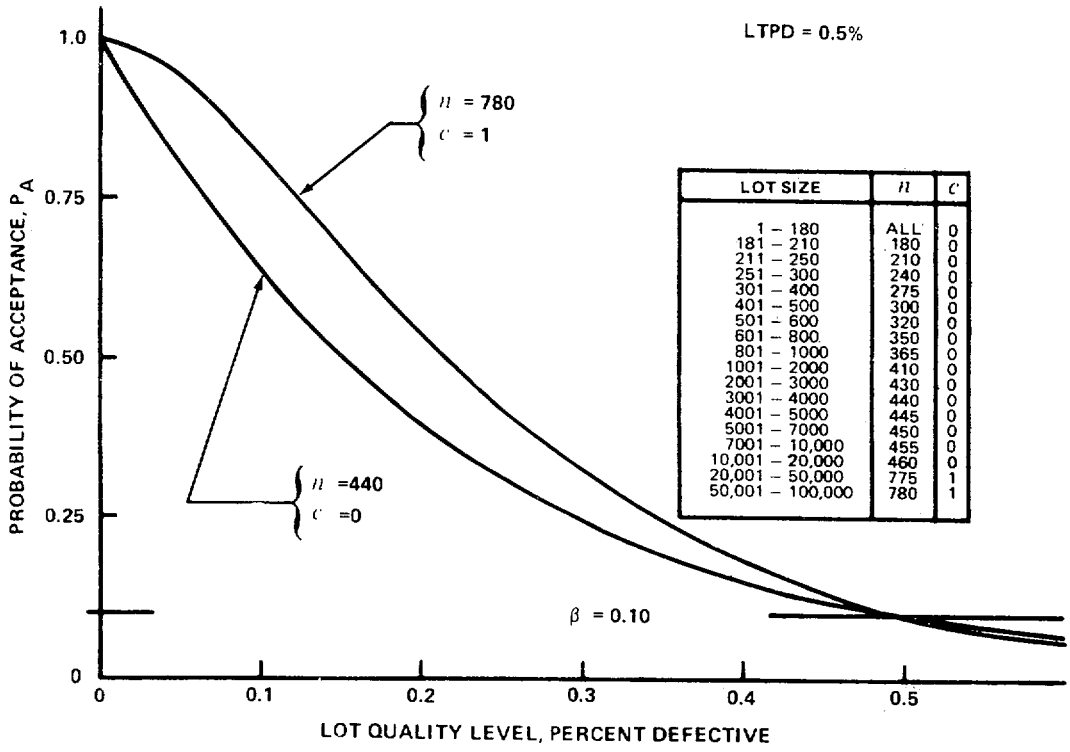
BIBLIOGRAPHY

1. A. J. Duncan, "Quality Control and Industrial Statistics," 3rd ed., Irwin, Homewood, Illinois, 1965. Duncan's book presents theory and principles for analyzing and comparing various standard plans for effectiveness, efficiency, and economy. In addition, he includes material useful for designing sampling plans for optimum operation for special conditions. Duncan also covers in a similar fashion related subjects in the field of quality control, such as control charts, tests of hypotheses, and analysis of variance.

2. E. L. Grant, "Statistical Quality Control," 3rd ed., McGraw-Hill Book Company, New York, 1964. Chapters on Probability Theory and Acceptance Sampling treat principles and theory of the most commonly used acceptance sampling plans including Dodge-Romig tables and MIL-STD-105D (the current revision of military sampling by attributes).

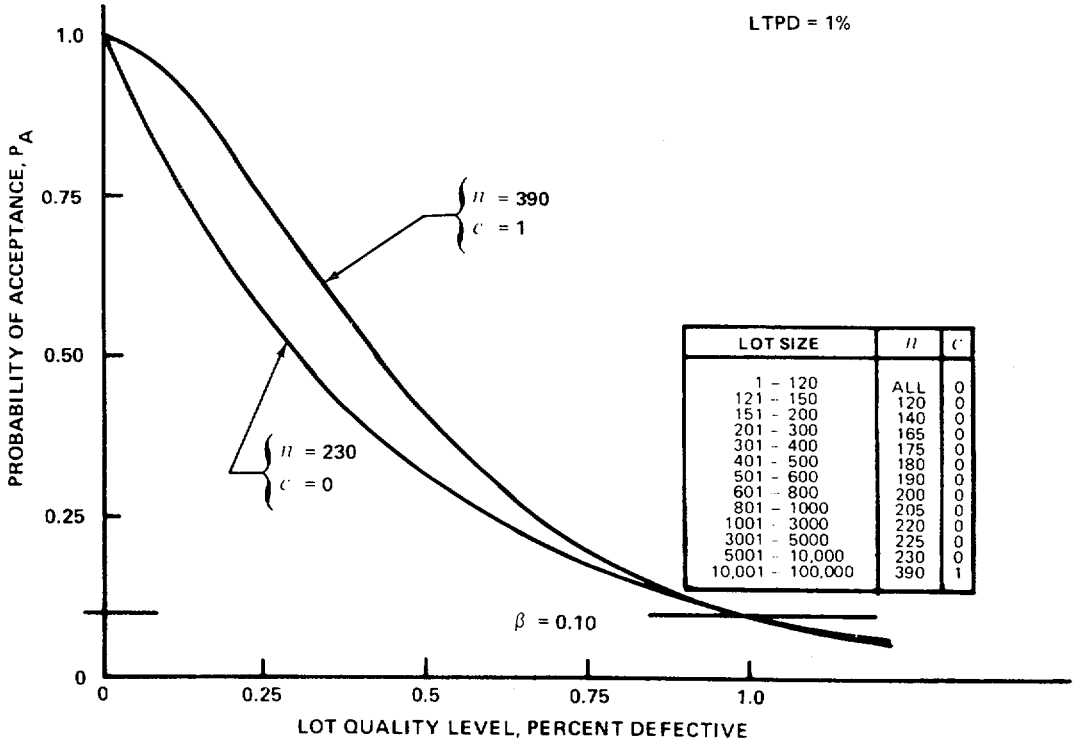
3. J. M. Juran and F. M. Gryna, "Quality Planning and Analysis," McGraw-Hill Book Company, New York, 1970. Chapter 17 entitled "Acceptance Sampling" is a concise treatment of the practical application of sampling plans. This chapter explains the concept of sampling in relatively nontechnical terms, discusses briefly the economics of sampling, sampling risks, and sampling criteria. There is given a very abbreviated section (17-5) on theory, with reference to another source, and examples of analyses of some common sampling plans. A comparison is made of Attributes and Variable plans. Concise descriptions of the following commonly used plans are given: Dodge-Romig sampling inspection tables, MIL-STD-105D, and MIL-STD-414 (military sampling by variables). The use of other information such as control chart evidence that the process is in a state of control is also briefly summarized.

4. J. M. Juran (ed.), "Quality Control Handbook," 2nd ed., McGraw-Hill Book Company, New York, 1962. Acceptance sampling plans specifically are covered in section 13 from pages 13-69 to 13-118. Material covered is about the same as the references above, but in the form and style of a manual or handbook. Section 8 entitled "Acceptance of Quality" covers such general subjects as inspection planning, interpretation of specifications, classification of quality characteristics, providing instruments, judging conformance, physical control of product, rejection of vendor-supplied product, fraud and collusion, flinching, and inadvertent shipment of defectives. This section covers practical problems and ramifications of operating the product acceptance function.



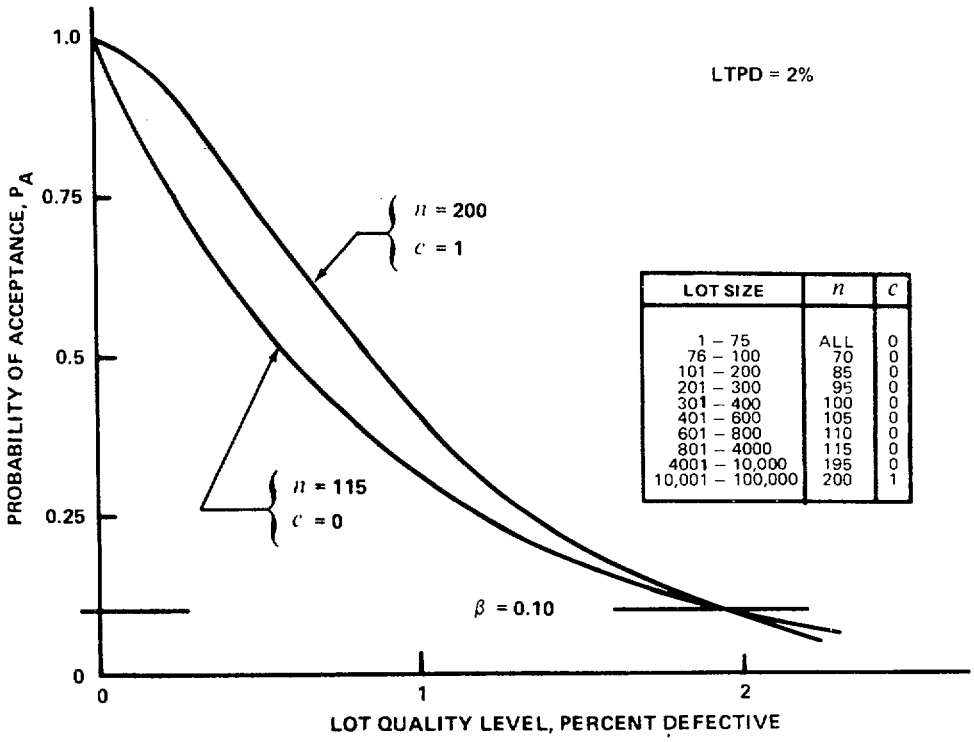
LOT SIZE	n	c
1 – 180	ALL	0
181 – 210	180	0
211 – 250	210	0
251 – 300	240	0
301 – 400	275	0
401 – 500	300	0
501 – 600	320	0
601 – 800	350	0
801 – 1000	365	0
1001 – 2000	410	0
2001 – 3000	430	0
3001 – 4000	440	0
4001 – 5000	445	0
5001 – 7000	450	0
7001 – 10,000	455	0
10,001 – 20,000	460	0
20,001 – 50,000	775	1
50,001 – 100,000	780	1

Figure 1. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 0.5%.



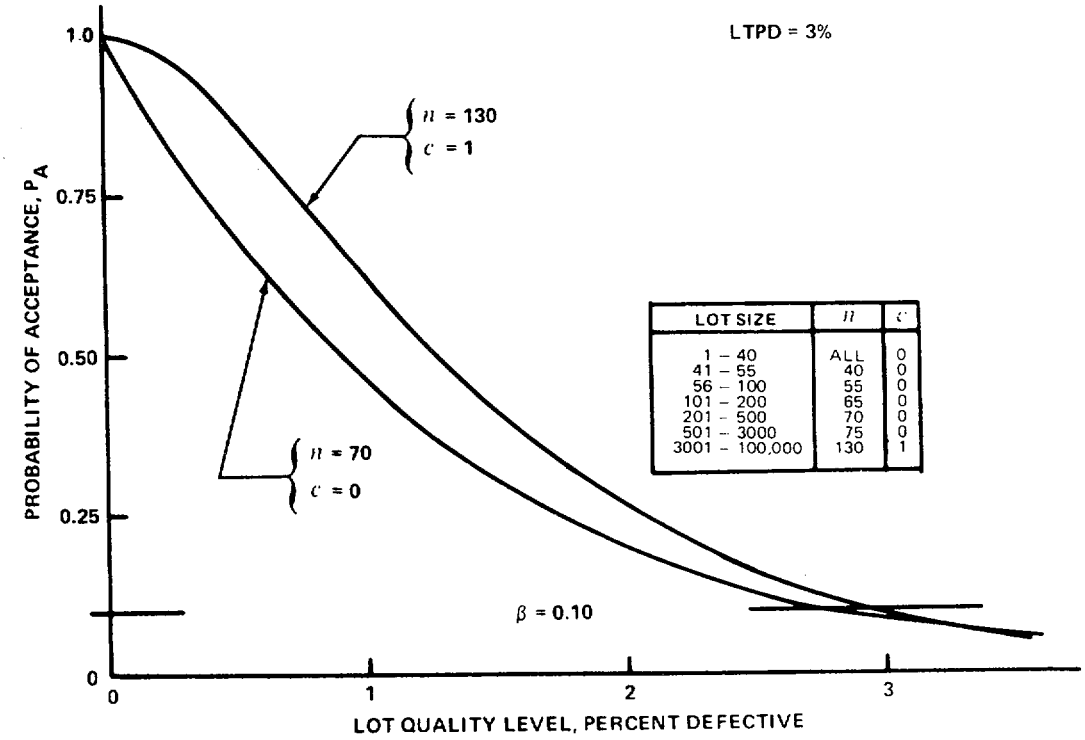
LOT SIZE	n	c
1 – 120	ALL	0
121 – 150	120	0
151 – 200	140	0
201 – 300	165	0
301 – 400	175	0
401 – 500	180	0
501 – 600	190	0
601 – 800	200	0
801 – 1000	205	0
1001 – 3000	220	0
3001 – 5000	225	0
5001 – 10,000	230	0
10,001 – 100,000	390	1

Figure 2. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 1.0%.



LOT SIZE	n	c
1 – 75	ALL	0
76 – 100	70	0
101 – 200	85	0
201 – 300	95	0
301 – 400	100	0
401 – 600	105	0
601 – 800	110	0
801 – 4000	115	0
4001 – 10,000	195	0
10,001 – 100,000	200	1

Figure 3. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 2%.



LOT SIZE	n	c
1 – 40	ALL	0
41 – 55	40	0
56 – 100	55	0
101 – 200	65	0
201 – 500	70	0
501 – 3000	75	0
3001 – 100,000	130	1

Figure 4. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 3%.

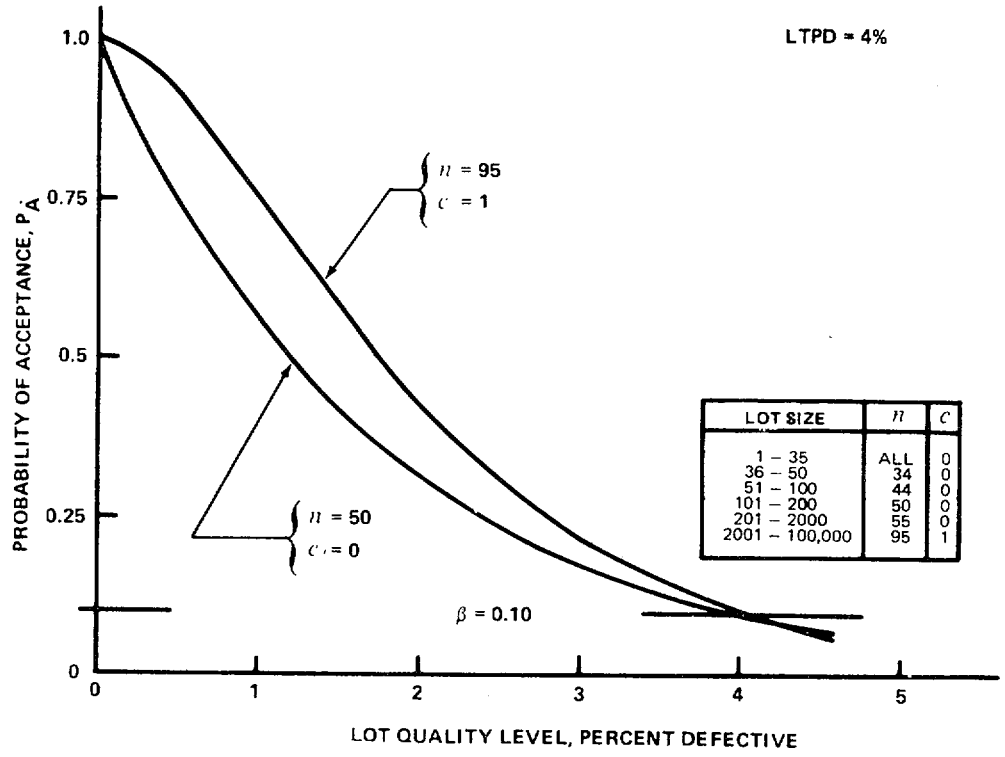


Figure 5. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 4%.

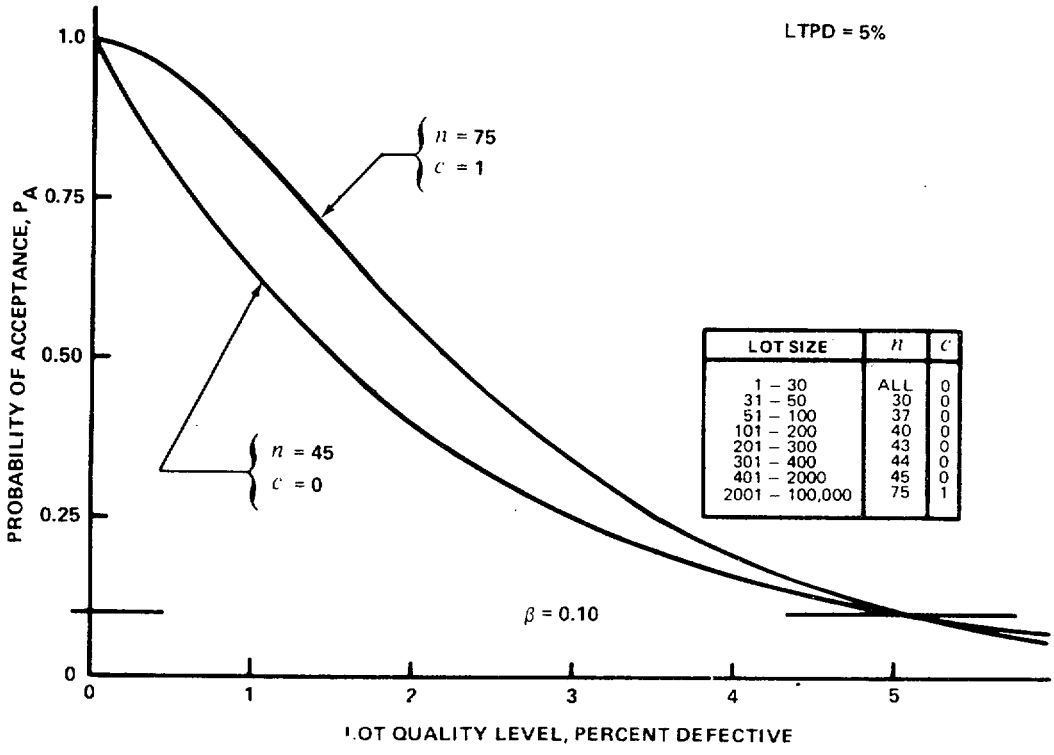
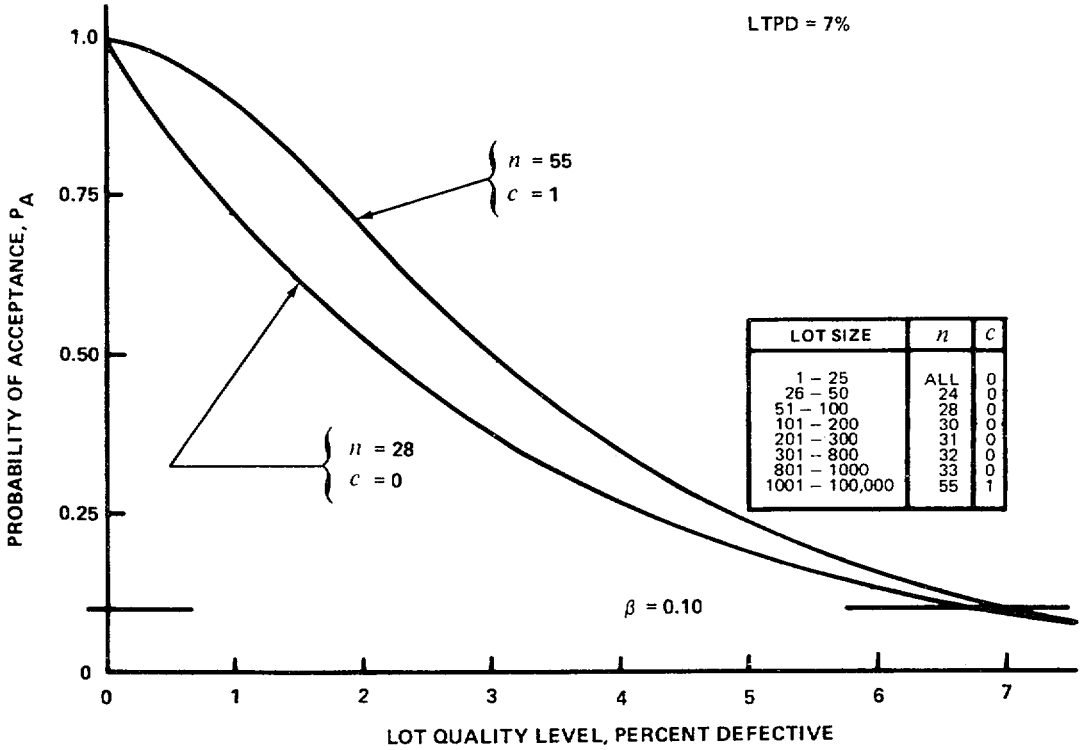
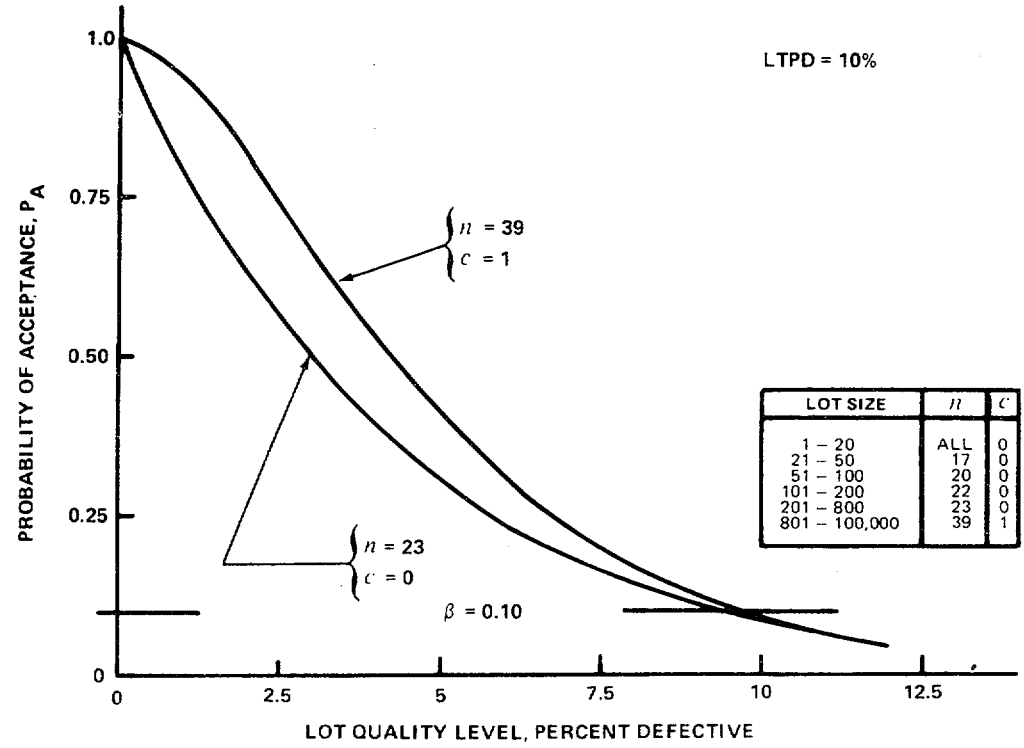


Figure 6. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 5%.



LOT SIZE	n	c
1 – 25	ALL	0
26 – 50	24	0
51 – 100	28	0
101 – 200	30	0
201 – 300	31	0
301 – 800	32	0
801 – 1000	33	0
1001 – 100,000	55	1

Figure 7. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 7%.



LOT SIZE	n	c
1 – 20	ALL	0
21 – 50	17	0
51 – 100	20	0
101 – 200	22	0
201 – 800	23	0
801 – 100,000	39	1

Figure 8. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 10%.